Ardea Biosciences, Inc./DE
Form 10-K
March 13, 2009

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 1-33734
Ardea Biosciences, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**94-3200380**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification 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:

Title of Each Class:	**Name of Each Exchange on Which Registered:**
Common Stock, par value $0.001 per share	**The Nasdaq Global 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 o No þ

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 o No þ

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. o

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

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

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2008 totaled approximately $92,000,000 based on the closing price of $12.82 as reported by the Nasdaq Global Market. As of March 6, 2009, there were 17,854,549 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 2009 annual meeting of stockholders are incorporated by reference into Part III.

TABLE OF CONTENTS

Table of Contents

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 RDEA806, RDEA594, RDEA427, RDEA119, RDEA436 and our other compounds, the results of clinical and other studies, the size of the market 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, ongoi expect, management believes, we believe, we intend and similar words or phrases. Accordingly, 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.

Table of Contents

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. In December 2006, Ardea changed its name from IntraBiotics Pharmaceuticals, Inc.

ITEM 1. *BUSINESS.*

Overview and Business Strategy

Ardea Biosciences, Inc., of San Diego, California, is a biotechnology company focused on the discovery and development of small-molecule therapeutics for the treatment of gout, human immunodeficiency virus, or HIV, cancer and inflammatory diseases. We are currently pursuing multiple development programs, including the following:

Product Portfolio

Product Candidate	Target Indication	Development Status
RDEA594	Gout	Phase 1 ongoing
RDEA806	HIV	Phase 2a completed
RDEA427	HIV	Phase 0* completed
RDEA119	Cancer	Phase 1 and Phase 1/2 ongoing
RDEA119	Inflammation	Phase 1 completed
RDEA436	Inflammation	Phase 0* completed

* First-in-human micro-dose pharmacokinetic study in normal healthy volunteers.

GOUT

RDEA594

RDEA594 is an inhibitor of URAT1, a transporter in the kidney which regulates uric acid excretion from the body. RDEA594 has been well tolerated in Phase 1 studies to date in normal healthy volunteers and has demonstrated significant dose-related decreases in serum uric acid of up to 30% over the first 24 hours after administration of single ascending doses. We are currently evaluating RDEA594 in a multiple ascending dose Phase 1 study in normal healthy volunteers. We plan to complete this study in the first quarter of 2009. We also plan to initiate a Phase 2 dose-ranging study of RDEA594 in gout patients in the first half of 2009, with the goal of completing that study by the end of 2009. We are also conducting a pilot Phase 2a proof-of-concept study of RDEA806, RDEA594 s prodrug, in gout patients to provide an early confirmation of RDEA594 s activity in the target population. In Phase 1 studies of RDEA806 in normal healthy volunteers, increased urinary excretion of uric acid was observed in the first 24 hours after dosing, with statistically significant, exposure-dependent decreases in serum uric acid of 35% to 50% observed during multiple dosing out to 14 days. We plan to complete the Phase 2a study in the first quarter of 2009 and do not plan any further studies of RDEA806 in gout.

HIV

RDEA806

RDEA806 is our lead non-nucleoside reverse transcriptase inhibitor, or NNRTI, for the treatment of HIV. *In vitro* preclinical tests have shown RDEA806 to be a potent inhibitor of a wide range of HIV viral isolates, including isolates that are resistant to efavirenz (SUSTIVA®/Stocrin® from Bristol-Myers Squibb Company and Merck & Co., Inc.), the most widely prescribed NNRTI, in addition to other currently available NNRTIs. *In vitro* preclinical tests have also shown RDEA806 to have a high genetic barrier to resistance. *In vivo* preclinical tests suggest that RDEA806 does not pose a risk of reproductive toxicity. Based on both preclinical and clinical data, we anticipate that RDEA806 could be amenable to a once-daily oral dosing regimen, may have limited pharmacokinetic interactions with other drugs and may be readily co-formulated in a single pill with other HIV antiviral

Table of Contents

drugs, such as Truvada® (emtricitabine and tenofovir from Gilead Sciences, Inc.), which is important for patient compliance and efficacy.

RDEA806 has successfully completed Phase 1 and Phase 2a studies and has been evaluated in over 250 subjects. Results from a Phase 2a monotherapy proof-of-concept study of RDEA806 demonstrated placebo-adjusted plasma viral load reductions of up to 2.0 $\log_{10}$ on day 8 with once-daily dosing of RDEA806. In addition, all dosing regimens tested were well tolerated. We have continued preparing RDEA806 for further clinical development by obtaining additional regulatory approvals to conduct our planned international Phase 2b HIV trial and by successfully completing a number of important preparatory safety and supportive toxicology studies including a Thorough QT study. Results from the Thorough QT study demonstrated that QTc intervals were not increased by any dose of RDEA806 tested. In addition, the study provided information on the lack of pharmacokinetic differences between Caucasians and African-Americans. These results provide further support for RDEA806 s cardiac safety profile as well as its potential to improve current standard-of-care therapy as ethnicity-based differences in metabolism, which can lead to increased side effects in African-Americans, have been documented with efavirenz (Sustiva®, Bristol-Myers Squibb).

RDEA427

The lead compound in our next generation NNRTI program, RDEA427, is from a chemical class that is distinct from the RDEA806 chemical class. Based on early preclinical data, we believe that RDEA427 may share certain of the positive attributes of RDEA806, but may also have even greater activity against a wide range of drug-resistant viral isolates. We have evaluated RDEA427, in a human micro-dose pharmacokinetic study and have selected it for clinical development based on a plasma half-life of greater than 40 hours. The timing of future studies of RDEA806 and RDEA427 will be determined in part by the results of our partnering efforts.

CANCER

RDEA119

RDEA119, our lead mitogen-activated ERK kinase, or MEK, inhibitor for the treatment of cancer, is a potent and selective inhibitor of MEK, which is believed to play an important role in cancer cell proliferation, apoptosis and metastasis. *In vivo* preclinical tests have shown RDEA119 to have potent anti-tumor activity.

Data from an ongoing Phase 1 study of RDEA119 in advanced cancer patients suggests that RDEA119 has a pharmacokinetic profile allowing for convenient once-daily oral dosing. Once the maximum tolerated dose is determined, we plan to evaluate the activity of RDEA119 in advanced cancer patients with selected tumor types, such as hepatocellular, sarcoma, glioma, non-small cell lung, colon, pancreatic or thyroid cancer or melanoma.

In addition, preclinical *in vitro* and *in vivo* studies of RDEA119 have demonstrated synergistic activity across multiple tumor types when RDEA119 is used in combination with other anti-cancer agents, including sorafenib (Nexavar® from Onyx Pharmaceuticals, Inc. and Bayer HealthCare AG). We are currently conducting a Phase 1/2 study of RDEA119 in combination with sorafenib in advanced cancer patients to evaluate the safety, tolerability, pharmacokinetics and anti-tumor activity of this combination therapy.

INFLAMMATION

RDEA119

In vivo preclinical tests have also shown RDEA119 to significantly inhibit production of inflammatory cytokines. Results from a completed Phase 1 study in normal healthy volunteers demonstrated that RDEA119 was well tolerated with a pharmacokinetic profile allowing for convenient once-daily oral dosing.

RDEA436

The lead compound in our next generation MEK inhibitor program, RDEA436, is from a chemical class that is distinct from the RDEA119 chemical class. Based on early preclinical data, we believe that RDEA436 may potentially share certain of the positive attributes of RDEA119, and may have even greater potency than RDEA119.

Table of Contents

We have evaluated RDEA436 in a Phase 0 study and have selected it for clinical development. We received regulatory approval in December 2008 to initiate a Phase 1 study of RDEA436 evaluating safety, pharmacokinetics and inflammatory disease biomarkers in normal healthy volunteers. The timing of future studies of RDEA119 and RDEA436 for inflammatory diseases will be determined in part by the results of our partnering efforts.

Market Opportunity

We believe that there is a significant market opportunity for our products, 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, a painful and debilitating disease caused by abnormally elevated levels of uric acid. There has been only one new drug approved in the United States for the treatment of gout in the last 40 years. According to the National Arthritis Data Workgroup, an estimated 6.1 million adults in the United States in 2005 had experienced at least one episode of gout. The incidence and severity 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 1988-2005 and over $11.2 billion in gout-related hospital costs were incurred in 2005 in the United States. In addition, according to a 2008 Nerac Inc. survey, approximately 5.0 million patients in the European Union suffer from gout. Many chronic gout sufferers are unable to achieve target reductions in uric acid with current treatments. Approximately 80% to 90% of gout patients are under excretors of uric acid. Scientists have recently discovered defects in multiple transporters in the kidney that play important roles in uric acid transport and are genetically linked to a higher risk of gout. URAT1 has been identified as the most important transporter for uric acid. We are developing products for the treatment of hyperuricemia and gout that inhibit URAT1, thereby increasing the excretion of uric acid and lowering serum uric acid levels. In addition, we believe there may be opportunities to develop uric acid-lowering agents to treat diseases other than gout. Evidence suggests that the chronic elevation of uric acid associated with gout, known as hyperuricemia, may also have systemic consequences, including an increased risk for kidney dysfunction, elevated CRP, hypertension and possibly other cardiovascular risk factors.

In 2007, sales of HIV antivirals in the seven major drug markets (the United States, Japan, France, Germany, Italy, Spain and the United Kingdom) were approximately $9.3 billion and are expected to reach $15.1 billion in 2017, according to Datamonitor. While the treatment of HIV has improved dramatically over the past decade, we believe that there remains a significant need for new treatments that are effective against drug-resistant virus, safer for women and African-Americans, well tolerated and convenient to take. According to the Centers for Disease Control and Prevention (CDC), 56,300 people were newly infected with HIV in 2006, 40% more than estimated previously. African-Americans accounted for more than 45% of the new infections. Women account for 27% of the new infections. We are developing products for the treatment of HIV that are highly active against resistant strains, have a high genetic barrier to resistance, have a better safety profile than current drugs in African-Americans and women, can be taken once a day, and are easy to formulate in a combination pill with current drugs.

We also believe that there is growing interest in the potential for targeted therapies, including kinase inhibitors, for the treatment of both cancer and inflammatory disease. Sales of products used in the treatment of cancer were expected to exceed $45.0 billion in 2008, according to IMS Health Incorporated, fueled by strong acceptance of innovative and effective targeted therapies. The failure rate of kinase inhibitor compounds in clinical development in oncology is only 53% versus 82% in the oncology field as a whole. In 2007, the worldwide market for targeted therapies for inflammatory diseases was more than $8.6 billion. Given the role that MEK appears to play in cancer and inflammatory diseases and the increasing preference for oral therapies, we believe that RDEA119 and our next generation MEK inhibitors, if successfully developed, approved and commercialized, could participate in these growing markets.

Valeant Relationship

On December 21, 2006, we acquired intellectual property and other assets from Valeant Research & Development, Inc. related to RDEA806 and our next generation NNRTI program, and RDEA119 and our next generation MEK inhibitor program. Concurrent with the closing of the acquisition from Valeant, we hired a new senior management team and changed our name from IntraBiotics Pharmaceuticals, Inc. to Ardea Biosciences, Inc.

Table of Contents

In consideration for the assets purchased from Valeant and subject to the satisfaction of certain conditions, Valeant has the right to receive development-based milestone payments and sales-based royalty payments from us. There is one set of milestones for RDEA806 and the next generation NNRTI program and a separate set of milestones for RDEA119 and the next generation MEK inhibitor program. In the event of the successful commercialization of a product incorporating RDEA806 or a compound from the next generation NNRTI program, resulting milestone payments could total up to $25.0 million. In the event of the successful commercialization of a product incorporating RDEA119 or a compound from the next generation MEK inhibitor program, resulting milestone payments could total up to $17.0 million. Milestones are paid only once for each program, regardless of how many compounds are developed or commercialized. The first milestone payments of $2.0 million and $1.0 million in the NNRTI program and the MEK inhibitor program, respectively, would be due after the first patient is dosed in the first Phase 2b study, and approximately 80% of the total milestone payments in each program would be due upon United States Food and Drug Administration acceptance and approval of a New Drug Application, or NDA. The royalty rates on all products are in the mid-single digits. We agreed to further develop these compounds with the objective of obtaining marketing approval in the United States, the United Kingdom, France, Spain, Italy and Germany.

Valeant also has the right to exercise a one-time option to repurchase commercialization rights in territories outside the United States and Canada (the Valeant Territories) to the first NNRTI compound derived from the acquired intellectual property to complete a Phase 2b study in HIV. If Valeant exercises this option, which it can do following the completion of a Phase 2b HIV study, but prior to the initiation of a Phase 3 study, we would be responsible for completing Phase 3 studies and for registration of the product in the United States and the European Union. Valeant would pay us a $10.0 million option fee, up to $21.0 million in milestone payments based on regulatory approvals, and a mid-single-digit royalty on product sales in the Valeant Territories.

Research and Development Expenses

Our research and development expenses for the three years ended December 31, 2008, 2007 and 2006 were $44.9 million, $23.1 million and $0.1 million, respectively. Research and development expenses increased substantially in 2008 and 2007 primarily due to continued development and progression of our clinical and preclinical programs.

Clinical Supplies and Manufacturing

We have no in-house manufacturing capabilities. We rely on third-party contract manufacturers to produce our product candidates to support our development activities. Our clinical trial material, critical to our operations, is purchased 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 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 of our potential competitors have significantly more financial, technical and other resources than we do, which may allow them to have a competitive advantage. In addition, they may have substantially more experience in effecting strategic combinations, in-licensing technology, developing drugs, obtaining regulatory approvals and

Table of Contents

manufacturing and marketing products. We cannot give any assurances that we can effectively compete 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 third 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 two issued United States patents, 16 pending United States non-provisional applications, seven pending United States provisional applications, eight pending international applications and 80 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, they would be subject to extensive government regulation in the United States. Additionally, if we seek to market and distribute any such products abroad, they would also be subject to extensive foreign government regulation.

In the United States, the Food and Drug Administration, or FDA, regulates pharmaceutical products. FDA regulations govern the testing, manufacturing, advertising, promotion, labeling, sale and distribution of pharmaceutical products, and generally require approval of new drugs through a rigorous process. We also may be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are studied 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.

Table of Contents

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 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.

A 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.

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. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. 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, RDEA806, RDEA119 and RDEA594, and we may file additional INDs during 2009. We are required to file an IND before we can commence any clinical trials for our product candidates in the United States.

We cannot assure you that submission of an IND for any of our preclinical product candidates will result in authorization to commence clinical trials. Nor can we assure you that any of our current or future clinical trials will result in approval to market our products. 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 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.

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

Table of Contents

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.

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 drugs 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.

Additional Regulation

Third-Party Reimbursement

In the United States, physicians, hospitals and other healthcare providers that purchase pharmaceutical products generally rely on third-party payers, 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 payers 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 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

Table of Contents

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 6, 2009, we employed 81 regular full-time employees (including 28 people who have a Ph.D. and one person who has a Pharm.D.), 64 of whom are involved full-time in research, clinical 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 agreements 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. 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.

Table of Contents

Risks Related to Our Business

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

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 research and development and preclinical and clinical testing of compounds. The amounts paid to advance the preclinical and clinical development of our product candidates, including RDEA806, RDEA594, RDEA427, RDEA119, RDEA436 and our other compounds, may continue to increase. Any compounds we advance through preclinical and clinical development will require extensive and costly development, preclinical testing and clinical trials prior to seeking regulatory approval for commercial sales. Our most advanced product candidates, RDEA806, RDEA594, RDEA427, RDEA119, RDEA436, and any other compounds we advance further into development, may never be approved for commercial sales. The time required to achieve product sales and profitability is lengthy and highly uncertain and we cannot assure you that we will be able to achieve or maintain product sales.

We are not currently profitable and may never become profitable.

To date, we have generated limited revenues and we do not anticipate generating significant revenues for at least several years, if ever. We may increase our operating expenses over at least the next several years as we plan to advance our product candidates, including RDEA806, RDEA594, RDEA427, RDEA119, RDEA436, 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 are not necessarily predictive of future results, we can provide no assurances that, even if our product candidates are successful in preclinical studies, such product candidates will have favorable results in clinical trials or receive regulatory approval.

Positive results from preclinical studies should not be relied upon as evidence that clinical trials will succeed. Even if our product candidates achieve positive results in clinical studies, we will be required to demonstrate through clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. If any product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, then we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts of any of our product candidates, then we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

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

Our product candidates will require preclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. Delays in the commencement of clinical testing of our product candidates could significantly increase our product development costs and delay product commercialization. In addition, many of

the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

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

- delays in demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;

Table of Contents

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 a 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 insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial.

Delays in the completion of, or the termination of, clinical testing of our current and potential product candidates could result in increased costs to us and delay or prevent us from generating revenues.

Once a clinical trial for any current or potential product candidate has begun, it may be delayed, suspended or terminated by us or the FDA, or other regulatory authorities due to a number of factors, including:

ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;

failure to conduct clinical trials in accordance with regulatory requirements;

lower than anticipated retention rate of patients in clinical trials;

the imposition of a clinical hold;

lack of adequate funding to continue clinical trials;

negative results of clinical trials;

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

If our internal discovery and development efforts are unsuccessful, we will be required to obtain rights to new products or product candidates from third parties, which we may not be able to do.

Our long-term ability to earn product revenue depends on our ability to successfully advance our product candidates through clinical development and regulatory approval and to identify and obtain new products or product candidates through internal development or licenses from third parties. If the development programs we acquired from Valeant and our internal development programs are not successful, we will need to obtain rights to new products or product candidates from third parties. We may be unable to obtain suitable product candidates or products from third parties for a number of reasons, including:

- we may be unable to purchase or license products or product candidates on terms that would allow us to make a sufficient financial return from resulting products;

Table of Contents

competitors may be unwilling to assign or license products or product candidate rights to us (in particular, if we are not able to successfully advance the further development of the product candidates we acquired from Valeant); or

we may be unable to identify suitable products or product candidates within, or complementary to, our areas of interest relating to the treatment of gout, HIV, cancer and inflammatory diseases.

If we are unable to obtain rights to new products or product candidates from third parties, our ability to generate product revenues and achieve profitability may suffer.

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

There can be no assurance that if our clinical trials of any potential product candidate are successfully initiated and completed, we will be able to submit an 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 an NDA or similar application with respect to any future 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 application 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 any future product candidate in clinical trials, we may be unable to generate sufficient revenues to attain profitability and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

If we successfully develop products, but those products do not achieve and maintain market acceptance, our business will not be profitable.

Even if any of our product candidates are approved for commercial sale by the FDA or other regulatory authorities, 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

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

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

new products or technologies are introduced that are more favorably received than our potential future products, are more cost effective or render our potential future products obsolete; or

complications arise with respect to use of our potential future products.

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

Based on current projections, excluding any funds that we may receive from future business development activities, we believe that our existing cash, cash equivalents and short- term investments and interest earned thereon, will be adequate to fund our anticipated levels of operations into the second quarter of 2010. However, our

Table of Contents

business and operations may change in a manner that would consume available resources at a greater rate than anticipated. In particular, because most of our resources for the foreseeable future will be used to advance our product candidates, we may not be able to accurately anticipate our future research and development funding needs. We will need to raise substantial additional capital in the future to, among other things:

- fund our research, discovery and development programs;
- advance our product candidates into and through clinical trials and the regulatory review and approval process;
- establish and maintain manufacturing, sales and marketing operations;
- commercialize our product candidates, if any, that receive regulatory approval; and
- acquire rights to products or product candidates, technologies or businesses.

Our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

- the rate of progress and cost of our research and development activities;
- 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 the current unprecedented volatile economic conditions affecting financial markets. 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.

We may need to decrease the size of our organization, and we may experience difficulties in managing those organizational changes.

We may need to decrease the number of our employees in response to the recent global financial crisis or other adverse events. If our future staffing is inadequate because of additional unanticipated attrition or because we failed 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 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. Any drop in employee morale or other potential operational disruptions resulting from our restructuring efforts could divert the attention of our management away from our operations. Our restructuring efforts may harm our reputation and actually increase our expenses in the short-term.

Table of Contents

We cannot assure you that any restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from restructuring activities.

Raising additional funds by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may raise additional funds through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants 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, pay dividends, redeem capital stock or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. For example, we might be required to relinquish all or a portion of our sales and marketing rights with respect to potential products or license intellectual property that enables licensees to develop competing products in order to complete any such transaction.

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

Our short-term investments consist of securities of the United States government, its federal agencies, entities controlled by the federal government and municipal bonds. These investments are subject to general credit, liquidity, market and interest rate risks, which may further be exacerbated by United States sub-prime mortgage defaults and other factors, which have affected various sectors of the financial markets and caused credit and liquidity issues. During the year ended December 31, 2008, 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 do not have internal manufacturing capabilities, and if we fail to develop and maintain internal capabilities or supply relationships with collaborators or other outside manufacturers, we may be unable to develop or commercialize any products.

Our ability to develop and commercialize any products we may develop will depend in part on our ability to manufacture, or arrange for collaborators or other parties to manufacture, our products at a competitive cost, in accordance with regulatory requirements, and in sufficient quantities for clinical testing and eventual commercialization. We currently do not have any significant manufacturing arrangements or agreements, as our current product candidates will not require commercial-scale manufacturing for at least several years, if ever. Our inability to enter into or maintain manufacturing agreements with collaborators or capable contract manufacturers on acceptable terms could delay or prevent the development and commercialization of our products, which would adversely affect our ability to generate revenues and would increase our expenses.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may be unable to generate product revenue.

We do not currently have a sales organization for the sales, marketing and distribution of pharmaceutical products. In order to commercialize any products, we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We have not yet

determined whether we will attempt to establish internal sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop. The establishment and development of our own sales force to market any products we may develop will be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capacity. If we are unable to establish our sales and marketing capability or any other non-technical capabilities necessary to

Table of Contents

commercialize any product we may develop, we will need to contract with third parties to market and sell any products we may develop. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

If we are unable to attract and retain key management and scientific staff, we may be unable to successfully develop or commercialize our product candidates.

We are a small company, and our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. In particular, our research and drug discovery and development programs depend on our ability to attract and retain highly skilled chemists, biologists and preclinical personnel, especially in the fields of HIV, gout, cancer and inflammatory diseases. If we are unable to hire or retain these employees, we may not be able to advance our research and development programs at the pace we anticipate. We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical businesses, particularly in the San Diego, California area. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our research and development objectives. In addition, all of our employees are at will employees, which means that any employee may quit at any time and we may terminate any employee at any time. Currently, we do not have employment agreements with any employees or members of senior management that provide us any guarantee of their continued employment. If we lose members of our senior management team, we may not be able to find suitable replacements and our business may be harmed as a result.

Our quarterly results and stock price may fluctuate significantly.

We expect our results of operations and future stock price to continue to be subject to significant quarterly 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 research or commercialization milestones under any agreement that we enter into with collaborators and the timely payment by potential commercial collaborators of any amounts payable to us or by us to Valeant or any other party, including the milestone payments that we may make to Valeant;
- the addition or termination of research or development programs or funding support;
- the status of development of our product candidates, including results of preclinical studies and any future clinical trials;
- variations in the level of expenses related to our product candidates or potential product candidates during any given period;
- our execution of collaborative, licensing or other arrangements, and the timing and accounting treatment of payments we make or receive under these arrangements;
- our recommendation of additional compounds for preclinical development; and
- fluctuations in the stock prices of other companies in the biotechnology and pharmaceuticals industries and in the financial markets generally.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. In particular, if our quarterly operating 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.

Table of Contents

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

In 2006, we acquired pharmaceutical research and development programs, including our most advanced product candidates, from Valeant, and there is no guarantee that we will be able to successfully develop the acquired product candidates. We may attempt to acquire businesses, technologies, services or other products or in-license technologies that we believe are a strategic fit with our existing development programs, at the appropriate time and as resources permit. In any acquisition, the process of integrating the acquired business, 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. These operational and financial risks include:

- assumption and exposure to unknown liabilities of the acquired business;
- disruption of our business and diversion of our management s time and attention to acquiring and developing acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- negative effect on our earnings (or loss) per share;
- difficulty and cost in combining and integrating the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, contractors or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We may fail to realize the anticipated benefits of any 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.

Valeant s exercise of its option to repurchase commercialization rights in territories outside the United States and Canada (the Valeant Territories) could limit the market for our first NNRTI product and adversely affect our

business.

Under the asset purchase agreement that we entered into with Valeant on December 21, 2006, Valeant retains a one-time option to repurchase commercialization rights in the Valeant Territories for our first NNRTI product derived from the acquired intellectual property to advance to a Phase 2b HIV clinical trial. If Valeant exercises this option, which it can do following the completion of a Phase 2b clinical trial, but prior to the initiation of a Phase 3 clinical trial, Valeant would pay us a $10.0 million option fee, up to $21.0 million in milestone payments based on regulatory approvals, and a mid-single-digit royalty on product sales in the Valeant Territories. However, Valeant would then own all commercialization rights in the Valeant Territories, which may adversely impact the amount of aggregate revenue we may be able to generate from sales of our NNRTI product and may negatively impact our

Table of Contents

potential for long-term growth. Also, if Valeant exercises its option to repurchase commercialization rights in the Valeant Territories and experiences difficulties in commercializing our NNRTI product in the Valeant Territories, then our commercialization efforts in the United States and Canada may be adversely impacted. Finally, Valeant s option may adversely impact any efforts we may undertake to license our NNRTI product to a potential commercial partner who requires worldwide rights to the product.

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

We agreed to use reasonable efforts to develop the product candidates in the pharmaceutical research and development programs we acquired from Valeant, with the objective of obtaining marketing approval for RDEA806, RDEA119 and the lead product candidates from the next generation NNRTI and MEK inhibitor programs in the United States, the United Kingdom, France, Spain, Italy and Germany. If we fail to make sufficient effort to develop the product candidates, then we may be subject to a potential lawsuit or lawsuits from Valeant under the asset purchase agreement. If such a lawsuit 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 achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

Section 404 of the Sarbanes-Oxley Act requires on-going management assessments, beginning with the year ended December 31, 2007, of the effectiveness of our internal controls over financial reporting and, beginning with the year ending December 31, 2008, will further require 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.

Table of Contents

Risks Related to Our Industry

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

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection of our product candidates and their uses, as well as successfully defending these patents against 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. 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 United States 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 United States patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the United States Patent Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our United States patent position. Furthermore, we may not have identified all United States 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, HIV, cancer and inflammatory diseases. As a result, we may not be able to enforce our patents effectively because we may not be able to prevent healthcare providers from prescribing, administering or using another company s product that contains the same active substance as our products when treating patients with gout, HIV, cancer or inflammatory diseases.

Table of Contents

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 United States and foreign issued patents and pending patent applications owned by others in gout, HIV, cancer, inflammatory diseases and the other fields in which we 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 product candidates that incorporate the challenged intellectual property;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our processes so that they do not infringe, which could be costly and time-consuming and may not be possible.

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

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

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

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our employees, consultants and other advisors. These agreements may not effectively prevent disclosure of confidential information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In

addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Table of Contents

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 any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced.

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

We believe that a significant number of drugs are currently under development and may become available in the future for the treatment of gout, HIV, cancer and inflammatory diseases. Potential competitors may develop treatments for gout, HIV, cancer or inflammatory diseases 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 most advanced product candidates.

If we cannot establish pricing of our product candidates acceptable to the United States 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 United States 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 any products and related treatments.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the United States Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. The trend toward managed health care in the United States, which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care, control pharmaceutical prices or reduce government insurance programs, may result in lower prices for our product candidates. While we cannot predict whether any

Table of Contents

legislative or regulatory proposals affecting our business will be adopted, the announcement or adoption of these proposals could have a material and adverse effect on our potential revenues and gross margins.

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

We 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 involves the controlled use of hazardous materials, including chemicals that cause cancer, volatile solvents, radioactive materials and biological materials that have the potential to transmit disease. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products. If we fail to comply with these laws and regulations or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial 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.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our research and drug discovery and development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our research and drug discovery and development programs may be adversely affected and the further development of our product candidates may be delayed. In addition, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

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. 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 as of

Table of Contents

June 17, 2009 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 governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit large stockholders from consummating a merger with, or acquisition of us. These provisions may prevent a merger or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our common stock.

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

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

ITEM 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. ***SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.***

None.

Table of Contents

PART II

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

Information About Our Common Stock

Our common stock trades on the Nasdaq Global 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.

	High	Low
Year Ended December 31, 2008		
First Quarter	$ 16.25	$ 11.20
Second Quarter	$ 15.30	$ 12.36
Third Quarter	$ 15.07	$ 9.26
Fourth Quarter	$ 14.16	$ 6.29

	High	Low
Year Ended December 31, 2007		
First Quarter	$ 6.50	$ 4.15
Second Quarter	$ 6.05	$ 4.60
Third Quarter	$ 9.20	$ 5.00
Fourth Quarter	$ 15.50	$ 7.00

Holders

The number of record holders of our common stock as of March 6, 2009 was approximately 68.

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.

The holders of our Series A preferred stock were entitled to receive cumulative dividends at the rate of 8% per annum of the original purchase price of $10,000 per share of Series A preferred stock, prior to and in preference to any declaration or payment of a dividend to the holders of our common stock. The dividends were payable quarterly in shares of our common stock. The number of shares payable was determined based on the average closing sale price of our common stock for each of the five trading days immediately preceding the applicable dividend payment date. Until accrued and unpaid dividends on the Series A preferred stock were paid and set apart, no dividends or other distributions in respect of any other shares of our capital stock could be declared. There are currently no shares of Series A Preferred Stock outstanding. All outstanding shares of Series A Preferred Stock were automatically converted into shares of common stock in May 2008.

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.

Table of Contents

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, 2008 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). The graph assumes that $100 was invested on December 31, 2003 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.

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 beginning on page 25 and the consolidated financial statements and related notes thereto beginning on page F-2 of this annual report on Form 10-K.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Collaboration revenues	$ 304	$ 3,095	$	$	$
Expenses:					
Research and development	44,858	23,103	72	255	11,519
General and administrative	11,921	7,566	2,674	2,980	4,819
Restructuring and other charges				648	858
Loss from operations	(56,475)	(27,574)	(2,746)	(3,883)	(17,196)
Interest income	1,524	2,128	2,377	1,502	700
Other income, net	(44)	375	2	(1)	(204)
Change in fair value on revaluation of warrants				(789)	
Net Loss	(54,995)	(25,071)	(367)	(3,171)	(16,700)
Non-cash dividends on Series A preferred stock	(60)	(240)	(240)	(240)	(260)
Net loss applicable to common stockholders	$ (55,055)	$ (25,311)	$ (607)	$ (3,411)	$ (16,960)
Basis and diluted net loss per share applicable to common stockholders	$ (3.79)	$ (2.55)	$ (0.07)	$ (0.37)	$ (2.24)
Shares used in computing basic and diluted net loss per share applicable to common stockholders	14,544	9,934	9,326	9,134	7,559
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 57,743	$ 66,215	$ 48,669	$ 48,830	$ 50,743
Working capital	$ 49,463	$ 62,548	$ 48,338	$ 48,820	$ 50,462
Total assets	$ 61,475	$ 68,840	$ 50,240	$ 49,171	$ 51,185
Noncurrent portion of obligations under capital leases and notes payable	$ 6,132	$	$	$	$
Accumulated deficit	$ (316,543)	$ (261,488)	$ (236,177)	$ (235,570)	$ (232,159)
Total stockholders equity	$ 45,958	$ 63,739	$ 49,064	$ 48,820	$ 50,508

Table of Contents

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, 2008 to the results for the year ended December 31, 2007 and comparing the results for the year ended December 31, 2007 to the results for the year ended December 31, 2006.

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, 2008. 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 discovery and development of small-molecule therapeutics for the treatment of gout, HIV, cancer and inflammatory diseases. We have five product candidates in clinical trials including:

RDEA594: An inhibitor of the URAT1 kidney transporter for the treatment of hyperuricemia and gout;

RDEA806: A non-nucleoside reverse transcriptase inhibitor (NNRTI) for the treatment of HIV. RDEA806, the prodrug of RDEA594, is also being evaluated in a pilot Phase 2a proof-of-concept study in gout patients to provide an early confirmation of RDEA594 s activity in the target population.

RDEA427: A next generation NNRTI for the treatment of HIV;

RDEA119: An inhibitor of mitogen-activated ERK kinase (MEK) for the treatment of cancer and inflammatory diseases; and

RDEA436: A next generation inhibitor of MEK for the treatment of cancer and inflammatory diseases.

In addition to our product candidates in clinical development, we have other programs at the discovery or preclinical stage.

Research and Development Expense

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

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

Table of Contents

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 2009 research and development costs to decrease from 2008 levels due to reduced company-funded activity in our HIV, cancer, and inflammatory disease research and development programs.

General and Administrative Expense

General and administrative expense primarily consist 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, net

Other income, net 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 December 2008, we completed a single ascending dose Phase 1 clinical study of RDEA594 in normal healthy volunteers, demonstrating that single doses of up to 600 mg of RDEA594 were well tolerated, with linear increases in drug levels observed throughout the dose ranges investigated, and with up to an 11-hour elimination half life. A dose-related decrease in serum uric acid was observed, with overall reductions compared to placebo of up to 30% over the first 24 hours, which is about twice that observed in prior studies with a single 800 mg dose of RDEA806, RDEA594 s prodrug, given as an enteric-coated tablet;

In December 2008, we completed a $30.6 million gross proceeds private placement of 2,737,336 newly issued shares of common stock and warrants to purchase 684,332 shares of common stock at a total purchase price of $11.17 per unit, with each unit consisting of one share of common stock and one warrant to purchase 0.25 shares of common stock;

In November 2008, we received an $8.0 million growth capital loan from Oxford Finance Corporation and Silicon Valley Bank;

In October 2008, based on positive in vitro synergy data, we initiated a Phase 1/2 study of RDEA119 in combination with sorafenib (Nexavar®, Onyx Pharmaceuticals and Bayer HealthCare) in advanced cancer patients; and

We have continued to prepare RDEA806 for further clinical development by obtaining additional regulatory approvals to conduct our planned international Phase 2b HIV study and by successfully completing a number of important safety and toxicology studies including a Thorough QT study. Results from the Thorough QT study demonstrated that QTc intervals were not increased by any dose of RDEA806 tested. In addition, the study provided information on the lack of pharmacokinetic differences between Caucasians and African-Americans. These results provide further support for RDEA806 s cardiac safety profile as well as its potential to improve current standard-of-care therapy as ethnicity-based differences in metabolism, which can lead to increased side effects in African-Americans, have been documented with efavirenz (Sustiva®,

Bristol-Myers Squibb).

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 United States generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that

Table of Contents

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 accrued clinical liabilities and share-based compensation. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

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

Accrued Clinical Liabilities

We review and accrue clinical costs based on work performed, which relies on estimates of the services received and 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.

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. The benefits provided under all of these plans are subject to the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123R, *Share-Based Payment*, which we adopted effective January 1, 2006 under the modified prospective application method. The valuation provisions of SFAS 123R apply to new awards and to awards that are outstanding on the adoption date and are subsequently modified or cancelled.

We estimate the fair value of stock options granted using the Black-Scholes-Merton, or 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 the weighted-average volatility of our stock, factoring in daily share price observations and the historical price volatility of certain peers within our industry sector. In computing expected volatility, the length of the historical period used is equal to the length of the expected term of the option and the share purchase right. 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, under Staff Accounting Bulletin, or SAB, No. 107, *Share-Based Payments* and SAB No. 110.

As share-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be 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

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*. SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes resulting from the application of SFAS 157 relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. On January 1, 2008, we adopted the provisions of SFAS 157. See Note 3 to our financial statements for further

Table of Contents

details on the impact of the adoption of SFAS 157 on our consolidated results of operations and financial condition for the year ended December 31, 2008.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*. SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. At this time, we have not elected to account for any of our financial assets or liabilities using the provisions of SFAS 159. As such, the adoption of SFAS 159, on January 1, 2008, did not have an impact on our consolidated results of operations or financial condition for the year ended December 31, 2008.

In June 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force, or EITF, on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods or services are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. On January 1, 2008, we adopted the provisions of EITF 07-3, which did not have an impact on our consolidated results of operations and financial condition for the year ended December 31, 2008.

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*. The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The EITF concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each participating company s financial statements pursuant to the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The EITF also concluded that the equity method of accounting under Accounting Principles Board Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. Furthermore, the EITF concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities operations; and whether the partners payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2008, and companies will be required to apply the provisions through retrospective application. We plan to adopt EITF 07-1 at the beginning of fiscal 2009 and are evaluating the impact of the adoption on our results of operations and financial condition.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP. SFAS 162 shall be effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not currently believe that the adoption of SFAS 162 will have a material impact on our results of operations and financial condition.

Results of Operations

Year Ended December 31, 2008 and 2007

Revenues

For the year ended December 31, 2008, revenues decreased to $0.3 million from $3.1 million for the year ended December 31, 2007. Historically, our revenues have resulted from the research services we provided under

our master services agreement with Valeant for its preclinical neuropharmacology program. The decrease in revenues from 2007 levels was due to the earlier than anticipated identification of a clinical development candidate from that program and Valeant s subsequent reduction in the utilization of our research and development services. The master services agreement has since terminated by its terms.

Research and Development Expense

For the year ended December 31, 2008, research and development expense increased to $44.9 million from $23.1 million for the same period in 2007. The increase in research and development expense was primarily due to continued development and progression of our clinical and preclinical programs, which included increased spending of approximately $16.1 million on clinical research organizations, professional outside services, and research and clinical trial supplies and materials for the year ended December 31, 2008. In addition, the increase in research and development expense was a result of additional personnel costs of approximately $3.1 million and an increase in share-based compensation expense of approximately $1.4 million for the year ended December 31, 2008 resulting from increased headcount in 2008 as compared to 2007.

General and Administrative Expense

For the year ended December 31, 2008, general and administrative expense increased to $11.9 million from $7.6 million for the same period in 2007. The increase in general and administrative expense was primarily the result of higher share-based compensation expense of approximately $2.3 million and additional personnel costs of approximately $1.9 million due to increased headcount in 2008 as compared to 2007.

Other Income, net

For the year ended December 31, 2008, other income, net decreased to $1.5 million from $2.5 million for the same period in 2007. The decrease in other income, net was primarily a result of lower average interest rates and lower average cash balances for 2008 as compared to 2007, as well as increased interest expense in 2008 associated with our growth capital loan, tenant improvements loan and capital lease obligation entered into in 2008. There were no comparable obligations in 2007.

Year Ended December 31, 2007 and 2006

Revenues

For the year ended December 31, 2007, we earned $3.1 million in revenues under the master services agreement with Valeant for our research services and development of a clinical development candidate for Valeant s preclinical neuropharmacology program. There were no revenues for the year ended December 31, 2006.

Research and Development Expense

For the year ended December 31, 2007, research and development expense increased to $23.1 million from $0.1 million for the year ended December 31, 2006. The increase in research and development expenses was due to the startup of our research and development programs in December 2006. Research and development expense for the year ended December 31, 2007, primarily consisted of approximately $11.2 million for clinical research organizations, professional outside services, and research and clinical trial supplies and materials, approximately $6.8 million for research and development personnel costs, approximately $2.5 million for facility related costs and approximately $0.7 million in share-based compensation expense.

General and Administrative Expense

For the year ended December 31, 2007, general and administrative expense increased to $7.6 million from $2.7 million for the year ended December 31, 2006. The increase in general and administrative expense was primarily the result of additional personnel costs of approximately $2.3 million and increased share-based compensation expense of $0.2 million due to increased headcount in 2007 as compared to 2006. In addition,

Table of Contents

the increase was also due to higher costs of approximately $1.6 million for professional fees for legal, audit and public relations, and consulting fees for other general corporate purposes.

Other Income, net

For the year ended December 31, 2007, other income, net increased to $2.5 million from $2.4 million primarily due to an increase in other income from the sale of fixed assets in 2007, partially offset by a decrease in interest income as a result of lower average cash balances in 2007 as compared to 2006.

Liquidity and Capital Resources

From inception through December 31, 2008, we have incurred a cumulative net loss of approximately $316.5 million and have financed our operations through public and private offerings of securities, proceeds from our growth capital loan, revenues from collaborative agreements and interest income from invested cash balances.

In December 2008, we entered into a Securities Purchase Agreement for the private placement of 2,737,336 newly issued unregistered shares of our common stock and warrants to purchase 684,332 shares of common stock at a total purchase price of approximately $11.17 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.25 shares of common stock at an exercise price of $11.14 per share. The net proceeds from the private placement were approximately $30.5 million. On January 13, 2009, we filed a registration statement with the SEC covering the resale of these shares and the shares issuable upon exercise of the warrants. This registration statement was declared effective by the SEC on January 21, 2009.

In November 2008, we entered into an agreement with Oxford Finance Corporation and Silicon Valley Bank, or the Lenders, pursuant to which the Lenders provided us with an approximately three-year, $8.0 million growth capital loan. Interest accrues 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. In addition, we are required to pay a total loan commitment fee of approximately $0.5 million, of which $0.1 million was paid upon entering into the loan agreement and the remaining $0.4 million is due at the end of the term of the loan. We have the option to prepay the outstanding balance of the loan in full, subject to a prepayment fee. The loan is collateralized by our general assets, excluding intellectual property. There are no financial covenants associated with the loan. In connection with the loan, we issued to the Lenders warrants to purchase up to an aggregate of 56,010 shares of our common stock at an exercise price of $8.57 per share. The warrants are currently exercisable and expire seven years from the date of issuance.

We lease our office and laboratory facilities and certain equipment under operating leases. In March 2008, we exercised our right under our sublease agreement to borrow approximately $250,000 for costs incurred and paid for certain tenant improvements recently completed at our new facility. 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 addition, in July 2008, we entered into a capital lease agreement for approximately $318,000 to finance the purchase of certain equipment. The agreement is secured by the equipment, bears interest at 6.05% per annum, and is payable in monthly installments of principal and interest of approximately $10,000 for 36 months beginning in August 2008.

As of December 31, 2008, we had $57.7 million in cash, cash equivalents, and short-term investments compared to $66.2 million as of December 31, 2007. The decrease in cash, cash equivalents and short-term investments for the year ended December 31, 2008 was due to the use of our financial resources to fund our clinical and preclinical programs, increased personnel costs, and for other general corporate purposes, partially offset by the proceeds received from our growth capital loan and the sale of equity securities.

Under the asset purchase agreement with Valeant, we will be required to pay Valeant $2.0 million after the first patient is dosed in the first Phase 2b study for the NNRTI program. We expect to dose the first patient in the Phase 2b study in 2009, the timing of which will be determined in part by the results of ongoing partnering discussions.

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 upon the number of patients

Table of Contents

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 fund our obligations under these commitments from our current financial resources.

In addition, we entered into employment agreements with our executive officers and certain other key employees that, under certain circumstances, provide for the continuation of salary and certain other benefits if terminated under specified circumstances. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. As of December 31, 2008, no events have occurred resulting in the obligation of any such payments.

The following table summarizes our contractual obligations as of December 31, 2008. Long-term debt and capital lease obligations include interest.

	Payment Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In thousands)		
Long-term debt obligations	$ 9,963	$ 2,858	$ 6,950	$ 91	$ 64
Operating lease obligations	6,529	984	2,055	2,166	1,324
Capital lease obligations	300	116	184		
Purchase Obligations	1,291	1,188	103		
Other long-term liabilities	400		400		
Total	$ 18,483	$ 5,146	$ 9,692	$ 2,257	$ 1,388

At December 31, 2008, purchase obligations primarily consisted of commitments with third-party manufacturers of materials to be used in our clinical and pre clinical studies. Approximately $0.7 million of the total purchase obligations were not included in our consolidated financial statements for the year ended December 31, 2008. We intend to use our current financial resources to fund our commitments under these purchase obligations.

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 and research programs we pursue; the terms and timing of any collaborative, licensing and other arrangements that we may establish; 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 and interest earned thereon, will be sufficient to fund our operations as currently planned into the second quarter of 2010. This projection assumes we do not raise any additional funds, including through the sale of additional securities, additional debt financings or establishment of collaborative or licensing arrangements with corporate partners.

We have no current means of generating material cash flows from operations. There can be no assurance that our product development efforts with respect 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. Accordingly, we will continue to seek capital by various means, including by selling our equity securities, additional debt financing and by establishing one or more collaborative or licensing arrangements. However, there can be no assurance that additional financing will be available to us on acceptable terms, if at all.

Table of Contents

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, changes in 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. As of December 31, 2008, we owned financial instruments that are sensitive to market risk, including interest rate risk, as part of our investment portfolio. To minimize our exposure to market risk, we have generally limited our investments to cash and securities of the government of the United States of America and its federal agencies or high-grade corporate and municipal bonds with maturity dates of less than one year. Due to the short-term nature of our investments, a 50-basis point movement in market interest rates over the three-month period following December 31, 2008 would not have a material impact on the fair value of our portfolio as of December 31, 2008. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk. We also do not invest in any derivative financial instruments, derivative commodity instruments, auction rate securities or other market risk sensitive instruments, positions or transactions.

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 III of this annual report on Form 10-K.

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

None.

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, 2008. 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, 2008.

There was no change in our internal control over financial reporting during the quarter ended December 31, 2008 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;

Table of Contents

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, 2008. 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, 2008, 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.

(c) Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Ardea Biosciences, Inc.

We have audited Ardea Biosciences, Inc. s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Ardea Biosciences, Inc. 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 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 its 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

Table of Contents

controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Ardea Biosciences, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity, and cash flows for each year in the three-year period ended December 31, 2008, of Ardea Biosciences, Inc. and our report dated March 12, 2009 expressed an unqualified opinion.

/s/ Stonefield Josephson, Inc.

San Francisco, California
March 12, 2009

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 2009 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2008. 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. 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 2009 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2008. 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 2009 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2008. 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 2009 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2008. Such information is incorporated herein by reference.

Table of Contents

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

Information required by this item will be contained in our Definitive Proxy Statement for our 2009 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2008. Such information is incorporated herein by reference.

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:

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.

Table of Contents

Exhibit	Document Description
2.1	Asset Purchase Agreement with Valeant Research & Development and Valeant Pharmaceuticals International dated December 21, 2006(1)
3.1	Restated Certificate of Incorporation filed with the Delaware Secretary of State on September 10, 2008(2)
3.2	Amended and Restated Bylaws(3)
4.1	Registration Rights Agreement, dated December 19, 2007, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto(4)
4.2	Registration Rights Agreement, dated January 4, 2008, by and among Ardea Biosciences, Inc. and the stockholders 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
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)
10.1	Form of Indemnity Agreement(8)
10.2*	Senior Executive Severance Benefit Plan, as amended and restated on November 7, 2008
10.3*	Executive Severance Benefit Plan, as amended and restated on November 7, 2008
10.4*	2002 Non-Officer Equity Incentive Plan and related documents, as amended on February 3, 2003(9)
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
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(10)
10.9*	Executive Employment Agreement, effective March 22, 2007, between the Company and Christopher W. Krueger(11)
10.10*	Amended and Restated 2004 Stock Incentive Plan(12)
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(13)
10.13*	Executive Employment Agreement, effective as of May 27, 2008, between the Company and John W. Beck(14)
10.14	Loan and Security Agreement, dated November 12, 2008, by and among Ardea Biosciences, Inc. and Oxford Finance Corporation and Silicon Valley Bank
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)
23.1	Consent of Independent Registered Public Accounting Firm
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

* 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.

Table of Contents

(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 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on October 15, 2007.

(11) Incorporated by reference to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on May 8, 2007.

(12) Incorporated by reference to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on July 3, 2007.

(13) Incorporated by reference to our Form 10-K (File No. 001-33734) filed with the Securities and Exchange Commission on March 24, 2008.

(14) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on May 13, 2008.

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 Barry D. Quart, Pharm. D.	President and Chief Executive Officer *(Principal Executive Officer)*	March 13, 2009
/s/ JOHN W. BECK John W. Beck, C.P.A.	Senior Vice President, Finance and Operations and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 13, 2009
/s/ HENRY J. FUCHS Henry J. Fuchs, M.D.	Director	March 13, 2009
/s/ CRAIG A. JOHNSON Craig A. Johnson	Director	March 13, 2009
/s/ JOHN POYHONEN John Poyhonen	Director	March 13, 2009
/s/ JACK S. REMINGTON Jack S. Remington, M.D.	Director	March 13, 2009
/s/ KEVIN C. TANG Kevin C. Tang	Director	March 13, 2009

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

TO THE STOCKHOLDERS AND BOARD OF DIRECTORS OF
ARDEA BIOSCIENCES, INC. (Formerly IntraBiotics Pharmaceuticals, Inc.)

We have audited the accompanying consolidated balance sheets of Ardea Biosciences, Inc. (formerly IntraBiotics Pharmaceuticals, Inc.) as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2008. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Ardea Biosciences, Inc. (formerly IntraBiotics Pharmaceuticals, Inc.) as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2008 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, 2008, 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 12, 2009 expressed an unqualified opinion.

/s/ Stonefield Josephson, Inc.

San Francisco, California
March 12, 2009

Table of Contents

ARDEA BIOSCIENCES, INC.
(formerly IntraBiotics Pharmaceuticals, Inc.)

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	December 31, 2007
	(In thousands, except per share and par value amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,551	$ 46,384
Short-term investments, available-for-sale	16,192	19,831
Receivables	384	1,224
Prepaids and other current assets	237	210
Total current assets	58,364	67,649
Property and equipment, net	2,310	879
Other assets	801	312
Total assets	$ 61,475	$ 68,840
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,260	$ 2,200
Accrued clinical liabilities	2,278	456
Accrued payroll and employee liabilities	1,758	1,612
Other accrued liabilities	545	833
Current portion of obligations under capital lease	102	
Current portion of obligations under notes payable	1,958	
Total current liabilities	8,901	5,101
Deferred rent	84	
Non-current portion of obligations under capital lease	175	
Non-current portion of obligations under notes payable	5,957	
Other long-term liabilities	400	
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, 2008 and 300 shares outstanding and $3,000 aggregate liquidation preference at December 31, 2007		1,634
Common stock, $0.001 par value: 70,000,000 shares authorized; 17,835,734 and 13,312,686 shares issued and outstanding at December 31, 2008 and 2007, respectively	17	13
Additional paid-in capital	362,345	323,566

Accumulated other comprehensive income	139	14
Accumulated deficit	(316,543)	(261,488)
Total stockholders equity	45,958	63,739
Total liabilities and stockholders equity	$ 61,475	$ 68,840

See accompanying notes.

Table of Contents

ARDEA BIOSCIENCES, INC.
(formerly IntraBiotics Pharmaceuticals, Inc.)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2008	2007	2006
	(In thousands, except per share amounts)		
Collaboration revenues	$ 304	$ 3,095	$
Operating expenses:			
Research and development	44,858	23,103	72
General and administrative	11,921	7,566	2,674
Total operating expenses	56,779	30,669	2,746
Loss from operations	(56,475)	(27,574)	(2,746)
Other income, net:			
Interest income	1,524	2,128	2,377
Interest expense	(215)		
Other income, net	171	375	2
Total other income, net	1,480	2,503	2,379
Net loss	(54,995)	(25,071)	(367)
Non-cash dividends on Series A preferred stock	(60)	(240)	(240)
Net loss applicable to common stockholders	$ (55,055)	$ (25,311)	$ (607)
Basic and diluted net loss per share applicable to common stockholders	$ (3.79)	$ (2.55)	$ (0.07)
Shares used in computing basic and diluted net loss per share applicable to common stockholders	14,544	9,934	9,326

See accompanying notes.

Table of Contents

ARDEA BIOSCIENCES, INC.
(formerly IntraBiotics Pharmaceuticals, Inc.)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Convertible Preferred Stock	Common Stock		Additional Paid-In	Deferred Stock	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders
	Amount	Shares	Amount	Capital	Compensation	(Loss)	Deficit	Equity
				(In thousands)				
Balances at December 31, 2005	$ 1,634	9,288	$ 9	$ 282,828	$ (45)	$ (36)	$ (235,570)	$ 48,820
Issuance of common stock upon exercise of stock options		8		20				20
Issuance of common stock as dividend on series A preferred stock		66		240			(240)	
Share-based compensation				551				551
Amortization of deferred stock compensation				(45)	45			
Comprehensive loss:								
Net loss							(367)	(367)
Unrealized gain on securities						40		40
Comprehensive loss								(327)
Balances at December 31, 2006	$ 1,634	9,362	$ 9	$ 283,594	$	$ 4	$ (236,177)	$ 49,064
Issuance of common stock in private offering, net		3,019	3	37,225				37,228
Issuance of common stock upon exercise of stock options		99		282				282
Issuance of common stock upon exercise of warrants		789	1	815				816
Issuance of common stock as dividend on series A preferred stock		44		240			(240)	
Share-based compensation				1,410				1,410
Comprehensive loss:								
Net loss							(25,071)	(25,071)
Unrealized gain on securities						10		10

Comprehensive loss								(25,061)
Balances at December 31, 2007	$ 1,634	13,313	$ 13	$ 323,566	$	$ 14	$ (261,488)	$ 63,739
Conversion of series A preferred stock	(1,634)	1,578	2	1,632				
Issuance of common stock and warrants in private placement, net		2,737	2	30,539				30,541
Issuance of common stock under Employee Stock Purchase Plan		62		491				491
Issuance of common stock upon exercise of stock options		117		544				544
Issuance of common stock upon exercise of warrants		20						
Issuance of common stock as dividend on series A preferred stock		9		120			(60)	60
Issuance of warrants in connection with debt financing				343				343
Share-based compensation expense				5,110				5,110
Comprehensive loss:								
Net loss							(54,995)	(54,995)
Unrealized gain on securities						125		125
Comprehensive loss								(54,870)
Balances at December 31, 2008	$	17,836	$ 17	$ 362,345	$	$ 139	$ (316,543)	$ 45,958

See accompanying notes.

Table of Contents

ARDEA BIOSCIENCES, INC.
(formerly IntraBiotics Pharmaceuticals, Inc.)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Operating activities:			
Net loss	$ (54,995)	$ (25,071)	$ (367)
Adjustments to reconcile net loss to net cash used for operating activities:			
Share-based compensation	5,110	1,410	551
Depreciation	535	249	
Amortization of debt discount and debt issuance costs	62		
Gain on disposal of property and equipment	(28)	(332)	
Deferred rent	84		
Amortization of premium/(accretion of discount) on short-term investments	79	215	
Change in operating assets and liabilities:			
Receivables	840	(819)	(188)
Prepaids and other current assets	(27)	230	(316)
Other assets		(312)	
Accounts payable	60	1,966	176
Accrued clinical liabilities	1,822	452	(95)
Accrued payroll and employee liabilities	146	1,392	219
Other accrued liabilities	(228)	115	525
Net cash (used for) provided by operating activities	(46,540)	(20,505)	505
Investing activities:			
Purchases of short-term investments	(33,920)	(48,579)	(200,024)
Proceeds from sale or maturity of short-term investments	37,605	62,432	212,232
Proceeds from sale of property and equipment	80	332	
Purchases of property and equipment	(1,700)	(401)	(726)
Net cash provided by investing activities	2,065	13,784	11,482
Financing activities:			
Net proceeds from issuance of notes payable	8,250		
Payments of debt issuance costs	(127)		
Payments on capital lease and note payable obligations	(57)		
Net proceeds from issuance of common stock	31,576	38,326	20
Net cash provided by financing activities	39,642	38,326	20
Net (decrease) increase in cash and cash equivalents	(4,833)	31,605	12,007
Cash and cash equivalents at beginning of year	46,384	14,779	2,772

Cash and cash equivalents at end of year	$ 41,551	$ 46,384	$ 14,779
Supplemental disclosure of cash flow information:			
Interest paid	$ 134	$	$
Supplemental schedule of non-cash information:			
Capital lease obligations incurred for property and equipment	$ 318	$	$
Net unrealized gain on short-term investments	$ 125	$ 10	$ 40
Accrued debt issuance costs	$ 400	$	$
Issuance of common stock dividend on Series A preferred stock	$ (60)	$ (240)	$ (240)
Issuance of warrants in connection with note payable obligation	$ 343	$	$

See accompanying notes.

Table of Contents

ARDEA BIOSCIENCES, INC.
(formerly IntraBiotics Pharmaceuticals, Inc.)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

Ardea Biosciences, Inc. (the Company) is a biotechnology company focused on the discovery and development of small-molecule therapeutics for the treatment of gout, human immunodeficiency virus (HIV), cancer and inflammatory 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 United States generally accepted accounting principles (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. Actual results could differ materially from those estimates.

Reclassification

Certain amounts in the 2006 and 2007 financial statements have been reclassified to conform to the 2008 presentation.

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. In accordance with Statement of Financial Accounting Standard (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS 115), 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, 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, 2008 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 financial instruments and the adoption of SFAS No. 157, *Fair Value Measurements* (SFAS 157).

Table of Contents

ARDEA BIOSCIENCES, INC.
(Formerly IntraBiotics Pharmaceuticals, Inc.)

NOTES TO FINANCIAL STATEMENTS (Continued)

Concentration of Credit Risk

Cash and 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 government-asset-backed securities, obligations of government agencies 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. 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 depreciated on a straight-line basis over the shorter of the estimated useful life or the lease term.

Impairment of Long-Lived Assets

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal 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 the 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 and a charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from the actual results.

Revenue Recognition

The Company recognizes revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*. Amounts received for research funding are recognized as revenues as the research services that are the subject of such funding are performed. Revenue from milestones is recognized when earned, as evidenced by written acknowledgement from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement.

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, outside service providers, facilities costs, fees paid to consultants, professional services, 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 services received and 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.

Table of Contents

ARDEA BIOSCIENCES, INC.
(Formerly IntraBiotics Pharmaceuticals, Inc.)

NOTES TO FINANCIAL STATEMENTS (Continued)

Share-Based Compensation Expense

On January 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment* (SFAS 123R), which is a revision of SFAS No. 123, *Accounting and Disclosure of Stock-Based Compensation* (SFAS 123). SFAS 123R requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including stock options and purchases under the Company s 2000 Employee Stock Purchase Plan (the ESPP), based on estimated fair values. SFAS 123R supersedes the Company s previous accounting under Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees* (APB 25), and SFAS 123, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission (SEC) issued SAB No. 107 (SAB 107), which discusses the interaction between SFAS 123R and certain SEC rules and regulations and provides the SEC s staff views regarding the valuation of share-based payment arrangements for public companies.

The Company adopted SFAS 123R using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company s fiscal year 2006. The Company s Consolidated Statements of Operations as of and for the three years ended December 31, 2008 reflect the impact of SFAS 123R. In accordance with the modified prospective transition method, the Company s Consolidated Statements of Operations for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123R. Share-based compensation expense recognized under SFAS 123R for the years ended December 31, 2008, 2007 and 2006, respectively was approximately $5,110,000, $1,410,000 and $558,000. As of December 31, 2008, there was approximately $14,239,000 of total unrecognized compensation cost related to non-vested share-based payment awards granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize that cost over a weighted-average period of 2.9 years.

Options or stock awards issued to non-employees, other than non-employee directors, have been determined in accordance with Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Deferred charges for options granted to such non-employees are periodically remeasured as the options vest.

SFAS 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods as share-based compensation expense in the Company s Consolidated Statements of Operations. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimated forfeitures based on historical experience.

For the three years ended December 31, 2008, the Company s Consolidated Statement of Operations included compensation expense for share-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Compensation expense for all share-based payment awards is recognized using the straight-line single-option method of attributing the value of

share-based compensation to expense.

As permitted by SFAS 123R, the Company utilizes the Black-Scholes option-pricing model as its method of valuation for stock options and purchases under the ESPP. The Company s determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the Company s stock price as well as assumptions regarding a number of highly complex and subjective variables.

Table of Contents

ARDEA BIOSCIENCES, INC.
(Formerly IntraBiotics Pharmaceuticals, Inc.)

NOTES TO FINANCIAL STATEMENTS (Continued)

Valuation and Expense Information Under SFAS 123R

The following table summarizes share-based compensation expense (in thousands) related to employee and director stock options and ESPP purchases under SFAS 123R for the years ended December 31, 2008, 2007 and 2006:

	December 31,		
	2008	**2007**	**2006**
Research and development	$ 2,098	$ 665	$
General and administrative	3,012	745	558
Share-based compensation expense included in operating expenses	$ 5,110	$ 1,410	$ 558

For the years ended December 31, 2008, 2007, and 2006 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:

	December 31,		
	2008	**2007**	**2006**
Risk-free interest rate	3.1%	4.2%	4.7%
Dividend yield	0.0%	0.0%	0.0%
Volatility	74.0%	71.7%	24.8%
Expected life (years)	5.2-6.3	6.25	2.0-6.1

ESPP:

	December 31,		
	2008	**2007**	**2006**
Risk-free interest rate	2.1%	4.20%	
Dividend yield	0.0%	0.0%	
Volatility	90.6%	71.0%	
Expected life (years)	1.22	1.25	

The weighted-average fair values of options granted were $9.21, $3.72, and $1.35 for the years ended December 31, 2008, 2007 and 2006, respectively. The weighted-average purchase price of shares purchased through the ESPP was

$7.87 for the year ended December 31, 2008. There were no shares purchased through the ESPP for the years ended December 31, 2007 and 2006.

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 used the weighted-average volatility of the Company s common stock and the historical stock price volatility of certain peers within the Company s industry sector. In computing expected volatility, the length of the historical period used is equal to the length of the expected term of the option or share purchase right.

Table of Contents

ARDEA BIOSCIENCES, INC.
(Formerly IntraBiotics Pharmaceuticals, Inc.)

NOTES TO FINANCIAL STATEMENTS (Continued)

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 by SAB 107 and SAB 110.

Warrants

The Company issued warrants to purchase shares of its common stock in conjunction with debt and equity financing arrangements. The Company accounted for its warrants in accordance with EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company s Own Stock* (EITF 00-19). The terms of the warrants were evaluated against the criteria within EITF 00-19 to determine the appropriate classification as equity or a liability. As of December 31, 2008, all warrants issued are classified as equity.

Net Loss per Share

Basic and diluted net loss per share is calculated in accordance with Statement of Financial Accounting Standard No. 128, *Earnings per Share,* and SAB No. 98. 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 for 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, stock options and warrants are not included in the computation of net loss per share because their effect is anti-dilutive. The shares used to compute basic and diluted net loss per share represent the weighted-average common shares outstanding.

Comprehensive Loss

SFAS No. 130*, Reporting Comprehensive Income* (SFAS 130), requires that all components of comprehensive income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. In accordance with SFAS 130, unrealized gains and losses on available-for-sale securities are included in other comprehensive income (loss) and represent the difference between the Company s net loss and comprehensive net loss for all periods presented.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (the FASB) issued SFAS 157. SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes resulting from the application of SFAS 157 relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. On January 1, 2008, the Company adopted the provisions of SFAS 157. See Note 3 for further details on the impact of the adoption of SFAS 157 on the Company s consolidated

results of operations and financial condition for the year ended December 31, 2008.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. At this time, the Company has not elected to account for any of its financial assets or liabilities using the provisions of SFAS 159. As such, the adoption of

Table of Contents

ARDEA BIOSCIENCES, INC.
(Formerly IntraBiotics Pharmaceuticals, Inc.)

NOTES TO FINANCIAL STATEMENTS (Continued)

SFAS 159, on January 1, 2008, did not have an impact on the Company s consolidated results of operations or financial condition for the year ended December 31, 2008.

In June 2007, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods or services are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. On January 1, 2008, the Company adopted the provisions of EITF 07-3, which did not have an impact on the Company consolidated results of operations and financial condition for the year ended December 31, 2008.

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The EITF concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each participating company s financial statements pursuant to the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The EITF also concluded that the equity method of accounting under APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. Furthermore, the EITF concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities operations; and whether the partners payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2008, and companies will be required to apply the provisions through retrospective application. The Company plans to adopt EITF 07-1 at the beginning of fiscal 2009 and is evaluating the impact of the adoption on its results of operations and financial condition.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP. SFAS 162 shall be effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not currently believe that the adoption of SFAS 162 will have a material impact on its results of operations and financial condition.

3. Fair Value of Financial Instruments

Effective January 1, 2008, the Company adopted SFAS 157. SFAS 157 provides a definition of fair value, establishes a hierarchy for measuring fair value under GAAP, and requires certain disclosures about fair values used in the

financial statements. SFAS 157 does not extend the use of fair value beyond what is currently required by other pronouncements, and it does not pertain to share-based compensation under SFAS 123R or to leases under SFAS No. 13, *Accounting for Leases*.

In February 2008, FASB Staff Position (FSP) FAS 157-2, *Effective Date of FASB Statement No. 157*, was issued. This FSP provides a one-year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least

Table of Contents

ARDEA BIOSCIENCES, INC.
(Formerly IntraBiotics Pharmaceuticals, Inc.)

NOTES TO FINANCIAL STATEMENTS (Continued)

annually. Therefore, the Company has adopted the provisions of SFAS 157 with respect to financial assets and liabilities only.

SFAS 157 defines fair value 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 under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a 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, which are the following:

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

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

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

The Company measures the following financial assets at fair value on a recurring basis. The fair value of these financial assets at December 31, 2008 (in thousands) were as follows:

		Fair Value Measurements at Reporting Date Using		
	Balance at December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 7,911	$ 7,911	$	$
United States Government agency securities	14,692		14,692	
Municipal bonds	1,500		1,500	
Total	$ 24,103	$ 7,911	$ 16,192	$

Unrealized gains and losses associated with the Company s investments, if any, are reported in stockholders equity in accordance with SFAS 115. For the year ended December 31, 2008, the Company recognized approximately $125,000 in net unrealized gains associated with its short-term investments.

Table of Contents

ARDEA BIOSCIENCES, INC.
(Formerly IntraBiotics Pharmaceuticals, Inc.)

NOTES TO FINANCIAL STATEMENTS (Continued)

4. Balance Sheet Details

Cash Equivalents and Short-Term Investments

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

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
United Stated Government agency securities	$ 14,552	$ 140	$	$ 14,692
Municipal bonds	1,501		(1)	1,500
Total	$ 16,053	$ 140	$ (1)	$ 16,192

	December 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
United States Government agency securities	$ 17,829	$ 14	$	$ 17,843
Corporate bonds	1,988	&#151		