

LA JOLLA PHARMACEUTICAL CO

Form 10-K

March 16, 2007

**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, 2006**

**OR**

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

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

**Commission file number: 0-24274**

**LA JOLLA PHARMACEUTICAL COMPANY**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation or organization)

**33-0361285**

(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: **None**

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

Title of each class:

**Common Stock, par value \$0.01 per share**

Name of each exchange on which registered:

**The Nasdaq Global Market**

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

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

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

Indicate by check mark 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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2006 totaled approximately \$79,995,000 based on the closing price of \$3.67 as reported by the Nasdaq Global Market. As of March 2, 2007, there were 32,712,200 shares of the Company's common stock (\$0.01 par value) outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

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

Portions of the annual stockholders' report for the year ended December 31, 2006 are incorporated by reference into Parts I and II. Portions of the proxy statement for the 2007 annual stockholders' meeting are incorporated by reference into Part III.

---

### TABLE OF CONTENTS

#### **PART I**

<u>Item 1.</u>	<u>Business</u>	1
<u>Item 1A.</u>	<u>Risk Factors</u>	13
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	24
<u>Item 2.</u>	<u>Properties</u>	25
<u>Item 3.</u>	<u>Legal Proceedings</u>	25
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	25

#### **PART II**

<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	25
<u>Item 6.</u>	<u>Selected Financial Data</u>	28
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	29
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	36
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	36
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	36
<u>Item 9A.</u>	<u>Controls and Procedures</u>	36
<u>Item 9B.</u>	<u>Other Information</u>	39

#### **PART III**

<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	39
<u>Item 11.</u>	<u>Executive Compensation</u>	39
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	39

<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	39
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	39
<b><u>PART IV</u></b>		
<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	40
	<u>Signatures</u>	41
<u>EXHIBIT 10.53</u>		
<u>EXHIBIT 10.66</u>		
<u>EXHIBIT 23.1</u>		
<u>EXHIBIT 31.1</u>		
<u>EXHIBIT 31.2</u>		
<u>EXHIBIT 32.1</u>		

---

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

The forward-looking statements in this report involve significant risks 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 analyses of clinical results of Riquent®, our drug candidate for the treatment of systemic lupus erythematosus ( lupus or SLE ), and any other drug candidate that we may develop, including the results of any trials or models that are ongoing or that we may initiate in the future, could result in a finding that these drug candidates are not effective in large patient populations, do not provide a meaningful clinical benefit, or may reveal a potential safety issue requiring us to develop new candidates. The results from our current clinical studies of Riquent also may not be sufficient to obtain regulatory clearance to market Riquent either in the United States or any other country, and we may be required to conduct additional clinical studies. There can be no assurance, however, that we will have the necessary resources to complete any current or future trials or that any such trials will sufficiently demonstrate the safety and efficacy of Riquent. Additional risk factors include the uncertainty and timing of: our clear need to raise capital to complete our current clinical studies; obtaining required regulatory approvals, including delays associated with any approvals that we may obtain; timely supply of drug product for clinical trials and for possible commercialization; our ability to pass all necessary regulatory inspections; successfully marketing and selling our products, whether directly or through collaborative relationships; our ability to make use of the orphan drug designation for Riquent; future profitability; and our dependence on patents and other proprietary rights, as well as possible actions by third parties against us based on their own intellectual property rights. Readers are cautioned to not place undue reliance upon forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date hereof. Interested parties are urged to review the risks described below under the Risk Factors and elsewhere in this report and in other reports and registration statements filed with the Securities and Exchange Commission from time to time.

---

**Table of Contents**

**PART I**

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

**Item 1. Business**

**Overview**

La Jolla Pharmaceutical Company was incorporated in Delaware in 1989. In October 2004, we established a subsidiary, La Jolla Limited, in England in connection with potential development efforts for Riquent® in Europe. We are a biopharmaceutical company dedicated to improving and preserving human life by developing innovative pharmaceutical products. Our leading product in development is Riquent, which is designed to treat lupus renal disease by preventing or delaying renal flares. 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. We believe that Riquent has the potential to prevent or delay renal flares associated with lupus renal disease without these severe, negative side effects.

**Recent Developments**

On March 8, 2007, we announced positive interim antibody results from our ongoing double-blind, placebo-controlled randomized Phase 3 trial of Riquent. Analyses of interim antibody data indicate that patients treated with 900 mg or 300 mg per week doses of Riquent had greater reductions in antibodies to double-stranded DNA ( dsDNA ) than patients treated with 100 mg per week or placebo. The results showed a significant dose response when comparing all Riquent-treated patients to placebo-treated patients ( $p < 0.0001$ ), and each Riquent dose group to the placebo dose group ( $p < 0.0015$  for 100 mg,  $p < 0.0001$  for 300 mg and 900 mg).

On February 1, 2007, we announced that we had made continued progress in enrolling patients in our Phase 3 clinical trial of Riquent in that we had enrolled 202 patients in the study and 74 clinical trial sites were open to enroll patients, including newly added sites in Europe and Mexico. In addition, we also announced that following recent discussions with the United States Food and Drug Administration (the FDA ), we have implemented several enhancements to further strengthen the Phase 3 study, which remains under a Special Protocol Assessment. These enhancements include:

Focus on higher doses all new patients entering the study will be randomized in equal numbers to receive weekly doses of either 300 mg or 900 mg of Riquent or placebo, with no further patients randomized to the 100 mg dose group.

Increase sample size the study sample size is increased from approximately 600 to approximately 730 patients, which is expected to increase the likelihood of achieving a statistically significant outcome for the individual dose groups when compared with placebo as well as overall.

Broaden analysis of patient population the primary endpoint will be assessed in all patients and will no longer be restricted to the high-affinity subpopulation. We believe that the increased binding capability of higher doses will eliminate the need for an affinity measurement prior to treatment.

Combine current studies to increase efficiency and enhance the quality of data, we also combined the Phase 2 clinical pharmacology study with the Phase 3 study so that Riquent blood levels will be collected in the same patient population as the definitive efficacy data.

**Table of Contents**

**Developments in 2006**

On January 11, 2006, we announced that we would initiate a multi-dose clinical study of Riquent in lupus patients to evaluate the ability of higher doses of Riquent to further reduce antibodies to dsDNA. This study is part of our overall clinical development program of Riquent, which includes the ongoing Phase 3 clinical benefit trial to evaluate the use of Riquent in preventative and acute settings. Subsequently, in February 2007, this Phase 2 clinical pharmacology study was combined with the Phase 3 study.

On January 12, 2006, we announced that we had regained compliance with the Nasdaq Stock Market minimum bid price rule and that we were eligible to remain listed on the Nasdaq Global Market.

On March 15, 2006, we announced that Deirdre Y. Gillespie, M.D. was appointed to serve as our new President and Chief Executive Officer following the resignation of Steven B. Engle on March 14, 2006. We also announced that our board of directors had appointed Craig R. Smith, M.D., a current independent director, to serve as Chairman of the board.

On June 22, 2006, we announced that our Marketing Authorization Application (the MAA ) had been accepted for review by the European Medicines Agency (the EMEA ) for potential approval to market Riquent in the European Union (the EU ). The MAA was filed with the EMEA on March 31, 2006. The EMEA s review of the MAA would follow its centralized marketing authorization procedure. Riquent has already received orphan medicinal product designation in Europe, which will provide 10 years of market exclusivity from the date of the EU s authorization, if any.

On July 17, 2006, we announced that Michael J. B. Tansey, M.D., Ph.D. had joined the Company as Chief Medical Officer on a part-time basis, whereby 65% of his time is devoted to his position with the Company. Effective December 4, 2006, Dr. Tansey became a full-time employee, assuming the title of Executive Vice President and Chief Medical Officer.

On August 9, 2006, we announced that we had reactivated enrollment in our Phase 3 trial of Riquent.

On September 27, 2006, we announced that we had made considerable progress on our Phase 3 trial of Riquent in that we had added 27 new clinical trial sites able to screen and enroll patients for a total of 58 sites (22 in the United States and 36 in Asia).

On October 12, 2006, we announced that we had requested the withdrawal of our MAA. In a preliminary assessment of the MAA, the EMEA reviewers indicated that additional clinical data would be needed prior to potential approval. Based on our review of the assessment, we believe that the ongoing clinical studies of Riquent should provide the necessary data; however, the data will not be available within the timeframe that the EMEA regulations allow for the review of the current Riquent application. Therefore, we decided to withdraw the current application, and plan to refile the MAA after the completion of the ongoing clinical trials, if they are successful.

On November 6, 2006, we announced that we had made further progress in enrolling patients and opening sites for our Phase 3 clinical trial of Riquent. As of November 2006, 82 patients had been enrolled in the study, more than 150 additional patients were in screening for potential enrollment and we had activated 65 clinical trial sites, including newly-added sites in Europe.

**Business Strategy**

Our near term objective is to focus on the development of Riquent, our therapeutic drug candidate for the treatment of lupus renal disease. Additionally, we will also seek to expand our drug development programs. Our strategy includes the following key elements:

*Complete clinical studies of Riquent to satisfy regulatory requirements.* Based on the FDA s approvable letter we received in October 2004, we are required to complete an additional, randomized, double-blind study that demonstrates the clinical benefit of Riquent prior to any potential approval in the United States. The letter indicated that the successful completion of our ongoing clinical trial, which we initiated in August 2004, would appear to

## **Table of Contents**

satisfy this requirement. Our primary goal is to complete this study in order to satisfy the requirement set forth in the FDA's letter. We restarted enrollment in the United States for this study in the third quarter of 2006, after a final review of the revised protocol by the FDA, and expanded the study to Europe and Asia later in 2006. We expect to further expand the study globally in 2007 and target completing patient enrollment into the study around the end of 2007.

*Seek additional funding, including through collaborative arrangements and through public and/or private financings, to develop and commercialize product candidates.* In order to continue our development and potential commercialization of Riquent and other product candidates, we will need significant additional funding. Our choice of financing alternatives may vary depending on a number of factors, including the interest of other entities in strategic transactions with us, the market price of our securities and conditions in the financial markets. There can be no guarantee that additional financing will be available on favorable terms, if at all, whether through collaborative arrangements, the issuance of securities, or otherwise.

*Initiate commercialization planning activities.* During 2007, we expect to develop a commercialization plan for the United States market including marketing, sales and manufacturing activities. If Riquent is ultimately approved in the United States, as to which we can provide no assurance, we currently anticipate marketing Riquent ourselves using a specialty pharmaceutical sales force which would target the rheumatology and nephrology specialists who treat the majority of lupus patients with renal disease. If Riquent is approved outside of the United States, as to which we can provide no assurance, we currently expect to seek a marketing collaboration with one or more partners. We also expect to enter into arrangements with contract manufacturing companies to expand our own production capacity in order to meet potential commercial demand.

*Develop additional therapeutics for other life-threatening diseases.* We seek to expand our drug development pipeline with products that are commercially synergistic with Riquent by licensing or acquiring rights to compounds and drug candidates that have been developed outside of the Company as well as by collaborating with third parties to further our efforts on drug candidates developed internally.

In recent years, we have focused our product development efforts on our programs for lupus and anti-inflammatory disorders. In the years ended December 31, 2006, 2005 and 2004, we incurred expenses of approximately \$32.9 million, \$22.6 million and \$33.2 million, respectively, for product research and development on these programs.

### **Riquent Program**

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 chronic kidney inflammation, which can lead to kidney failure, 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 50% of lupus patients will develop kidney disease which is a leading cause of death in lupus.

Antibodies to dsDNA can be detected in up to 85% of lupus patients who are not receiving immunosuppressive therapy. Antibodies to dsDNA are widely believed to cause kidney disease (nephritis), often resulting in morbidity and mortality in lupus patients. Episodes of potentially life-threatening kidney inflammation called renal flares often require intensive care, treatment with high-dose corticosteroids and immunosuppressive agents, and hospitalization. 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 and may be carcinogenic. Treatment with immunosuppressive therapies can leave patients vulnerable to serious infection, which is a significant cause of



sickness and death in these patients.

**Table of Contents**

Riquent was developed based on our patented Tolerance Technology® and is comprised of a lupus disease specific epitope attached to a carrier platform. The family of molecules based on this technology are called Toleragens®. The design of Riquent is based on scientific evidence of the role of antibodies to dsDNA in lupus. We have designed Riquent to suppress the production of antibodies to dsDNA in lupus patients without suppressing the normal function of the immune system. Published studies of lupus patients indicate that a rise in the level of antibodies to dsDNA may be predictive of renal flares in lupus patients with renal involvement, and that reducing antibodies to dsDNA by treating with corticosteroids can prevent relapse. Furthermore, based on published data from our own Phase 2/3 and Phase 3 trials, a reduction in the levels of antibodies to dsDNA significantly correlated with a reduced risk of renal flare and improved health-related quality of life. Based on these same published data, a rise in antibodies to dsDNA significantly correlated with an increased risk of renal flare and no change or deterioration in health-related quality of life. In a mouse model of lupus nephritis that generates elevated levels of antibodies to dsDNA, administration of Riquent reduced the production of antibodies to dsDNA, reduced the number of antibody-forming cells, reduced kidney disease and extended the life of the animals. We believe that our own and other studies provide evidence that reducing levels of antibodies to dsDNA may provide an effective therapy for lupus nephritis.

*Riquent Clinical Trial History*

Phase 1 trial

Based on our pre-clinical findings, we filed an Investigational New Drug application for Riquent with the FDA in August 1994. In a double-blind, placebo-controlled Phase 1 clinical trial conducted in December 1994, healthy volunteers received Riquent and displayed no drug-related adverse effects. Upon completion of our Phase 1 trial, we began four Phase 2 clinical trials.

Phase 2 trials

Our Phase 2 clinical trials included a single-dose trial, a repeat dose-escalating trial and two dose-ranging trials.

In 1994, we initiated a single-dose clinical trial to evaluate the safety of a single, 100 mg intravenous dose of Riquent in four female lupus patients. Riquent was well tolerated by all four patients, with no drug-related adverse clinical symptoms and no clinically significant complement level changes.

In 1995, we initiated a repeat dose-escalating clinical trial in which two female lupus patients each received doses of 10, 10, 50, 50, 100 and 100 mg of Riquent at two-week intervals. After the 10-week dosing regimen was completed, the patients were monitored for six weeks. Riquent was well tolerated by both patients. Six weeks after the last dose, the antibodies to dsDNA levels in both patients remained suppressed below baseline levels.

Also 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. The drug was well tolerated with no clinically significant dose-related adverse reactions observed.

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 patients treated weekly with placebo, 10 mg or 50 mg of Riquent, antibodies to dsDNA increased by 100%, 53% and 10%, respectively, while in patients treated weekly with 100 mg of Riquent, antibodies to dsDNA decreased by 43%, a statistically significant difference from placebo. Seven Riquent-treated patients had serious adverse events, but none were considered related to Riquent treatment.

## **Table of Contents**

### **Phase 2/3 trial**

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. The trial design was then changed whereby, patients received alternating eight week drug holidays followed by 12 weeks of weekly treatments with 50mg of Riquent or placebo. Patients were in the trial for up to 18 months. More than 200 patients at more than 50 sites in North America and Europe enrolled in the trial. This trial was conducted with Abbott Laboratories as part of our joint development agreement.

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. In September 1999, our joint development agreement for Riquent with Abbott Laboratories was terminated.

In November 1999, we announced results from retrospective analyses of the data from the Phase 2/3 clinical trial which showed that a certain group of patients treated with Riquent with high affinity antibodies had fewer renal flares and longer time to treatment with high-dose corticosteroids and/or cyclophosphamide ( HDCC ). These results were based on an analysis of the trial using a blood test that we developed and that appears to predict which patients will respond to treatment with Riquent at the doses being administered at that time.

The high-affinity patients treated with Riquent experienced significantly longer time to renal flare ( $p = 0.007$ ), the primary endpoint of the trial, fewer renal flares ( $p = 0.008$ ), longer time to treatments with HDCC ( $p = 0.0003$ ) and fewer exposures to HDCC ( $p < 0.001$ ) when compared to the placebo-treated group. Also in the Phase 2/3 trial, mean levels of circulating antibodies to dsDNA in patients treated with Riquent were reduced by a statistically significant amount relative to placebo during drug treatment ( $p < 0.0001$ ). Further, in a group of high-affinity patients with impaired renal function (defined as serum creatinine  $\geq 1.5$  mg/dL), there were six renal flares in 11 patients treated with placebo and no renal flares in 11 patients treated with Riquent ( $p = 0.012$ ).

### **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. The double-blind, placebo-controlled study was conducted at 91 sites in North America and Europe and was designed to evaluate the potential of Riquent to delay and reduce the number of renal flares and to delay and reduce the need for treatment with HDCC and/or other immunosuppressive drugs in high-affinity patients. Patients in the trial were treated weekly with either 100 mg of Riquent or placebo for a period of up to 22 months.

In February 2003, we announced that Riquent appeared to be well tolerated with no apparent differences in the overall incidence of serious adverse events or adverse events between Riquent-treated and placebo-treated patients. 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.

In the trial, there were fewer renal flares, fewer treatments with HDCC and fewer Major SLE flares in Riquent-treated patients compared with placebo-treated patients, but the differences were not statistically significant. There was a 25% reduction in the incidence of renal flare and a 21% reduction in the incidence of Major SLE flare. The estimated median time to renal flare was 123 months in the Riquent-treated group and 89 months in the placebo-treated group. There was a statistically significant reduction in antibodies to dsDNA in the Riquent-treated group compared with the placebo-treated group ( $p < 0.0001$ ). In patients with impaired renal function at baseline, Riquent-treated patients had fewer renal flares, treatments with HDCC and Major SLE flares compared with patients on placebo, but the sample size of this subgroup was small and the differences were not statistically significant.

In March 2003, we announced results from several retrospective analyses of trial data indicating that renal flares occurred approximately one-fifth as often in patients with sustained reductions in antibodies to dsDNA compared with patients with unchanged or increasing antibodies (Phase 3:  $p < 0.0001$ ; Phase 2/3:  $p = 0.0004$ ). Patients with sustained reductions also reported improved or maintained health-related quality of life compared with patients without sustained reductions in antibodies to dsDNA, regardless of treatment group. In November 2003, we

## **Table of Contents**

announced analyses using Cox's Proportional Hazards Regression Model demonstrating that a 50% reduction in antibodies to dsDNA from baseline was associated with a 52% lower risk of renal flare in the Phase 2/3 trial ( $p = 0.0007$ ) and a 53% lower risk in the Phase 3 trial ( $p < 0.0001$ ).

Further, in March 2004, we announced statistically significant but retrospective results from the Phase 3 and Phase 2/3 trials showing that, after one year of treatment, the number of lupus patients with a reduction in proteinuria of at least 50% from baseline was greater in the Riquent-treated group than in the placebo-treated group. Proteinuria, or protein in the urine, results from ongoing kidney inflammation. 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.

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. Under Subpart H, drugs in development for serious, life-threatening diseases with an unmet medical need can be approved on an accelerated basis if the FDA determines that the effect of the drug on a surrogate endpoint is reasonably likely to predict clinical benefit and that a post-marketing clinical trial can be successfully completed following drug approval which confirms the clinical benefit. As previously described, in our Phase 3 and Phase 2/3 trials, patients treated with Riquent had significantly reduced levels of antibodies to dsDNA compared with patients treated with placebo. 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.

### **Current Phase 3 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 (SPA). The SPA process is a formal procedure that results in a binding written agreement between a company and the FDA concerning the design of a clinical trial or other study. While we delayed additional patient enrollment in March 2005 to conserve cash, in the third quarter of 2006 we reinitiated enrollment in the trial and, on February 1, 2007, announced that 202 patients of the projected 730 patients had been enrolled in the study and 74 clinical trial sites were open to enroll patients in the United States, Europe, Asia and Mexico. We expect to activate more than 100 clinical trial sites and complete patient enrollment into the study around the end of 2007.

In the current Phase 3 clinical benefit trial compared to the previous Phase 3 study, virtually all patients are being treated with one of two higher doses of Riquent or placebo, the number of patients to be studied was more than doubled, the primary endpoint was refined, the use of immunosuppressive agents was further restricted, and the treatment duration was changed to 12 months. As in the previous Phase 3 study, patients in the study all have a history of lupus renal disease. The primary endpoint, time to renal flare, was refined in order to eliminate the hematuria component, which appears to be less specific for lupus renal disease. These changes were all based on results of the previous Phase 2/3 and Phase 3 trials of Riquent.

On February 1, 2007, following further discussions with the FDA, we announced that all new patients entering the study will be randomized in equal numbers to receive weekly doses of either 300 mg or 900 mg of Riquent or placebo, with no further patients randomized to the 100 mg dose group. The approximately 30 patients currently being treated with 100 mg will continue at that dose through the completion of the study. 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.

The study's sample size has been increased to approximately 730 patients which is expected to increase the likelihood of achieving a statistically significant outcome for the individual dose groups when compared with placebo as well as overall. The number of patients to be enrolled is more than twice the approximately 300 patients in the previous Phase 3 study. The trial is designed to be successful based on the results from the last Phase 3 study, where all drug-treated patients received a dose of 100 mg per week of Riquent. In determining how many patients should be enrolled in the current Phase 3 clinical benefit trial, no additional clinical benefit from treatment with the higher doses

was assumed.

**Table of Contents**

In other changes to the study design, the study entry criteria further restricts the use of immunosuppressive agents which, in the previous Phase 3 study, may have reduced the renal flare rate. Also, the current design was changed to a fixed 12-month patient evaluation period. In the previous Phase 3 trial, patients were treated for up to 22 months.

Also, the primary endpoint will be assessed in all patients and will no longer be restricted to the high-affinity subpopulation. We believe that the increased binding capability of higher doses will eliminate the need for an affinity measurement prior to treatment.

To increase efficiency and enhance the quality of data, we also combined the Phase 2 clinical pharmacology study with the Phase 3 study so that Riquent blood levels will be collected in the same patient population as the definitive efficacy data. These changes were all incorporated into the approved SPA.

We also reached an agreement with the FDA to assess the dose response of the treatment with Riquent on antibodies to dsDNA by conducting an analysis to evaluate the effect of higher doses on the reduction of these antibodies. In March 2007, we performed an interim antibody analysis of our ongoing double-blind, placebo-controlled randomized Phase 3 trial of Riquent. The analyses of interim antibody data indicate that patients treated with 900 mg or 300 mg per week doses of Riquent had greater reductions in antibodies to dsDNA than patients treated with 100 mg per week or placebo. The results showed a significant dose response when comparing all Riquent-treated patients to placebo-treated patients ( $p < 0.0001$ ), and each Riquent dose group to the placebo dose group ( $p < 0.0015$  for 100 mg,  $p < 0.0001$  for 300 mg and 900 mg).

The analyses assessed the impact of treatment with Riquent on reducing antibodies to dsDNA in 101 patients by measuring the percent of antibody reduction from baseline compared with placebo following weekly treatment with 100 mg, 300 mg or 900 mg of Riquent or placebo. All demographics and baseline characteristics were comparable across dosing groups and there were 16 to 30 patients per treatment group.

Following eight weeks of treatment, the median percent reduction in antibodies to dsDNA for Riquent-treated patients compared with placebo-treated patients was 36% (100 mg), 48% (300 mg), and 66% (900 mg). Antibody reduction for each dose group was significantly better than placebo. Approximately three times as many patients treated with 900 mg of Riquent (38%) had at least a 50% or greater antibody reduction at week 8 compared with patients treated with 100 mg (13%). Patients reached their maximum reduction after four weeks of treatment at which time separation between doses was also seen.

As indicated in our earlier studies, maintaining antibody reductions over time in individual patients was associated with a significantly reduced renal flare rate. The data from the interim antibody analysis indicate that the higher the Riquent dose, the greater the consistency of response and the greater the magnitude of this response. While more than twice as many 900 mg-treated patients (58%) as 100 mg-treated patients (25%) had a consistent 20% reduction, six times as many 900 mg-treated patients (39%) had a consistent 40% reduction, compared with 100 mg-treated patients (6%). Twice as many patients on 900 mg as 300 mg had a consistent 50% reduction, but no patients on 100 mg or placebo achieved this level of consistent reduction. A consistent reduction is defined as a patient whose percent antibody reduction exceeded a specified level at weeks 4, 6 and 8.

To date, Riquent has been well tolerated in the ongoing Phase 3 study. The adverse event profile for all patients in the study, including those treated with the 300 mg and 900 mg doses, does not appear to differ from that seen in previous studies where 100 mg of Riquent was the treatment dose.

We also plan to conduct an interim analysis for efficacy at a point in time when approximately two-thirds of the projected number of renal flares have been observed. The level of statistical significance for the primary endpoint required for approval takes this interim analysis into account.

**Table of Contents**

To assess the tolerability of higher doses, a safety study in healthy volunteers was completed in 2005. Subjects received a single dose of Riquent at 600 mg, 1200 mg, or 2400 mg. Riquent appeared to be well tolerated in these subjects.

*Riquent Regulatory Status*

**Orphan drug designation for Riquent**

In September 2000, the FDA granted us orphan drug designation for Riquent for the treatment of lupus nephritis. The Orphan Drug Act potentially enables us to obtain research funding, tax credits for certain research expenses and a waiver of the application user fees. In addition, the Orphan Drug Act allows for seven years of exclusive marketing rights to a specific drug for a specific orphan indication. Exclusivity is conferred upon receipt of marketing approval from the FDA to the first sponsor who obtains such approval for a designated drug. The marketing exclusivity prevents FDA approval during the seven-year period of the same drug, as defined in the FDA regulations, from another company for the same orphan indication. Whether we will be able to take advantage of some of the benefits afforded by the orphan drug designation will ultimately be determined by the FDA only after further review of our NDA.

In November 2001, the European Commission granted us orphan medicinal product designation in the European Union for Riquent for treatment of lupus nephritis. Orphan designation in Europe provides for 10 years of marketing exclusivity in the European Union and enables us to receive significant fee reductions for scientific advice from the Committee for Orphan Medicinal Products, marketing authorization and inspections.

**FDA fast track designation for Riquent**

On May 30, 2005, the FDA granted fast track designation for Riquent for the treatment of lupus renal disease. The FDA's fast track program is designed to facilitate the development and to expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address an unmet medical need.

**Inflammatory and Autoimmune Programs**

*SSAO Inflammation Program*

Because substantially all of our resources are currently being devoted to the development of Riquent, further development of the SSAO program depends on the future availability of additional capital.

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 adhesion activities. SSAO contributes to the adhesion of white blood cells to endothelial cells and is amplified in inflamed blood vessels. The enzyme also contributes to the production of molecules that exacerbate inflammation. 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 and chronic heart failure.

Preclinical studies in animal models of multiple sclerosis, rheumatoid arthritis, inflammatory bowel disease, stroke, systemic inflammation and acute inflammation have shown that treatment with our lead compound inhibitors both maintained function and reduced disease activity compared with placebo treatment. The impact of these lead compounds on animal models of multiple sclerosis and rheumatoid arthritis was similar to that of methotrexate, a widely used anti-inflammatory agent.

## **Table of Contents**

Data published by our scientists in 2005 in two 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.

### *Antibody-Mediated Thrombosis Program*

We have used our Tolerance Technology to develop a drug candidate, LJP 1082, to treat antibody-mediated thrombosis. Because substantially all of our resources are currently being devoted to the development of Riquent we have suspended development of LJP 1082. Whether we will again devote any resources to this program depends on a number of factors, including the progress of our Riquent development program and the future availability of additional capital.

### **Collaborative Arrangements**

In circumstances where we believe that a collaborative agreement is necessary or strategically beneficial to us, we intend to pursue collaborative arrangements with other pharmaceutical companies to assist in our research programs and the clinical development and commercialization of our drug candidates and to access their research, drug development, manufacturing, marketing and financial resources. There can be no assurance that we will be able to negotiate arrangements with any collaborative partner on acceptable terms, or at all. If a collaborative relationship is established, there can be no assurance that the collaborative partner will continue to fund any particular program or that it will not pursue alternative technologies or develop alternative drug candidates, either individually or in collaboration with others, including our competitors, as a means for developing treatments for the diseases we have targeted. Furthermore, competing products, either developed by a collaborative partner or to which a collaborative partner has rights, may result in the withdrawal of support by the collaborative partner with respect to all or a portion of our technology.

Failure to establish or maintain collaborative arrangements will require us to fund our own research and development activities, resulting in significant expenditure of our own capital, and will require us to develop our own marketing capabilities for any drug candidate that may receive regulatory approval. The failure of any collaborative partner to continue funding any particular program, or to commercialize successfully any product, could delay or halt the development or commercialization of any products involved in such program. As a result, the failure to establish or maintain collaborative arrangements could hurt our business, financial condition and results of operations.

### **Manufacturing**

We currently operate a production facility that we believe provides sufficient capacity to meet our anticipated requirements for research, clinical trial and any initial commercial launch of Riquent. If Riquent is approved, we expect to have the capacity to manufacture approximately 100 kg of Riquent per year. If Riquent is approved, and if future demand for Riquent exceeds our current capacity, we expect to increase our manufacturing capacity by improving our manufacturing processes, making capital investments in our current facilities and engaging third party contract manufacturers.

We are required to comply with the FDA's and other regulatory agencies' current Good Manufacturing Practices (cGMPs) when we manufacture our drug candidates for clinical trials. We will also be required to comply with the cGMPs if Riquent, or our other drug candidates, are manufactured for commercial purposes. We have limited manufacturing experience and we can provide no assurance that we will be able to successfully transition to commercial production.

In order to meet the demand for any of our drugs that may be approved or to attempt to improve our manufacturing efficiency, we may enter into arrangements with third party contract manufacturers. If we choose to contract for manufacturing services, the FDA and comparable foreign regulators will have to approve the contract manufacturers prior to our use, and these contractors would be required to comply with strictly enforced manufacturing standards. Currently, we also enter into agreements with contractors to prepare our drug candidates for use by patients. If we encounter delays or difficulties in establishing or maintaining relationships with contractors to produce, package or distribute finished products, clinical trials, market introduction and subsequent



## **Table of Contents**

sales of such products would be adversely affected. Our dependence on others for production, packaging or distribution of our products may adversely affect our profit margins and our ability to develop and deliver our products on a timely and competitive basis.

There are currently a limited number of suppliers that produce the raw materials that are necessary to make Riquent. In order to manufacture Riquent in sufficient quantities for our clinical trials and possible commercialization, our suppliers will be required to provide us with an adequate supply of chemicals and reagents. If we are unable to obtain sufficient quantities of chemicals or reagents, our ability to develop and deliver products on a timely and competitive basis will be negatively affected.

### **Marketing and Sales**

If we obtain FDA approval in the United States, we currently anticipate that we would market Riquent ourselves using a specialty pharmaceutical sales force of 40 to 50 sales representatives who would initially target the rheumatology and nephrology specialists who treat the majority of lupus patients with renal disease. We estimate that the majority of these patients are treated at approximately 1,000 clinical centers. If we obtain approval outside of the United States, we currently expect to seek a marketing collaboration with a partner.

We currently have no arrangements with others for the marketing of any of our drug candidates. There can be no assurance that we will be able to enter into any marketing agreements on favorable terms, if at all, or that any such agreements that we may enter into will result in payments to us. Under any co-promotion or other marketing and sales arrangements that we may enter into with other companies, any revenues that we may receive will be dependent on the efforts of others and there can be no assurance that such efforts will be successful.

To the extent that we choose to attempt to develop our own marketing and sales capability (whether domestic or international), we will compete with other companies that have experienced and well-funded marketing and sales operations. Furthermore, there can be no assurance that we, or any collaborative partner, will be able to establish sales and distribution capabilities without undue delays or expenditures, or gain market acceptance for any of our drug candidates. The ultimate size of the markets for our products is uncertain and difficult to estimate. Moreover, we may not earn as much income as we hope due to possible changes in healthcare reimbursement policies by governments and other third party payers.

### **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 111 issued patents and have 65 pending patent applications in the United States and in foreign countries covering various technologies and drug candidates, including our lupus drug candidates (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. Our issued patents include:

Lupus Toleragens six issued United States patents, two issued Australian patents, one granted Portuguese patent, one granted Norwegian patent, one granted European patent (which has been unbundled as 13 European national patents), 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 three 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).

## **Table of Contents**

### **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 is intense and expected to 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 more rapidly than we can, or develop and market technologies and products that are more effective than those we are developing or that would render our technology and proposed products obsolete or noncompetitive.

With respect to the development of Riquent, we believe that our ability to compete successfully will depend on our ability to attract and retain experienced scientists, develop patented or proprietary technologies and products, obtain regulatory approvals, effectively manufacture and market products either alone or through third parties, and secure additional capital resources to fund anticipated net losses for at least the next several years. If Riquent is commercialized, we expect that competition among marketed products will be based in large part on product safety, efficacy, reliability, availability, price and patent position.

### **Government Regulation**

#### **United States**

Our research and development activities and the future manufacturing and marketing of any products we develop 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 are 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



## **Table of Contents**

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 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 s quality 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.

### **Foreign**

We 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 Riquent 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 an MAA; 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 EMEA, must operate in conformity with European good manufacturing practice, and must pass inspections by the European health authorities.

## **Table of Contents**

Upon receiving the MAA, the Committee for Human Medicinal Products (the CHMP), 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.

### **Employees**

As of March 2, 2007, we employed 84 full-time employees (including eight people who have a Ph.D. and two people who have an M.D., one of which also has a Ph.D.), 68 of whom are involved full-time in clinical, development and manufacturing activities. All members of our senior management team have had prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced personnel, but competition for personnel is intense and there can be no assurance that we will be able to attract and retain the individuals needed. None of our employees are covered by 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 Exchange Act of 1934, as amended, are available free of charge through our website at [www.ljpc.com](http://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.**

*We may not have sufficient financial resources to complete the ongoing Phase 3 clinical benefit trial of Riquent.*

We will need to successfully complete the ongoing Phase 3 clinical benefit study of Riquent prior to any FDA or any foreign regulatory approvals. We expect that the ongoing Phase 3 clinical benefit trial will involve approximately 730 patients and take two to three years to complete. We expect that the actual costs of completing the ongoing Phase 3 clinical benefit trial of Riquent will exceed our current cash resources. If we expend all of the funds that we have raised and do not receive funding from a collaborative agreement with a corporate partner or obtain other financing, we would not have the financial resources to complete the ongoing Phase 3 clinical benefit trial or to continue the development of Riquent, and it would be difficult or impossible for us to continue to operate.

*In order to complete our ongoing clinical trial of Riquent, we will need to enroll a sufficient number of patients who meet the trial criteria. If we are unable to successfully complete the trial, our business will be adversely affected and it may be difficult or impossible for us to continue to operate.*

We expect that the ongoing Phase 3 clinical benefit trial of Riquent will involve approximately 730 patients, which is significantly more than were involved in our previous Phase 3 trial. In order to complete this trial, we will need to locate and enroll a sufficient number of patients who meet the criteria for the trial. We may have difficulty enrolling patients because, among other matters, there are specific limitations on the medications that a patient may be taking upon entry into the trial. If we are unable to timely enroll a sufficient number of patients, we will not be able to successfully complete the ongoing trial. As a result, it may be difficult or impossible for us to continue to operate.

**Table of Contents**

***Results from our clinical trials may not be sufficient to obtain regulatory approvals to market Riquent or our other drug candidates in the United States or other countries on a timely basis, if at all.***

Our drug candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. In order to sell any product that is under development, we must first receive regulatory approval. To obtain regulatory approval, we must conduct clinical trials and toxicology studies that demonstrate that our drug candidates are safe and effective. The process of obtaining FDA and foreign regulatory approvals is costly, time consuming, uncertain and subject to unanticipated delays.

The FDA and foreign regulatory authorities have substantial discretion in the approval process and may not agree that we have demonstrated that Riquent is safe and effective. If Riquent is ultimately not found to be safe and effective, we would be unable to obtain regulatory approval to manufacture, market and sell Riquent. Although we have received an approvable letter from the FDA, the analysis of the data from our earlier Phase 3 trial of Riquent showed that the trial did not reach statistical significance with respect to its primary endpoint, time to renal flare, or with respect to its secondary endpoint, time to treatment with high-dose corticosteroids or cyclophosphamide. In a preliminary assessment of the MAA, the EMEA reviewers indicated that additional clinical data would be needed prior to potential approval. Based on our review of the EMEA assessment, we believe that the ongoing clinical studies of Riquent should provide the necessary data; however, the data will not be available within the timeframe that the EMEA regulations allow for review of the current Riquent application. Therefore, we decided to withdraw the current application, and plan to refile the MAA after the completion of the ongoing clinical trials if they are successful. We can provide no assurances that the FDA or foreign regulatory authorities will ultimately approve Riquent or, if approved, what the indication for Riquent will be.

As currently designed, our ongoing Phase 3 trial contains multiple dosing levels. Even if the Phase 3 clinical trial is successful, the FDA or foreign regulatory authorities may require additional studies to define dosing recommendations before we can obtain approval to market Riquent.

Because substantially all of our resources are currently being devoted to Riquent, our inability to obtain any regulatory approval of Riquent as a result of the current Phase 3 trial would have a severe negative effect on our business, and, in the future, we may not have the financial resources to continue the development of Riquent or any other potential drug candidates.

***We are currently devoting nearly all of our resources to the development and approval of Riquent. Accordingly, our efforts with respect to other drug candidates have significantly diminished.***

Future development of our small molecules for the treatment of autoimmune diseases and acute and chronic inflammatory disorders depends on our ability to obtain third party financing for this program including through a joint venture, partnership or other collaborative arrangement. As a result, progress with respect to drug candidates other than Riquent, if any, will be significantly delayed and our success and ability to continue to operate depends on whether we obtain regulatory approval to market Riquent.

***Current and future clinical trials may be delayed or halted.***

Current and future clinical trials of Riquent, trials of drugs related to Riquent, or clinical trials of other drug candidates may be delayed or halted. For example, in 2005, we limited patient enrollment in our ongoing clinical benefit trial in an effort to reduce costs. In addition, our Phase 2/3 clinical trial of Riquent was terminated before planned patient enrollment was completed. Current and future trials may be delayed or halted for various reasons, including:

supplies of drug product are not sufficient to treat the patients in the studies;

patients do not enroll in the studies at the rate we expect;

we do not have sufficient financial resources;

the products are not effective;

**Table of Contents**

patients experience negative side effects or other safety concerns are raised during treatment;

the trials are not conducted in accordance with applicable clinical practices; or

there is political unrest at foreign clinical sites or natural disasters at any of our sites.

If any current or future trials are delayed or halted, we may incur significant additional expenses, and our potential approval of Riquent may be delayed, which could have a severe negative effect on our business.

***We may be required to design and conduct additional trials for Riquent.***

We may be required to design and conduct additional studies to further demonstrate the safety and efficacy of Riquent, which may result in significant expense and delay. The FDA and foreign regulatory authorities may require new or additional clinical trials because of inconclusive results from current or earlier clinical trials (including the Phase 2/3 and Phase 3 trials of Riquent), a possible failure to conduct clinical trials in complete adherence to FDA good clinical practice standards and similar standards of foreign regulatory authorities, the identification of new clinical trial endpoints, or the need for additional data regarding safety or efficacy. It is possible that the FDA or foreign regulatory authorities may not ultimately approve Riquent or our other drug candidates for commercial sale in any jurisdiction, even if we believe future clinical results are positive.

***We may experience shortages of Riquent for use in our clinical studies.***

We may experience shortages of Riquent for use in our clinical studies. We are implementing a commercial scale manufacturing process for Riquent, but we have only manufactured a limited number of lots of Riquent at this commercial scale. In addition, the drug supply needed for our Phase 3 trial as modified will require us to manufacture significant quantities of Riquent in a compressed time frame. If we are unable to manufacture Riquent in accordance with applicable FDA good manufacturing practices at this commercial scale, or if we incur production delays our ability to timely complete clinical trials of Riquent will be negatively affected.

***If we encounter delays or difficulties in establishing or maintaining relationships with manufacturing or distribution contractors, our ability to timely complete necessary clinical trials and potentially deliver commercial products may be negatively affected.***

We may enter into arrangements with contract manufacturing companies to expand our own production capacity in order to meet demand for our products or to attempt to improve manufacturing efficiency. If we choose to contract for manufacturing services, the FDA and comparable foreign regulators would have to approve the contract manufacturers prior to our use, and these contractors would be required to comply with strictly enforced manufacturing standards. We may also enter into agreements with contractors to prepare and distribute our drug candidates for use by patients in clinical trials or commercially. If we encounter delays or difficulties in establishing or maintaining relationships with contractors to produce, package or distribute our drug candidates, if they are unable to meet our needs, if they are not approved by the regulatory authorities, or if they fail to adhere to applicable manufacturing standards, our ability to timely complete necessary clinical trials and to introduce our products into the market would be negatively affected.

***Our limited manufacturing capabilities and experience could result in shortages of drugs for future sale, and our revenues and profit margin could be negatively affected.***

We have never operated a commercial manufacturing facility and we will be required to manufacture Riquent pursuant to applicable FDA good manufacturing practices. Our inexperience could result in manufacturing delays or interruptions and higher manufacturing costs. This could negatively affect our ability to supply the market on a timely and competitive basis. The sales of our products, if any, and our profit margins may also be negatively affected. In addition, substantial capital investment in the expansion and build-out of our manufacturing facilities and/or the engagement of third party contract manufacturers will be required to enable us to manufacture Riquent, if approved, in sufficient commercial quantities. We have limited manufacturing experience, and we may be unable to successfully transition to commercial production.



**Table of Contents**

***Our suppliers may not be able to provide us with sufficient quantities of materials that we need to manufacture our products.***

We rely on outside suppliers to provide us with specialized chemicals and reagents that we use to manufacture our drugs. In order to manufacture Riquent and our other drug candidates in sufficient quantities for our clinical trials and possible commercialization, our suppliers will be required to provide us with an adequate supply of chemicals and reagents. Our ability to obtain these chemicals and reagents is subject to the following risks:

our suppliers may not be able to increase their own manufacturing capabilities in order to provide us with a sufficient amount of material for our use;

some of our suppliers may be required to pass FDA inspections or validations or to obtain other regulatory approvals of their manufacturing facilities or processes, and they may be delayed or unable to do so;

the materials that our suppliers use to manufacture the chemicals and reagents that they provide us may be costly or in short supply; and

there are a limited number of suppliers that are able to provide us with the chemicals or reagents that we use to manufacture our drugs.

If we are unable to obtain sufficient quantities of chemicals or reagents, our ability to produce products for clinical studies and, therefore, to introduce products into the market on a timely and competitive basis, will be impeded. The subsequent sales of our products, if any, and our profit margins may also be negatively affected.

***An interruption in the operation of our sole manufacturing facility could disrupt our operations.***

We have only one drug manufacturing facility. A significant interruption in the operation of this facility, whether as a result of a natural disaster or other causes, could significantly impair our ability to manufacture drugs for our clinical trials or possible commercialization.

***Retaining our current personnel and recruiting additional personnel will be critical to our success.***

We are highly dependent on the principal members of our scientific and management staff, the loss of whose services may delay the achievement of our research and development objectives. Retaining our current key personnel to perform clinical development, manufacturing, regulatory, and business development activities will be critical to our near term success. We expect that recruiting additional qualified personnel to conduct clinical development, manufacturing, regulatory, business development, and marketing and sales activities will be required to successfully further develop Riquent and any additional drug candidates. Because competition for experienced clinical, manufacturing, regulatory, scientific, business development, and marketing and sales personnel among numerous pharmaceutical and biotechnology companies and research and academic institutions is intense, we may not be able to attract and retain these people. If we cannot attract and retain qualified people, our ability to conduct necessary clinical trials, manufacture drug, comply with regulatory requirements, enter into collaborative agreements and develop and sell potential products may be negatively affected because, for instance, the trials may not be conducted properly, or the manufacturing or sales of our products may be delayed. In addition, we rely on consultants and advisors to assist us in formulating our clinical, manufacturing, regulatory, business development, and marketing and sales strategies. All of our consultants and advisors have outside employment and may have commitments or consulting or advisory contracts with other entities that may limit their ability to contribute to our business.

**Table of Contents**

***We will need additional funds to support our operations.***

Our operations to date have consumed substantial capital resources. Before we can obtain FDA or foreign regulatory approval for Riquent, we will need to successfully complete the ongoing Phase 3 clinical benefit trial and possibly additional trials. Therefore, we expect to expend substantial amounts of capital resources for additional product development and clinical trials of Riquent. We may also devote substantial additional capital resources to establish commercial-scale manufacturing capabilities and to market and sell potential products. These expenses may be incurred prior to or after any regulatory approvals that we may receive. Even with the net proceeds of approximately \$62.3 million from our stock and warrant offering in December 2005, we will need additional funds to finance our future operations. Our future capital requirements will depend on many factors, including:

the scope and results of our clinical trials;

our ability to manufacture sufficient quantities of drug to support clinical trials;

our ability to obtain regulatory approval for Riquent;

the time and costs involved in applying for regulatory approvals;

continued scientific progress in our development programs;

the size and complexity of our development programs;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

competing technological and market developments;

our ability to establish and maintain collaborative research and development arrangements;

our need to establish commercial manufacturing capabilities; and

our ability to develop effective marketing and sales programs.

We expect to incur substantial losses each year for at least the next several years as we continue our planned clinical trial, manufacturing, regulatory, and development activities. If we receive regulatory approval for Riquent, or any of our other drug candidates, our manufacturing, marketing and sales activities are likely to substantially increase our expenses and our need for additional working capital. In the future, it is possible that we will not be able to obtain additional funds and thus not have adequate resources to support continuation of our business activities.

***We may need to sell stock or assets, enter into collaborative agreements, significantly reduce our operations, or merge with another entity to continue operations.***

Our business is highly cash-intensive and we will need a significant amount of additional cash to continue our operations. There can be no guarantee that additional financing will be available to us on favorable terms, or at all, whether through issuance of additional securities, entry into collaborative arrangements, or otherwise. If adequate funds are not available, we may delay, scale back or halt the ongoing Phase 3 clinical benefit trial of Riquent, reduce the size of our workforce, sell or license our technologies or obtain funds through other arrangements with collaborative partners or others that require us to relinquish rights to our technologies or potential products. We also may merge with another entity to continue our operations. Any one of these outcomes could have a negative impact on our ability to develop products or achieve profitability if our products are brought to market. If, and to the extent, we obtain additional funding through sales of securities, any investment in us will be diluted, and dilution can be particularly substantial when the price of our common stock is low.

**Table of Contents*****Our freedom to operate our business or profit fully from sales of our products may be limited if we enter into collaborative agreements.***

We may need to collaborate with other pharmaceutical companies to gain access to their financial, research, drug development, manufacturing, or marketing and sales resources. However, we may not be able to negotiate arrangements with any collaborative partners on favorable terms, if at all. Any collaborative relationships that we enter into may include restrictions on our freedom to operate our business or may limit our revenues from potential products. If a collaborative arrangement is established, the collaborative partner may discontinue funding any particular program or may, either alone or with others, pursue alternative technologies or develop alternative drug candidates for the diseases we are targeting. Competing products, developed by a collaborative partner or to which a collaborative partner has rights, may result in the collaborative partner withdrawing support as to all or a portion of our technology.

Without collaborative arrangements, we must fund our own clinical development, manufacturing, and marketing and sales activities, which accelerates the depletion of our cash and requires us to develop our own manufacturing and marketing and sales capabilities. Therefore, if we are unable to establish and maintain collaborative arrangements and if other sources of cash are not available, we will experience a severe adverse effect on our ability to develop products and, if developed and approved, to manufacture, market and sell them successfully. ***Our blood test to measure the binding affinity for Riquent has not been validated by independent laboratories, may require regulatory review as part of the Riquent approval process and results to date may not be reproduced in current or future clinical trials.***

In 1998, we developed a blood test intended to identify the lupus patients who are most likely to respond to the 100 mg dose of Riquent, by measuring the strength of the binding between Riquent and a patient's antibodies. This affinity assay was used to identify, prospectively in the previous Phase 3 trial and retrospectively in the Phase 2/3 trial, the patients included in the efficacy analyses. Independent laboratories have not validated the assay, and the results of the affinity assay observed in our previous clinical trials of Riquent may not be reproducible in current or future clinical trials or may not be observed in the broader lupus patient population. Although the FDA has reviewed the assay as part of the NDA review process of Riquent, the FDA has agreed that the assay will not be included as part of the primary endpoint assessment in the current Phase 3 trial. However, foreign regulatory authorities may require that the assay be reviewed as part of their approval process for Riquent. If the assay is required, we may be required to conduct additional studies on the assay post-approval. Additional regulatory inspections or approval may be required for the testing laboratory that conducts the assay if the assay is required. If foreign regulatory authorities require the use of the assay to identify potential patients for treatment with Riquent, or if they require additional studies on the assay or additional regulatory approval of the testing laboratory, the approval and possible commercialization of Riquent in these countries may be delayed or prevented, which would have a severe negative effect on our business. ***Any regulatory approvals that we may obtain for our product candidates may be limited and subsequent issues regarding safety or efficacy could cause us to remove products from the market.***

If the FDA or foreign regulatory authorities grant approval of Riquent or any of our other drug candidates, the approval may be limited to specific conditions or patient populations, or limited with respect to its distribution, including to specified facilities or physicians with special training or experience. The imposition of any of these restrictions or other restrictions on the marketing and use of Riquent could adversely affect any future sales of Riquent. Furthermore, even if a drug candidate is approved, it is possible that a subsequent issue regarding its safety or efficacy would require us to remove the drug from the market.

***Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and review, including validation of our manufacturing facilities and processes.***

Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, we, and any third-party manufacturers, will

**Table of Contents**

be required to adhere to regulations setting forth cGMPs. These regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. Furthermore, we, and any third-party manufacturers, will be subject to periodic inspection by regulatory authorities. These inspections may result in compliance issues that would require the expenditure of significant financial or other resources to address. If we, or any third-party manufacturers that we may engage, fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Although a successful pre-approval inspection was conducted by the FDA in July 2004, we have never operated a commercial manufacturing facility and we have not yet completed the validation of our manufacturing processes. If we are unable to maintain validated conditions at our manufacturing facilities or fail to successfully validate our manufacturing processes to the satisfaction of the regulatory authorities, they will not approve Riquent for commercial use.

***The size of the market for our potential products is uncertain.***

We estimate that the number of people who suffer from lupus in the United States and Europe is potentially more than 1,000,000 and those with renal impairment, which Riquent is designed to treat, is approximately 300,000. However, there is limited information available regarding the actual size of these patient populations. In addition, it is uncertain whether the results from previous or future clinical trials of Riquent will be observed in broader patient populations, and the number of patients who may benefit from Riquent may be significantly smaller than the estimated patient populations. Furthermore, management of patients with renal disease by specialists other than nephrologists and rheumatologists is likely to reduce our ability to access patients who may benefit from Riquent.

***Our drugs may not achieve market acceptance.***

Even if Riquent or our other drug candidates receive regulatory approval, patients and physicians may not readily or quickly accept our proposed methods of treatment. In order for Riquent or our other drug candidates to be commercially successful, we will need to increase the awareness and acceptance of our drug candidates among physicians, patients and the medical community. Riquent is designed to be administered weekly by intravenous injection. It is possible that providers and patients may resist an intravenously administered therapeutic. It is also possible that physician treatment practices may change and that the use of other drugs, either newly approved or currently on the market for other conditions, may become widely utilized by clinicians for the treatment of patients with lupus and reduce the potential use of Riquent in this patient population. In addition, if we are unable to manufacture drugs at an acceptable cost, physicians may not readily prescribe drugs that we may manufacture due to cost-benefit considerations when compared to other methods of treatment. If we are unable to achieve market acceptance for approved products, our revenues and potential for profitability will be negatively affected.

***We lack experience in marketing products for commercial sale.***

In order to commercialize any drug candidate approved by the FDA or foreign regulatory authorities, we must either develop marketing and sales programs or enter into marketing arrangements with others. If we cannot do either of these successfully, we will not generate meaningful sales of any products that may be approved. If we develop our own marketing and sales capabilities, we will be required to employ a sales force, establish and staff a customer service department, and create or identify distribution channels for our drugs. We will compete with other companies that have experienced and well-funded marketing and sales operations. In addition, if we establish our own sales and distribution capabilities, we will incur material expenses and may experience delays or have difficulty in gaining market acceptance for our drug candidates. We currently have no marketing arrangements with others. There can be no guarantee that, if we desire to, we will be able to enter into any marketing agreements on favorable terms, if at all, or that any such agreements will result in payments to us. If we enter into co-promotion or other marketing and sales arrangements with other companies, any revenues that we may receive will be dependent on the efforts of others. There can be no guarantee that these efforts will be successful.

**Table of Contents**

***We may not earn as much revenue as we hope due to possible changes in healthcare reimbursement policies.***

The continuing efforts of government and healthcare insurance companies to reduce the costs of healthcare may reduce the amount of revenue that we can generate from sales of future products, if any. For example, in certain foreign markets, pricing and profitability of prescription drugs are subject to government control. In the United States, we expect that there will continue to be a number of federal and state proposals to implement similar government controls. In addition, an increasing emphasis on managed care in the United States will continue to put pressure on drug manufacturers to reduce prices. Price control initiatives could reduce the revenue that we receive for any products we may develop and sell in the future. Moreover, even if Riquent were approved we cannot predict what the dosage requirements or degree of efficacy would be and therefore whether or not healthcare reimbursement policies would enable a sales price that allows us to be profitable.

***We have a history of losses and may not become profitable.***

We have incurred operating losses each year since our inception in 1989 and had an accumulated deficit of approximately \$299.8 million as of December 31, 2006. We expect to incur substantial losses each year for at least the next several years as we conduct clinical trials of our drug candidates, seek regulatory approval and continue our clinical development, manufacturing, and regulatory activities. In addition, assuming we ultimately receive approval from the FDA or foreign regulatory authorities for Riquent or our other drug candidates, we will be required to establish commercial manufacturing capabilities and marketing and sales programs which may result in substantial additional losses. To achieve profitability we must, among other matters, complete the development of our products, obtain all necessary regulatory approvals and establish commercial manufacturing, marketing and sales capabilities. The amount of losses and the time required by us to reach sustained profitability are highly uncertain and we may never achieve profitability. We do not expect to generate revenues from the sale of Riquent, if approved, or our other products, if any, in the near term, and we may never generate product revenues.

***Our success in developing and marketing our drug candidates depends significantly on our ability to obtain patent protection for Riquent and any other developed products. In addition, we will need to successfully preserve our trade secrets and operate without infringing on the rights of others.***

We depend on patents and other unpatented intellectual property to prevent others from improperly benefiting from products or technologies that we may have developed. We currently own 111 issued patents and 65 pending patent applications in the United States and in foreign countries. These patents and patent applications cover various technologies and drug candidates, including Riquent. There can be no assurance, however, that any additional patents will be issued, that the scope of any patent protection will be sufficient to protect us or our technology, or that any current or future issued patent will be held valid if subsequently challenged. There is a substantial backlog of biotechnology patent applications at the United States Patent and Trademark Office that may delay the review and issuance of any patents. The patent position of biotechnology firms like ours is highly uncertain and involves complex legal and factual questions, and no consistent policy has emerged regarding the breadth of claims covered in biotechnology patents or the protection afforded by these patents. We intend to continue to file patent applications as believed appropriate for patents covering both our products and processes. There can be no assurance that patents will be issued from any of these applications, or that the scope of any issued patents will protect our technology.

We do not necessarily know if others, including competitors, have patents or patent applications pending that relate to compounds or processes that overlap or compete with our intellectual property or which may affect our freedom to operate. We are aware of certain families of patents and patent applications that contain claims covering subject matter that may affect our ability to develop, manufacture and sell our products in the future. We have conducted investigations into these patent families to determine what impact, if any, the patent families could have on our continued development, manufacture and, if approved by the FDA, sale of our drug candidates, including Riquent. Based on our investigations to date, we currently do not believe that these patent families are likely to impede the advancement of our drug candidates, including Riquent.

However, there can be no assurance that upon our further investigation, these patent families or other patents will not ultimately be found to impact the advancement of our drug candidates, including Riquent. If the United States Patent and Trademark Office or any foreign counterpart issues or has issued patents containing



**Table of Contents**

competitive or conflicting claims, and if these claims are valid, the protection provided by our existing patents or any future patents that may be issued could be significantly reduced, and our ability to prevent competitors from developing products or technologies identical or similar to ours could be negatively affected. In addition, there can be no guarantee that we would be able to obtain licenses to these patents on commercially reasonable terms, if at all, or that we would be able to develop or obtain alternative technology. Our failure to obtain a license to a technology or process that may be required to develop or commercialize one or more of our drug candidates may have a material adverse effect on our business. In addition, we may have to incur significant expenses and management time in defending or enforcing our patents.

We also rely on unpatented intellectual property such as trade secrets and improvements, know-how, and continuing technological innovation. While we seek to protect these rights, it is possible that:

others, including competitors, will develop inventions relevant to our business;

our confidentiality agreements will be breached, and we may not have, or be successful in obtaining, adequate remedies for such a breach; or

our trade secrets will otherwise become known or be independently discovered by competitors.

We could incur substantial costs and devote substantial management time in defending suits that others might bring against us for infringement of intellectual property rights or in prosecuting suits that we might bring against others to protect our intellectual property rights.

***The technology underlying our products is uncertain and unproven.***

All of our product development efforts are based on unproven technologies and therapeutic approaches that have not been widely tested or used. To date, no products that use our technology have been commercialized. The FDA has not determined that we have proven Riquent to be safe and effective in humans, and the technology on which it is based has been used only in our pre-clinical tests and clinical trials. Clinical trials of Riquent may be viewed as a test of our entire approach to developing therapies for antibody-mediated diseases. If Riquent does not work as intended, or if the data from our clinical trials indicates that Riquent is not safe and effective, the applicability of our technology for successfully treating antibody-mediated diseases will be highly uncertain. As a result, there is a significant risk that our therapeutic approaches will not prove to be successful, and there can be no guarantee that our drug discovery technologies will result in any commercially successful products.

***Because a number of companies compete with us, many of which have greater resources than we do, and because we face rapid changes in technology in our industry, we cannot be certain that our products will be accepted in the marketplace or capture market share.***

Competition from domestic and foreign biotechnology companies, large pharmaceutical companies and other institutions is intense and is expected to increase. A number of companies and institutions are pursuing the development of pharmaceuticals in our targeted areas. Many of these companies are very large, and have financial, technical, sales and distribution and other resources substantially greater than ours. The greater resources of these competitors could enable them to develop competing products more quickly than we are able to, and to market any competing product more quickly or effectively so as to make it extremely difficult for us to develop a share of the market for our products. These competitors also include companies that are conducting clinical trials and pre-clinical studies for the treatment of lupus. Our competitors may develop or obtain regulatory approval for products more rapidly than we do. If the FDA were to approve a drug that is significantly similar in structure to Riquent for the same indication that Riquent is designed to treat, and such drug received marketing exclusivity under the Orphan Drug Act, the FDA may be prevented from approving Riquent. Also, the biotechnology and pharmaceutical industries are subject to rapid changes in technology. Our competitors may develop and market technologies and products that are more effective or less costly than those we are developing, or that would render our technology and proposed products obsolete or noncompetitive.

**Table of Contents**

***We may not be able to take advantage of the orphan drug designation for Riquent.***

In September 2000, the FDA granted us orphan drug designation for Riquent for the treatment of lupus nephritis. The Orphan Drug Act potentially enables us to obtain research funding and tax credits for certain research expenses. In addition, the Orphan Drug Act allows for seven years of exclusive marketing rights to a specific drug for a specific orphan indication. Exclusivity is conferred upon receipt of marketing approval from the FDA to the first sponsor who obtains such approval for a designated drug. The marketing exclusivity prevents FDA approval during the seven-year period of the same drug, as defined in the FDA regulations, from another company for the same orphan indication. Whether we will be able to take advantage of some of the benefits afforded by the orphan drug designation will ultimately be determined by the FDA only after further review of our NDA.

***The use of Riquent or other potential products in clinical trials, as well as the sale of any approved products, may expose us to lawsuits resulting from the use of these products.***

The use and possible sale of Riquent or other potential products may expose us to legal liability and negative publicity if we are subject to claims that our products harmed people. These claims might be made directly by patients, pharmaceutical companies, or others. We currently maintain \$10.0 million of product liability insurance for claims arising from the use of our products in clinical trials. However, product liability insurance is becoming increasingly expensive. In addition, in the event of any commercialization of any of our products, we will likely need to obtain additional insurance, which will increase our insurance expenses. There can be no guarantee that we will be able to maintain insurance or that insurance can be acquired at a reasonable cost, in sufficient amounts, or with broad enough coverage to protect us against possible losses. Furthermore, it is possible that our financial resources would be insufficient to satisfy potential product liability or other claims. A successful product liability claim or series of claims brought against us could negatively impact our business and financial condition.

***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. We may have to incur significant costs to comply with environmental regulations if and when our manufacturing increases to commercial volumes. Current or future environmental laws may significantly affect our operations because, for instance, our production process may be required to be altered, thereby increasing our production costs. In our research and manufacturing activities, we use 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.

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

***The ownership of our common stock is concentrated.***

As of March 2, 2007, our three largest stockholders beneficially owned approximately 47% of our currently outstanding shares of common stock. Investors who purchase our common stock may be subject to certain risks due to the concentrated ownership of our common stock. For example, the sale by any of our large stockholders of a significant portion of that stockholder's holdings could have a material adverse effect on the market price of our common stock. In addition, two of these stockholders have the ability, either alone or jointly, to appoint four members of our board of directors. Accordingly, these two stockholders, either directly or indirectly, have the ability to significantly influence the outcome of all matters submitted to a vote of our stockholders.



**Table of Contents**

***Our common stock price is volatile and may decline even if our business is doing well.***

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:

our clinical trial results;

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;

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

developments concerning potential agreements with collaborators;

comments by securities analysts and general market conditions; and

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.

***Future sales of our stock by our stockholders could negatively affect the market price of our stock.***

Sales of our common stock in the public market, or the perception that such sales could occur, could result in a drop in the market price of our securities. As of March 2, 2007, there were:

Approximately 32,701,431 shares of common stock that have been issued in registered offerings or were otherwise freely tradable in the public markets.

Approximately 10,769 shares of common stock eligible for resale in the public market pursuant to SEC Rule 144.

4,399,992 shares of common stock underlying warrants which have been registered for resale under a Registration Statement on Form S-3.

4,666,178 shares of common stock that may be issued on the exercise of outstanding stock options granted under our various stock option plans at a weighted average exercise price of \$9.12 per share.

Approximately 605,377 shares of common stock reserved for future issuance pursuant to awards granted under our equity incentive and employee stock purchase plans, which shares are covered by effective registration statements under the Securities Act of 1933, as amended (the Securities Act ).

Pursuant to a registration statement on Form S-3 filed on December 10, 2002, we registered an aggregate amount of \$125,000,000 of our common stock for issuance from time to time. As of March 2, 2007, there was \$53,937,500 of our common stock available for future issuance.



**Table of Contents**

We cannot estimate the number of shares of common stock that may actually be resold in the public market because this will depend on the market price for our common stock, the individual circumstances of the sellers and other factors. We also have a number of stockholders that own significant blocks of our common stock. If these stockholders sell significant portions of their holdings in a relatively short time, for liquidity or other reasons, the market price of our common stock could drop significantly.

***Our stock may be removed from listing on the Nasdaq Global Market and may not qualify for listing on any stock exchange, in which case it may be difficult to maintain a market in our stock.***

In 2005, we received a notice from the Nasdaq Stock Market that our stock price fell below the required minimum bid price. We have since regained compliance with the minimum bid price rule, but we are required to maintain compliance in order to maintain our listing. 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 this were to happen, we may not be able to secure listing on other exchanges or quotation systems. If our stock is no longer traded on an exchange or quotation system, it may be difficult for our stockholders to sell the shares that they own. This would have a negative effect on the price and liquidity of our 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 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 attest to, and report on, management's assessment of our internal control over financial reporting. We evaluated our internal control over financial reporting as of December 31, 2006 in order to comply with Section 404 and concluded that our disclosure controls and procedures were effective as of such date. In addition, our independent registered public accounting firm reported on our assertion with respect to the effectiveness of our internal control over financial reporting as of December 31, 2006. 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.

**Table of Contents****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 additional space can be secured at commercially reasonable rates.

**Item 3. Legal Proceedings.**

We are not currently a party to any legal proceedings.

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

None.

**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. On December 21, 2005, we implemented a one-for-five reverse stock split. The dollar amounts below have been adjusted to reflect the impact of the reverse stock split.

	Prices	
	High	Low
Year Ended December 31, 2006		
First Quarter	\$5.65	\$3.28
Second Quarter	4.95	3.47
Third Quarter	4.10	3.50
Fourth Quarter	3.79	2.77
Year Ended December 31, 2005		
First Quarter	\$9.50	\$3.00
Second Quarter	5.35	1.80
Third Quarter	5.00	3.65
Fourth Quarter	4.95	2.60

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 2, 2007 was approximately 227.

**Table of Contents**

**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.

**Stock Performance Graph**

The following graph compares the cumulative total stockholder return on our common stock for the five years ended December 31, 2006 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, 2001 in our common stock and each index and that all dividends were reinvested. No cash dividends have been declared on our common stock. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

**Table of Contents**

	12/31/2001	12/31/2002	12/31/2003	12/31/2004	12/31/2005	12/31/2006
<b>La Jolla Pharmaceutical Company*</b>	\$ 100	\$72.71	\$ 47.65	\$ 18.68	\$ 8.28	\$ 6.78
<b>Nasdaq US</b>	\$ 100	\$69.13	\$103.36	\$112.49	\$114.88	\$126.22
<b>Nasdaq Pharmaceuticals</b>	\$ 100	\$64.62	\$ 94.72	\$100.88	\$111.09	\$108.75

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

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

	Years Ended December 31,				
	2002	2003	2004	2005	2006
	(In thousands, except per share amounts)				
<b>Consolidated Statements of Operations Data:</b>					
Expenses:					
Research and development	\$ 37,696	\$ 32,385	\$ 33,169	\$ 22,598	\$ 32,938
General and administrative	6,944	6,908	7,568	5,405	9,287
Loss from operations	(44,640)	(39,293)	(40,737)	(28,003)	(42,225)
Interest expense	(51)	(210)	(190)	(116)	(46)
Interest income	1,373	665	383	756	2,826
Net loss	\$(43,318)	\$(38,838)	\$(40,544)	\$(27,363)	\$(39,445)
Basic and diluted net loss per share	\$ (5.15)	\$ (4.24)	\$ (3.40)	\$ (1.77)	\$ (1.21)
Shares used in computing basic and diluted net loss per share (1)	8,409	9,161	11,941	15,446	32,588
<b>Balance Sheet Data:</b>					
Working capital	\$ 46,490	\$ 28,914	\$ 17,539	\$ 70,124	\$ 37,673
Total assets	\$ 61,864	\$ 41,944	\$ 33,026	\$ 80,928	\$ 49,525
Noncurrent portion of obligations under capital leases and notes payable	\$ 1,111	\$ 1,341	\$ 716	\$ 142	\$ 196
Stockholders' equity	\$ 53,799	\$ 36,427	\$ 26,001	\$ 77,130	\$ 43,089

(1) Shares have been adjusted to reflect the one-for-five reverse stock split effective December 21, 2005.





**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:

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

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

*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, 2006 to the results for the year ended December 31, 2005 and comparing the results for the year ended December 31, 2005 to the results for the year ended December 31, 2004.

*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, 2006. 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.

**Recent Developments**

**2007**

On March 8, 2007, we announced positive interim antibody results from our ongoing double-blind, placebo-controlled randomized Phase 3 trial of Riquent. Analyses of interim antibody data indicate that patients treated with 900 mg or 300 mg per week doses of Riquent had greater reductions in antibodies to dsDNA than patients treated with 100 mg per week or placebo. The results showed a significant dose response when comparing all Riquent-treated patients to placebo-treated patients ( $p < 0.0001$ ), and each Riquent dose group to the placebo dose group ( $p < 0.0015$  for 100 mg,  $p < 0.0001$  for 300 mg and 900 mg).

On February 1, 2007, we announced that we had made continued progress in enrolling patients in our Phase 3 clinical trial of Riquent in that we had enrolled 202 patients in the study and 74 clinical trial sites were open to enroll patients, including newly added sites in Europe and Mexico. In addition, we also announced that following recent discussions with the FDA, we have implemented several enhancements to further strengthen the Phase 3 study, which remains under Special Protocol Assessment. These enhancements include:

**Focus on higher doses** all new patients entering the study will be randomized in equal numbers to receive weekly doses of either 300 mg or 900 mg of Riquent or placebo, with no further patients randomized to the 100 mg dose group.

**Increase sample size** the study sample size is increased from approximately 600 to approximately 730 patients, which is expected to increase the likelihood of achieving a statistically significant outcome for the individual dose groups when compared with placebo as well as overall.

**Table of Contents**

Broaden analysis of patient population – the primary endpoint will be assessed in all patients and will no longer be restricted to the high-affinity subpopulation. We believe that the increased binding capability of higher doses will eliminate the need for an affinity measurement prior to treatment.

Combine current studies – to increase efficiency and enhance the quality of data, we also combined the Phase 2 clinical pharmacology study with the Phase 3 study so that Riquent blood levels will be collected in the same patient population as the definitive efficacy data.

**2006**

On January 11, 2006, we announced that we would initiate a multi-dose clinical study of Riquent in lupus patients to evaluate the ability of higher doses of Riquent to further reduce antibodies to dsDNA. This study is part of our overall clinical development program of Riquent, which includes the ongoing Phase 3 clinical benefit trial to evaluate the use of Riquent in preventative and acute settings. Subsequently, in February 2007, this Phase 2 clinical pharmacology study was combined with the Phase 3 study.

On January 12, 2006, we announced that we had regained compliance with the Nasdaq Stock Market minimum bid price rule and that we were eligible to remain listed on the Nasdaq Global Market.

On March 15, 2006, we announced that Deirdre Y. Gillespie, M.D. was appointed to serve as our new President and Chief Executive Officer following the resignation of Steven B. Engle on March 14, 2006. We also announced that our board of directors had appointed Craig R. Smith, M.D., a current independent director, to serve as Chairman of the board.

On June 22, 2006, we announced that our MAA had been accepted for review by the EMEA for potential approval to market Riquent in the EU. The MAA was filed with the EMEA on March 31, 2006. The EMEA's review of the MAA would follow its centralized marketing authorization procedure. Riquent has already received orphan medicinal product designation in Europe, which will provide 10 years of market exclusivity from the date of the EU's authorization, if any.

On July 17, 2006, we announced that Michael J. B. Tansey, M.D., Ph.D. had joined the Company as Chief Medical Officer on a part-time basis, whereby 65% of his time is devoted to his position with the Company. Effective December 4, 2006, Dr. Tansey became a full-time employee, assuming the title of Executive Vice President and Chief Medical Officer.

On August 9, 2006, we announced that we had reactivated enrollment in our Phase 3 trial of Riquent.

On September 27, 2006, we announced that we had made considerable progress on our Phase 3 trial of Riquent in that we had added 27 new clinical trial sites able to screen and enroll patients for a total of 58 sites (22 in the United States and 36 in Asia).

On October 12, 2006, we announced that we had requested the withdrawal of our MAA. In a preliminary assessment of the MAA, the EMEA reviewers indicated that additional clinical data would be needed prior to potential approval. Based on our review of the assessment, we believe that the ongoing clinical studies of Riquent should provide the necessary data; however, the data will not be available within the timeframe that the EMEA regulations allow for the review of the current Riquent application. Therefore, we decided to withdraw the current application, and plan to refile the MAA after the completion of the ongoing clinical trials, if they are successful.

On November 6, 2006, we announced that we had made further progress in enrolling patients and opening sites for our Phase 3 clinical trial of Riquent. As of November 2006, 82 patients had been enrolled in the study, more than 150 additional patients were in screening for potential enrollment and we had activated 65 clinical trial sites, including newly-added sites in Europe.

## **Table of Contents**

### **Overview**

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. We expect that our research and development expenses will increase significantly in the future. For example, we are conducting and expanding a Phase 3 clinical trial of Riquent which the FDA has indicated appears to satisfy the requirement that we conduct an additional randomized, double-blind study. This study is expected to involve approximately 730 patients and take two to three years to complete. Therefore, we expect to expend substantial amounts of capital resources for the clinical development and manufacturing of Riquent. We may also devote substantial additional capital resources to establish commercial-scale manufacturing capabilities and to market and sell potential products. These expenses may be incurred prior to or after any regulatory approvals that we may receive. In addition, our research and development expenses may increase if we initiate any additional clinical studies of Riquent or if we increase our activities related to any additional drug candidates. We will need additional funds to finance our future operations. Our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and the financial information included in this report are not necessarily indicative of our future operating results or financial condition.

We expect our net loss to fluctuate from quarter to quarter as a result of the timing of expenses incurred and the revenues earned from any potential collaborative arrangements that we may establish. Some of these fluctuations may be significant. As of December 31, 2006, our accumulated deficit was approximately \$299.8 million.

Our business is subject to significant risks, including, but not limited to, the risks inherent in research and development efforts, including clinical trials, the lengthy, expensive and uncertain process of seeking regulatory approvals, the need for additional financing or a collaborative partner, uncertainties associated with both obtaining and enforcing patents, the potential enforcement of the patent rights of others against us, uncertainties regarding government reforms regarding product pricing and reimbursement levels, technological change, competition, manufacturing uncertainties, our lack of marketing experience, the uncertainty of receiving future revenue from product sales or other sources such as collaborative relationships, and the uncertainty of future profitability. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons, including the possibilities that the products will be ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by the proprietary rights of third parties or competing products.

### **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 and clinical/regulatory expenses. 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.

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

#### *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

**Table of Contents**

associated with long-lived assets requires judgment and assumptions that could differ materially from the actual results. While we believe our current and historical operating and cash flow losses are indicators of impairment, we believe the future cash flows to be received from the long-lived assets will exceed the assets' carrying value. We have recognized approximately \$0.1 million in impairment losses for each of the years ended December 31, 2006 and 2005. There were no impairment losses recognized for the year ended December 31, 2004.

Costs related to successful patent applications 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.

*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, completion of studies and other events. We follow 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; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

*Share-Based Compensation*

We adopted Statement of Financial Accounting Standard ( SFAS ) No. 123R, *Share-Based Payments* ( 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 year ended December 31, 2006 reflects 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 impact of SFAS 123R. Share-based compensation expense recognized under SFAS 123R for the year ended December 31, 2006 was approximately \$5.0 million. As of December 31, 2006, there was approximately \$8.1 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, 2006 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.

Prior to January 1, 2006, we had adopted the disclosure-only provision of SFAS No. 123, *Accounting and Disclosure of Stock-Based Compensation* ( SFAS 123 ). Accordingly, we had not previously recognized compensation expense, except for compensation expense related to stock options granted to consultants and restricted stock granted to certain members of management. Had we recognized compensation expense in accordance with SFAS 123 for the year ended December 31, 2005 and 2004, our net loss would have increased by approximately \$3.8 million and approximately \$6.9 million, respectively, or \$0.25 and \$0.57, respectively, per basic and diluted share.

**New Accounting Pronouncements**

In February 2007, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an amendment of FASB Statement No. 115* ( SFAS 159 ). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings.

**Table of Contents**

SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the impact of SFAS 159 on our consolidated results of operations and financial condition.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108 ( SAB 108 ). SAB 108 addresses the process and diversity in practice of quantifying financial statement misstatements resulting in the potential build up of improper amounts on the balance sheet. SAB 108 is effective for annual periods ending after November 15, 2006. The adoption of SAB 108 did not have a material effect on our consolidated results of operations and financial position as of and for the year ended December 31, 2006.

In September 2006, FASB issued SFAS No. 157, *Fair Value Measurements* ( 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. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We currently do not believe that the adoption of SFAS 157 will have a material impact on our consolidated results of operations and financial condition.

In June 2006, FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN 48 provides guidance on the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted by us in fiscal 2007. We are currently evaluating the impact of this standard on our consolidated results of operations and financial condition.

On January 1, 2006, we adopted SFAS No. 154, *Accounting Changes and Error Corrections a replacement of APB Opinion No. 20 and FASB Statement No. 3* ( SFAS 154 ). SFAS 154 changed the requirements for the accounting for and reporting of a change in accounting principle. SFAS 154 applies to all voluntary changes in accounting principles and changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition methods. The adoption of SFAS 154 did not affect our consolidated results of operations and financial condition as of and for the year ended December 31, 2006. Its effects on future periods will depend on the nature and significance of any future accounting changes subject to SFAS 154.

**Results of Operations*****Years Ended December 31, 2006, 2005 and 2004***

*Research and Development Expense.* Our research and development expense increased to \$32.9 million for the year ended December 31, 2006 from \$22.6 million in 2005. The increase in research and development expenses in 2006 from 2005 resulted primarily from an increase in Riquent-related drug production and clinical trial expenses of approximately \$8.2 million. In addition, the increase was due to share-based compensation expense recorded in connection with the adoption of SFAS 123R of approximately \$1.8 million and an increase in Riquent-related consulting expenses of approximately \$0.6 million. These increases were partially offset by a decrease in termination benefits, mainly relating to severance, of approximately \$1.0 million that was recorded in 2005 in connection with the termination of 44 research and development personnel, and the savings in salaries and related expenses as a result of this reduction in personnel.

Our research and development expense decreased to \$22.6 million for the year ended December 31, 2005 from \$33.2 million in 2004. The decrease in research and development expenses in 2005 from 2004 resulted primarily from a reduction in expenses related to the purchase of raw materials for the production of Riquent of approximately \$4.9 million and a reduction in consulting and professional services of approximately \$1.9 million due to a decrease in activities related to the development of Riquent. Also contributing to these decreases were the cost savings related to our March 2005 restructuring.

**Table of Contents**

Research and development expense of \$32.9 million for the year ended December 31, 2006 consisted of \$29.1 million for lupus research and development related expense and \$3.8 million for SSAO research and development related expense. Total lupus research and development expense consisted primarily of salaries and other costs related to manufacturing, clinical and research personnel, Riquent-related drug production and clinical trial expenses, fees for consulting and professional outside services and depreciation expense. Total SSAO research and development expense consisted primarily of salaries and other costs related to research and development personnel, research supplies, rent and lease expense, depreciation expense and fees for pharmacology, toxicology and other SSAO-related studies.

We expect that our research and development expense will increase significantly in the future. For example, we are conducting and expanding a clinical trial of Riquent that the FDA has indicated appears to satisfy the requirement that we conduct an additional randomized, double-blind study. This study is expected to involve approximately 730 patients and take two to three years to complete. As patient enrollment expands in our Phase 3 trial as modified, our expenses for the manufacturing of Riquent will also increase. Additionally, our research and development expenses may increase significantly if we initiate any additional clinical studies of Riquent or if we increase our activities related to the development of additional drug candidates.

*General and Administrative Expense.* Our general and administrative expense increased to \$9.3 million for the year ended December 31, 2006 from \$5.4 million in 2005. The increase in general and administrative expense in 2006 from 2005 resulted primarily from share-based compensation expense recorded in connection with the adoption of SFAS 123R of approximately \$3.2 million. The increase was also due to the expense recorded in the first quarter of 2006 for severance paid to the former Chairman and Chief Executive Officer of approximately \$0.9 million and an increase in general corporate consulting and professional outside services of approximately \$0.6 million. These increases were partially offset by a decrease in termination benefits, mainly relating to severance, of approximately \$0.5 million that was recorded in 2005 in connection with the termination of 16 general and administrative personnel, and the savings in salaries and related expenses as a result of this reduction in personnel.

Our general and administrative expense decreased to \$5.4 million for the year ended December 31, 2005 from \$7.6 million in 2004. The decrease in general and administrative expense in 2005 from 2004 resulted primarily from a reduction in consulting fees for pre-marketing and other general corporate activities of approximately \$2.5 million. This decrease was partially offset by the termination benefits recorded in connection with the March 2005 restructuring noted above.

General and administrative expense will increase in the future to support our ongoing clinical trials as patient enrollment and the manufacturing of Riquent increases. Additionally, general and administrative expense may increase in the future if there is an increase in research and development or commercialization activities.

*Interest Income and Expense.* Our interest income increased to \$2.8 million for the year ended December 31, 2006 from \$0.8 million in 2005. The increase in interest income in 2006 was due to higher average balances of cash and short-term investments and higher average interest rates on our investments as compared to 2005. Our interest income increased to \$0.8 million for the year ended December 31, 2005 from \$0.4 million for 2004 due to higher average interest rates on our investments and higher average balances of cash and short-term investments as compared to 2004.

Interest expense was comparable for the years ended December 31, 2006 and December 31, 2005. Interest expense decreased to \$0.1 million for the year ended December 31, 2005 from \$0.2 million in 2004. The decrease in interest expense in 2005 as compared to 2004 was due to lower principal balances on outstanding notes payable obligations because there were no new debt obligations entered into in 2005.

*Net Operating Loss and Research Tax Credit Carryforwards.* As of December 31, 2006, we had available net operating loss carryforwards and research tax credit carryforwards of approximately \$275.4 million and \$14.0 million, respectively, for federal income tax purposes, which will begin to expire in 2007. Approximately \$3.1 million of the federal net operating loss carryforward expired in 2006 and approximately \$0.1 million of the federal research tax credit carryforward expired in 2006. In addition, approximately \$4.6 million of the federal net operating loss carryforwards will begin to expire in 2007 unless utilized and approximately \$0.3 million of the federal research tax credit carryforwards will begin to expire in 2007.





**Table of Contents**

unless utilized. As of December 31, 2006, we had available net operating loss carryforwards and research tax credit carryforwards of approximately \$144.3 million and \$7.8 million, respectively, for California income tax purposes, which will begin to expire in 2009 unless utilized. Approximately \$0.3 million of the California net operating loss carryforward is set to expire in 2009 unless utilized. Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our net operating loss and research tax credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within a three-year period.

**Liquidity and Capital Resources**

From inception through December 31, 2006, we have incurred a cumulative net loss of approximately \$299.8 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, 2006, we had raised \$337.0 million in net proceeds from sales of equity securities.

As of December 31, 2006, we had \$42.9 million in cash, cash equivalents and short-term investments, as compared to \$72.9 million as of December 31, 2005. Our working capital as of December 31, 2006 was \$37.7 million, as compared to \$70.1 million as of December 31, 2005. The decrease in cash, cash equivalents and short-term investments resulted from the use of our financial resources to fund our manufacturing and clinical trial activities, research and development efforts, and for other general corporate purposes. We invest our cash in United States government-backed securities, debt instruments of entities with strong credit ratings and money market funds. As of December 31, 2006, we classified all of our investments 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, 2006, available-for-sale securities and cash equivalents of \$14.2 million have stated maturity dates of one year or less and \$27.1 million have maturity dates 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, 2006, approximately \$1.1 million of equipment (\$0.5 million net of depreciation) is financed under notes payable obligations. In December 2006, we entered into a credit facility to fund equipment purchases up to \$1.8 million until the end of the second quarter of 2008. In addition, we lease our office and laboratory facilities and certain equipment under operating leases. We have also entered into non-cancelable purchase commitments for an aggregate of \$2.8 million with third-party manufacturers of materials to be used in the production of Riquent. We intend to use our current financial resources to fund our obligations under these purchase commitments. In the future, we may increase our investments in property and equipment if we expand our research and development and manufacturing facilities and capabilities.

The following table summarizes our contractual obligations as of December 31, 2006. Long-term debt obligations include interest.

	Total	Payment due by period (in thousands)			More than 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
Long-term debt obligations	\$ 433	\$ 209	\$ 224	\$	\$
Operating lease obligations	2,292	801	1,474	17	
Purchase obligations	2,856	2,856			
Total	\$5,581	\$3,866	\$1,698	\$ 17	\$

We intend to use our financial resources to fund the current clinical studies of Riquent, possible future clinical trials, manufacturing activities, research and development efforts and for working capital and other general corporate purposes. The amounts that we actually spend for each purpose may vary significantly depending on a number of factors, including the results from current and future clinical trials, the continued analysis of the clinical trial data of Riquent, the outcome of our meetings with regulatory authorities, the timing of any regulatory applications and

approvals, and technological developments. Expenditures also will depend on any establishment of collaborative arrangements and contract research as well as the availability of other funding or financings.

We anticipate that our existing cash, cash investments and the interest earned thereon, will be sufficient to fund our operations as currently planned through at least December 31, 2007. This projection is based on the assumption that we do not raise any additional funds, either through the sale of additional securities or a collaborative agreement with a

**Table of Contents**

corporate partner and that we do not engage in any significant commercialization activities or significant activities in our other research programs. We will continually evaluate our planned activities. If we do not raise any additional funds in 2007, we may take one or more significant cost reducing measures including reducing our workforce and/or suspending the enrollment of additional patients into the current Phase 3 trial. Any significant change in our planned activities or in the assumptions underlying our cash projection referred to above could result in a change to such cash projection.

We have no current means of generating cash flow from operations. Our lead drug candidate, Riquent, will not generate revenues, if at all, until it has received regulatory approval and has been successfully manufactured, marketed and sold. This process, if completed, will take a significant amount of time. Our other drug candidates are much less developed than Riquent. There can be no assurance that our product development efforts with respect to Riquent or any other drug candidate will be successfully completed, that required regulatory approvals will be obtained or that any product, if introduced, will be successfully marketed or achieve commercial acceptance. Accordingly, we must continue to rely on outside sources of financing to meet our capital needs for the foreseeable future.

We will continue to seek capital through any number of means, including by issuing our equity securities and by establishing one or more collaborative arrangements. However, there can be no assurance that additional financing will be available to us on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as we continue to use existing resources or if the development of Riquent is delayed or terminated. There is also no assurance that we will be able to enter into further collaborative relationships. In the future, it is possible that we will not have adequate resources to support continuation of our business activities.

**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 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. Although the investment-grade securities that we hold are subject to changes in the financial standing of the issuer of such securities, we do not believe that we are subject to any material risks arising from the maturity dates of the debt instruments or changes in interest rates because the interest rates of the securities in which we invest that have a maturity date greater than one year are reset periodically within time periods not exceeding 92 days. We currently do not invest in any securities that are materially and directly affected by foreign currency exchange rates or commodity prices.

**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-20 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.

**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 Exchange Act)) as of December 31, 2006. Based on this evaluation, our principal executive and principal financial officers concluded that our disclosure controls and procedures were effective as of December 31, 2006.

**Table of Contents**

There was no change in our internal control over financial reporting during the quarter ended December 31, 2006 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, 2006. 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, 2006, 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 and on our assessment of our internal control over financial reporting. The report appears below.

*(c) Report Of Independent Registered Public Accounting Firm On Internal Control Over Financial Reporting*

The Board of Directors and Stockholders

La Jolla Pharmaceutical Company

We have audited management's assessment, included in the accompanying Management Report on Internal Control over Financial Reporting, that La Jolla Pharmaceutical Company maintained effective internal control over financial reporting as of December 31, 2006 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

**Table of Contents**

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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that La Jolla Pharmaceutical Company maintained effective internal control over financial reporting as of December 31, 2006 is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, La Jolla Pharmaceutical Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006 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, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006 of La Jolla Pharmaceutical Company and our report dated March 7, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
March 7, 2007

**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 2007 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2006. Such information is incorporated herein by reference.

We have adopted a code of conduct that applies to our Chief Executive 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](http://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 2007 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2006. 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 2007 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2006. 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 2007 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2006. 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 2007 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2006. Such information is incorporated herein by reference.

**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, 2006 and 2005 F-2

Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004 F-3

Consolidated Statements of Stockholders Equity for the years ended December 31, 2006, 2005 and 2004 F-4

Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004 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.

**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 14, 2007

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 Deirdre Y. Gillespie, M.D.	President, Chief Executive Officer and Assistant Secretary (Principal Executive Officer)	March 14, 2007
/s/ Gail A. Sloan Gail A. Sloan	Vice President of Finance and Secretary (Principal Financial and Accounting Officer)	March 14, 2007
/s/ Thomas H. Adams Thomas H. Adams, Ph.D.	Director	March 14, 2007
/s/ Robert A. Fildes Robert A. Fildes, Ph.D.	Director	March 14, 2007
/s/ Stephen M. Martin Stephen M. Martin	Director	March 14, 2007
/s/ Nader J. Naini Nader J. Naini	Director	March 14, 2007
/s/ Craig R. Smith Craig R. Smith, M.D.	Director	March 14, 2007
/s/ Martin Sutter Martin Sutter	Director	March 14, 2007



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

/s/ James N. Topper

Director

March 14, 2007

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

/s/ Frank E. Young

Director

March 14, 2007

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

**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, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006. Our audits also include the financial statement schedule listed in the Index at Item 15(a). 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, La Jolla Pharmaceutical Company changed its method of accounting for Share-Based Payments in accordance with Statement of Financial Accounting Standards No. 123R (revised 2004) effective January 1, 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of La Jolla Pharmaceutical Company's internal control over financial reporting as of December 31, 2006, 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 7, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
March 7, 2007

F-1

---

**Table of Contents**

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,829	\$ 6,411
Short-term investments	39,080	66,466
Prepays and other current assets	1,004	903
 Total current assets	 43,913	 73,780
 Property and equipment, net	 2,333	 4,037
Patent costs and other assets, net	3,279	3,111
	 \$ 49,525	 \$ 80,928
 <b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,125	\$ 866
Accrued clinical/regulatory expenses	1,530	227
Accrued expenses	1,137	1,284
Accrued payroll and related expenses	1,265	778
Current portion of obligations under notes payable	183	501
 Total current liabilities	 6,240	 3,656
 Non-current portion of obligations under notes payable	 196	 142
 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, 32,692,676 and 32,533,047 shares issued and outstanding at December 31, 2006 and 2005, respectively	327	325
Additional paid-in capital	342,519	337,117
Accumulated deficit	(299,757)	(260,312)
 Total stockholders equity	 43,089	 77,130
	 \$ 49,525	 \$ 80,928

*See accompanying notes.*



**Table of Contents**

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

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Expenses:			
Research and development	\$ 32,938	\$ 22,598	\$ 33,169
General and administrative	9,287	5,405	7,568
 Total expenses	 42,225	 28,003	 40,737
 Loss from operations	 (42,225)	 (28,003)	 (40,737)
Interest expense	(46)	(116)	(190)
Interest income	2,826	756	383
 Net loss	 \$(39,445)	 \$(27,363)	 \$(40,544)
 Basic and diluted net loss per share	 \$ (1.21)	 \$ (1.77)	 \$ (3.40)
 Shares used in computing basic and diluted net loss per share (1)	 32,588	 15,446	 11,941

*See accompanying notes.*

- (1) On December 21, 2005, the Company effected a one-for-five reverse stock split, which has been applied retroactively to all periods presented.

**Table of Contents**

La Jolla Pharmaceutical Company  
 Consolidated Statements of Stockholders Equity  
 (In thousands)  
 For the Years Ended December 31, 2004, 2005 and 2006

	Common stock		Additional paid-in capital	Other comprehensive income (loss)	Accumulated deficit	Total stockholders equity
	Shares	Amount				
Balance at December 31, 2003	10,225	\$102	\$228,803	\$ (73)	\$(192,405)	\$ 36,427
Issuance of common stock, net	2,000	20	29,343			29,363
Issuance of common stock under Employee Stock Purchase Plan	76	1	574			575
Exercise of stock options	1		12			12
Share-based compensation expense			118			118
Net loss					(40,544)	(40,544)
Net unrealized gains on available-for-sale securities				50		50
Comprehensive loss						(40,494)
Balance at December 31, 2004	12,302	123	258,850	(23)	(232,949)	26,001
Issuance of common stock, net	20,050	200	77,955			78,155
Issuance of common stock under Employee Stock Purchase Plan	95	1	287			288
Exercise of stock options	3		6			6
Share-based compensation expense	83	1	19			20
Net loss					(27,363)	(27,363)
Net unrealized gains on available-for-sale securities				23		23
Comprehensive loss						(27,340)
Balance at December 31, 2005	32,533	325	337,117		(260,312)	77,130
Issuance of common stock under Employee Stock Purchase Plan	80	1	226			227

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

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

*See accompanying notes.*

F-4

---

**Table of Contents**

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

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Operating activities</b>			
Net loss	\$(39,445)	\$(27,363)	\$(40,544)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	1,987	2,109	2,083
Loss on write-off/disposal of patents, licenses and property and equipment	420	405	198
Share-based compensation expense	5,051	20	118
Accretion of interest income, net	36	(125)	26
Changes in operating assets and liabilities:			
Prepays and other current assets	(101)	(120)	174
Accrued clinical/regulatory expenses	1,303	(420)	123
Accounts payable and accrued expenses	1,112	(1,366)	2,373
Accrued payroll and related expenses	487	(432)	(482)
Net cash used for operating activities	(29,150)	(27,292)	(35,931)
<b>Investing activities</b>			
Purchases of short-term investments	(16,700)	(82,350)	(37,365)
Sales of short-term investments	44,050	36,236	45,297
Additions to property and equipment	(335)	(123)	(1,882)
Increase in patent costs and other assets	(536)	(361)	(723)
Net cash provided by (used for) investing activities	26,479	(46,598)	5,327
<b>Financing activities</b>			
Net proceeds from issuance of common stock	353	78,449	29,950
Proceeds from issuance of notes payable	263		478
Payments on obligations under notes payable	(527)	(995)	(903)
Payments on obligations under capital leases		(14)	(81)
Net cash provided by financing activities	89	77,440	29,444
(Decrease) increase in cash and cash equivalents	(2,582)	3,550	(1,160)
Cash and cash equivalents at beginning of period	6,411	2,861	4,021
Cash and cash equivalents at end of period	\$ 3,829	\$ 6,411	\$ 2,861
<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	\$ 46	\$ 116	\$ 190



*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**

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. The Company is actively seeking additional funding, including through collaborative arrangements and through the public and/or private financings, to finance its continuing development efforts and to commercialize its technologies. The Company believes that additional funds can be obtained in the near future; however, there is no assurance such funds will be available to the Company when needed or that such funds would be available under favorable terms. In the event that the Company cannot obtain additional funds in the near future, the Company has indicated its ability and intent to cut back on certain expenditures and/or reduce its operations, which could have an impact on completing its development efforts in a timely manner. The Company believes that it has the ability to manage its working capital to fund the Company's operations through at least December 31, 2007.

**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 (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosures made in the accompanying notes to the consolidated financial statements. Actual results could differ materially from those estimates.

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

Cash and cash equivalents consist of cash and 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 market. 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 (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, management has classified the Company's cash equivalents and short-term investments as available-for-sale securities in the accompanying consolidated financial statements. Available-for-sale securities are stated at fair market value, with unrealized gains and losses reported in other comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in interest income and have been immaterial for each of the years presented. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

**Fair Value of Financial Instruments**

Financial instruments, including cash and cash equivalents, accounts payable and accrued expenses, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments. Short-term investments are carried at fair value. None of the Company's debt instruments that were outstanding at December 31, 2006 have readily ascertainable market values; however, the carrying values are considered to approximate their fair values.

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**1. Organization and Summary of Significant Accounting Policies (continued)****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 in United States government-backed securities, debt instruments of entities that it believes have strong credit ratings and money market funds. The Company has established guidelines relative to the diversification of its cash investments and their maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. To date, the Company has not experienced any impairment losses on its cash, cash equivalents and short-term investments.

**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. Although the Company believes its current and historical operating and cash flow losses are indicators of impairment, the Company believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value. The Company has recognized approximately \$0.1 million in impairment losses for each of the years ended December 31, 2006 and 2005.

**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,	
	2006	2005
Laboratory equipment	\$ 6,347	\$ 6,477
Computer equipment and software	4,682	4,825
Furniture and fixtures	488	473
Leasehold improvements	3,268	3,184
	14,785	14,959
Less: Accumulated depreciation	(12,452)	(10,922)
	\$ 2,333	\$ 4,037

Depreciation expense for the years ended December 31, 2006, 2005 and 2004 was \$1,840,000, \$1,991,000, and \$1,978,000, respectively.

**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 successful patent applications 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 successful patent application costs and accumulated amortization were \$2,102,000 and  
F-7

---

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

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

\$734,000 at December 31, 2006 and \$1,733,000 and \$652,000 at December 31, 2005, respectively. Total pending patent application costs were \$1,761,000 and \$1,915,000 at December 31, 2006 and 2005, respectively. Capitalized costs related to patent applications are charged to operations at the time a determination is made not to pursue such applications. Amortization expense for the years ended December 31, 2006, 2005 and 2004 was \$139,000, \$107,000, and \$94,000, respectively. The expected future annual amortization expense of successful patent applications for each of the succeeding five years is estimated to be approximately \$167,000.

**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; however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to the Company's results of operations.

**Share-Based Compensation**

On January 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment* ( SFAS 123R ), which is a revision of SFAS No. 123, *Accounting and Disclosure of Stock-Based Compensation* ( SFAS 123 ). SFAS 123R requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including stock options, restricted stock and purchases under the La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (the ESPP ), based on estimated fair values. SFAS 123R supersedes the Company's previous accounting under Accounting Principles Board Opinion ( APB ) No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ), and SFAS 123, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission ( SEC ) issued Staff Accounting Bulletin ( SAB ) No. 107 ( SAB 107 ), which discusses the interaction between SFAS 123R and certain SEC rules and regulations and provides the SEC's staff views regarding the valuation of share-based payment arrangements for public companies. The Company has applied the provisions of SAB 107, related to the calculation of its expected term, in its adoption of SFAS 123R.

The Company adopted SFAS 123R using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year 2006. The Company's Consolidated Statement of Operations as of and for the year ended December 31, 2006 reflects the impact of SFAS 123R. In accordance with the modified prospective transition method, the Company's Consolidated Statements of Operations for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123R.

Share-based compensation expense recognized under SFAS 123R for the year ended December 31, 2006 was approximately \$5,048,000. As of December 31, 2006, there was approximately \$8,120,000 of total unrecognized compensation cost related to non-vested share-based payment awards granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize that cost over a weighted-average period of 1.2 years.

Prior to January 1, 2006, the Company had adopted the disclosure-only provision of SFAS 123. Accordingly, the Company had not previously recognized compensation expense, except for compensation expense related to stock options granted to consultants and restricted stock granted to certain members of management.

Options or stock awards issued to non-employees, other than non-employee directors, have 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 January 2006 and January 2005,

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

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

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 each grant. The Company recognized compensation expense for these stock option grants of approximately \$3,000 and \$8,000 for the years ended December 31, 2006 and 2005, respectively.

The table below reflects net loss (in thousands) and basic and diluted net loss per share for the years ended December 31, 2005 and 2004 assuming the Company determined compensation expense in accordance with SFAS 123:

	<b>Year Ended December 31, 2005</b>	<b>Year Ended December 31, 2004</b>
Net loss as reported	\$(27,363)	\$ (40,544)
Net loss pro forma	\$(31,206)	\$ (47,439)
Basic and diluted net loss per share as reported	\$ (1.77)	\$ (3.40)
Basic and diluted net loss per share pro forma	\$ (2.02)	\$ (3.97)

The assumptions used to calculate share-based compensation expense for 2005 and 2004 are discussed below. SFAS 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods as share-based compensation expense in the Company's Consolidated Statements of Operations. For the year ended December 31, 2006, the Company's Consolidated Statement of Operations included compensation expense for share-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Compensation expense for all share-based payment awards granted prior to the adoption of SFAS 123R will continue to be recognized using the straight-line single-option method of attributing the value of share-based compensation to expense. Compensation expense for all share-based payment awards granted after December 31, 2005 is recognized using the straight-line single-option method. As share-based compensation expense recognized in the Consolidated Statement of Operations for the fiscal year 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. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

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. 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 the Company have characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, in management's opinion the existing valuation models may not provide an accurate measure of the fair value of the employee and director stock options granted by the Company. Although the fair value of the employee and director stock options granted by the Company 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.

F-9

---

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**1. Organization and Summary of Significant Accounting Policies (continued)****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 year ended December 31, 2006:

	<b>Year Ended December 31, 2006</b>
Research and development	\$ 1,833
General and administrative	3,215
Share-based compensation expense included in operating expenses	\$ 5,048

For the years ended December 31, 2006, 2005, and 2004 the Company estimated the fair value of each option grant and ESPP purchase right on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

*Options:*

	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Risk-free interest rate	4.8%	4.1%	3.9%
Dividend yield	0.0%	0.0%	0.0%
Volatility	113.7%	119.0%	127.9%
Expected life (years)	5.9	5.9	5.9

*ESPP:*

	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Risk-free interest rate	4.8%	4.1%	3.4%
Dividend yield	0.0%	0.0%	0.0%
Volatility	46.4%	125.4%	129.1%
Expected life (years)	3 months	5.9	5.9

The weighted-average fair values of options granted were \$3.92, \$2.81 and \$13.24 for the years ended December 31, 2006, 2005 and 2004, respectively. The weighted-average purchase prices of shares purchased through the ESPP were \$2.98, \$3.04 and \$7.57 for the years ended December 31, 2006, 2005 and 2004, 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. Prior to fiscal 2006, the Company used its historical stock price volatility in accordance with SFAS 123 for purposes of its pro forma information. 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 the SAB 107 simplified method, the expected life calculated by the





**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

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

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 year ended December 31, 2006. Prior to the adoption of SFAS 123R on January 1, 2006, the Company utilized an estimate of expected life for ESPP that was consistent with its estimate for options.

Because share-based compensation expense recognized in the Consolidated Statement of Operations for fiscal year 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. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

**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 will vest with respect to the remaining 10,000 shares upon the first anniversary of the issuance date. On September 15, 2006, the vesting provisions with respect to 10,000 shares of restricted stock were met and therefore the Company's repurchase rights lapsed.

In December 2006, 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. All of these additional shares of restricted stock immediately vested on the date of issuance.

In accordance with SFAS 123R, the Company recognized approximately \$381,000 in compensation expense for the restricted stock grants noted above for the year ended December 31, 2006, which includes compensation expense for the acceleration of vesting.

**Reverse Stock Split**

On December 12, 2005, the Company's stockholders approved a one-for-five reverse stock split of the Company's common stock, effective as of the close of business on December 21, 2005. All share and per share figures presented herein have been adjusted to reflect the reverse stock split, except for shares of authorized common stock.

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

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

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. The number of weighted-average unvested common shares subject to repurchase for the years ended December 31, 2006 and December 31, 2005 were 8,000 and 4,119, respectively. There were no unvested common shares subject to repurchase for the year ended December 31, 2004.

**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 (loss).

**Recently Issued Accounting Standards**

On January 1, 2006, the Company adopted SFAS No. 154, *Accounting Changes and Error Corrections a replacement of APB Opinion No. 20 and FASB Statement No. 3* (SFAS 154). SFAS 154 changed the requirements for the accounting for and reporting of a change in accounting principle. SFAS 154 applies to all voluntary changes in accounting principles and changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition methods. The adoption of SFAS 154 did not affect the Company's consolidated results of operations and financial condition as of and for the year ended December 31, 2006. Its effects on future periods will depend on the nature and significance of any future accounting changes subject to SFAS 154. In June 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN 48 provides guidance on the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted by the Company in fiscal 2007. The Company is currently evaluating the impact of this standard on its consolidated results of operations and financial condition.

In September 2006, the Securities and Exchange Commission issued SAB No. 108 (SAB 108). SAB 108 addresses the process and diversity in practice of quantifying financial statement misstatements resulting in the potential build up of improper amounts on the balance sheet. SAB 108 is effective for annual periods ending after November 15, 2006. The adoption of SAB 108 did not have a material effect on the Company's consolidated results of operations and financial position as of and for the year ended December 31, 2006.

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

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

In September 2006, FASB issued SFAS No. 157, *Fair Value Measurements* ( 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. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company does not currently believe that the adoption of SFAS 157 will have a material impact on its consolidated results of operations and financial condition.

In February 2007, FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* ( SFAS 159 ). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact of SFAS 159 on its consolidated results of operations and financial condition.

**2. Cash Equivalents and Short-term Investments**

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>December 31, 2006</b>				
Money market accounts	\$ 2,189	\$	\$	\$ 2,189
United States corporate debt securities	12,024			12,024
Government-asset-backed securities	27,056			27,056
	\$41,269	\$	\$	\$ 41,269

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>December 31, 2005</b>				
Money market accounts	\$ 5,337	\$	\$	\$ 5,337
United States corporate debt securities	12,821			12,821
Government-asset-backed securities	53,645			53,645
	\$71,803	\$	\$	\$ 71,803

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, 2006 and 2005 were \$2,189,000 and \$5,337,000, 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, 2006, available-for-sale securities and cash equivalents of \$14,213,000 mature in one year or less and \$27,056,000 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.

### **3. 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.

F-13

---

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**3. Commitments (continued)**

In September 2002, the Company entered into an additional non-cancelable operating lease for additional research space. In July 2006, the Company extended the term of this lease until December 2006. This lease expired on December 31, 2006.

In July 2003, the Company entered into a capital lease agreement for \$111,000 to finance the purchase of certain equipment. The agreement was secured by the equipment, bore interest at 7.00% per annum, and was payable in quarterly installments of principal and interest of approximately \$15,000 for eight quarters. The final quarterly installment was made in March 2005.

Annual future minimum lease payments as of December 31, 2006 are as follows (in thousands):

Years ended December 31,	Operating Leases
2007	\$ 801
2008	898
2009	542
2010	34
2011 and there-after	17
Total	\$ 2,292

**Purchase Obligations**

As of December 31, 2006, the Company had total purchase obligations of approximately \$2,856,000, which primarily 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, 2006, approximately \$964,000 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.

Rent expense under all operating leases totaled \$1,065,000, \$1,046,000 and \$1,205,000 for the years ended December 31, 2006, 2005 and 2004, respectively. There was no equipment under capital leases included in property and equipment as of December 31, 2006 or 2005.

**4. Long-Term Debt**

The following is a summary of the notes payable obligations that are secured by the financed equipment of approximately \$1,062,000 as of December 31, 2006:

Date of Note	Interest Rate (%)	Monthly Payments	Original Note Amount (in thousands)
September 26, 2003	8.27	\$4,000 for 42 months	\$ 150
December 18, 2003	8.27	\$2,000 for 42 months	83
March 31, 2004	8.27	First 36 months at \$5,000; last six months at \$4,000	189
June 25, 2004	8.77	First 36 months at \$4,000; last six months at \$2,000	132
September 28, 2004	8.44	First 36 months at \$5,000; last six months at \$1,000	157
December 28, 2006	10.56	First 36 months at \$8,000; last 12 months at \$3,000	263

\$ 974

Annual future minimum notes payable payments as of December 31, 2006 are as follows (in thousands):

<b>Years ended December 31,</b>	<b>Notes Payable</b>
2007	\$ 209
2008	94
2009	92
2010	38
Total	433
Less amount representing interest	(54)
Present value of net minimum notes payable payments	379
Less current portion	(183)
Noncurrent portion of notes payable	\$ 196

F-14

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**5. Restructuring Charges**

In March 2005, the Company restructured its operations in order to reduce costs. In accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, the Company recorded total restructuring charges of approximately \$1,488,000 in connection with the termination of 60 employees (approximately \$1,174,000), the impairment of certain long-term assets (approximately \$152,000), and retention payments for key executives (approximately \$162,000). This action followed an announcement by the Company in March 2005 that, based on the outcome of a meeting with the FDA, the Company's lead drug candidate, Riquent, was unlikely to receive accelerated approval under the FDA's Subpart H regulation.

In fiscal 2005, approximately \$991,000 of the total restructuring charges was included in research and development expense and approximately \$497,000 was included in general and administrative expense. The restructuring plan was completed in September 2005 and actual total charges paid were approximately \$1,336,000. The non-cash charge of \$152,000 for write-downs of impaired assets as a result of the restructuring was included in research and development expense in the first quarter of 2005.

**6. Stockholders' Equity**

**Preferred Stock**

As of December 31, 2006, 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 100,000 shares of preferred stock as nonredeemable Series A Junior Participating Preferred Stock (Series A Preferred Stock). 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 \$1,000 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 1,000 votes, subject to adjustments. Cumulative quarterly dividends of the greater of \$0.25 or, subject to certain adjustments, 1,000 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.

**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. As of December 31, 2006, all of the warrants were outstanding and 4,399,992 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 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.



**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**6. Stockholders Equity (continued)**

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 will vest with respect to the remaining 10,000 shares upon the first anniversary of the issuance date. On September 15, 2006, the vesting provisions with respect to 10,000 shares of restricted stock were met and therefore the Company's repurchase rights lapsed.

In December 2006, 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. All of these additional shares of restricted stock immediately vested on the date of issuance.

In accordance with SFAS 123R, the Company recognized approximately \$381,000 in compensation expense for the restricted stock grants noted above for the year ended December 31, 2006, which includes compensation expense for the acceleration of vesting.

In addition, 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 1994 Plan ) 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 1,109,329 options outstanding under the 1994 Plan as of December 31, 2006.

In May 2004, the Company adopted the La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (the 2004 Plan ) under which, as amended, 4,160,000 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, 2006, there were a total of 3,193,050 options outstanding and 10,000 unvested shares of restricted stock granted under the 2004 Plan and 855,285 shares remained available for future grant.

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**6. Stockholders Equity (continued)**

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

	Options Available  For Grant	Outstanding Options	
		Number of Shares	Weighted- Average Exercise Price
Balance at December 31, 2003	76,376	1,495,243	\$ 23.96
Additional shares authorized	400,000		
Granted	(361,929)	361,929	\$ 14.83
Exercised		(972)	\$ 12.41
Cancelled	60,698	(60,698)	\$ 21.32
Expired	(44,020)		
Balance at December 31, 2004	131,125	1,795,502	\$ 22.22
Additional shares authorized	3,760,000		
Granted	(743,981)	743,981	\$ 3.35
Restricted stock granted	(83,518)		
Exercised		(3,106)	\$ 2.37
Cancelled	388,349	(388,349)	\$ 20.15
Expired	(261,744)		
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
Expired	(100,983)		
Balance at December 31, 2006	855,285	4,302,379	\$ 9.83

As of December 31, 2006, options exercisable have a weighted-average remaining contractual term of 6.3 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, 2006, 2005, and 2004 was \$74,000, \$5,000 and \$4,000, respectively. As of December 31, 2006 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 \$245,000 and \$187,000, respectively.

	Years Ended December 31,					
	2006		2005		2004	
	Options	Weighted- Average Exercise Price	Options	Weighted- Average Exercise Price	Options	Weighted- Average Exercise Price
Exercisable at end of year	1,859,139	\$ 16.27	1,276,090	\$ 22.24	1,213,889	\$ 24.25
	\$ 3.92		\$ 2.81		\$ 13.24	

Weighted-average fair  
value of options granted  
during the year

F-17

---

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**6. Stockholders Equity (continued)**

Exercise prices and weighted-average remaining contractual lives for the options outstanding (excluding shares of restricted stock) as of December 31, 2006 were:

Options Outstanding	Range of Exercise Prices	Weighted- Average Remaining Contractual Life (in years)	Weighted- Average Exercise Price	Options Exercisable	Weighted- Average Exercise Price of Options Exercisable
421,323	\$ 1.72 \$ 3.23	7.81	\$ 2.49	258,567	\$ 2.31
407,300	\$ 3.25 \$ 3.99	9.43	\$ 3.78	21,500	\$ 3.40
360,809	\$ 4.03 \$ 4.30	8.78	\$ 4.20	217,096	\$ 4.20
1,086,647	\$ 4.46	9.29	\$ 4.46	249,703	\$ 4.46
811,500	\$ 4.90 \$ 5.26	9.20	\$ 5.26		\$
362,552	\$ 5.38 \$15.75	6.39	\$14.32	264,986	\$14.23
441,396	\$ 15.95 \$25.45	4.58	\$22.12	436,435	\$22.15
410,852	\$ 25.65 \$60.31	4.79	\$34.35	410,852	\$34.35
4,302,379	\$ 1.72 \$60.31	7.94	\$ 9.83	1,859,139	\$16.27

At December 31, 2006, the Company has reserved 5,157,664 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, 600,000 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, 2006 and 2005, 80,017 and 94,650 shares of common stock were issued under the ESPP, respectively. As of December 31, 2006, 431,982 shares of common stock have been issued under the ESPP and 168,018 shares of common stock are available for future issuance.

	Years Ended December 31,		
	2006	2005	2004
Weighted-average fair value of Employee Stock Purchase Plan purchases	\$2.98	\$3.04	\$7.57

**Stockholder Rights Plan**

The Company has adopted a Stockholder Rights Plan (the "Rights Plan"), which was amended in July 2000, December 2005 and March 2006. 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 State of Wisconsin Investment Board, 20% or more, Essex Woodland Health Ventures Fund V, L.P., 29% or more, Frazier Healthcare V, L.P., 19% or more, or Alejandro Gonzalez, 19% or more), the Rights permit the holders (other than the 15% holder, or, in the case of State of Wisconsin Investment Board, 20% holder, Essex Woodland Health Ventures Fund V, L.P., 29% holder, Frazier Healthcare V, L.P., 19% holder, or Alejandro Gonzalez, 19% holder) 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, 2008.

F-18

---

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**7. 401(k) Plan**

The Company has established a 401(k) defined contribution retirement plan (the 401(k) 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.

**8. Income Taxes**

At December 31, 2006, the Company had federal and California income tax net operating loss carryforwards of approximately \$275,445,000 and \$144,337,000, 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. The Company also had federal and California research tax credit carryforwards of approximately \$14,033,000 and \$7,795,000, respectively. The federal net operating loss and research tax credit carryforwards will continue to expire through 2026 unless previously utilized. The California net operating loss will begin to expire in 2009 unless previously utilized.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of the Company's net operating loss and research tax credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within a three-year period.

Significant components of the Company's deferred tax assets are shown below (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 104,705	\$ 92,892
Research and development credits	19,100	17,033
Capitalized research and development	7,691	5,558
Total deferred tax assets	131,496	115,483
Net deferred tax assets	131,496	115,483
Valuation allowance for deferred tax assets	(131,496)	(115,483)
Net deferred taxes	\$	\$

Significant components of the Company's deferred tax assets as of December 31, 2006 and 2005 relate primarily to its net operating loss and tax credit carry-forwards. A valuation allowance of \$131,496,000 and \$115,483,000 as of December 31, 2006 and 2005, respectively, have been recognized to offset the deferred tax assets as realization of such assets is uncertain.

**Table of Contents**

La Jolla Pharmaceutical Company  
Notes to Consolidated Financial Statements

**9. Selected Quarterly Financial Data (unaudited)**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2006 and 2005 (in thousands except per share amounts):

	Mar. 31,	Quarters Ended		Dec. 31,
		Jun. 30,	Sept. 30,	
<b>2006</b>				
Expenses:				
Research and development	\$ 7,890	\$ 8,187	\$ 7,687	\$ 9,174
General and administrative	3,725	1,900	1,546	2,116
Loss from operations	(11,615)	(10,087)	(9,233)	(11,290)
Interest income, net	747	742	695	596
Net loss	\$(10,868)	\$ (9,345)	\$ (8,538)	\$(10,694)
Basic and diluted net loss per share	\$ (0.33)	\$ (0.29)	\$ (0.26)	\$ (0.33)
Shares used in computing basic and diluted net loss per share	32,480	32,503	32,534	32,660
<b>2005</b>				
Expenses:				
Research and development	\$ 7,348	\$ 5,182	\$ 4,969	\$ 5,099
General and administrative	1,908	1,235	1,081	1,181
Loss from operations	(9,256)	(6,417)	(6,050)	(6,280)
Interest (expense) income, net	114	163	123	240
Net loss	\$ (9,142)	\$ (6,254)	\$ (5,927)	\$ (6,040)
Basic and diluted net loss per share	\$ (0.66)	\$ (0.42)	\$ (0.40)	\$ (0.33)
Shares used in computing basic and diluted net loss per share (1)	13,881	14,781	14,808	18,274

(1)

Shares have been adjusted to reflect the one-for-five reverse stock split effective December 21, 2005.

F-20

---



**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (2)
3.3	Form of Common Stock Certificate (3)
4.1	Rights Agreement, dated as of December 3, 1998, between the Company and American Stock Transfer & Trust Company (4)
4.2	Amendment No. 1 to the Rights Agreement, dated as of July 21, 2000, between the Company and American Stock Transfer & Trust Company (5)
4.3	Amendment No. 2 to the Rights Agreement, dated as of December 14, 2005, between the Company and American Stock Transfer & Trust Company (6)
4.4	Amendment No. 3 to the Rights Agreement, dated as of March 1, 2006, between the Company and American Stock Transfer & Trust Company (1)
10.1	Form of Indemnification Agreement (7)*
10.2	Industrial Real Estate Lease, effective July 27, 1992, by and between the Company and BRE Properties, Inc. (8)
10.3	First Amendment to Lease, dated March 15, 1993, by and between the Company and BRE Properties, Inc. (8)
10.4	Second Amendment to Lease, dated July 18, 1994, by and between the Company and BRE Properties, Inc. (9)
10.5	Third Amendment to Lease, dated January 26, 1995, by and between the Company and BRE Properties, Inc. (10)
10.6	Fourth Amendment to Lease, dated July 8, 2004, by and between the Company and EOP-Industrial Portfolio, LLC (11)
10.7	Building Lease Agreement, effective November 1, 1996, by and between the Company and WCB II-S BRD Limited Partnership (12)
10.8	First Amendment to Lease, dated May 4, 2001, by and between the Company and Spieker Properties, L.P. (11)
10.9	Second Amendment to Lease, dated July 8, 2004, by and between the Company and EOP-Industrial Portfolio, LLC (11)
10.10	La Jolla Pharmaceutical Company 1994 Stock Incentive Plan (Amended and Restated as of May 16, 2003) (13)*

10.11	La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (Amended and Restated as of May 18, 2006) (33)*
10.12	La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (31)*
10.13	Form of Option Grant under the La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (15)*
10.14	Reserved.

---

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.15	Reserved.
10.16	Steven B. Engle Employment Agreement (8)*
10.17	Amendment No. 1 to Steven B. Engle Employment Agreement (16)*
10.18	Amendment No. 2 to Steven B. Engle Employment Agreement (17)*
10.19	Amendment No. 3 to Steven B. Engle Employment Agreement (13)*
10.20	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Matthew Linnik, Ph.D. (1)*
10.21	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Bruce Bennett, Jr. (1)*
10.22	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Josefina Elchico (1)*
10.23	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Paul Jenn, Ph.D. (1)*
10.24	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Theodora Reilly (1)*
10.25	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Gail Sloan (1)*
10.26	Supplement to employment offer letter for Kenneth R. Heilbrunn (18)*
10.27	Retention Agreement, dated October 6, 2005, by and between the Company and Steven B. Engle (19)*
10.28	Retention Agreement, dated October 6, 2005, by and between the Company and Matthew Linnik, Ph.D. (19)*
10.29	Retention Agreement, dated October 6, 2005, by and between the Company and Bruce Bennett (19)*
10.30	Retention Agreement, dated October 6, 2005, by and between the Company and Josefina T. Elchico (19)*
10.31	Retention Agreement, dated October 6, 2005, by and between the Company and Paul Jenn, Ph.D. (19)*
10.32	

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

Retention Agreement, dated October 6, 2005, by and between the Company and Theodora Reilly (19)\*

10.33 Retention Agreement, dated October 6, 2005, by and between the Company and Gail Sloan (19)\*

10.34 Retention Agreement, dated October 6, 2005, by and between the Company and Andrew Wiseman, Ph.D. (19)\*

10.35 Retention Agreement, dated October 6, 2005, by and between the Company and Lisa Koch (32)\*

10.36 Underwriting Agreement, dated January 28, 2005, by and between the Company and Pacific Growth Equities, LLC (20)

---

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.37	Underwriting Agreement, dated as of February 19, 2004, between the Company and Pacific Growth Equities, LLC (21)
10.38	Underwriting Agreement, dated as of August 7, 2003, between the Company and Pacific Growth Equities, LLC (22)
10.39	Registration Rights Agreement, dated October 6, 2005, between the Company and the initial purchasers (19)
10.40	Form of Registration Rights Agreement, dated January 2002, between the Company and the initial purchasers (23)
10.41	Form of Registration Rights Agreement, dated February 5, 2001, between the Company and the initial purchasers (24)
10.42	Form of Registration Rights Agreement, dated July 19, 2000, between the Company and the initial purchasers (24)
10.43	Form of Registration Rights Agreement, dated February 10, 2000, between the Company and the initial purchasers (24)
10.44	Securities Purchase Agreement, dated as of October 6, 2005, between the Company and the initial purchasers (19)
10.45	Form of Stock Purchase Agreement, dated January 2002, between the Company and the initial purchasers (23)
10.46	Form of Stock Purchase Agreement, dated February 5, 2001, between the Company and the initial purchasers (24)
10.47	Form of Stock Purchase Agreement, dated July 19, 2000, between the Company and the initial purchasers (24)
10.48	Form of Stock Purchase Agreement, dated February 10, 2000, between the Company and the initial purchasers (24)
10.51	Master Security Agreement, effective as of September 6, 2002, by and between the Company and General Electric Capital Corporation (25)
10.52	Promissory Note, dated as of December 28, 2006, by and between the Company and General Electric Capital Corporation
10.53	Promissory Note, dated as of September 28, 2004, by and between the Company and General Electric Capital Corporation (26)
10.54	Promissory Note, dated as June 25, 2004, between the Company and General Electric Capital Corporation (11)

- 10.55 Promissory Note, dated as March 31, 2004, between the Company and General Electric Capital Corporation (27)
- 10.56 Promissory Note, dated as of December 18, 2003, between the Company and General Electric Capital Corporation (28)
- 10.57 Promissory Note, dated as of September 26, 2003, between the Company and General Electric Capital Corporation (24)
-

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.58	Promissory Note, dated as of June 27, 2003, between the Company and General Electric Capital Corporation (13)
10.59	Promissory Note, dated as of April 23, 2003, between the Company and General Electric Capital Corporation (29)
10.60	Promissory Note, dated as of December 30, 2002, between the Company and General Electric Capital Corporation (29)
10.61	Amendment to Promissory Note, dated as of September 27, 2002, by and between the Company and General Electric Capital Corporation (25)
10.62	Promissory Note, dated as of September 26, 2002, by and between the Company and General Electric Capital Corporation (25)
10.63	Employment Agreement, dated March 15, 2006, by and between the Company and Deirdre Y. Gillespie, M.D. (30)*
10.64	Separation Agreement, dated March 17, 2006, by and between the Company and Steven B. Engle (30)*
10.65	Employment Offer Letter, dated July 10, 2006 and executed July 14, 2006, by and between the Company and Michael Tansey, M.D. (34)*
10.66	Employment Agreement, dated December 4, 2006, by and between the Company and Michael Tansey, M.D.*
21.1	Subsidiaries of La Jolla Pharmaceutical Company (15)
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.

(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  
Registration  
Statement on  
Form 8-A  
(Registration  
No. 000-24274)  
filed December 4,  
1998 and  
incorporated by  
reference herein.
- (5) Previously filed  
with the  
Company's  
Current Report  
on Form 8-K  
filed January 26,  
2001 and



incorporated by reference herein. The changes effected by the Amendment are also reflected in the Amendment to Application for Registration on Form 8-A/A filed on January 26, 2001.

(6) Previously filed with the Company's Current Report on Form 8-K filed December 16, 2005 and incorporated by reference herein.

(7) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005 and incorporated by reference herein.

---

**Table of Contents**

- (8) 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.
  
- (9) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994 and incorporated by reference herein.
  
- (10) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1995 and incorporated by reference herein.
  
- (11) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 and

incorporated by  
reference  
herein.

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

(13) Previously filed  
with the  
Company's  
Quarterly  
Report on Form  
10-Q for the  
quarter ended  
June 30, 2003  
and  
incorporated by  
reference  
herein.

(14) Previously filed  
with the  
Company's  
Current Report  
on Form 8-K  
filed May 20,  
2005 and  
incorporated by  
reference  
herein.

(15) Previously filed  
with the  
Company's  
Annual Report  
on Form 10-K  
for the year  
ended  
December 31,  
2004 and  
incorporated by

reference  
herein.

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

(17) 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.

(18) Previously filed  
with the  
Company's  
Quarterly  
Report on Form  
10-Q for the  
quarter ended  
June 30, 2002  
and  
incorporated by  
reference  
herein.

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

herein.

(20) Previously filed with the Company's Current Report on Form 8-K filed January 28, 2005 and incorporated by reference herein.

(21) Previously filed with the Company's Current Report on Form 8-K filed February 20, 2004 and incorporated by reference herein.

(22) Previously filed with the Company's Current Report on Form 8-K filed August 12, 2003 and incorporated by reference herein.

(23) Previously filed with the Company's Current Report on Form 8-K filed January 16, 2002 and incorporated by reference herein.

(24) Previously filed with the Company's Quarterly

Report on Form  
10-Q for the  
quarter ended  
September 30,  
2003 and  
incorporated by  
reference  
herein.

(25) Previously filed  
with the  
Company's  
Quarterly  
Report on Form  
10-Q for the  
quarter ended  
September 30,  
2002 and  
incorporated by  
reference  
herein.

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

(27) Previously filed  
with the  
Company's  
Quarterly  
Report on Form  
10-Q for the  
quarter ended  
March 31, 2004  
and  
incorporated by  
reference  
herein.

(28) 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.

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

(30) Previously filed  
with the  
Company's  
Current Report  
on Form 8-K  
filed March 20,  
2006 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,  
2005 and  
incorporated by  
reference  
herein.

(32) Previously filed  
with the  
Company's  
Quarterly

Report on Form  
10-Q for the  
quarter ended  
June 30, 2006  
and  
incorporated by  
reference  
herein.

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

(34) Previously filed  
with the  
Company's  
Current Report  
on Form 8-K  
filed July 18,  
2006 and  
incorporated by  
reference  
herein.