LA JOLLA PHARMACEUTICAL CO Form 10-K March 31, 2009

#### **Table of Contents**

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549 FORM 10-K

## **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

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_

## Commission file number: 0-24274 LA JOLLA PHARMACEUTICAL COMPANY

(Exact name of registrant as specified in its charter)

#### Delaware

33-0361285

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

## 6455 Nancy Ridge Drive, San Diego, CA 92121

(Address of principal executive offices, including Zip Code)
Registrant s telephone number, including area code: **(858) 452-6600**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 \$0.01 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 b

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

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 b 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 the Form 10-K or any amendment to this Form 10-K.

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

Large Accelerated filer accelerated filer b

Non-accelerated filer o

Smaller reporting company o

C

(Do not check if a smaller reporting company)

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

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 \$69,285,000 based on the closing price of \$2.18 as reported by the Nasdaq Global Market. As of March 19, 2009, there were 55,549,528 shares of the Company s common stock (\$0.01 par value) outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the annual stockholders report for the year ended December 31, 2008 are incorporated by reference into Parts I and II. Portions of the proxy statement for the 2009 annual stockholders meeting are incorporated by reference into Part III.

## **TABLE OF CONTENTS**

PA	١R	ГΙ	

Item 1. Business	1
Item 1A. Risk Factors	9
Item 1B. Unresolved Staff Comments	12
Item 2. Properties	12
Item 3. Legal Proceedings	12
Item 4. Submission of Matters to a Vote of Security Holders	13
PART II	
Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	14
Item 6. Selected Financial Data	16
Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations	17
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	25
Item 8. Financial Statements and Supplementary Data	25
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	25
Item 9A. Controls and Procedures	26
Item 9B. Other Information	28
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	28
Item 11. Executive Compensation	28
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	28
Item 13. Certain Relationships and Related Transactions, and Director Independence	28
Item 14. Principal Accountant Fees and Services	28
PART IV	

Item 15. Exhibits, Financial Statement Schedules	29
Signatures	30
<u>EX-10.57</u>	
EX-10.58 EX-10.59	
EX-10.60	
<u>EX-10.61</u>	
EX-10.62	
EX-10.63 EX-10.64	
EX-10.65	
EX-23.1	
EX-31.1 EX-31.2	
EX-32.1	

#### **Table of Contents**

#### FORWARD-LOOKING STATEMENTS

The forward-looking statements in this report involve significant risks, assumptions and uncertainties, and a number of factors, both foreseen and unforeseen, could cause actual results to differ materially from our current expectations. Forward-looking statements include those that express a plan, belief, expectation, estimation, anticipation, intent, contingency, future development or similar expression. The analysis of the data from our Phase 3 ASPEN trial of Riquent showed that the trial did not reach statistical significance with respect to its primary endpoint, delaying time to renal flare or for either secondary endpoint, improvement in proteinuria or time to major SLE flare and we decided to stop the study. Additional risk factors include the uncertainty and timing of initiating a strategic transaction to maximize the value of our remaining assets and continuing as a going concern. Accordingly, you should not rely upon forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements are subject to the risks, uncertainties and other factors described in Management s Discussion and Analysis of Financial Condition and Results of Operations and in the Risk Factors contained in this Annual Report on Form 10-K, and in other reports and registration statements that we file with the Securities and Exchange Commission from time to time. We expressly disclaim any intent to update forward-looking statements.

#### **Table of Contents**

#### PART I

In this report, all references to we, our, us and the Company refer to La Jolla Pharmaceutical Company, a Delaw corporation, and our wholly owned subsidiary.

## Item 1. Business

#### Overview

La Jolla Pharmaceutical Company was incorporated in Delaware in 1989. We are a biopharmaceutical company that has historically focused on the development and testing of Riquent as a treatment for Lupus nephritis. Lupus is an antibody-mediated disease caused by abnormal B cell production of antibodies that attack healthy tissues. Current treatments for this autoimmune disorder often address only symptoms of the disease, or nonspecifically suppress the normal operation of the immune system, which can result in severe, negative side effects and hospitalization. From August 2004 to February 2009, Riquent was being studied in a double-blinded multicenter Phase 3 clinical trial, called the ASPEN trial.

On January 4, 2009, we entered into a development and commercialization agreement (the <u>Development Agreement</u>) with BioMarin CF Limited (<u>BioMarin CF</u>), a wholly-owned subsidiary of BioMarin Pharmaceutical Inc. (<u>BioMarin Pharma</u>). Under the terms of the Development Agreement, BioMarin CF was granted co-exclusive rights to develop and commercialize Riquent in the United States, Europe and all other territories of the world, excluding the Asia Pacific region, and the non-exclusive right to manufacture Riquent anywhere in the world. In January 2009, BioMarin CF paid us a non-refundable commencement payment of \$7.5 million and BioMarin Pharma purchased \$7.5 million of a newly designated series of our preferred stock. As described below, this agreement was terminated on March 27, 2009. See Note 10 to our audited consolidated financial statements included in Part IV.

In February 2009, we were informed by an Independent Monitoring Board for the Riquent Phase 3 ASPEN study that the monitoring board completed their review of the first interim efficacy analysis of Riquent and determined that continuing the study was futile. We subsequently unblinded the data and found that there was no statistical difference in the primary endpoint, delaying time to renal flare, between the Riquent-treated group and the placebo-treated group, although there was a significant difference in the reduction of antibodies to double-stranded DNA. There were 56 renal flares in 587 patients treated with either 300-mg or 900-mg of Riquent, and 28 renal flares in 283 patients treated with placebo.

Based on these results, we immediately discontinued the Riquent Phase 3 ASPEN study and the further development of Riquent. We had previously devoted substantially all of our research, development and clinical efforts and financial resources toward the development of Riquent. In connection with the termination of our clinical trials for Riquent, we subsequently initiated steps to significantly reduce our operating costs, including a planned substantial reduction in personnel, which we expect will be effected early in the second quarter of 2009. We have also ceased the manufacture of Riquent at our facility in San Diego, California.

Following the futile results of the first interim efficacy analysis of Riquent, BioMarin CF has elected to not exercise its full license rights to the Riquent program under the Development Agreement. Thus, the Development Agreement between the parties terminated on March 27, 2009 in accordance with its terms. Pursuant to the Securities Purchase Agreement between us and BioMarin Pharma, all of the Company s preferred shares purchased by BioMarin Pharma were converted into common shares. Additionally, all rights to Riquent have been returned to us.

In light of our decision to discontinue development of our Riquent clinical program, we are seeking to maximize the value of our remaining assets. We are currently evaluating our strategic alternatives, which include the following:

Sell or out-license our remaining assets, including our SSAO compounds, although we do not expect to receive any substantive value for them;

Pursue potential other strategic transactions, which could include mergers, license agreements or other collaborations, with third parties; or

1

## **Table of Contents**

Implement an orderly wind down of the Company if other alternatives are not deemed viable and in the best interests of the Company.

Following the negative results of the ASPEN trial, we recorded a significant charge for the impairment of our Riquent assets, including our Riquent-related patents, and it is unlikely that we will realize any substantive value from these assets in the future. Additionally, there is a substantial risk that we may not successfully implement any of these strategic alternatives, and even if we determine to pursue one or more of these alternatives, we may be unable to do so on acceptable terms. Any such transactions may be highly dilutive to our existing stockholders and may deplete our limited remaining capital resources.

2

#### **Table of Contents**

#### **About Lupus**

Lupus is a life-threatening, antibody-mediated disease in which disease-causing antibodies damage various tissues. According to recent statistics compiled by the Lupus Foundation of America, epidemiological studies and other sources, the number of lupus patients in the United States is estimated to be between 500,000 and 1,000,000, and approximately 16,000 new cases are diagnosed each year. Approximately nine out of 10 lupus patients are women, who usually develop the disease during their childbearing years. Lupus is characterized by a multitude of symptoms that can include kidney inflammation, which can lead to kidney failure (lupus nephritis), serious episodes of cardiac and central-nervous-system inflammation, as well as extreme fatigue, arthritis and rashes. Approximately 80% of all lupus patients progress to serious symptoms. Approximately 40-45% of lupus patients will develop kidney disease, which is a leading cause of death in lupus.

Lupus nephritis is characterized by periods of extreme, acute inflammation called renal flares which often require aggressive treatment with high-dose corticosteroids, immunosuppressive agents, and hospitalization. Patients not experiencing a renal flare often have less severe, chronic inflammation which can also contribute to the morbidity and mortality of lupus nephritis. Patients experiencing a renal flare have more severe inflammation as evidenced by indicators of diminished kidney function such as elevated serum creatinine or increased proteinuria. Proteinuria, or protein in the urine, is believed to be a pathological indicator of renal disease. The reduction of proteinuria is one of the goals for the treatment of lupus patients with renal disease. Monitoring the level of a patient s proteinuria is a routine and important way to help determine the severity and progression of renal disease. Over time, lupus nephritis can lead to deterioration of kidney function and to end-stage kidney disease, requiring long-term renal dialysis or kidney transplantation to sustain a patient s life.

Current treatments for lupus patients who have a renal flare often involve repeated administration of corticosteroids, often at high levels, that can lead to serious side effects when used long-term. Many patients with renal flares are also treated with immunosuppressive therapy, including anti-cancer or transplantation drugs, which can have a general suppressive effect on the immune system, may be carcinogenic and/or can cause birth defects. Treatment with immunosuppressive therapies can leave patients vulnerable to serious infection, which is a significant cause of sickness and death in these patients. Importantly, many patients do not respond adequately to treatment with immunosuppressive therapies and fail to achieve full remission, a return to normal renal function or the level of renal function prior to the flare. As a result, low to moderate levels of inflammation remain as evidenced by elevated urine protein (proteinuria), elevated serum creatinine, and other markers of abnormal kidney function. This incomplete response to treatment with immunosuppressive therapies increases the risk of additional renal flares as well as the risk of end-stage kidney disease and death.

3

## **Table of Contents**

Riquent Clinical Trial History

### Early clinical studies:

We have conducted several clinical studies of Riquent, including a Phase 1 trial in healthy volunteers and four Phase 2 trials in lupus patients. The first tested a single dose, the second was a repeat dose-escalating clinical trial in two patients. In 1995, we conducted a double-blind, placebo-controlled dose-ranging trial, in which 58 lupus patients with mild lupus symptoms were treated for a four-month period with Riquent or placebo, and then were monitored for two months. Patients in the weekly treatment groups showed a dose-response correlation between increasing doses of Riquent and reductions of levels of antibodies to dsDNA. In 1999, we completed a second double-blind, placebo-controlled dose-ranging trial, in which 74 lupus patients received weekly injections of 10 , 50 or 100 mg of Riquent or placebo for a 12-week period.

In December 1996, we initiated a double-blind, placebo-controlled, multi-center Phase 2/3 clinical trial of Riquent in which lupus patients with a history of lupus nephritis received placebo or weekly doses of 100 mg of Riquent for the first 16 weeks of the trial. More than 200 patients at more than 50 sites in North America and Europe enrolled in the trial. In May 1999, an interim analysis of the Phase 2/3 trial indicated that the trial was unlikely to reach statistical significance for the primary endpoint, time to renal flare, and the trial was stopped.

## Previous Phase 3 trial

Based on the observations from our Phase 2/3 trial and following discussions with the FDA, we initiated a Phase 3 clinical trial in September 2000 to further evaluate the safety and efficacy of Riquent in the treatment of lupus renal disease. Patients in the trial were treated weekly with either 100-mg of Riquent or placebo for a period of up to 22 months. The trial data indicated that treatment with Riquent did not increase length of time to renal flare, the primary endpoint, or time to treatment with HDCC, the secondary endpoint, in a statistically significant manner when compared with placebo through the end of the study.

Notwithstanding the failure to reach the primary or secondary endpoints in the earlier Phase 3 trial, in 2004, we filed a New Drug Application (NDA) for Riquent with the FDA. Our NDA submission was prepared on our understanding that the FDA could potentially approve Riquent on the basis of our clinical trial results or under the accelerated approval regulation known as Subpart H. In October 2004, we received a letter from the FDA indicating that Riquent is approvable, but that an additional, randomized, double-blind study demonstrating the clinical benefit of Riquent would need to be completed prior to approval. The FDA letter indicated that the successful completion of the clinical trial that we initiated in August 2004 would appear to satisfy this requirement.

4

#### **Table of Contents**

#### Phase 3 ASPEN trial

A placebo-controlled Phase 3 clinical benefit trial, designed to meet the FDA s requirement that we conduct an additional randomized, double-blind study, was initiated in August 2004 under a Special Protocol Assessment (<u>SPA</u>). The FDA confirmed that the primary endpoint required to establish efficacy is the time to renal flare for the combined population of patients treated with weekly Riquent doses of 300-mg and 900-mg, compared with placebo. In February 2009, an interim efficacy analysis of the Phase 3 ASPEN study indicated that the trial was unlikely to reach statistical significance for the primary endpoint, delaying time to renal flare, and was stopped. We also stopped further development of Riquent.

The results from the Phase 3 study indicated that there was no statistical difference in delaying time to renal flare between the Riquent-treated group and the placebo-treated group, although there was a statistically significant reduction in antibodies to double-stranded DNA, which caused us to question our general hypothesis that reductions in double-stranded DNA would delay the time to renal flare. There were 56 renal flares in 587 patients treated with either 300-mg or 900-mg of Riquent and 28 renal flares in 283 patients treated with placebo. No statistical difference was observed between Riquent-treated and placebo-treated patients for either secondary endpoint, percent of patients with a 50% reduction in proteinuria at 12 months or time to Major SLE Flare. Riquent appeared to be well tolerated. The analysis included data from 870 patients who were treated for up to 18 months. Approximately 90% of the patients were female and the median age was 32. Approximately fifty percent of the patients were from Asia; the remaining 50% were from the United States, Mexico, Latin America and Europe.

## **Inflammatory Program**

## SSAO Inflammation Program

On December 2, 2003, we announced the discovery of novel, orally-active small molecules for the treatment of autoimmune diseases and acute and chronic inflammatory disorders. Our scientists have generated highly selective inhibitors of SSAO, an enzyme that has been implicated in inflammatory responses in many tissues and organs. SSAO, also known as vascular adhesion protein-1 or VAP-1, was recently discovered to be a dual-function molecule with enzymatic and cell adhesion activities. SSAO on blood vessels contributes to inflammation by helping white blood cells leave the blood and penetrate inflamed tissue. The enzyme also contributes to the production of molecules that exacerbate inflammation, including formaldehyde and oxygen free radicals. SSAO inhibitors are designed to reduce inflammation by blocking the white blood cells and reducing the levels of inflammatory mediators.

Increases in the levels of plasma or membrane-associated SSAO have been reported for many inflammation-associated diseases including rheumatoid arthritis, inflammatory bowel disease, diabetes, atherosclerosis psoriasis and chronic heart failure. In addition, treatment of animals with SSAO inhibitors has been shown to provide significant benefit in several inflammation-based diseases.

Data published by our scientists in 2005 and 2006 in peer-reviewed articles show that these novel, orally-active small molecule inhibitors of SSAO/VAP-1 may provide clinical benefit for the treatment of stroke, ulcerative colitis, and other autoimmune diseases and inflammatory disorders. Peer-reviewed data published in 2007 identified and characterized a lead compound and described its role in inhibiting inflammation in the lungs of rodents.

Substantially all of our resources have historically been devoted to the development of Riquent and we have therefore not committed significant resources to this program in the past. We expect that SSAO would only be developed further if we were to sell or out-license the compound or engage in a strategic transaction, such as a merger, where the other party has resources to fund its continued development. At present, we do not have the resources to advance this program.

## **Manufacturing**

Our manufacturing activities have historically consisted of the manufacture of Riquent. In February 2009, we ceased all drug manufacturing activities as a result of the futility determination of the Riquent Phase 3 ASPEN study and we stopped further development of Riquent.

5

#### **Table of Contents**

#### **Patents and Proprietary Technologies**

We file patent applications in the United States and in foreign countries for the protection of our proprietary technologies and drug candidates as we deem appropriate. We currently own 133 issued patents and have 29 pending patent applications in the United States and in foreign countries covering various technologies and drug candidates, including Riquent (Toleragens), our SSAO inhibitor technology (currently there are no issued patents to our SSAO inhibitor technology), our antibody-mediated thrombosis drug candidates (Toleragens), our Tolerance Technology, and our carrier platform and linkage technologies for our Toleragens. As noted above, following the futility finding in the ASPEN trial, we recorded significant impairment charges for our Riquent-related patents and have written down the value of these assets to near zero as of December 31, 2008. Our issued patents, substantially all of which relate to Riquent, include:

Lupus Toleragens eight issued United States patents, three issued Australian patents, one granted Portuguese patent, two granted Norwegian patents, one granted European patent (which has been unbundled as 13 European national patents), a second granted European patent (which has been unbundled as 15 European national patents), two granted Chinese patents, one granted Hong Kong patent, one granted South Korean patent, two granted Canadian patents, two granted Finnish patents, one granted Irish patent, and one granted Japanese patent (expiring between 2010 and 2020); and

Tolerance Technology five issued United States patents, one issued Australian patent, one granted European patent (which has been unbundled as 15 European national patents), one granted Japanese patent, two granted Canadian patents, one granted South Korean patent and one granted Irish patent (expiring between 2011 and 2012).

#### **Competition**

The biotechnology and pharmaceutical industries are subject to rapid technological change. Competition from domestic and foreign biotechnology companies, large pharmaceutical companies and other institutions has historically been intense and may increase. A number of companies are pursuing the development of pharmaceuticals in our targeted areas. These include companies that are conducting clinical trials and pre-clinical studies for the treatment of lupus.

In addition, there are a number of academic institutions, both public and private, engaged in activities relating to the research and development of therapeutics for autoimmune, inflammatory and other diseases. Most of these companies and institutions have substantially greater facilities, resources, research and development capabilities, regulatory compliance expertise, and manufacturing and marketing capabilities than we do. In addition, other technologies may in the future be the basis of competitive products. There can be no assurance that our competitors will not develop or obtain regulatory approval for products that would render our technology and any potential products obsolete or noncompetitive.

6

## **Table of Contents**

## **Government Regulation**

### **United States**

Biotechnology research and development activities and the manufacturing and marketing of products are subject to significant regulation by numerous government authorities in the United States and other countries. In the United States, the Federal Food, Drug and Cosmetic Act and the Public Health Service Act govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion, and distribution of our drug candidates and any products we may develop. In addition to FDA regulations, we have historically been subject to other federal, state and local regulations, such as the Occupational Safety and Health Act and the Environmental Protection Act, as well as regulations governing the handling, use and disposal of radioactive and other hazardous materials used in our research activities. Product development and approval within this regulatory framework takes a number of years and involves the expenditure of substantial resources. In addition, this regulatory framework is subject to changes that may adversely affect approval, delay an application or require additional expenditures.

The steps required before a pharmaceutical compound may be marketed in the United States include: pre-clinical laboratory and animal testing; submission to the FDA of an Investigational New Drug application, which must become effective before clinical trials may commence; conducting adequate and well-controlled clinical trials to establish the safety and efficacy of the drug; submission to the FDA of an NDA or Biologic License Application (BLA) for biologics; satisfactory completion of an FDA preapproval inspection of the manufacturing facilities to assess compliance with cGMPs; and FDA approval of the NDA or BLA prior to any commercial sale or shipment of the drug. In addition to obtaining FDA approval for each product, each drug-manufacturing establishment must be registered with the FDA and be operated in conformity with cGMPs. Drug product manufacturing facilities located in California also must be licensed by the State of California in compliance with separate regulatory requirements.

Pre-clinical testing includes laboratory evaluation of product chemistry and animal studies to assess the safety and efficacy of the product and its formulation. The results of pre-clinical testing are submitted to the FDA as part of an Investigational New Drug Application and, unless the FDA objects, the Investigational New Drug Application becomes effective 30 days following its receipt by the FDA.

Clinical trials involve administration of the drug to healthy volunteers and to patients diagnosed with the condition for which the drug is being tested under the supervision of a qualified clinical investigator. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the Investigational New Drug application. Each clinical trial is conducted under the auspices of an independent Institutional Review Board (IRB) in the United States or Ethics Committee (EC) outside the United States for each trial site. The IRB or EC considers, among other matters, ethical factors and the safety of human subjects.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap or be repeated. In Phase 1, the phase in which the drug is initially introduced into healthy human subjects or patients, the drug is tested for adverse effects, dosage tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase 2 trials involve the testing of a limited patient population in order to characterize the actions of the drug in targeted indications, to determine drug tolerance and optimal dosage, and to identify possible adverse side effects and safety risks. When a compound appears to be effective and to have an acceptable safety profile in Phase 2 clinical trials, Phase 3 clinical trials are undertaken to further evaluate and confirm clinical efficacy and safety within an expanded patient population at multiple clinical trial sites. The FDA reviews the clinical plans and monitors the results of the trials and may discontinue the trials at any time if significant safety issues arise. Similarly, an IRB may suspend or terminate a trial at a study site which is not being conducted in accordance with the IRB s requirements or which has been associated with unexpected serious harm to subjects.

The results of pre-clinical testing and clinical trials are submitted to the FDA in the form of an NDA or BLA for marketing approval. The submission of an NDA or BLA also is subject to the payment of user fees, but a waiver of the fees may be obtained under specified circumstances. The testing and approval process is likely to require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all, or that conditions of any approval, such as warnings, contraindications, or scope of indications will not materially

#### **Table of Contents**

impact the potential market acceptance and profitability of the drug product. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it generally follows such recommendations. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments, and the risks and benefits of the product demonstrated in clinical trials.

Additional pre-clinical testing or clinical trials may be requested during the FDA review period and may delay any marketing approval. After FDA approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications. In addition, after approval, some types of changes to the approved product, such as manufacturing changes, are subject to further FDA review and approval. The FDA mandates that adverse effects be reported to the FDA and may also require post-marketing testing to monitor for adverse effects, which can involve significant expense. Adverse effects observed during the commercial use of a drug product or which arise in the course of post-marketing testing can result in the need for labeling revisions, including additional warnings and contraindications, and, if the findings significantly alter the risk/benefit assessment, the potential withdrawal of the drug from the market.

Among the conditions for FDA approval is the requirement that the prospective manufacturer squality control and manufacturing procedures conform to the FDA s cGMP requirements. Domestic manufacturing facilities are subject to biannual FDA inspections and foreign manufacturing facilities are subject to periodic inspections by the FDA or foreign regulatory authorities. If the FDA finds that a company is not operating in compliance with cGMPs, the continued availability of the product can be interrupted until compliance is achieved and, if the deficiencies are not corrected within a reasonable time frame, the drug could be withdrawn from the market. In addition, the FDA strictly regulates labeling, advertising and promotion of drugs. Failure to conform to requirements relating to licensing, manufacturing, and promoting drug products can result in informal or formal sanctions, including warning letters, injunctions, seizures, civil and criminal penalties, adverse publicity and withdrawal of approval.

Biotechnology research and development activities and the manufacturing and marketing of products are also subject to numerous and varying foreign regulatory requirements governing the design and conduct of clinical trials and marketing approval for pharmaceutical products to be marketed outside of the United States. The approval process varies among countries and regions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval.

The steps to obtain approval to market a pharmaceutical compound in the European Union include: pre-clinical laboratory and animal testing; conducting adequate and well controlled clinical trials to establish safety and efficacy; submission of a Marketing Authorization Application (the <u>MA</u>A ); and the issuance of a product marketing license by the European Commission prior to any commercial sale or shipment of drug. In addition to obtaining a product marketing license for each product, each drug manufacturing establishment must be registered with the European Medicines Agency (the <u>EME</u>A ) must operate in conformity with European good manufacturing practice, and must pass inspections by the European health authorities.

Upon receiving the MAA, the Committee for Human Medicinal Products (the <u>CHM</u>P), a division of the EMEA, will review the MAA and may respond with a list of questions or objections. The answers to the questions posed by the CHMP may require additional tests to be conducted. Responses to the list of questions or objections must be provided to and deemed sufficient by the CHMP within a defined timeframe. Ultimately, a representative from each of the European Member States will vote whether to approve the MAA.

Foreign regulatory approval processes include all of the risks associated with obtaining FDA approval, and approval by the FDA does not ensure approval by the health authorities of any other country.

#### **Table of Contents**

#### **Employees**

As of March 19, 2009, we employed 94 regular full-time employees (including five people who have a Ph.D. and three people who have an M.D., one of which also has a Ph.D.), 75 of whom are trained in clinical, development and manufacturing activities. We are currently taking steps to significantly reduce our personnel resources and related expenses and expect that we will have significantly fewer employees starting in the second quarter of 2009 as we reduce the size of our operations in response to the failure of the ASPEN trial. None of our employees are covered by collective bargaining agreements and management considers relations with our employees to be good.

## **Available Information**

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website at www.ljpc.com as soon as reasonably practicable after we electronically file or furnish the reports with or to the Securities and Exchange Commission.

#### **Item 1A. Risk Factors**

## I. RISK FACTORS RELATING TO LA JOLLA PHARMACEUTICAL COMPANY AND THE INDUSTRY IN WHICH WE OPERATE.

In light of our decision to discontinue development of our Riquent clinical program, we are seeking to maximize the value of our remaining assets, address our liabilities and attempt to pursue mergers or similar strategic transactions. We may be unable to satisfy our liabilities and can provide no assurances that we can be successful in pursuing a strategic transaction.

In February 2009, we were informed by an Independent Monitoring Board for the Riquent Phase 3 ASPEN study that the monitoring board completed their review of the first interim efficacy analysis and determined that continuing the study was futile. Based on these results, we immediately discontinued the Riquent Phase 3 ASPEN study and the development of Riquent. We had previously devoted substantially all of our research, development and clinical efforts and financial resources toward the development of Riquent and, in light of the failure of the trial, we subsequently incurred a significant impairment charge as we wrote down the value of our Riquent assets to near zero. In connection with the termination of our clinical trials for Riquent, we initiated steps to significantly reduce our operating costs including a substantial reduction in personnel. We have also ceased the manufacture of Riquent at our facility in San Diego, California and have begun exploring strategic alternatives to maximize stockholder value, as described above.

There is a substantial risk that we may not successfully implement any of these strategic alternatives, and even if we determine to pursue one or more of these alternatives, we may be unable to do so on acceptable financial terms. Any such transactions may require us to incur non-recurring or other charges and may pose significant integration challenges and/or management and business disruptions, any of which could materially and adversely affect our business and financial results. Additionally, pursuing these transactions would deplete some portion of our limited capital resources and may not result in a transaction that is ultimately consummated. We may be unable to discharge our liabilities or negotiate favorable settlement terms with our creditors.

Stockholders should recognize that in our efforts to address our liabilities and fund the future development of our Company, we may pursue strategic alternatives that result in the stockholders of the Company having little or no continuing interest in the assets or equity of the Company. We will continue to evaluate our alternatives in light of our cash position, including the possibility that we may need to seek protection under the provisions of the U.S. Bankruptcy Code.

We may need to liquidate the Company in a voluntary dissolution under Delaware law or seek protection under the provisions of the U.S. Bankruptcy Code, and in either event, it is unlikely that stockholders would receive any value for their shares.

We have not generated any revenues from product sales, and have incurred losses in each year since our inception in 1989. We expect that it will be very difficult to raise capital to continue our operations and our

Ç

#### **Table of Contents**

independent registered public accounting firm has issued an opinion with an explanatory paragraph to the effect that there is substantial doubt about our ability to continue as a going concern. We do not believe that we could succeed in raising additional capital needed to sustain our operations without some strategic transaction, such as a merger. If we are unable to consummate such a transaction, we expect that we would need to cease all operations and wind down. Although we are currently evaluating our strategic alternatives with respect to all aspects of our business, we cannot assure you that any actions that we take would raise or generate sufficient capital to fully address the uncertainties of our financial position. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business. If we are unable to settle our obligations to our creditors or if we are unable to consummate a strategic transaction, we would likely need to liquidate the Company in a voluntary dissolution under Delaware law or seek protection under the provisions of the U.S. Bankruptcy Code. In that event, we, or a trustee appointed by the court, may be required to liquidate our assets. In either of these events, we might realize significantly less from our assets than the values at which they are carried on our financial statements. The funds resulting from the liquidation of our assets would be used first to satisfy obligations to creditors before any funds would be available to pay our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we are required to liquidate under Delaware law or the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares. See Liquidity and Capital Resources in Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations and Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

## We recorded an impairment loss for the year ended December 31, 2008 and may need to record additional charges in the future.

In light of our decisions to discontinue the development of Riquent, evaluate the possible sale of our equipment and other personal property assets, reduce our workforce, and consider our strategic alternatives with respect to all aspects of our business, management considered whether, under Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, any events or circumstances had occurred since December 31, 2007 and prior to December 31, 2008 that would indicate an impairment of our long-lived assets. After completing our evaluation and considering all external and internal information available as of the impairment analysis, we concluded that, as of December 31, 2008, the carrying amount of the asset group was not fully recoverable and that a material impairment did exist. Accordingly, our financial statements reflect a non-cash charge of \$2.8 million for impairment of assets during the fourth quarter of 2008. As we continue to evaluate our business and our assets under SFAS 144, we may need to reflect additional impairment charges in the future, which would negatively impact our financial results and our overall value of the Company.

## We face environmental liabilities related to certain hazardous materials used in our operations.

Due to the nature of our manufacturing processes, we are subject to stringent federal, state and local laws governing the use, handling and disposal of certain materials and wastes. Historically, in our research and manufacturing activities we have used radioactive and other materials that could be hazardous to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. The risk of accidental injury or contamination from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any resulting damages, and any such liability could exceed our resources. Although we maintain general liability insurance, we do not specifically insure against environmental liabilities.

10

#### **Table of Contents**

#### II. RISK FACTORS RELATED SPECIFICALLY TO OUR STOCK.

The price of our common stock has been volatile and has declined significantly and we may face delisting from Nasdaq.

Due to the futility determination of the Riquent clinical trial, our stock has experienced significant price and volume volatility during February and March 2009. Our stock is currently trading below \$0.25 per share and we could continue to experience further declines in our stock price. Our stock is currently trading below the minimum bid price, which is in violation of Nasdaq s continued listing requirements. Although Nasdaq has suspended the enforcement of rules requiring a minimum \$1.00 closing bid price and the rules requiring a minimum market value of publicly held shares, this suspension is currently only in effect through July 19, 2009. We will likely be non-compliant with Nasdaq s continued listing requirements when this suspension is lifted. If our stock continues to trade below \$1.00 when the temporary suspension is lifted, Nasdaq may commence delisting procedures against us. In addition to the minimum bid price rule, the Nasdaq Global Market has several other continued listing requirements. Failure to maintain compliance with any Nasdaq listing requirement could cause our stock to be removed from listing on Nasdaq. If we were delisted, the market liquidity of our common stock could be adversely affected and the market price of our common stock could decrease. Such a delisting could also adversely affect our ability to effect a strategic transaction, such as a merger with a third party. In addition, our stockholders—ability to trade or obtain quotations on our shares could be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask price for our common stock.

Specifically, you may not be able to resell your shares at or above the price you paid for such shares or at all. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management s attention and resources, which could hurt our business, operating results and financial condition.

## Our common stock price is volatile and may continue to decline.

The market price of our common stock has been and is likely to continue to be highly volatile. Market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The following factors, among others, can have a significant effect on the market price of our securities:

limited financial resources:

announcements regarding mergers or other strategic transactions;

future sales of significant amounts of our common stock by us or our stockholders;

actions or decisions by the FDA and other comparable agencies;

announcements of technological innovations or new therapeutic products by us or others;

developments in patent or other proprietary rights;

public concern as to the safety of drugs discovered or developed by us or others;

developments concerning potential and existing agreements with collaborators;

general market conditions and comments by securities analysts; and

1 1

#### **Table of Contents**

government regulation, including any legislation that may impact the price of any commercial products that we may seek to sell.

The realization of any of the risks described in these Risk Factors could have a negative effect on the market price of our common stock.

Failure to achieve and maintain effective internal control over financial reporting 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 us to evaluate annually the effectiveness of our internal controls over financial reporting as of the end of each fiscal year beginning in 2004 and to include a management report assessing the effectiveness of our internal control over financial reporting in all future annual reports beginning with the annual report on Form 10-K for the fiscal year ended December 31, 2004. Section 404 also requires our independent registered public accounting firm to report on our internal control over financial reporting. We evaluated our internal control over financial reporting as of December 31, 2008 in order to comply with Section 404 and concluded that our disclosure controls and procedures were effective as of such date. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we cannot provide any assurances that we will be able to conclude in the future that we have effective internal control over financial reporting in accordance with Section 404. If we fail to achieve and maintain a system of effective internal control over financial reporting, it could have a material adverse effect on our business and stock price.

## Anti-takeover devices may prevent changes in our board of directors and management.

We have in place several anti-takeover devices, including a stockholder rights plan, which may have the effect of delaying or preventing changes in our management or deterring third parties from seeking to acquire significant positions in our common stock. For example, one anti-takeover device provides for a board of directors that is separated into three classes, with their terms in office staggered over three year periods. This has the effect of delaying a change in control of our board of directors without the cooperation of the incumbent board. In addition, our bylaws require stockholders to give us written notice of any proposal or director nomination within a specified period of time prior to the annual stockholder meeting, establish certain qualifications for a person to be elected or appointed to the board of directors during the pendency of certain business combination transactions, and do not allow stockholders to call a special meeting of stockholders.

We may also issue shares of preferred stock without further stockholder approval and upon terms that our board of directors may determine in the future. The issuance of preferred stock could have the effect of making it more difficult for a third party to acquire a majority of our outstanding stock, and the holders of such preferred stock could have voting, dividend, liquidation and other rights superior to those of holders of our common stock.

## Item 1B. Unresolved Staff Comments.

None.

## Item 2. Properties.

We lease two adjacent buildings in San Diego, California covering a total of approximately 54,000 square feet. One building contains our research and development laboratories and clinical manufacturing facilities and the other contains our corporate offices and warehouse. Both building leases expire in July 2009. Each lease is subject to an escalation clause that provides for annual rent increases. We believe that these facilities will be adequate to meet our needs for the near term. Over the longer term, management believes that space can be secured at commercially reasonable rates.

## Item 3. Legal Proceedings.

We are not currently a party to any legal proceedings.

12

## **Table of Contents**

Item 4. Submission of Matters to a Vote of Security Holders.

None.

13

#### **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 Market under the symbol LJPC. 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.

	I		
	High	Low	
Year Ended December 31, 2008			
First Quarter	\$4.25	\$1.45	
Second Quarter	2.35	1.59	
Third Quarter	2.50	1.01	
Fourth Quarter	1.20	0.58	
Year Ended December 31, 2007			
First Quarter	\$8.57	\$2.80	
Second Quarter	8.68	4.35	
Third Quarter	5.59	3.15	
Fourth Quarter	4.50	3.15	

We have never paid dividends on our common stock and we do not anticipate paying dividends in the foreseeable future. The number of record holders of our common stock as of March 19, 2009 was approximately 206.

## **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 of Form 10-K.

14

#### **Table of Contents**

#### **Stock Performance Graph**

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.

	12/3	31/2003	12	2/31/2004	12	2/31/2005	12	2/31/2006	12	2/31/2007	12	2/31/2008
La Jolla												
Pharmaceutical												
Company*	\$	100	\$	39.20	\$	17.37	\$	14.23	\$	18.40	\$	2.72
Nasdaq US	\$	100	\$	108.84	\$	111.16	\$	122.11	\$	132.42	\$	63.80
Nasdaq												
<b>Pharmaceuticals</b>	\$	100	\$	106.51	\$	117.29	\$	114.81	\$	120.74	\$	112.34

\* La Jolla
Pharmaceutical
Company stock
prices have been
adjusted to
reflect the
one-for-five
reverse stock
split effective
December 21,
2005.

15

## **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 at page 17 and the consolidated financial statements of the Company and related notes thereto beginning at page F-2 of this report.

	Years Ended December 31,						
	2008	2007	2006	2005	2004		
Consolidated Statements of Operations Data:		(In thousand	ds, except per sha	ire amounts)			
Expenses: Research and development General and administrative Asset impairment	\$ 51,025 9,702 2,810	\$ 46,635 9,058	\$ 32,834 9,287 104	\$ 22,598 5,405	\$ 33,169 7,568		
Loss from operations	(63,537)	(55,693)	(42,225)	(28,003)	(40,737)		
Interest expense Interest income	(96) 779	(82) 2,699	(46) 2,826	(116) 756	(190) 383		
Net loss	\$(62,854)	\$(53,076)	\$(39,445)	\$(27,363)	\$(40,544)		
Basic and diluted net loss per share	\$ (1.26)	\$ (1.40)	\$ (1.21)	\$ (1.77)	\$ (3.40)		
Shares used in computing basic and diluted net loss per share (1)	49,689	37,818	32,588	15,446	11,941		
<b>Balance Sheet Data:</b>							
Working capital Total assets Noncurrent portion of obligations	\$ 2,996 \$ 20,839	\$ 29,881 \$ 44,405	\$ 37,673 \$ 49,525	\$ 70,124 \$ 80,928	\$ 17,539 \$ 33,026		
under capital leases and notes payable Stockholders equity	\$ 213 \$ 3,390	\$ 388 \$ 33,521	\$ 196 \$ 43,089	\$ 142 \$ 77,130	\$ 716 \$ 26,001		

(1) Shares have been adjusted to reflect the one-for-five reverse stock split effective December 21,

## **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 footnotes 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 and recent developments. This section provides a general description of our business and operating history and 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 1 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, 2006.

Liquidity and capital resources. This section provides an analysis of our cash flows and a discussion of our outstanding debt and commitments, both firm and contingent, that existed as of December 31, 2008, as well as material subsequent changes. Included in the discussion of outstanding debt is a discussion of our financial capacity to fund our future commitments and a discussion of other financing arrangements.

## **Overview and Recent Developments**

Since our inception in May 1989, we have devoted substantially all of our resources to the research and development of technology and potential drugs to treat antibody-mediated diseases. We have never generated any revenue from product sales and have relied on public and private offerings of securities, revenue from collaborative agreements, equipment financings and interest income on invested cash balances for our working capital.

On January 4, 2009, we entered into a development and commercialization agreement (the <u>Development Agreement</u>) with BioMarin CF Limited (<u>BioMarin CF</u>), a wholly-owned subsidiary of BioMarin Pharmaceutical Inc. (<u>BioMarin Pharma</u>). Under the terms of the Development Agreement, BioMarin CF was granted co-exclusive rights to develop and commercialize Riquent in the United States, Europe and all other territories of the world, excluding the Asia Pacific region, and the non-exclusive right to manufacture Riquent anywhere in the world. In January 2009, BioMarin CF paid us a non-refundable commencement payment of \$7.5 million and BioMarin Pharma purchased \$7.5 million of a newly designated series of our preferred stock. As described below, this agreement was terminated on March 27, 2009. See Note 10 to our audited consolidated financial statements included in Part IV.

In February 2009, we were informed by an Independent Monitoring Board for the Riquent Phase 3 ASPEN study that the monitoring board completed their review of the first interim efficacy analysis of Riquent and determined that continuing the study was futile. We subsequently unblinded the data and found that there was no statistical difference in the primary endpoint, delaying time to renal flare, between the Riquent-treated group and the placebo-treated group, although there was a significant difference in the reduction of antibodies to double-stranded DNA. There were 56 renal flares in 587 patients treated with either 300-mg or 900-mg of Riquent, and 28 renal flares in 283 patients treated with placebo.

Based on these results, we immediately discontinued the Riquent Phase 3 ASPEN study and the further development of Riquent. We had previously devoted substantially all of our research, development and clinical efforts and financial resources toward the development of Riquent. In connection with the termination of our clinical

## **Table of Contents**

trials for Riquent, we subsequently initiated steps to significantly reduce our operating costs, including a planned substantial reduction in personnel, which we expect will be effected early in the second quarter of 2009. We have also ceased the manufacture of Riquent at our facility in San Diego, California.

Following the futile results of the first interim efficacy analysis of Riquent, BioMarin CF has elected to not exercise its full license rights to the Riquent program under the Development Agreement. Thus, the Development Agreement between the parties terminated on March 27, 2009 in accordance with its terms. Pursuant to the Securities Purchase Agreement between us and BioMarin Pharma, all of the Company s preferred shares purchased by BioMarin Pharma were converted into common shares. Additionally, all rights to Riquent have been returned to us.

In light of our decision to discontinue development of our Riquent clinical program, we are seeking to maximize the value of our remaining assets. We are currently evaluating our strategic alternatives, which include the following:

Sell or out-license our remaining assets, including our SSAO compounds, although we do not expect to receive any significant value for them;

Pursue potential other strategic transactions, which could include mergers, license agreements or other collaborations, with third parties; or

Implement an orderly wind down of the Company if other alternatives are not deemed viable and in the best interests of the Company.

Following the negative results of the ASPEN trial, we recorded a significant charge for the impairment of our Riquent assets, including our Riquent-related patents, and it is unlikely that we will realize any substantive value from these assets in the future. Additionally, there is a substantial risk that we may not successfully implement any of these strategic alternatives, and even if we determine to pursue one or more of these alternatives, we may be unable to do so on acceptable terms. Any such transactions may be highly dilutive to our existing stockholders and may deplete our limited remaining capital resources.

In January 2009, we sold \$10 million of face-value auction rate securities to our broker-dealer, UBS A.G. (<u>UB</u>S). As of December 31, 2008, we had recognized a total impairment charge of \$2.3 million as a result of the illiquidity of these securities, which was fully offset by a \$2.3 million realized gain from UBS is repurchase agreement that provides for a put option on these securities. Following the sale of these investments, we no longer hold any auction-rate securities.

On May 12, 2008, we sold 15.6 million Units (the <u>Units</u>, where each Unit consists of one share of common stock, \$0.01 par value per share and a warrant to purchase 0.25 shares of Common Stock) in an underwritten public offering at a price of approximately \$1.92 per Unit, resulting in net proceeds totalling approximately \$28.0 million. The warrants, which represent the right to acquire a total of 3.9 million shares of common stock, are exercisable at a price of \$2.15 per share and have a five-year term. Certain of our principal stockholders, including affiliates of certain of our directors, purchased an aggregate of approximately \$24.3 million, or approximately 81%, of the Units sold.

## **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. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to patent costs, clinical/regulatory expenses and, effective January 1, 2008, the fair value of our financial instruments. 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 for 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.

18

#### **Table of Contents**

We believe the following critical accounting policies involve significant judgments and estimates used in the preparation of our consolidated financial statements (see also Note 1 to our consolidated financial statements included in Part IV).

Impairment and useful lives of long-lived assets

We regularly review our long-lived assets for impairment. Our long-lived assets include costs incurred to file our patent applications. We evaluate the recoverability of long-lived assets by measuring the carrying amount of the assets against the estimated undiscounted future cash flows associated with them. At the time such evaluations indicate that the future undiscounted cash flows of certain long-lived assets are not sufficient to recover the carrying value of such assets, the assets are adjusted to their fair values. The estimation of the undiscounted future cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from the actual results.

Costs related to issued patents are amortized using the straight-line method over the lesser of the remaining useful life of the related technology or the remaining patent life, commencing on the date the patent is issued. Legal costs and expenses incurred in connection with pending patent applications have been capitalized. We expense all costs related to abandoned patent applications. If we elect to abandon any of our currently issued or unissued patents, the related expense could be material to our results of operations for the period of abandonment. The estimation of useful lives for long-lived assets requires judgment and assumptions that could differ materially from the actual results. In addition, our results of operations could be materially impacted if we begin amortizing the costs related to unissued patents.

As a result of the futility determination in the ASPEN trial, we decided to discontinue the Riquent Phase 3 ASPEN study and halt the further development of Riquent. We had previously devoted substantially all of our research, development and clinical efforts and financial resources toward the development of Riquent. Therefore, the future cash flows from our Riquent-related patents are no longer expected to exceed their carrying values. In addition, during 2009 the Company expects to sell substantially all of its laboratory equipment, as well as a large portion of its furniture and fixtures and computer equipment and software.

We performed a recoverability test of the long-lived assets included in our Riquent asset group in accordance with Statement of Financial Accounting Standards No. (<u>SFAS</u>) 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (<u>SFAS</u> 144). The recoverability test was based on the estimated undiscounted future cash flows expected to result from our long-lived assets. Based on the recoverability analysis performed, management does not believe that the estimated undiscounted future cash flows expected to result from the disposition of certain of the Company s long-lived assets are sufficient to recover the carrying value of these assets. Accordingly, we recorded a non-cash charge for the impairment of long-lived assets of \$2.8 million for the year ended December 31, 2008 to write down the value of our long-lived assets to their estimated fair values. We recognized \$0 and \$0.1 million in impairment losses for the years ended December 31, 2007 and 2006, respectively.

Accrued clinical/regulatory expenses

We review and accrue clinical trial and regulatory-related expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, sites activated and other events. We follow this method because reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. Accrued clinical/regulatory costs are subject to revisions as trials progress to completion. 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.

Share-based compensation

We adopted SFAS 123R, *Share-Based Payment*, (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 our 2006 fiscal year. Our Consolidated Statement of Operations as of and for the years ended December 31, 2008, 2007 and 2006 reflect the impact of SFAS 123R. In accordance with the modified prospective transition method, our Consolidated Statements of Operations for prior periods have not been restated to reflect, and do not include, the

#### **Table of Contents**

impact of SFAS 123R. Share-based compensation expense recognized under SFAS 123R for the years ended December 31, 2008 and December 31, 2007 was approximately \$4.4 million and \$4.8 million, respectively. As of December 31, 2008, there was approximately \$4.9 million 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. We currently expect to recognize the remaining unrecognized compensation cost over a weighted-average period of 1.2 years. Additional share-based compensation expense for any new share-based payment awards granted after December 31, 2008 under all equity compensation plans cannot be predicted at this time because it will depend on, among other matters, the amounts of share-based payment awards granted in the future.

Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Because the employee and director stock options granted by us have characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, in our opinion the existing valuation models may not provide an accurate measure of the fair value of the employee and director stock options granted by us. Although the fair value of the employee and director stock options granted by us is determined in accordance with SFAS 123R using an option-pricing model, that value may not be indicative of the fair value observed in a willing-buyer/willing-seller market transaction.

Fair value of financial instruments

Effective January 1, 2008, we adopted SFAS No. 157, Fair Value Measurements (<u>SFAS 15</u>7). In February 2008, the Financial Accounting Standards Board (<u>FASB</u>) issued FASB Staff Position (<u>FSP</u>) No. SFAS 157-2, Effective Date of FASB Statement No. 157, which provides a one-year deferral of the effective date of SFAS No. 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 annually. Therefore, we have adopted the provisions of SFAS 157 with respect to financial assets and liabilities only.

SFAS 157 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 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:

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 adoption of this statement impacted our calculation of fair value associated with our investments, specifically our auction rate securities, which became illiquid during the first quarter of 2008. In accordance with SFAS 157, we valued these securities using Level 3 hierarchical inputs due to the lack of actively traded market data. These inputs include management s assumptions of pricing by market participants, including assumptions about risk. We based our fair value determination on estimated discounted future cash flows of interest income over a projected period reflective of the length of time we anticipate it will take the securities to become liquid. We considered any impairment on these investments to be other-than-temporary, thus any changes in fair value were recorded to the audited consolidated statement of operations for the year ended December 31, 2008. Because we were required to value those securities using only Level 3 inputs, our valuation determinations are somewhat subjective and the actual fair values as determined at a later date or by a third party may be different than the fair values we have determined.

## **Table of Contents**

During the fourth quarter of 2008, our broker-dealer, UBS, offered to repurchase our outstanding auction-rate securities at their par value. We accepted this offer in November 2008 and, in January 2009, we sold all of our auction rate securities to UBS at par value of \$10.0 million. As of December 31, 2008, we had recognized a total impairment charge of \$2.3 million as a result of the illiquidity of these securities, which was fully offset by a \$2.3 million realized gain from UBS a repurchase agreement that provides for a put option on these securities. (See Notes 2 and 10 to our audited consolidated financial statements included in Part IV)

## **New Accounting Pronouncements**

On January 1, 2008, we adopted the provisions of SFAS 157. SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice 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. The adoption did not have an impact on the audited consolidated financial statements or on our consolidated results of operations and financial condition for the year ended December 31, 2008.

On January 1, 2008, we adopted the provisions of 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, 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 did not have an impact on our consolidated results of operations and financial condition for the year ended December 31, 2008.

In June 2007, FASB ratified the consensus reached by the Emerging Issues Task Force (<u>EITF</u>) on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (<u>EITF 07-3</u>). 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 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 May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (<u>SFAS 162</u>). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles. SFAS 162 becomes effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to Statement on Auditing Standards No. 69, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*, for periods completed after January 1, 2009. We do not expect that the adoption of SFAS 162 will have a material effect on our consolidated financial statements.

#### **Results of Operations**

## Years Ended December 31, 2008, 2007 and 2006

Research and Development Expense. Our research and development expense increased to \$51.0 million for the year ended December 31, 2008 from \$46.6 million in 2007. The increase in research and development expenses in 2008 from 2007 resulted primarily from an increase in clinical trial expenses of approximately \$7.8 million, offset by a decrease in Riquent-related drug production of \$4.1 million.

Research and development expense of \$50.8 million for the year ended December 31, 2008 related to lupus research and development-related expense consisting primarily of Riquent-related clinical trial expenses and clinical

## **Table of Contents**

drug supply, salaries and other costs related to manufacturing, clinical and research personnel and fees for consulting and professional outside services.

Our research and development expense increased to \$46.6 million for the year ended December 31, 2007 from \$32.9 million in 2006. The increase in research and development expenses in 2007 from 2006 resulted primarily from an increase in Riquent-related drug production and clinical trial expenses of approximately \$16.0 million. This increase was partially offset by a decrease of approximately \$3.2 million in expenses in 2007 as compared to 2006 for the development of our SSAO program, as all of our resources were being devoted to the development of Riquent and further development of the SSAO program depends on our ability to sell, out-license or enter into a collaborative arrangement for this program.

We expect that our research and development expense will decrease significantly during 2009 as we discontinued the research, development and manufacturing of Riquent during February 2009 and will be reducing our research and development workforce substantially in the second quarter of 2009. Because we have not yet ascertained which strategic option we may ultimately pursue, we do not know the specific number of personnel reductions that will be made. We do expect, however, that the reductions in force will be substantial.

General and Administrative Expense. Our general and administrative expense increased to \$9.7 million for the year ended December 31, 2008 from \$9.1 million in 2007. The increase in general and administrative expense in 2008 from 2007 resulted primarily from an increase in general corporate consulting, professional outside services and salaries and wages of approximately \$1.0 million, primarily as a result of our potential partnering efforts for Riquent. This increase was offset by a decrease in our miscellaneous business expenses related to lower patent abandonments during 2008 compared to 2007 (see 2008 patent impairment discussion below) and a decrease in depreciation as a result of more assets being fully depreciated in 2008.

Our general and administrative expense decreased to \$9.1 million for the year ended December 31, 2007 from \$9.3 million in 2006. The decrease in general and administrative expense in 2007 from 2006 resulted primarily from a decrease in termination benefits, which for 2006 were mainly severance of approximately \$0.9 million and compensation expense of approximately \$0.8 million for accelerated stock option vesting related to the former Chairman and Chief Executive Officer's departure in the first quarter of 2006. This decrease was partially offset by the increase in the write-off of selected patent applications for technologies not related to Riquent or our small molecule SSAO inhibitors program of approximately \$0.7 million, an increase in share-based compensation expense of approximately \$0.5 million for stock options granted in 2006 and 2007 and an increase in consulting expenses for business development and market research of approximately \$0.4 million.

We expect that our general and administrative expense will decrease significantly during 2009 as we discontinued the development of Riquent during February 2009 and will be reducing our general and administrative workforce substantially in the second quarter of 2009.

Asset Impairments. We recorded a \$2.8 million non-cash impairment charge in 2008 (none in 2007 and \$0.1 million in 2006) because we no longer believe that the estimated undiscounted future cash flows expected to result from the disposition of certain of the Company s long-lived assets are sufficient to recover the carrying value of these assets. This impairment charge was due to the negative results from the Riquent Phase 3 ASPEN study announced in February 2009, which is an indicator of impairment.

Interest Income and Expense. Our interest income decreased to \$0.8 million for the year ended December 31, 2008 from \$2.7 million for 2007 due to lower average balances of cash and short-term investments and lower average interest rates on our investments as compared to 2007. Our interest income was comparable for the years ended December 31, 2007 and 2006. Interest expense was comparable for the years ended December 31, 2008, 2007 and 2006.

Net Operating Loss and Research Tax Credit Carryforwards. At December 31, 2008, we had federal and California income tax net operating loss carryforwards that are subject to Section 382/383 limitations of net operating loss and research and development credit carryforwards. In February 2009, we experienced a change in ownership at a time when our enterprise value was minimal. As a result of this ownership change and the low enterprise value, our federal and California net operating loss carryforwards and federal research and development credit carryforwards as of December 31, 2008 will be subject to limitation under IRC Section 382/383 and more likely than not will expire

unused.

22

#### **Table of Contents**

## **Liquidity and Capital Resources**

From inception through December 31, 2008, we have incurred a cumulative net loss of approximately \$415.7 million and have financed our operations through public and private offerings of securities, revenues from collaborative agreements, equipment financings and interest income on invested cash balances. From inception through December 31, 2008, we had raised approximately \$404.0 million in net proceeds from sales of equity securities.

On May 12, 2008, we sold 15.6 million Units (comprised of 15.6 million shares of common stock and common stock warrants to purchase an additional 3.9 million shares) for net proceeds totalling approximately \$28.0 million. The warrants are exercisable at a price of \$2.15 per share and have a five-year term.

As of December 31, 2008, we had \$19.4 million in cash, cash equivalents and short-term investments, as compared to \$39.4 million as of December 31, 2007. Our working capital as of December 31, 2008 was \$3.0 million, as compared to \$29.9 million as of December 31, 2007. The decrease in cash, cash equivalents and short-term investments resulted from the use of our financial resources to fund our clinical trial and manufacturing activities and for other general corporate purposes. This decrease is partially offset by the net proceeds of approximately \$28.0 million from the sale of 15.6 million Units in May 2008. We invest our cash in money market funds invested in U.S. Treasury bills, and AAA rated asset-backed student loan auction rate securities. As of December 31, 2008, all of our investments are classified as available-for-sale securities because we expect to sell them in order to support our current operations regardless of their maturity dates.

As of December 31, 2008, we classified all of our student loan auction rate securities as short-term available-for-sale securities as we will need additional cash in the near term and may be required to liquidate these auction rate securities in order to continue our operations. As of December 31, 2008, all of our short-term available-for-sale securities have stated maturity dates of more than one year, however, their interest rates are reset periodically within time periods not exceeding 92 days. In the event we need to access the funds that are in an illiquid state, we will not be able to do so without a loss of principal until the securities are settled at par by the broker-dealer, a future auction on these auction rate securities is successful or they are redeemed by the issuer at par. As a result, we have recorded a realized impairment loss on these investments in 2008 of approximately \$2.3 million.

In November 2008, we accepted a redemption offer by UBS to sell all \$10.0 million of our outstanding auction rate securities (<u>ARS Rights agreement</u>), all of which were maintained by UBS. As of December 31, 2008, the fair value of the ARS Rights were recorded as as a realized gain of \$2.3 million and a corresponding short-term investment. The realized gain from recording the ARS Rights fully offsets the realized impairment loss on auction rate securities that was recorded during 2008 (see Note 2 to our audited consolidated financial statements included in Part IV). During January 2009, all of our auction rate securities were sold to UBS at par value of \$10.0 million (see Note 10 to our audited consolidated financial statements included in Part IV).

In December 2008, we secured a credit facility (the <u>Credit Facility</u>) with UBS in the amount of \$6.0 million, fully collateralized by our auction rate securities. There was no net interest cost to us as the interest rate charged by UBS was contractually equal to the coupon rates of the auction rate securities. There were no costs related to the establishment of the Credit Facility. During December 2008, we drew the full \$6.0 million available under the Credit Facility, for working capital purposes, of which \$5.9 million was outstanding as of December 31, 2008. During January 2009, the amount outstanding on the credit facility as of December 31, 2008 was settled in full and the Credit Facility agreement was terminated (see Note 10 to our audited consolidated financial statements included in Part IV).

In January 2009, we entered into a development and commercialization agreement with BioMarin CF. Under the terms of the agreement, BioMarin CF paid us a non-refundable commencement payment of \$7.5 million and BioMarin Pharma purchased \$7.5 million of Series B Preferred Stock. On March 27, 2009 and as a result of the termination of the Development Agreement, the Series B Preferred Stock converted into 10,173,120 shares of Common Stock.

As of December 31, 2008, approximately \$3.8 million worth of property and equipment (\$0.2 million net of depreciation and 2008 impairment charges) secured our notes payable and capital lease obligations. We lease our office and laboratory facilities and these leases expire on July 31, 2009. We also lease certain equipment under operating leases. We have also entered into non-cancelable purchase commitments for an aggregate of \$1.3 million

with third-party manufacturers of materials to be used in the production of Riquent, approximately \$0.8\$ million of 23

#### **Table of Contents**

which is included in the audited consolidated balance sheet as of December 31, 2008. We intend to use our current financial resources to fund our obligations under these purchase commitments.

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 (in thousands)

		Less than	V 1	`	More than
			1-3	3-5	
	Total	1 Year	Years	Years	5 Years
Credit facility	\$5,933	\$5,933	\$	\$	\$
Long-term debt obligations	373	177	196		
Operating lease obligations	658	491	148	19	
Capital lease obligations	55	15	40		
Purchase obligations	1,290	1,290			
Total	\$8,309	\$7,906	\$384	\$ 19	\$

We intend to use our financial resources, including the \$15 million we received from our collaborative agreement and sale of preferred stock in January 2009, to fund our current obligations and to pursue other strategic alternatives that may become available to us. In the future, it is possible that we will not have adequate resources to support continued operations and we will need to cease operations.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include but are not limited to the following:

our ability to sell, out-license or otherwise dispose of our assets, including our SSAO compound;

our ability to consummate a merger with another company; or

our ability to negotiate favorable settlement terms with our creditors, as well as any actions that may be taken by our creditors, which could force us to wind down the Company.

There can be no assurance that we will be able to enter into any strategic transactions on acceptable terms, if any, and our negotiating position may worsen as we continue to utilize our existing resources.

24

## **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.

We invest our excess cash in interest-bearing investment-grade securities, which we sell from time to support our current operations. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions in any material fashion. We currently do not invest in any securities that are materially and directly affected by foreign currency exchange rates or commodity prices.

All of our investment securities are classified as available-for-sale and are therefore reported on the balance sheet at market value. Our investment securities consist of money market funds invested in U.S. Treasury bills, and asset-backed student loan auction rate securities. As of December 31, 2008, our short-term investments included \$7.7 million (net of a realized impairment loss of \$2.3 million) of AAA rated student loan auction rate securities and \$2.3 million for the value of our auction rate securities put rights. Our auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals through auctions.

During November 2008, we executed a written agreement with UBS to participate in the ARS Rights program for all \$10.0 million of our outstanding auction rate securities, all of which were maintained by UBS. Under the terms of the ARS Rights agreement, the applicable exercise period began on January 2, 2009 and ends January 4, 2011. ARS Rights represent an asset akin to a put option, whereby the holder has the right to put the auction rate securities back to the broker-dealer during the exercise period for a payment equal to the par value of the auction rate securities. As of December 31, 2008, the fair value of the ARS Rights were recorded as a realized gain of \$2.3 million and a corresponding short-term investment. The realized gain from recording the ARS Rights fully offsets the realized impairment loss on auction rate securities that was recorded during 2008 (see Note 2 to our audited consolidated financial statements included in Part IV). During January 2009, pursuant to the ARS Rights agreement, all of our auction rate securities were sold to UBS at par value of \$10.0 million (see Note 10 to our audited consolidated financial statements included in Part IV).

Based on our cash, cash equivalents and short-term investments at December 31, 2008, a hypothetical 10% increase or decrease in interest rates would increase or decrease our annual interest income and cash flows by an immaterial amount.

## Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary data required by this item are set forth above under the caption Quarterly Results of Operations on page F-26 and at the end of this report beginning on page F-2 and is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

25

#### **Table of Contents**

## 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 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 <u>Exchange Act</u>)) as of December 31, 2008. Based on this evaluation, our principal executive and principal financial 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;

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.

26

## **Table of Contents**

(c) Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of La Jolla Pharmaceutical Company

We have audited La Jolla Pharmaceutical 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 (the COSO criteria ). La Jolla Pharmaceutical Company s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s 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 included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and 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 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, La Jolla Pharmaceutical Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of La Jolla Pharmaceutical Company as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders—equity, and cash flows for each of the three years in the period ended December 31, 2008 and our report dated March 27, 2009 expressed an unqualified opinion thereon that included an explanatory paragraph regarding La Jolla Pharmaceutical Company—s ability to continue as a going concern.

/s/ Ernst & Young LLP San Diego, California March 27, 2009

27

#### **Table of Contents**

## 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 (<u>SE</u>C) 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 Chief Executive Officer, Principal Financial Officer, Principal Accounting Officer, and to all of our other officers, directors, employees and agents. The code of conduct is available at the Corporate Governance section of the Investor Relations page on our website at www.ljpc.com. We intend to disclose future amendments to certain provisions of our code of conduct on the above website within four business days following the date of such amendment or waiver.

## **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 SEC 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 SEC 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 SEC within 120 days of December 31, 2008. Such information is incorporated herein by reference.

## Item 14. Principal Accountant Fees and Services.

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

28

## **Table of Contents**

## **PART IV**

## Item 15. Exhibits, Financial Statement Schedules.

- (a) Documents filed as part of this report.
- 1. The following consolidated financial statements of La Jolla Pharmaceutical Company are filed as part of this report under Item 8 Financial Statements and Supplementary Data:

Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets at December 31, 2008 and 2007	F-2
Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006	F-3
Consolidated Statements of Stockholders Equity for the years ended December 31, 2008, 2007 and 2006	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006	F-5
Notes to Consolidated Financial Statements	F-6

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.

29

## **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.

LA JOLLA PHARMACEUTICAL COMPANY

March 30, 2009 By: /s/ Deirdre Y. Gillespie

Deirdre Y. Gillespie, M.D.

President, Chief Executive Officer and

**Assistant Secretary** 

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 and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Deirdre Y. Gillespie	President, Chief Executive Officer and Assistant Secretary (Principal Executive Officer)	March 30, 2009
Deirdre Y. Gillespie, M.D	Secretary (Finicipal Executive Officer)	Wiaicii 30, 2009
/s/ Niv E. Caviar	Executive Vice President, Chief Business Officer	M1 20 2000
Niv E. Caviar	and Chief Financial Officer (Principal Financial Officer)	March 30, 2009
/s/ Gail A. Sloan	Vice President of Finance and Secretary (Principal	
Gail A. Sloan	Accounting Officer)	March 30, 2009
/s/ Thomas H. Adams	Director	March 30, 2009
Thomas H. Adams, Ph.D.		
/s/ Robert A. Fildes	Director	March 30, 2009
Robert A. Fildes, Ph.D.		
/s/ Stephen M. Martin	Director	March 30, 2009
Stephen M. Martin		
/s/ Craig R. Smith	Director	March 30, 2009
Craig R. Smith, M.D.		
/s/ Martin Sutter	Director	March 30, 2009
Martin Sutter		
/s/ James N. Topper	Director	March 30, 2009

James N. Topper, M.D., Ph.D.

/s/ Frank E. Young Director March 30, 2009

Frank E. Young, M.D., Ph.D.

30

#### **Table of Contents**

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of La Jolla Pharmaceutical Company

We have audited the accompanying consolidated balance sheets of La Jolla Pharmaceutical Company as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the 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 consolidated financial position of La Jolla Pharmaceutical Company at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that La Jolla Pharmaceutical Company will continue as a going concern. As more fully described in Note 1, La Jolla Pharmaceutical Company has incurred recurring operating losses, an accumulated deficit of \$415.7 million and working capital of \$3.0 million at December 31, 2008. These conditions, among others, as discussed in Note 1 to the consolidated financial statements, raise substantial doubt about La Jolla Pharmaceutical Company s ability to continue as a going concern. Management s plans in regard to these matters also are described in Note 1. The 2008 consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), La Jolla Pharmaceutical 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 and our report dated March 27, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California March 27, 2009

F-1

## **Table of Contents**

# La Jolla Pharmaceutical Company Consolidated Balance Sheets (In thousands, except share and par value amounts)

	December 31,			,
		2008		2007
Assets				
Current assets:	¢	0.447	¢	4 272
Cash and cash equivalents Short-term investments, available-for-sale	\$	9,447 10,000	\$	4,373 34,986
Prepaids and other current assets		785		1,018
repaids and other earrent assets		703		1,010
Total current assets		20,232		40,377
Property and equipment, net		357		1,271
Patent costs and other assets, net		250		2,757
	\$	20,839	\$	44,405
Liabilities and stockholders equity				
Current liabilities:				
Accounts payable	\$	4,626	\$	2,203
Accrued clinical/regulatory expenses	Ψ	3,957	4	6,282
Accrued expenses		1,008		664
Accrued payroll and related expenses		1,549		1,199
Credit facility		5,933		
Current portion of obligations under notes payable		152		138
Current portion of obligations under capital leases		11		10
Total current liabilities		17,236		10,496
Non-current portion of obligations under notes payable		179		344
Non-current portion of obligations under capital leases		34		44
Commitments				
Stockholders equity:				
Preferred stock, \$0.01 par value; 8,000,000 shares authorized, no shares				
issued or outstanding				
Common stock, \$0.01 par value; 225,000,000 shares authorized, 55,549,528				
and 39,629,660 shares issued and outstanding at December 31, 2008 and				
2007, respectively		555		396
Additional paid-in capital		418,522		385,944
Other comprehensive income				14
Accumulated deficit	(	(415,687)	(	352,833)
Total stackhaldons aguity		2 200		22 521
Total stockholders equity		3,390		33,521

\$ 20,839

\$ 44,405

See accompanying notes.

F-2

## **Table of Contents**

La Jolla Pharmaceutical Company Consolidated Statements of Operations (In thousands, except per share amounts)

	Years Ended December 31,			
	2008	2007	2006	
Expenses:				
Research and development	\$ 51,025	\$ 46,635	\$ 32,834	
General and administrative	9,702	9,058	9,287	
Asset impairments	2,810		104	
Total expenses	63,537	55,693	42,225	
Loss from operations	(63,537)	(55,693)	(42,225)	
Interest expense	(96)	(82)	(46)	
Interest income	779	2,699	2,826	
Net loss	\$(62,854)	\$(53,076)	\$(39,445)	
Basic and diluted net loss per share	\$ (1.26)	\$ (1.40)	\$ (1.21)	
Shares used in computing basic and diluted net loss per share	49,689	37,818	32,588	
See accompanying notes.				
F-3				

## **Table of Contents**

## La Jolla Pharmaceutical Company Consolidated Statements of Stockholders Equity For the Years Ended December 31, 2006, 2007 and 2008 (In thousands)

	Commo	n stock	Additional paid-in		v&ccumulated	Total stockholders
	Shares	Amount	capital	(loss)	deficit	equity
Balance at December 31, 2005 Issuance of common stock under	32,533	\$325	\$337,117	\$	\$(260,312)	\$ 77,130
Employee Stock Purchase Plan	80	1	226			227
Exercise of stock options	56	1	125			126
Share-based compensation expense	24		5,051			5,051
Net loss					(39,445)	(39,445)
Balance at December 31, 2006	32,693	327	342,519		(299,757)	43,089
Issuance of common stock, net Issuance of common stock under	6,670	67	37,845			37,912
Employee Stock Purchase Plan	97	1	260			261
Exercise of stock options	166	1	499			500
Share-based compensation expense	4	•	4,821			4,821
Net loss			,-		(53,076)	(53,076)
Net unrealized gains on					, , ,	, , ,
available-for-sale securities				14		14
Comprehensive loss						(53,062)
Balance at December 31, 2007	39,630	396	385,944	14	(352,833)	33,521
Issuance of common stock, net Issuance of common stock under	15,615	156	27,877			28,033
Employee Stock Purchase Plan	304	3	287			290
Exercise of stock options	1		3			3
Share-based compensation expense			4,411			4,411
Net loss					(62,854)	(62,854)
Net unrealized losses on						
available-for-sale securities				(14)		(14)
Comprehensive loss						(62,868)
Balance at December 31, 2008	55,550	\$555	\$418,522	\$	\$(415,687)	\$ 3,390
See accompanying notes.						
		F-4				

## **Table of Contents**

## La Jolla Pharmaceutical Company Consolidated Statements of Cash Flows (In thousands)

	Years 2008	per 31, 2006	
Operating activities			
Net loss	\$ (62,854)	\$ (53,076)	\$ (39,445)
Adjustments to reconcile net loss to net cash used for operating			, , ,
activities:			
Depreciation and amortization	990	1,687	1,987
Loss on write-off/disposal of patents, property and equipment and			
licenses	243	934	316
Loss on impairment of patents, property and equipment and licenses	2,810		104
Share-based compensation expense	4,411	4,821	5,051
Amortization (accretion) of investment premium/discount	240	(227)	36
Changes in operating assets and liabilities:			
Prepaids and other current assets	233	(14)	(101)
Accounts payable	2,423	78	1,259
Accrued clinical/regulatory expenses	(2,325)	4,752	1,303
Accrued expenses	344	(473)	(147)
Accrued payroll and related expenses	350	(66)	487
Net cash used for operating activities	(53,135)	(41,584)	(29,150)
Investing activities			
Purchases of short-term investments		(51,415)	(16,700)
Sales of short-term investments	24,665	55,750	44,050
Additions to property and equipment	(506)	(354)	(335)
Increase in patent costs and other assets	(116)	(628)	(536)
Net cash provided by investing activities	24,043	3,353	26,479
Financing activities			
Net proceeds from issuance of common stock	28,326	38,673	353
Proceeds from credit facility	6,000		
Proceeds from issuance of notes payable		312	263
Payments on obligations under notes payable	(151)	(209)	(527)
Payments on obligations under capital leases	(9)	(1)	
Net cash provided by financing activities	34,166	38,775	89
Increase (decrease) in cash and cash equivalents	5,074	544	(2,582)
Cash and cash equivalents at beginning of period	4,373	3,829	6,411
Cash and cash equivalents at end of period	\$ 9,447	\$ 4,373	\$ 3,829

Supplemental disclosure of cash flow information: Interest paid	\$ 96	\$ 82	\$ 46
Supplemental schedule of noncash investing and financing activities:  Capital lease obligations incurred for property and equipment	\$	\$ 55	\$
See accompanying notes. F-5			

#### **Table of Contents**

La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 1. Organization and Summary of Significant Accounting Policies

## **Organization and Business Activity**

La Jolla Pharmaceutical Company (the Company ) is a biopharmaceutical company dedicated to improving and preserving human life by developing innovative pharmaceutical products.

## **Basis of Presentation**

In February 2009, the Company announced that an Independent Monitoring Board for the Riquent Phase 3 ASPEN study had completed the review of their first interim efficacy analysis and determined that continuing the study was futile. Based on these results, the Company immediately discontinued the Riquent Phase 3 ASPEN study and the development of Riquent. The Company had previously devoted substantially all of its research, development and clinical efforts and financial resources toward the development of Riquent. In connection with the termination of the clinical trials for Riquent, the Company subsequently initiated steps to significantly reduce its operating costs including a planned substantial reduction in personnel, which is expected to be effected early in the second quarter of 2009. The Company has also ceased the manufacture of Riquent. In addition, the Company has incurred a net loss of \$62.9 million in 2008, has had cumulative net losses of \$415.7 million from inception to date and has limited financial resources at December 31, 2008.

These events raise substantial doubt about the Company s ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company s assets and the satisfaction of liabilities in the normal course of business and this does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

In light of the Company s decision to discontinue development of the Riquent clinical program, the Company is seeking to maximize the value of its remaining assets. The Company is currently evaluating its strategic alternatives, which include the following:

Sell or out-license the Company s remaining assets, including the Company s SSAO compounds;

Pursue potential other strategic transactions, which could include mergers, license agreements or other collaborations, with third parties; or

Implement an orderly wind down of the Company if other alternatives are not deemed viable and in the best interests of the Company.

## **Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, La Jolla Limited, which was incorporated in England in October 2004. There have been no significant transactions related to La Jolla Limited since its inception.

## **Use of Estimates**

The preparation of consolidated financial statements in conformity with United States generally accepted accounting principles (<u>GAAP</u>) 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.

## Cash, Cash Equivalents and Short-Term Investments

Cash and cash equivalents consist of cash and short-term, highly liquid investments which include money market funds and debt securities with maturities from purchase date of three months or less and are stated at estimated fair value. Short-term investments mainly consist of debt securities with maturities from purchase date of greater than three months. In accordance with Statement of Financial Accounting Standard (<u>SFAS</u>) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, management has classified the Company s cash equivalents and

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 1. Organization and Summary of Significant Accounting Policies (continued)

short-term investments as available-for-sale securities in the accompanying consolidated financial statements. Available-for-sale securities are recorded at estimated fair value, with unrealized gains and losses reported in other comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are 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.

## **Concentration of Risk**

Cash, cash equivalents and short-term investments are financial instruments which potentially subject the Company to concentrations of credit risk. The Company deposits its cash in financial institutions. At times, such deposits may be in excess of insured limits. The Company invests its excess cash primarily in government-asset-backed securities, and money market funds invested in U.S. Treasury bills. 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. As of December 31, 2008, there was insufficient demand at auctions for the Company s student loan auction rate securities, representing a par value of approximately \$10,000,000. During January 2009, the Company sold all of these auction rate securities to its broker-dealer at par value of \$10,000,000 (see Notes 2 and 10).

## Impairment of Long-Lived Assets and Assets to Be Disposed Of

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.

As a result of the futility determination in the Phase 3 ASPEN trial, the Company discontinued the Riquent Phase 3 ASPEN study and the development of Riquent. Based on these events, the future cash flows from the Company s Riquent-related patents are no longer expected to exceed their carrying values and the assets became impaired. This rendered substantially all of the Company s laboratory equipment, as well as a large portion of its furniture and fixtures and computer equipment and software impaired.

The Company performed a recoverability test of its long-lived assets in accordance with SFAS No. 144. The recoverability test was based on the estimated undiscounted future cash flows expected to result from the Company s long-lived assets. Based on the recoverability analysis performed, management does not believe that the estimated undiscounted future cash flows expected to result from the disposition of certain of the Company s long-lived assets are sufficient to recover the carrying value of these assets. Accordingly, the Company recorded a non-cash charge for the impairment of long-lived assets of \$2,810,000 for the year ended December 31, 2008 to write down the value of the Company s long-lived assets to their estimated fair values. Impairment charges included \$2,061,000 for patents, \$724,000 for property and equipment, and \$25,000 for licenses. The Company recognized \$0 and \$104,000 in impairment losses for the years ended December 31, 2007 and 2006, respectively.

F-7

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 1. Organization and Summary of Significant Accounting Policies (continued)

## **Property and Equipment**

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (primarily five years). Leasehold improvements and equipment under capital leases are stated at cost and depreciated on a straight-line basis over the shorter of the estimated useful life or the lease term.

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

	December 31,		
	2008	2007	
Laboratory equipment	\$ 6,171	\$ 6,498	
Computer equipment and software	4,654	4,727	
Furniture and fixtures	477	491	
Leasehold improvements	3,275	3,273	
	14,577	14,989	
Less: Accumulated depreciation	(14,220)	(13,718)	
	\$ 357	\$ 1,271	

Depreciation expense for the years ended December 31, 2008, 2007 and 2006 was \$737,000, \$1,471,000, and \$1,840,000, respectively. Impairment charges of \$724,000 during 2008 were reflected as a reduction to the above noted costs.

## **Patents**

The Company has filed numerous patent applications with the United States Patent and Trademark Office and in foreign countries. Legal costs and expenses incurred in connection with pending patent applications have been capitalized. Costs related to issued patents are amortized using the straight-line method over the lesser of the remaining useful life of the related technology or the remaining patent life, commencing on the date the patent is issued. Total issued patent application costs (net of 2008 impairment charges) and accumulated amortization were \$1,159,000 and \$1,116,000 at December 31, 2008 and \$2,492,000 and \$911,000 at December 31, 2007, respectively. Total pending patent application costs (less 2008 impairment charges) were \$207,000 and \$1,004,000 at December 31, 2008 and 2007, respectively. Capitalized costs related to patent applications are charged to operations at the time a determination is made not to pursue such applications or they become impaired. Amortization expense for the years ended December 31, 2008, 2007 and 2006 was \$245,000, \$207,000, and \$139,000, respectively.

## **Accrued Clinical/Regulatory Expenses**

The Company reviews and accrues clinical trial and regulatory-related expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. Accrued clinical/regulatory costs are subject to revisions as trials progress to completion. 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.

## **Share-Based Compensation**

On January 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment* (<u>SFAS 123</u>R), which is a revision of SFAS No. 123, *Accounting and Disclosure of Stock-Based Compensation* (<u>SFAS 123</u>). SFAS 123R requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including stock options, restricted stock and purchases under the La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (the <u>ESP</u>P), based on estimated fair values. SFAS 123R supersedes the Company s

previous accounting under Accounting Principles Board Opinion (  $\underline{\ \ APB}\ \ )$  No. 25,

F-8

## **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 1. Organization and Summary of Significant Accounting Policies (continued)

SFAS 123R and for the period permitted by SAB 107.

Accounting for Stock Issued to Employees (<u>APB 2</u>5), and SFAS 123, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission (<u>SEC</u>) issued Staff Accounting Bulletin (<u>SAB</u>) 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 has applied the provisions of SAB 107, related to the calculation of its expected term, in its adoption of

Share-based compensation expense recognized under SFAS 123R for the years ended December 31, 2008, 2007 and 2006, respectively was approximately \$4,422,000, \$4,810,000 and \$5,048,000. As of December 31, 2008, there was approximately \$4,940,000 of total unrecognized compensation cost related to non-vested share-based payment awards granted under all equity compensation plans. As share-based compensation expense recognized in the Consolidated Statement of Operations for the fiscal years 2008, 2007 and 2006 is based on awards ultimately expected to vest, share-based compensation expense 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. 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 1.2 years.

Compensation expense for options or stock awards issued to non-employees, other than non-employee directors, has been determined in accordance with Emerging Issues Task Force 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. In December 2008, the Company granted non-qualified stock options to purchase a total of 15,000 shares of common stock to a consultant at an exercise price equal to the fair market value of the stock at the date of the grant. The Company recognized compensation expense for these stock option grants of approximately \$1,000 for the year ended December 31, 2008. In September and October 2007, the Company granted non-qualified stock options to purchase a total of 12,000 shares of common stock to consultants at an exercise price equal to the fair market value of the stock at the date of each grant. For the years ended December 31, 2008 and 2007, the Company recognized compensation (credit) expense for these stock option grants of approximately (\$11,000) and \$11,000, respectively. In January 2006, the Company granted a non-qualified stock option to purchase 1,000 shares of common stock to a consultant at an exercise price equal to the fair market value of the stock at the date of the grant. The Company recognized compensation expense for these stock option grants of approximately \$3,000 for the year ended December 31, 2006.

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 Black-Scholes model was previously utilized for the Company s pro forma information required under SFAS 123. 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. These variables include, but are not limited to, the Company s expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors.

## Valuation and Expense Information Under SFAS 123R and APB 25

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

	December 31,			
	2008	2007	2006	
Research and development	\$ 1,961	\$ 1,907	\$ 1,833	
General and administrative	2,461	2,903	3,215	

Share-based compensation expense included in operating expenses \$4,422 \$4,810 \$5,048

F-9

## **Table of Contents**

# La Jolla Pharmaceutical Company

Notes to Consolidated Financial Statements

## 1. Organization and Summary of Significant Accounting Policies (continued)

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:

$\sim$	. •	
"	ptions.	•
$\mathbf{\mathcal{C}}$		

		December 31,		
		2008	2007	2006
Risk-free interest rate		3.2%	4.7%	4.8%
Dividend yield		0.0%	0.0%	0.0%
Volatility		115.1%	118.0%	113.7%
Expected life (years)		5.6	6.0	5.9
	F-10			

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

# **1.** Organization and Summary of Significant Accounting Policies (continued) *ESPP*:

	December 31,			
	2008	2007	2006	
Risk-free interest rate	1.1%	4.5%	4.8%	
Dividend yield	0.0%	0.0%	0.0%	
Volatility	99.6%	67.8%	46.4%	
Expected life (years)	3 months	3 months	3 months	

The weighted-average fair values of options granted were \$1.70, \$3.71 and \$3.92 for the years ended December 31, 2008, 2007 and 2006, respectively. The weighted-average purchase prices of shares purchased through the ESPP were \$0.95, \$2.69 and \$2.98 for the years ended December 31, 2008, 2007 and 2006, respectively.

The risk-free interest rate assumption is based on observed interest rates appropriate for the 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 historical stock price volatility as the expected volatility assumption required in the Black-Scholes option-pricing model consistent with SFAS 123R. The selection of the historical volatility approach was based on the availability of historical stock prices for the duration of the awards—expected term and the Company—s assessment that historical volatility is more representative of future stock price trends than other available methods.

The expected life of employee and director stock options represents the weighted-average period the stock options are expected to remain outstanding. Under SAB 107, the simplified method is an acceptable method of calculating the expected life of options granted through December 31, 2007. However, for options granted after December 31, 2007, companies are expected to use more detailed information about employee exercise behavior, if available, to calculate the expected life of options under SAB 107 rather than the simplified method. For option grants made during 2008, the Company calculated the expected life using historical option exercise data. Under this method of calculating the expected life of option grants, the expected life for option grants made during the year ended December 31, 2008 was 5.6 years for the new and existing employee grants and the director grants. Under the SAB 107 simplified method, the expected life calculated by the Company for option grants made during the year ended December 31, 2007 was 6.0 6.1 years for the new and existing employee grants and 5.5 years for the director grants. The expected life calculated by the Company for option grants made during the year ended December 31, 2006 was 5.8 years for the new and existing employee grants, 6.1 years for the new officer grants, and 5.3 6.0 years for the director grants. The expected life for ESPP purchase rights represents the length of each purchase period. Because employees purchase stock quarterly, the expected term for ESPP purchase rights is three months for shares purchased during the years ended December 31, 2008, 2007 and 2006.

Because share-based compensation expense recognized in the Consolidated Statement of Operations for fiscal years 2008, 2007 and 2006 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 were estimated based on historical experience.

F-11

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

# 1. Organization and Summary of Significant Accounting Policies (continued) Restricted Stock

On December 14, 2005, the Company issued 83,518 shares of restricted stock to certain members of management in exchange for services provided over the vesting period, pursuant to certain retention agreements dated October 6, 2005. The shares of restricted stock fully vested (i.e., the restrictions lapsed) one year from the date of grant and were subject to repurchase by the Company until the one-year anniversary of the date of issuance. Pursuant to a separation agreement dated March 17, 2006, the Company s repurchase right with respect to 29,120 shares of restricted stock granted to the former Chairman and Chief Executive Officer immediately lapsed upon his resignation on March 14, 2006. As such and in accordance with his retention agreement, the Company accelerated the vesting of these shares of restricted stock. In addition, the remaining 54,398 shares of restricted stock fully vested on December 14, 2006, the one-year anniversary of the date of issuance, and therefore the Company s repurchase right with respect to these shares of restricted stock has lapsed.

On March 15, 2006, the Company issued 20,000 shares of restricted stock to the new Chairman of the Board in exchange for services provided over the vesting period. The shares of restricted stock vested with respect to 10,000 shares six months after the issuance date and with respect to the remaining 10,000 shares upon the first anniversary of the issuance date. On September 15, 2006 and March 15, 2007, the vesting provisions with respect to the 20,000 shares of restricted stock were met and therefore the Company's repurchase rights lapsed.

In both December 2006 and March 2007, the Company issued an additional 3,600 shares of restricted stock to the Chairman of the Board in accordance with the Chairman Compensation Policy approved by the Board of Directors on March 14, 2006 regarding the tax liability associated with the restricted stock issued on March 15, 2006 and vested on September 15, 2006 and March 15, 2007. All of these additional shares of restricted stock immediately vested on the date of issuance.

There was no restricted stock issued in 2008.

In accordance with SFAS 123R, the Company recognized approximately \$36,000, and \$381,000, respectively, in compensation expense for the restricted stock grants noted above for the years ended December 31, 2007, and 2006, which includes compensation expense for the acceleration of vesting. There was no compensation expense related to restricted stock grants during the year ended December 31, 2008.

## **Net Loss Per Share**

Basic and diluted net loss per share is computed using the weighted-average number of common shares outstanding during the periods in accordance with SFAS No. 128, *Earnings per Share* and SAB No. 98. Basic earnings per share (<u>EPS</u>) is calculated by dividing the net income or 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 income or loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options, common stock subject to repurchase by the Company, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

F-12

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 1. Organization and Summary of Significant Accounting Policies (continued)

Because the Company has incurred a net loss for all three years presented in the Consolidated Statements of Operations, stock options, common stock subject to repurchase 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, reduced by the weighted-average unvested common shares subject to repurchase. There were no unvested common shares subject to repurchase for the years ended December 31, 2008 and 2007. The number of weighted-average unvested common shares subject to repurchase for the year ended December 31, 2006 was 8,000.

## **Comprehensive Loss**

In accordance with SFAS No. 130, *Reporting Comprehensive Income (Loss)*, unrealized gains and losses on available-for-sale securities are included in other comprehensive income.

## **Recently Issued Accounting Standards**

On January 1, 2008, the Company adopted the provisions of Financial Accounting Standards Board (<u>FASB</u>) SFAS No. 157, *Fair Value Measurements* (<u>SFAS 15</u>7). SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice 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. 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. On January 1, 2008, the Company adopted the provisions of FASB SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (<u>SFAS 159</u>). 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 SFAS 159 did not have an impact on the Company s consolidated results of operations and financial condition for the year ended December 31, 2008.* 

In June 2007, FASB ratified the consensus reached by the Emerging Issues Task Force (<u>EITF</u>) on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (<u>EITF 07-3</u>). 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 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 s consolidated results of operations and financial condition for the year ended December 31, 2008.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (<u>SFAS</u> 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles. SFAS 162 becomes effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to Statement on Auditing Standards No. 69, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*, for periods completed after January 1, 2009. The Company does not expect the adoption of SFAS 162 to have a material effect on the Company s consolidated financial statements.

F-13

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 2. Cash Equivalents and Short-term Investments

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

			Gros	ss C	Gross					4. 4.1
		ortized Cost	Unreali Gain	ized Uni is L	ealized osses		alized Sains	Realized Losses	E	stimated Fair Value
December 31, 2008 Money market accounts Asset-backed auction rate	\$ 2	2,686	\$	\$		\$		\$	\$	2,686
securities Auction security rights	10	0,000				2	2,270	(2,270)		7,730 2,270
	\$ 12	2,686	\$	\$		\$ 2	2,270	\$ (2,270)	\$	12,686
			C	Gross	Gros	SS			17.	
	A	mortized Cost		realized Gains	Unreali Losse		Realized Gains	Realized Losses		stimated Fair Value
December 31, 2007 Money market accounts Obligations of United	\$	2,051	\$		\$		\$	\$	\$	2,051
States government agencies		6,916		14						6,930
Asset-backed auction rate securities		28,056								28,056
	\$	37,023	\$	14	\$		\$	\$	\$	37,037

The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Included in cash and cash equivalents at December 31, 2008 and 2007 were \$2,686,000 and \$2,051,000, respectively, of securities classified as available-for-sale as the Company expects to sell them in order to support its current operations regardless of their maturity date. As of December 31, 2008, available-for-sale securities and cash equivalents of \$2,686,000 mature in one year or less and \$10,000,000 are due after one year. Securities that have a maturity date greater than one year have their interest rate reset periodically within time periods not exceeding 92 days.

As of December 31, 2008, the Company s cash, cash equivalents and short-term investments total \$19,447,000. The Company s investment securities consist of money market funds invested in U.S. Treasury bills and student loan auction rate securities. There has been insufficient demand at auction for all four of the Company s auction rate securities during 2008. As a result, these securities are currently not liquid. In the event the Company needs to access the funds that are in an illiquid state, it will not be able to do so without a loss of principal until a future auction on these auction rate securities is successful, the securities are settled at par by the broker-dealer or they are redeemed by the issuer. The Company may incur a loss of principal if the Company is required to sell or borrow against these securities in a privately negotiated transaction. As a result, the Company has recorded a realized impairment loss on these securities of \$2,270,000 in 2008. This realized loss was determined in accordance with SFAS 157, which was

adopted by the Company on January 1, 2008 (see Note 3). The Company s auction rate securities are classified as short-term investments, and the realized impairment loss is included in the Company s statement of operations. During the fourth quarter of 2008, the Company s broker-dealer, UBS, extended an offer of Auction Rate Securities Rights (<u>ARS Rights</u>) to holders of illiquid auction rate securities that were maintained by UBS as of February 13, 2008. The ARS Rights provide the holder with the ability to sell the auction rate securities, along with the ARS Rights, to UBS at the par value of the auction rate securities, during an applicable exercise period. The ARS Rights are not transferable, not tradeable, and will not be quoted or listed on any securities exchange or other trading network.

During November 2008, the Company executed a written agreement with UBS to participate in the ARS Rights program for all \$10,000,000 of its outstanding auction rate securities, all of which were maintained by UBS. Under the terms of the ARS Rights agreement, the applicable exercise period began on January 2, 2009 and ends January 4, 2011. ARS Rights represent an asset akin to a put option, whereby the Company has the right to put the auction rate securities back to the broker-dealer during the exercise period for a payment equal to the par value of the auction rate securities. As of December 31, 2008, the fair value of the ARS Rights were recorded as a realized gain

F-14

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 2. Cash Equivalents and Short-term Investments (continued)

of \$2,270,000 and a corresponding short-term investment. The realized gain from recording the ARS Rights fully offsets the realized impairment loss on auction rate securities that was recorded during 2008. During January 2009, all of the Company s auction rate securities were sold to UBS at par value of \$10,000,000 pursuant to the ARS Rights agreement (see Note 10).

## 3. Fair Value of Financial Instruments

As a basis for considering market participant assumptions in fair value measurements, SFAS 157 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). Due to the lack of actively traded market data for the Company's student loan auction rate securities, the value of these securities and resulting realized impairment loss was determined using Level 3 hierarchical inputs. These inputs include management s assumptions of pricing by market participants, including assumptions about risk. In accordance with SFAS 157, the Company used the concepts of fair value based on estimated discounted future cash flows of interest income over a projected five-year period reflective of the length of time the Company anticipates it will take the securities to become liquid. Discount rates ranging from approximately 5% to 10% were utilized when preparing this model. The Company classified all of the student loan auction rate securities as short-term available-for-sale securities as the Company will need additional cash in the near term and may be required to liquidate these auction rate securities in order to continue operations. Because of the Company s inability to hold these securities until their maturity (which ranges between 20-30 years), the Company believes the impairment of these securities is other-than-temporary. See Notes 1 and 10 for further details. 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) are as follows:

		Fair Value Measurements at Reporting Date							
		Quoted prices in active	Using						
		markets	Significant	Significant					
		for identical	other observable	unobservable					
Description	Balance at December 31, 2008	assets (Level 1)	inputs (Level 2)	inputs (Level 3)					
Description	31, 2000	(Level 1)	(Ecver 2)	(Ecvers)					
Cash and cash equivalents Short-term investments	\$ 9,447 7,730	\$ 9,447	\$	\$ 7,730					
ARS Rights (Note 2)	2,270			2,270					
Total	\$ 19,447	\$ 9,447	\$	\$ 10,000					

The following table sets forth the change in estimated fair value for the Company s auction rate securities (in thousands).

		U Significant In (Le Year Decemb	Measurement sing Unobservable puts evel 3) Ended er 31, 2008
Beginning balance		\$	
Transfers in to Level 3			
Auction rate securities			10,000
ARS Rights			2,270
Total realized/unrealized losses			
Included in net loss			(2,270)
Included in comprehensive loss			
Purchases, issuances and settlements			
Ending balance		\$	10,000
	F-15		

## **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 4. Commitments

#### Leases

In July 1992, the Company entered into a non-cancelable operating lease for the rental of its research and development laboratories and clinical manufacturing facilities. In October 1996, the Company entered into an additional non-cancelable operating lease for additional office space. In 2004, the Company exercised its options to extend these leases until July 2009.

In October 2007, the Company entered into a capital lease agreement for \$55,000 to finance the purchase of certain equipment. The agreement is secured by the equipment, bears interest at 10.00% per annum, and is payable in monthly installments of principal and interest of approximately \$1,000 for 60 months.

F-16

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 4. Commitments (continued)

Annual future minimum lease payments as of December 31, 2008 are as follows (in thousands):

Years ended December 31,	Operating Leases			Capital Leases	
2009	\$	491	\$	15	
2010 2011		66 49		14 14	
2012 2013 and there-after		32 19		12	
Total	\$	657		55	
Less amount representing interest				(10)	
Present value of net minimum lease payments Less current portion				45 (11)	
Noncurrent portion of capital lease obligations			\$	34	

Rent expense under all operating leases totaled \$900,000, \$869,000, and \$1,065,000 for the years ended December 31, 2008, 2007 and 2006, respectively. Equipment acquired under capital leases included in property and equipment totaled \$43,000 (net of accumulated amortization of \$12,000) and \$54,000 (net of accumulated amortization of \$1,000) at December 31, 2008 and 2007, respectively. Amortization expense associated with this equipment is included in depreciation and amortization expense.

## **Purchase Obligations**

As of December 31, 2008, the Company had total purchase obligations of approximately \$1,290,000, which consisted of non-cancelable purchase commitments with third-party manufacturers of materials to be used in the production of Riquent. For the year ended December 31, 2008, approximately \$459,000 of the total purchase obligations were not included in the Company s consolidated financial statements. The Company intends to use its current financial resources to fund its obligations under these purchase commitments.

## 5. Credit Facility

In December 2008, the Company secured a credit facility (the <u>Credit Facility</u>) with UBS in the amount of \$6,000,000, fully collateralized by the Company s auction rate securities. There was no net interest cost to the Company as the interest rate charged by UBS was contractually equal to the coupon rates of the auction rate securities. There were no costs related to the establishment of the Credit Facility. During December 2008, the Company drew the full \$6,000,000 available under the Credit Facility, of which \$5,933,000 was outstanding as of December 31, 2008. During January 2009, all of the Company s auction rate securities were sold to UBS at par value of \$10,000,000 pursuant to the ARS Rights agreement, at which time the amount outstanding on the Credit Facility as of December 31, 2008 was settled in full and the Credit Facility agreement was terminated (see Note 10).

## 6. Long-Term Debt

The following is a summary of the notes payable obligations that are secured by financed property and equipment of approximately \$3,788,000 (\$172,000 net of depreciation and 2008 impairment charges) as of December 31, 2008:

Original Note

Edgar Filing: LA JOLLA PHARMACEUTICAL CO - Form 10-K

	Interest		nount (in
<b>Date of Note</b>	Rate (%)	<b>Monthly Payments</b>	sands)
December 28, 2006	10.56	First 36 months at \$8,000; last 12 months at \$3,000	263
June 28, 2007	10.82	First 36 months at \$2,000; last 12 months at \$500	75
December 31, 2007	10.55	\$6,000 for 48 months	236
			\$ 574
		F-17	

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 6. Long-Term Debt (continued)

Annual future minimum notes payable payments as of December 31, 2008 are as follows (in thousands):

Years ended December 31,	otes yable
2009 2010 2011	\$ 177 127 69
Total Less amount representing interest	373 (42)
Present value of net minimum notes payable payments Less current portion	331 (152)
Noncurrent portion of notes payable	\$ 179

## 7. Stockholders Equity

## **Preferred Stock**

As of December 31, 2008, the Company s Board of Directors is authorized to issue 8,000,000 shares of preferred stock with a par value of \$0.01 per share, in one or more series.

The Company s Certificate of Designation filed with the Secretary of State of the State of Delaware designates 500,000 shares of preferred stock as nonredeemable Series A Junior Participating Preferred Stock (<u>Series A Preferred Stock</u>). Pursuant to the terms of the Company s Stockholder Rights Plan, in the event of liquidation, each share of Series A Preferred Stock is entitled to receive, subject to certain restrictions, a preferential liquidation payment of \$10,000 per share plus the amount of accrued unpaid dividends. The Series A Preferred Stock is subject to certain anti-dilution adjustments, and the holder of each share is entitled to 10,000 votes, subject to adjustments. Cumulative quarterly dividends of the greater of \$1.00 or, subject to certain adjustments, 10,000 times any dividend declared on shares of common stock, are payable when, as and if declared by the Board of Directors, from funds legally available for this purpose.

See Note 10 for discussion of preferred stock issued after December 31, 2008.

## Warrants

In connection with the December 2005 private placement, the Company issued warrants to purchase 4,399,992 shares of the Company s common stock. The warrants were immediately exercisable upon grant, have an exercise price of \$5.00 per share and remain exercisable for five years.

In connection with the May 2008 public offering, the Company issued warrants to purchase 3,903,708 shares of the Company s common stock. The warrants were immediately exercisable upon grant, have an exercise price of \$2.15 per share and remain exercisable for five years.

As of December 31, 2008, all of the warrants were outstanding and 8,303,700 shares of common stock are reserved for issuance upon exercise of the warrants.

#### **Restricted Stock**

On December 14, 2005, the Company issued 83,518 shares of restricted stock to certain members of management in exchange for services provided over the vesting period, pursuant to certain retention agreements dated October 6, 2005. The shares of restricted stock fully vested (i.e., the restrictions lapsed) one year from the date of grant and were subject to repurchase by the Company until the one-year anniversary of the date of issuance. Pursuant to a separation agreement dated March 17, 2006, the Company s repurchase right with respect to 29,120 shares of restricted stock

granted to the former Chairman and Chief Executive Officer immediately lapsed upon his resignation on March 14, 2006. As such and in accordance with his retention agreement, the Company accelerated

F-18

#### **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 7. Stockholder s Equity (continued)

the vesting of these shares of restricted stock. In addition, the remaining 54,398 shares of restricted stock fully vested on December 14, 2006, the one-year anniversary of the date of issuance, and therefore the Company s repurchase right with respect to these shares of restricted stock has lapsed.

On March 15, 2006, the Company issued 20,000 shares of restricted stock to the new Chairman of the Board in exchange for services provided over the vesting period. The shares of restricted stock vested with respect to 10,000 shares six months after the issuance date and vested with respect to the remaining 10,000 shares upon the first anniversary of the issuance date. On September 15, 2006 and March 15, 2007, the vesting provisions with respect to the 20,000 shares of restricted stock were met and therefore the Company s repurchase rights lapsed. In both December 2006 and March 2007, the Company issued an additional 3,600 shares of restricted stock to the Chairman of the Board in accordance with the Chairman Compensation Policy approved by the Board of Directors on March 14, 2006 regarding tax liability associated with the restricted stock issued on March 15, 2006 and vested on September 15, 2006 and March 15, 2007. All of these additional shares of restricted stock immediately vested on the date of issuance.

There was no restricted stock issued in 2008.

In accordance with SFAS 123R, the Company recognized approximately \$36,000, and \$381,000, respectively, in compensation expense for the restricted stock grants noted above for the years ended December 31, 2007, and 2006, which includes compensation expense for the acceleration of vesting. There was no compensation expense related to restricted stock grants during the year ended December 31, 2008. The total fair value of the restricted stock grants vested in 2007 was approximately \$77,000 of which approximately \$41,000 was recognized in 2006 and approximately \$36,000 was recognized in 2007. The total fair value of the restricted stock grants vested in 2006 was approximately \$352,000 of which approximately \$12,000 was recognized in 2005 and approximately \$340,000 was recognized in 2006.

## **Stock Option Plans**

In June 1994, the Company adopted the La Jolla Pharmaceutical Company 1994 Stock Incentive Plan (the <u>1994 Plan</u>) under which, as amended, 1,640,000 shares of common stock (post-reverse stock split) were authorized for issuance. The 1994 Plan expired in June 2004 and there were 748,612 options outstanding under the 1994 Plan as of December 31, 2008.

In May 2004, the Company adopted the La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (the \_\_2004 Plan ) under which, as amended, 6,400,000 shares of common stock (post-reverse stock split) have been authorized for issuance. The 2004 Plan provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to employees, directors, consultants and advisors of the Company with up to a 10-year contractual life and various vesting periods as determined by the Company s compensation committee or the board of directors, as well as automatic fixed grants to non-employee directors of the Company. As of December 31, 2008, there were a total of 4,878,348 options outstanding and no unvested shares of restricted stock granted under the 2004 Plan and 1,242,432 shares remained available for future grant.

A summary of the Company s stock option activity (including shares of restricted stock) and related data follows:

		<b>Outstanding Options</b>			
	Options Available	Number of	Weighted- Average Exercise		
	For Grant	Shares	Price		
Balance at December 31, 2005	3,190,231	2,148,028	\$ 16.09		
Granted	(2,450,745)	2,450,745	\$ 4.58		
Restricted stock granted	(23,600)				

Exercised (56,012) \$ 2.25 Cancelled 240,382 (240,382) \$ 14.04 F-19

## **Table of Contents**

## La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

## 7. Stockholder s Equity (continued)

		<b>Outstanding Options</b>			
	Options		Weighted-		
	Available	Number of	Average		
			Exercise		
	For Grant	Shares	Price		
Expired	(100,983)		\$ 26.39		
Balance at December 31, 2006	855,285	4,302,379	\$ 9.83		
Additional shares authorized	840,000				
Granted	(1,027,973)	1,027,973	\$ 4.30		
Restricted stock granted	(3,600)				
Exercised		(166,280)	\$ 3.01		
Cancelled	354,496	(354,496)	\$ 14.20		
Expired	(153,808)		\$ 25.80		
Balance at December 31, 2007	864,400	4,809,576	\$ 8.56		
Additional shares authorized	1,400,000				
Granted	(1,481,900)	1,481,900	\$ 2.02		
Exercised		(1,097)	\$ 2.51		
Cancelled	663,418	(663,418)	\$ 8.91		
Expired	(203,486)		\$ 19.80		
Balance at December 31, 2008	1,242,432	5,626,961	\$ 6.80		

For the year ended December 31, 2008, options cancelled (included in the above table) consisted of approximately 459,932 options forfeited with a weighted-average exercise price of \$4.09.

As of December 31, 2008, options exercisable have a weighted-average remaining contractual term of 6.4 years. The total intrinsic value of stock option exercises, which is the difference between the exercise price and closing price of the Company s common stock on the date of exercise, during the years ended December 31, 2008, 2007, and 2006 was \$2,000, \$500,000, and \$74,000, respectively. As of December 31, 2008 and 2007, the total intrinsic value, which is the difference between the exercise price and closing price of the Company s common stock of options outstanding and exercisable, was \$0 and \$844,000, respectively.

				Yea	ırs Ended	December				
	2008				31, 2007			2006		
	O	ptions	Weighted- Average Exercise Price	O	ptions	Weighted- Average Exercise Price	o	ptions	Weighted- Average Exercise Price	
Exercisable at end of year Weighted-average fair value of options granted	3,5	522,747	\$9.08	2,8	308,588	\$11.44	1,8	859,139	\$16.27	
during the year	\$	1.70		\$	3.71		\$	3.92		

Exercise prices and weighted-average remaining contractual lives for the options outstanding (excluding shares of restricted stock) as of December 31, 2008 were:

Options		Range of		Weighted- Average Remaining Contractual Life (in	A	Veighted- Average Exercise	Options	<i>I</i> ]	Veighted-Average Exercise Price of Options
Outstanding		Exercise Prices		years)		Price	Exercisable	Ex	ercisable
747,759	\$ 0.64	5	1.82	9.45	\$	1.66	9,821	\$	1.09
786,614	\$ 1.87	\$	2.42	8.38	\$	2.36	286,884	\$	2.34
541,869	\$ 3.06	9	3.60	8.01	\$	3.13	288,869	\$	3.16
667,678	\$ 3.61	9	4.44	7.37	\$	4.01	554,234	\$	4.03
791,568		\$ 4.46		7.29	\$	4.46	728,778	\$	4.46
853,500	\$ 4.60	9	5.26	7.27	\$	5.24	592,750	\$	5.25
664,395	\$ 5.36	9	14.85	6.68	\$	9.17	487,833	\$	10.46
573,578	\$ 15.70	\$	60.31	3.00	\$	29.09	573,578	\$	29.09
5,626,961	\$ 0.64	\$	6 60.31	7.29	\$	6.80	3,522,747	\$	9.08
			F-	20					

### **Table of Contents**

# La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

# 7. Stockholder s Equity (continued)

At December 31, 2008, the Company has reserved 6,869,393 shares of common stock for future issuance upon exercise of options granted or to be granted under the 1994 and 2004 Plans.

# **Employee Stock Purchase Plan**

Effective August 1, 1995, the Company adopted the ESPP under which, as amended, 850,000 shares of common stock are reserved for sale to eligible employees, as defined in the ESPP. Employees may purchase common stock under the ESPP every three months (up to but not exceeding 10% of each employee s base salary, or hourly compensation, and any cash bonus paid, subject to certain limitations) over the offering period at 85% of the fair market value of the common stock at specified dates. The offering period may not exceed 24 months. During the years ended December 31, 2008 and 2007, 303,937 and 97,104 shares of common stock were issued under the ESPP, respectively. As of December 31, 2008, 833,023 shares of common stock have been issued under the ESPP and 16,977 shares of common stock are available for future issuance.

		Years Ended December 31,		
		2008	2007	2006
Weighted-average fair value of Employee Stock Purcha	se Plan			
purchases		\$0.71	\$1.47	\$1.48
	F-21			

### **Table of Contents**

La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

# 7. Stockholder s Equity (continued) Stockholder Rights Plan

The Company has adopted a Stockholder Rights Plan (the Rights Plan ), which was amended and restated in December 2008 and subsequently amended in January 2009. The Rights Plan provides for a dividend of one right (a Right ) to purchase fractions of shares of the Company s Series A Preferred Stock for each share of the Company s common stock. Under certain conditions involving an acquisition by any person or group of 15% or more of the common stock (or in the case of Grandfathered Persons, as defined in the Rights Plan, the acquisition of common stock in excess of the applicable Grandfathered Percentage, as defined in the Rights Plan; or, in the case of BioMarin, 15% or more of shares not issued under the securities purchase agreement between BioMarin and the Company), the Rights permit the holders (other than the 15% holder, or, in the case of Grandfathered Persons, as defined in the Rights Plan, the acquisition of common stock in excess of the applicable Grandfathered Percentage, as defined in the Rights Plan; or, in the case of BioMarin, 15% or more of shares issued under the securities purchase agreement between BioMarin and the Company) to purchase the Company s common stock at a 50% discount upon payment of an exercise price of \$30 per Right. In addition, in the event of certain business combinations, the Rights permit the purchase of the common stock of an acquirer at a 50% discount. Under certain conditions, the Rights may be redeemed by the Board of Directors in whole, but not in part, at a price of \$0.001 per Right. The Rights have no voting privileges and are attached to and automatically trade with the Company s common stock. The Rights expire on December 2, 2018.

### 8. 401(k) Plan

The Company has established a 401(k) defined contribution retirement plan (the  $\underline{401(k) \text{ Plan}}$ ), which was amended in May 1999 to cover all employees. The 401(k) Plan was also amended in December 2003 to increase the voluntary employee contributions from a maximum of 20% to 50% of annual compensation (as defined). This increase was effective beginning January 1, 2004. The Company does not match employee contributions or otherwise contribute to the 401(k) Plan. In March 2009, the Company terminated the 401(k) Plan.

## 9. Income Taxes

The Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109* (FIN 48) on January 1, 2007. FIN 48 prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Upon implementation, the Company had no unrecognized tax benefits. As of December 31, 2008 there are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the Company s effective tax rate.

The Company is subject to taxation in the United States and various state jurisdictions. The Company s tax years for 1993 and forward are subject to examination by the United States and California tax authorities due to the carry forward of unutilized net operating losses and research and development credits.

F-22

### **Table of Contents**

# La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

### 9. Income Taxes (continued)

The Company has not completed its Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. The Company does not presently plan to complete its Section 382/383 analysis and unless and until this analysis has been completed, the Company has removed the deferred tax assets for net operating losses and research and development credits generated through 2008 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance

At December 31, 2008, the Company had federal and California income tax net operating loss carryforwards of approximately \$362,037,000 and \$202,859,000, respectively. The difference between the federal and California tax loss carryforwards is primarily attributable to the capitalization of research and development expenses for California income tax purposes. In addition, the Company has federal and California research and development tax credit carryforwards of \$16,483,000 and \$9,729,000, respectively. The federal net operating loss and research tax credit carryforwards will begin to expire in 2009 unless previously utilized. The California net operating loss carryforwards will begin to expire in 2010 unless previously utilized. The California research and development credit carryforwards will carry forward indefinitely until utilized. In February 2009, the Company experienced a change in ownership at a time when its enterprise value was minimal. As a result of this ownership change and the low enterprise value, the Company s federal and California net operating loss carryforwards and federal research and development credit carryforwards as of December 31, 2008 will be subject to limitation under IRC Section 382/383 and more likely than not will expire unused.

Significant components of the Company s deferred tax assets as of December 31, 2008 and 2007 are listed below. A valuation allowance of \$14,330,000 and \$10,923,000 at December 31, 2008 and 2007, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain. Amounts are shown in thousands as of December 31 of the respective years:

	December 31,	
	2008	2007
Deferred tax assets:		
Net operating loss carryforwards	\$	\$
Research and development credits		
Capitalized research and development and other	14,330	10,923
Total deferred tax assets	14,330	10,923
Net deferred tax assets	14,330	10,923
Valuation allowance for deferred tax assets	(14,330)	(10,923)
Net deferred taxes	\$	\$

# 10. Subsequent Events

countries of Oceania).

### **Development and Stock Purchase Agreement**

On January 4, 2009 (the <u>Effective Date</u>), the Company entered into a development and commercialization agreement (the <u>Development Agreement</u>) with BioMarin CF Limite<u>d (BioMarin</u> CF), a wholly-owned subsidiary of BioMarin Pharmaceutical Inc. (<u>BioMarin Pharma</u>), granting BioMarin CF co-exclusive rights to develop and commercialize Riquent (and certain potential follow-on products) (collectively, <u>Riquent</u>) in the Territory, and the non-exclusive right to manufacture Riquent anywhere in the world. The Territory includes all countries of the world except the Asia-Pacific Territory (i.e., all countries of East Asia, Southeast Asia, South Asia, Australia, New Zealand, and other

Under the terms of the Development Agreement, BioMarin CF paid the Company a non-refundable commencement payment of \$7,500,000 and purchased, through BioMarin Pharma, \$7,500,000 of a newly designated series of preferred stock (the <u>Series B Preferred Stock</u>), pursuant to a securities purchase agreement described more fully below.

Following the futile results of the first interim efficacy analysis of Riquent, BioMarin CF has elected to not exercise its full license rights to the Riquent program under the Development Agreement. Thus, the Development Agreement between the parties terminated on March 27, 2009 in accordance with its terms. All rights to Riquent have been returned to the Company.

F-23

### **Table of Contents**

# La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

# 10. Subsequent Events (continued)

In connection with the Development Agreement, the Company also entered into a securities purchase agreement, dated as of January 4, 2009 (the <a href="Purchase Agreement">Purchase Agreement</a>) with BioMarin Pharma. In accordance with the terms of the agreement, on January 20, 2009, the Company sold 339,104 shares of Series B Preferred Stock at a price per share of \$22.1171 for gross proceeds totaling \$7,500,000. On March 27, 2009, in connection with the termination of the Development Agreement, the Series B Preferred Stock converted into 10,173,120 shares of Common Stock.

### **Auction Rate Securities**

During January 2009, all of the Company s auction rate securities were sold to UBS at par value of \$10,000,000 pursuant to the ARS Rights agreement (see Note 2). Upon the sale of these auction rate securities, the amount outstanding on the Credit Facility agreement as of December 31, 2008 was settled in full and the Credit Facility was terminated.

F-24

### **Table of Contents**

La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

# 10. Subsequent Events (continued)

# Interim Efficacy Analysis Results and Restructuring Activities

In February 2009, the Company announced that an Independent Monitoring Board for the Riquent Phase 3 ASPEN study had completed the review of their first interim efficacy analysis of Riquent and determined that continuing the study was futile. The Company subsequently unblinded the data and found that there was no statistical difference in the primary endpoint, delaying time to renal flare, between the Riquent-treated group and the placebo-treated group, although there was a significant difference in the reduction of antibodies to double-stranded DNA. There were 56 renal flares in 587 patients treated with either 300-mg or 900-mg of Riquent, and 28 renal flares in 283 patients treated with placebo.

Based on these results, the Company immediately discontinued the Riquent Phase 3 ASPEN study and the further development of Riquent. The Company had previously devoted substantially all of its research, development and clinical efforts and financial resources toward the development of Riquent. In connection with the termination of the clinical trials for Riquent, the Company subsequently initiated steps to significantly reduce its operating costs, including a planned substantial reduction in personnel, which is expected to be effected early in the second quarter of 2009. The Company has also ceased the manufacture of Riquent at its facility in San Diego, California.

F-25

### **Table of Contents**

# La Jolla Pharmaceutical Company Notes to Consolidated Financial Statements

# 11. Selected Quarterly Financial Data (unaudited)

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2008 and 2007 (in thousands except per share amounts):

		Quarters Ended		
	Mar. 31,	Jun. 30,	Sept. 30,	Dec. 31,
2008				
Expenses:				
Research and development	\$ 11,338	\$ 12,732	\$ 14,099	\$ 12,856
General and administrative	1,906	2,069	2,791	2,936
Asset impairment				2,810
Loss from operations	(13,244)	(14,801)	(16,890)	(18,602)
Interest income (expense), net	(393)	(134)	(244)	1,454
Net loss	\$(13,637)	\$(14,935)	\$(17,134)	\$(17,148)
	+ (,,	+ (- 1,2 )	+ (= : ,== :)	+ (-1,-10)
Dagie and diluted not loss non share	\$ (0.24)	¢ (0.21)	\$ (0.21)	¢ (0.21)
Basic and diluted net loss per share	\$ (0.34)	\$ (0.31)	\$ (0.31)	\$ (0.31)
Shares used in computing basic and diluted net	20,621	40.050	55 227	55 402
loss per share	39,631	48,252	55,327	55,423
2007 Expenses:				
Research and development	\$ 10,375	\$ 12,186	\$ 11,448	\$ 12,626
General and administrative	1,980	2,112	2,585	2,381
Loss from operations	(12 255)	(14.208)	(14.022)	(15.007)
Loss from operations	(12,355)	(14,298)	(14,033)	(15,007)
Interest income, net	485	781	744	607
Net loss	\$(11,870)	\$(13,517)	\$(13,289)	\$(14,400)
Basic and diluted net loss per share	\$ (0.36)	\$ (0.34)	\$ (0.34)	\$ (0.36)
basic and direct loss per share	ψ (0.50)	Ψ (0.54)	ψ (0.54)	ψ (0.30)
Shares used in computing basic and diluted net loss per share	32,737	39,256	39,577	39,607
1055 per siture	52,131	37,230	57,511	57,007

# **EXHIBIT INDEX**

Exhibit Number 3.1	<b>Description</b> Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (2)
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock (32)
4.1	Form of Common Stock Certificate (3)
4.2	Rights Agreement, dated as of December 3, 1998, between the Company and American Stock Transfer & Trust Company (4)
4.2	Amended and Restated Rights Agreement, dated as of December 2, 2008, between the Company and American Stock Transfer & Trust Company (4)
4.3	Amendment No. 1 to Amended and Restated Rights Agreement, dated as of January 20, 2009 between the Company and American Stock Transfer & Trust Company (30)
10.1	Form of Indemnification Agreement (5)*
10.2	Industrial Real Estate Lease, effective July 27, 1992, by and between the Company and BRE Properties, Inc. (6)
10.3	First Amendment to Lease, dated March 15, 1993, by and between the Company and BRE Properties, Inc. (6)
10.4	Second Amendment to Lease, dated July 18, 1994, by and between the Company and BRE Properties, Inc. (7)
10.5	Third Amendment to Lease, dated January 26, 1995, by and between the Company and BRE Properties, Inc. (8)
10.6	Fourth Amendment to Lease, dated July 8, 2004, by and between the Company and EOP-Industrial Portfolio, LLC (9)
10.7	Building Lease Agreement, effective November 1, 1996, by and between the Company and WCB II-S BRD Limited Partnership (10)
10.8	First Amendment to Lease, dated May 4, 2001, by and between the Company and Spieker Properties, L.P. (9)
10.9	Second Amendment to Lease, dated July 8, 2004, by and between the Company and EOP-Industrial Portfolio, LLC (9)
10.10	La Jolla Pharmaceutical Company 1994 Stock Incentive Plan (Amended and Restated as of May 16, 2003) (11)*

# **Table of Contents**

Exhibit Number 10.11	<b>Description</b> La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (Amended and Restated as of June 20, 2008) (33)*
10.12	La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (Amended and Restated as of June 20, 2008) (33)*
10.13	Form of Option Grant under the La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (12)*
10.14	Steven B. Engle Employment Agreement (6)*
10.15	Amendment No. 1 to Steven B. Engle Employment Agreement (13)*
10.16	Amendment No. 2 to Steven B. Engle Employment Agreement (14)*
10.17	Amendment No. 3 to Steven B. Engle Employment Agreement (11)*
10.18	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Bruce Bennett, Jr. (1)*
10.19	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Josefina Elchico (1)*
10.20	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Paul Jenn, Ph.D. (1)*
10.21	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Theodora Reilly (1)*
10.22	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Gail Sloan (1)*
10.23	Retention Agreement, dated October 6, 2005, by and between the Company and Steven B. Engle $(15)^*$
10.24	Retention Agreement, dated October 6, 2005, by and between the Company and Matthew Linnik, Ph.D. (15)*
10.25	Retention Agreement, dated October 6, 2005, by and between the Company and Bruce Bennett $(15)$ *
10.26	Retention Agreement, dated October 6, 2005, by and between the Company and Josefina T. Elchico (15)*
10.27	Retention Agreement, dated October 6, 2005, by and between the Company and Paul Jenn, Ph.D. (15)*

# **Table of Contents**

Exhibit Number 10.28	<b>Description</b> Retention Agreement, dated October 6, 2005, by and between the Company and Theodora Reilly (15)*
10.29	Retention Agreement, dated October 6, 2005, by and between the Company and Gail Sloan (15)*
10.30	Retention Agreement, dated October 6, 2005, by and between the Company and Andrew Wiseman, Ph.D. (15)*
10.31	Retention Agreement, dated October 6, 2005, by and between the Company and Lisa Koch (24)*

# **Table of Contents**

Exhibit Number 10.36	<b>Description</b> Promissory Note, dated as March 31, 2003, between the Company and General Electric Capital Corporation (19)
10.37	Promissory Note, dated as of December 18, 2003, between the Company and General Electric Capital Corporation (20)
10.38	Promissory Note, dated as of September 26, 2003, between the Company and General Electric Capital Corporation (16)
10.39	Promissory Note, dated as of June 27, 2003, between the Company and General Electric Capital Corporation (11)
10.40	Promissory Note, dated as of April 23, 2003, between the Company and General Electric Capital Corporation (21)
10.41	Promissory Note, dated as of December 30, 2002, between the Company and General Electric Capital Corporation (21)
10.42	Amendment to Promissory Note, dated as of September 27, 2002, by and between the Company and General Electric Capital Corporation (17)
10.43	Promissory Note, dated as of September 26, 2002, by and between the Company and General Electric Capital Corporation (17)
10.44	Employment Agreement, dated March 15, 2006, by and between the Company and Deirdre Y. Gillespie, M.D. (22)*
10.45	Separation Agreement, dated March 17, 2006, by and between the Company and Steven B. Engle (22)*
10.46	Employment Offer Letter, dated July 10, 2006 and executed July 14, 2006, by and between the Company and Michael Tansey, M.D. (25)*
10.47	Employment Agreement, dated December 4, 2006, by and between the Company and Michael Tansey, M.D. (23)*
10.48	Underwriting Agreement, dated as of March 29, 2007, between the Company and Needham & Company, LLC and A.G. Edwards & Sons, Inc. (29)
10.49	Employment Agreement, dated May 10, 2007, by and between the Company and Niv Caviar (27)*
10.50	Promissory Note, dated as of June 28, 2007, between the Company and General Electric Capital Corporation (6)
10.51	Amendment to Chief Executive Officer Employment Agreement (6)*

10.52	Promissory Note, dated as of December 31, 2007, between the Company and General Electric Capital Corporation (31)
10.53	Employment Agreement, dated March 4, 2008, by and between the Company and Luke Seikkula (28)*
10.54	Underwriting Agreement, dated as of May 6, 2008, between the Company and UBS Securities, LLC and Canaccord Adams, Inc. (34)
10.55	Form of Warrant Agreement (34)
10.56	Reserved
10.57	Employment Agreement, dated March 4, 2008, by and between the Company and Lisa Koch-Hulle **
10.58	First Amendment to Employment Agreement, dated December 24, 2008, by and between the Company and Gail Sloan.**
10.59	First Amendment to Employment Agreement, dated December 24, 2008, by and between the Company and Niv Caviar.**
10.60	First Amendment to Employment Agreement, dated December 26, 2008, by and between the Company and Vicki Motte.**
10.61	First Amendment to Employment Agreement, dated December 26, 2008, by and between the Company and Luke Seikkula.**
10.62	First Amendment to Employment Agreement, dated December 29, 2008, by and between the Company and Josefina Elchico.**
10.63	First Amendment to Employment Agreement, dated December 29, 2008, by and between the Company and Lisa Koch-Hulle.**
10.64	First Amendment to Employment Agreement, dated December 30, 2008, by and between the Company and Michael Tansey.**
10.65	First Amendment to Employment Agreement, dated December 31, 2008, by and between the Company and Deirdre Gillespie.**

### **Table of Contents**

Exhibit Number 21.1	<b>Description</b> Subsidiaries of La Jolla Pharmaceutical Company (12)
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 Section 906 of the Sarbanes-Oxley Act of 2002

- \* This exhibit is a management contract or compensatory plan or arrangement.
- \*\* Filed herewith.
- (1) Previously filed with the Company s Current Report on Form 8-K filed March 1, 2006 and incorporated by reference herein.
- (2) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 and incorporated by reference herein.
- (3) Previously filed with the Company s Registration

Statement on Form S-3 (Registration No. 333-131246) filed January 24, 2006 and incorporated by reference herein.

- (4) Previously filed with the Company s Current Report on Form 8-K filed December 4, 2008 and incorporated by reference herein.
- (5) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2005 and incorporated by reference herein.
- (6) Previously filed with the Company s Registration Statement on Form S-1 (Registration No. 33-76480) filed June 3, 1994 and incorporated by reference herein.
- (7) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 1994 and incorporated by

reference herein.

# (8) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 1995 and incorporated by reference herein.

(9) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 and incorporated by reference herein.

(10) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 1996 and incorporated by reference herein.

(11) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 and

incorporated by reference herein.

# (12) Previously filed with the Company s Annual Report on Form 10-K for the year ended December 31, 2004 and incorporated by reference herein.

(13) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 1997 and incorporated by reference herein.

(14) Previously filed with the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 1999 and incorporated by reference herein.

(15) Previously filed with the Company s Current Report on Form 8-K filed October 7, 2005 and incorporated by

reference herein.

- (16) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated by reference herein.
- (17) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 and incorporated by reference herein.
- (18) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004 and incorporated by reference herein.
- (19) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 and incorporated by

reference herein.

# (20) Previously filed with the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2003 and incorporated by reference herein.

(21) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003 and incorporated by reference herein.

(22) Previously filed with the Company s Current Report on Form 8-K filed March 20, 2006 and incorporated by reference herein.

(23) Previously filed with the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and incorporated by reference

herein.

# (24) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006 and incorporated by reference herein.

- (25) Previously filed with the Company s Current Report on Form 8-K filed July 18, 2006 and incorporated by reference herein.
- (26) Previously filed with the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 and incorporated by reference herein.
- (27) Previously filed with the Company s Current Report on Form 8-K filed May 10, 2007 and incorporated by reference herein.

(28)

Previously filed with the Company s Current Report on Form 8-K filed March 4, 2008 and incorporated by reference herein.

(29) Previously filed with the Company s Current Report on Form 8-K filed March 30, 2007 and incorporated by reference herein.

- (30) Previously filed with the Company s Registration Statement on Form 8-A (Registration No. 000-24274) filed January 26, 2009 and incorporated by reference herein.
- (31) Previously filed with the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and incorporated by reference herein.
- (32) Previously filed with the Company s Current Report on Form 8-A12G filed December 4, 2008 and incorporated by reference herein.
- (33) Previously filed with the Company s Registration Statement on Form S-8 (Registration No. 333-151825) filed June 20.

2008 and incorporated by reference herein.

(34) Previously filed with the Company s Current Report on Form 8-K filed May 7, 2008 and incorporated by reference herein.