Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **DECEMBER 31, 2003**

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	**33-0361285**
(State or Other Jurisdiction of Incorporation of Organization)	(I.R.S. Employer Identification No.)

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:	Common Stock, par value $0.01 per share

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 [X] 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes [X] No [ ]

The aggregate market value of the common stock of the registrant held by non-affiliates as of June 30, 2003 (the last trading day of the second fiscal quarter) was $138,640,756, based on a closing price of $3.25 on the Nasdaq stock market on such date. The number of shares of the registrant's common stock, $0.01 par value per share, outstanding at March 5, 2004 was 61,124,583.

TABLE OF CONTENTS

DOCUMENTS INCORPORATED BY REFERENCE

Part II, Item 5 and Part III of this report incorporate information by reference from the registrant's proxy statement for its annual meeting of stockholders to be held on May 21, 2004, which proxy statement will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2003.

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements including without limitation those dealing with La Jolla Pharmaceutical Company's drug development plans and clinical trials. 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. Although our New Drug Application ("NDA") for Riquent® has been accepted by the United States Food and Drug Administration (the "FDA") for review, there is no guarantee that the FDA will approve Riquent in a timely manner, or at all. Our analyses of clinical results of Riquent, previously known as LJP 394, our drug candidate for the treatment of systemic lupus erythematosus ("SLE" or "lupus"), and LJP 1082, our drug candidate for the treatment of antibody-mediated thrombosis ("thrombosis"), are ongoing and 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 analysis of the data from our 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 to the secondary endpoint, time to treatment with high-dose corticosteroids or cyclophosamide. Although our NDA for Riquent has been accepted for review by the FDA, the results from our clinical trials of Riquent may not ultimately be sufficient to obtain regulatory clearance to market Riquent either in the United States or Europe, and we may be required to conduct additional clinical studies to demonstrate the safety and efficacy of Riquent in order to obtain marketing approval. There is no guarantee, however, that we will have the necessary resources to complete any additional trial, that we will elect to conduct an additional trial, or that any additional trial will sufficiently demonstrate the safety and efficacy of Riquent. Our blood test to measure the binding affinity for Riquent is experimental, has not been validated by independent laboratories and will likely be reviewed as part of the Riquent approval process. Our other potential drug candidates are at earlier stages of development and involve comparable risks. Analysis of our clinical trials could have negative or inconclusive results. Any positive results observed to date may not be indicative of future results. In any event, regulatory authorities may require additional clinical trials, or may not approve our drugs. Our ability to develop and sell our products in the future may be adversely affected by the intellectual property rights of third parties. Additional risk factors include the uncertainty and timing of: obtaining required regulatory approvals, including delays associated with any approvals that we may obtain; the clear need for additional financing; our ability to pass FDA pre-approval inspections of our manufacturing facilities and processes; the increase in capacity of our manufacturing capabilities for possible commercialization; successfully marketing and selling our products; our lack of manufacturing, marketing and sales experience; our ability to make use of the orphan drug designation for Riquent; generating future revenue from product sales or other sources such as collaborative relationships; future profitability; and our dependence on patents and other proprietary 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 heading "Risk Factors"

and elsewhere in this report and in our other reports and registration statements filed with the Securities and Exchange Commission from time to time.

PART I

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

Item 1. Business

Overview

La Jolla Pharmaceutical Company was incorporated in Delaware in 1989. We are a biopharmaceutical company focused on the research and development of highly specific therapeutic products for the treatment of certain life-threatening antibody-mediated diseases. These diseases, including autoimmune conditions such as lupus and antibody-mediated thrombosis, are caused by abnormal B cell production of antibodies that attack healthy tissues. Current treatments for these autoimmune disorders 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 our drug candidates, called Toleragens®, have the potential to treat the underlying cause of many antibody-mediated diseases without these severe, negative side effects.

Recent Developments

We submitted our NDA for Riquent with the FDA on December 14, 2003. In February 2004, our NDA for Riquent was accepted for review by the FDA. The acceptance of the NDA by the FDA indicates that the NDA is sufficiently complete to permit a substantive review of the application. We anticipate that further discussions with the FDA will be needed to determine whether any additional supportive information or studies will be required to support the approval of the NDA. Under the FDA's Subpart H regulation, 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 it is likely that a post-marketing clinical trial can be successfully completed following drug approval which confirms that clinical benefit. The FDA will determine whether to approve Riquent, either on the basis of our clinical trial results or under Subpart H, and the conditions of any approval, after it has reviewed our NDA. We are currently in discussion with the FDA about the design and timing of a post-marketing clinical trial that would be required if Riquent is approved under Subpart H. We are also currently meeting with European regulatory authorities to discuss potential next steps for Riquent in Europe. There can be no guarantee that meetings with the FDA and other regulatory agencies can be held in a timely manner, or at all, or that our meetings with them will result in our being able to continue to develop Riquent. If for any reason our development efforts as to Riquent are terminated, it would have a material adverse effect on our business and future prospects.

The evidence in the NDA supporting the safety and effectiveness of Riquent was derived from 12 clinical trials involving approximately 900 patients and subjects conducted over a period of approximately 10 years. Our submission was primarily based on data from our Phase 3 trial of Riquent that enrolled 298 patients with high-affinity antibodies to Riquent who were treated for up to 22 months and our Phase 2/3 trial that enrolled 189 patients with high-affinity antibodies to Riquent who were treated for up to 18 months.

It is possible that the FDA and European regulatory agencies may require additional clinical trials of Riquent, such as a post-marketing clinical trial under Subpart H or an additional

Phase 3 clinical trial, in order to obtain marketing approval of Riquent. The size, complexity and timing of any additional trial would require significant discussions with the agencies. If any additional trial is required prior to approval, the marketing approval of Riquent, if any, will be significantly delayed, even if the additional trial ultimately demonstrates the safety and efficacy of Riquent. In any event, we will require additional funding.

Further discussion of the results of our Phase 3 trial of Riquent is contained in this report under the heading “Riquent Clinical Trial History” beginning at page 6.

Antibody-Mediated Diseases

The immune system is the major biological defense mechanism responsible for recognizing and fighting disease. The immune system identifies antigens, such as bacteria, viruses and other disease-causing substances, and seeks to rid the body of these antigens. There are two fundamental types of immune responses: cell-mediated and antibody-mediated. These immune responses are controlled by the activities of white blood cells called T cells and B cells. T cells provide cell-mediated immunity and regulate B cells. B cells provide antibody-mediated immunity by producing antibodies that recognize and help to eliminate antigens.

Each B cell produces antibodies against a specific structure on the antigen’s surface called an epitope. The B cell is triggered to produce antibodies when the specific epitope is recognized by and binds to the antibody receptors on the surface of the B cell, and only when the B cell receives an appropriate signal from a T cell. When an epitope binds to the B cell with no corresponding T cell signal, the B cell may become “tolerized” and cease to produce antibodies.

A properly functioning immune system distinguishes between foreign, or “non-self,” antigens and the body’s own healthy tissues. In a malfunctioning immune system, healthy tissue may trigger an immune response that causes B cells to produce disease-causing antibodies, resulting in antibody-mediated autoimmune disease. For example, B cells can produce disease-causing antibodies that are associated with the impairment of kidney function and can result in the need for dialysis in people with lupus and with the development of blood clots that can result in stroke, heart attack, deep vein thrombosis and recurrent fetal loss in people with antibody-mediated thrombosis, also known as Antiphospholipid Syndrome. Other antibody-mediated disorders include the wasting of muscles in myasthenia gravis, organ rejection in xenotransplantation and Rh hemolytic disease in newborns.

Many currently available therapies for antibody-mediated diseases have significant shortcomings, including the potential for causing severe side effects and a lack of specificity. Mild forms of antibody-mediated diseases are generally treated with drugs that address only the disease symptoms and fail to suppress disease progression because such drugs do not affect the causative factors of the disease itself. Exacerbations of antibody-mediated diseases like lupus are generally treated with high levels of corticosteroids and immunosuppressive therapy (primarily anti-cancer or chemotherapy drugs and drugs designed to reduce the risk of organ transplant rejection), which can broadly suppress the normal function of the entire immune system. These therapies can leave patients susceptible to potentially life-threatening infections that may require hospitalization. Repeated dosing with corticosteroids may cause other serious conditions, including diabetes, hypertension, cataracts, osteonecrosis and psychosis, and an increased risk of severe infections that may limit the use of this therapy. The use of chemotherapy may lead to acute problems, including weight loss, nausea, an increased risk of severe infections and long-term adverse effects, including sterility and an increased risk of malignancies.

Tolerance Technology®

Our Tolerance Technology program focuses on the discovery and development of proprietary therapeutics, called Toleragens, which are intended to target and suppress the production of specific disease-causing antibodies without affecting the protective functions of the immune system. We believe that Toleragens have the potential to treat the underlying causes of antibody-mediated diseases, and that our Tolerance Technology may be applied broadly wherever specific antibodies are involved in causing diseases.

Since the 1970s, hundreds of papers have been published by the scientific community describing laboratory studies and a Nobel Prize was awarded for research in tolerance. The underlying science supporting our Tolerance Technology is based on these discoveries as well as on our own research.

Toleragens are composed of disease-specific epitopes and a carrier platform, which are proprietary chemical structures that we have developed and synthesized. To mimic the unique epitopes on an antigen's surface, we identify and synthesize epitopes specific to particular antibody-mediated diseases and attach or conjugate these epitopes to the carrier platform, which serves as a vehicle for presenting the epitopes to the antibody receptors on the targeted B cell. When the epitope binds to the antibody receptors on the B cell in the absence of a T cell signal, the B cell may become tolerized and cease to produce disease-causing antibodies.

We design our Toleragens to bind selectively to *disease-causing* B cells without affecting the function of *disease-fighting* B cells. This process involves: collecting and purifying the disease-causing antibodies from patients with the targeted disease; generating and selecting an epitope that strongly binds to the purified antibodies; modifying the epitope's structure to maximize its binding properties while eliminating, if necessary, structures that can activate a patient's T cells (this process is called "optimization"); and linking the optimized epitope to the carrier platform. We believe this process enables us to create Toleragens that will preferentially tolerize and shut down B cells that generate antibodies with the highest binding affinity, and which are believed to be the most harmful.

Business Strategy

Our objective is to become the leading developer of highly specific therapeutics for the treatment of life-threatening antibody-mediated diseases such as lupus, antibody-mediated thrombosis, organ rejection in xenotransplantation, myasthenia gravis and Rh hemolytic disease in newborns. Our strategy includes the following key elements:

Support the FDA's review of the NDA and submit the Marketing Authorisation Application for Riquent to European regulatory agencies for review. Our primary near-term goal is to support the review by the FDA of our NDA filing for Riquent and to submit the study results to regulatory agencies in Europe for their review. Thereafter, we expect to meet with these regulatory agencies, to provide additional results or analyses of Riquent data if requested and, with input from the agencies, to determine a future development strategy, if needed, for Riquent. No assurance can be given that we can reach agreements with any regulatory agencies regarding the future development or commercialization of Riquent.

Complete any additional analyses or clinical studies requested by the regulatory agencies. The FDA and European regulatory agencies may require us to complete a post-marketing clinical trial under Subpart H or to complete a second Phase 3 clinical trial in order to obtain marketing approval of Riquent. The size, complexity and timing of any required additional trial will not be known until after we meet with the agencies to discuss the clinical trial results of Riquent.

If one or more additional trials are required prior to approval, the marketing approval of Riquent, if any, will be significantly delayed even if the additional trial(s) ultimately demonstrates that Riquent is safe and effective.

Obtain FDA and European regulatory approval of Riquent and initiate commercialization 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 that can target the rheumatology and nephrology specialists who treat the majority of lupus patients with renal disease. If Riquent is approved in Europe, as to which we can provide no assurance, we currently expect to either market Riquent ourselves or seek a marketing collaboration with a European partner. We believe that the majority of European patients are treated at a limited number of major hospitals, and, as is the case in the United States, that a specialty pharmaceutical sales force could successfully market Riquent to the physicians at a majority of these sites.

Apply Tolerance Technology to other life-threatening antibody-mediated diseases. Our other research and development activities, while limited, are currently focused on chronic, life-threatening diseases and conditions caused by antibodies, such as antibody-mediated thrombosis, for which current therapies have significant limitations. We intend to use our Tolerance Technology to design therapeutics that specifically target other antibody-mediated diseases without adversely affecting normal immune system function. Potential development targets include antibody-mediated thrombosis, organ rejection in xenotransplantation, myasthenia gravis and Rh hemolytic disease in newborns.

Enter into collaborative relationships to develop and commercialize product candidates. We may seek collaborative relationships with other pharmaceutical companies to provide support for some of our early stage research programs and for the clinical development and commercialization of our drug candidates.

Expand intellectual property position. As of December 31, 2003, we owned 101 issued patents and 84 pending patent applications covering various technologies and drug candidates, including Riquent and LJP 1082. We hope to expand our position with future discoveries and additional patent filings.

Products Under Development

We have focused our product development efforts on our programs for lupus, antibody-mediated thrombosis and other antibody-mediated diseases. In each of the years ended December 31, 2003, 2002 and 2001, we incurred expenses of approximately $32.4 million, $37.7 million and $23.2 million, respectively, for product research and development on these programs.

The Lupus 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 250,000 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.

Antibodies to double stranded DNA ("dsDNA") can be detected in approximately 90% 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 that have a renal flare often involve repeated administration of corticosteroids, often at high levels that, when used long-term, can lead to serious side effects. Many patients with renal flares are also treated with immunosuppressive therapy, including anti-cancer drugs that 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.

We have designed Riquent to suppress the production of antibodies to dsDNA in lupus patients without suppressing the normal function of the immune system. The design of Riquent is based on scientific evidence of the role of antibodies to dsDNA in lupus. 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 suppressing antibodies to dsDNA by treating with corticosteroids can prevent relapse. 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.

Some studies of lupus patients indicate that antibodies to dsDNA with the highest binding affinity are associated with the most damage to the kidneys. We believe that Riquent preferentially targets these antibodies.

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, the single-dose clinical trial was initiated to evaluate the safety of a single, 100 mg intravenous dose of Riquent in four female lupus patients. We monitored antibody levels, blood chemistry, vital signs and complement (inflammation-promoting proteins) levels for 28 days after dosing. Riquent was well tolerated by all four patients, with no drug-related adverse clinical symptoms and no clinically significant complement level changes. In addition, no clinically significant immune complex formation (inflammation-promoting accumulation of antibodies and antigens) was observed, indicating the absence of an adverse immune response to Riquent. A transient reduction in antibodies to dsDNA levels was also observed. These results

were presented at the Annual Scientific Meeting of the American College of Rheumatology in October 1995.

In 1995, the repeat dose-escalating clinical trial was initiated 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 with no drug-related adverse clinical symptoms, no clinically significant complement changes and no significant immune complex formation. Six weeks after the last dose, the antibodies to dsDNA levels in both patients remained suppressed below baseline levels.

Also in 1995, we conducted our first double-blind, placebo-controlled dose-ranging trial, in which 58 lupus patients (53 females and five males) with mild lupus symptoms were treated for a four-month period with Riquent or placebo, and then were monitored for two months. Patients were enrolled who were clinically stable and had antibodies to dsDNA levels exceeding those generally found in healthy individuals. The patients were organized into nine treatment groups at three dose levels (1 mg, 10 mg and 50 mg) and three frequencies (once per week, once every two weeks and once every four weeks). Patients were randomized to one of the nine treatment groups so that at each dose and frequency four to seven patients received Riquent and one patient received placebo.

Patients in the weekly treatment groups showed a dose-response correlation between increasing doses of Riquent and reductions of levels of antibodies to dsDNA. In patients treated weekly with 10 mg or 50 mg doses of Riquent, antibodies to dsDNA were reduced by statistically significant levels and remained suppressed in certain patients for up to two months after the last dose. In this trial, patients treated weekly with 50 mg of Riquent exhibited a trend toward normalization of C3 complement levels in parallel to the reduction in antibodies to dsDNA.

Throughout this first dose-ranging trial, the drug was well tolerated with no clinically significant dose-related adverse reactions observed. Three patients experienced lupus renal flares, and three other patients were hospitalized as a result of transient adverse events that the treating clinicians believed were unrelated to the underlying disease or to Riquent. Two of the patients with renal flares withdrew from the study, as did four patients who experienced exacerbations of lupus and one patient who experienced a herpes rash. However, no relationship was observed between the development of an adverse event and the dose or the frequency of administration of Riquent.

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.

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 Riquent or placebo and were in the trial for up to 18 months. The purpose of the Phase 2/3 trial was to evaluate the safety of the drug and its potential to delay the time to or reduce the incidence of renal flares, to delay or reduce the need for immunosuppressive or corticosteroids and/or chemotherapy drugs and to improve patients' health-related quality of life ("HRQOL"). More than 200 patients at more than 50 sites in North America and Europe enrolled in the trial which

was conducted by Abbott Laboratories ("Abbott") and us 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 order to evaluate the data. Although both the drug- and placebo-treated groups exhibited serious adverse events, there were no statistically significant differences in the number of events in the two groups. In September 1999, the joint development agreement for Riquent between Abbott and us was terminated.

In November 1999, we announced encouraging initial results from the analysis of the data from the Phase 2/3 clinical trial which showed that a certain group of patients treated with Riquent 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 new blood test that we developed and that appears to predict which patients will respond to treatment with Riquent. Developed in 1998, the blood test measures the strength of the binding between Riquent and a patient's antibodies. Prior to using the blood test in the Phase 2/3 trial, we used it retrospectively to evaluate patient samples from the 1995 Phase 2 dose-ranging trial and found that the blood test predicted which patients would respond to drug treatment as measured by changes in antibody affinity following drug treatment.

In May 2000, we completed our analysis of the Phase 2/3 clinical trial data after testing more than 99% of the North American patient samples from the trial. The blood test showed that 89% of the patients in the trial had high-affinity antibodies to Riquent (the "high-affinity patients"). 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=0.002) 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). Levels of an important inflammation-related complement protein, C3, improved when antibodies were reduced. In lupus patients, it is generally observed that complement C3 levels decrease during active renal disease and increase with clinical improvement. The concurrent reduction of antibodies to dsDNA and increase in C3 complement levels is biologically consistent. As discussed above, this effect had been observed in the 1995 Phase 2 dose-ranging study of Riquent in 58 lupus patients.

The Phase 2/3 trial design included periods during which patients received no drug for approximately two months (the "off" periods) and weekly doses of 50 mg over three months (the "on" periods). When patients were on drug, mean levels of antibodies to dsDNA decreased. When patients were off drug, mean levels of antibodies to dsDNA increased. During the first four months of the trial, when patients were treated with 100 mg per week, there were nine renal flares in the placebo-treated group and four in the drug-treated group — approximately a 2:1 ratio in favor of drug treatment. Furthermore, in high-affinity patients, during the first four months of the trial, there were eight renal flares in the placebo-treated group and only one renal flare in the drug-treated group (p=0.035) — an 8:1 ratio in favor of drug treatment.

The results of the Phase 2/3 clinical trial were published in *Arthritis & Rheumatism,* Vol. 48, No. 2, February 2003, pp. 442-454 by Alarcon-Segovia, D., et al.

In patients with impaired renal function at baseline (defined as serum creatinine > 1.5 mg/dL), there were more renal flares in the patients treated with placebo than in the patients treated with Riquent (p=0.046). In a group of high-affinity patients with impaired renal function,

there were six renal flares in 10 patients treated with placebo and no renal flares in 11 patients treated with drug (p=0.004).

In January 2001, we announced that approximately 90% of patients in each of three previous clinical trials from whom blood serum specimens were available had high-affinity antibodies to Riquent prior to drug treatment. The ratios for the trials were: 89% of the 213 patients in the Phase 2/3 trial, 94% of the 31 patients in the Phase 2 trial completed in 1996, and 90% of the 60 patients in the Phase 2 trial completed in 1999. Patients in the Phase 2/3 trial had moderate to severe disease and a history of renal flares. Patients in the two dose-ranging Phase 2 trials had mild to moderate disease. Placebo- and drug-treated groups had similar percentages of patients with high-affinity antibodies at baseline in each clinical trial. These data suggest that the percentage of high-affinity patients in a larger population of lupus patients may be 90%, but a larger population of patients would need to be evaluated to confirm this result.

The Phase 2/3 trial also showed that 83% of patients in the trial who had a renal flare also had a treatment with HDCC and that 48% were hospitalized during the trial. In patients who entered the trial with impaired renal function and who experienced renal flare, serum creatinine levels worsened significantly and increased from an average of 1.9 mg/dL at baseline to 5.0 mg/dL at final visit.

Additional data from the Phase 2/3 trial indicated that treatment with Riquent appeared to be as effective as current immunosuppressive therapy in reducing antibodies to dsDNA. Patients on placebo who were treated with HDCC were compared to patients who received Riquent. Following treatment with HDCC, levels of antibodies to dsDNA in 38 patients receiving placebo were reduced within four weeks by a mean of 25%. In 100 patients treated weekly with 100 mg of Riquent, but not HDCC, antibodies to dsDNA were reduced within four weeks by an average of 36%. In patients requiring HDCC, mean levels of antibodies to dsDNA decreased 37% in 22 patients receiving Riquent treatment compared with 25% in 38 patients receiving placebo. In patients receiving HDCC, the median dose of corticosteroids was 50 mg per day.

Additional data from the Phase 2/3 trial indicated that treatment with Riquent had a positive impact on HRQOL in patients with lupus renal disease following 16 weeks of treatment with Riquent and following renal flares, when compared to placebo. HRQOL is a measure of a patient's sense of mental and physical well-being, or how the patient feels, and was measured by using a standard scoring instrument called the Medical Outcomes Study 36-Item Short Form, or SF-36®, that categorizes results in eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health, as well as mental and physical composite summary scores. Riquent-treated patients had better scores in certain domains when compared to baseline than did placebo-treated patients.

Results from the Phase 2/3 lupus study suggested three ways to improve the clinical trial design of a Phase 3 trial: (i) eliminate "off" periods during which patients are not treated with either drug or placebo; (ii) increase the dosing to 100 mg per week throughout the study; and (iii) evaluate the drug in high-affinity patients.

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 more than 70 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 chemotherapy 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. The trial design eliminated the two-month “off” periods from the Phase 2/3 trial during which patients were not treated with either drug or placebo.

The prospectively defined analysis groups in the Phase 3 trial were the high-affinity patients (the intent-to-treat population) and high-affinity patients with impaired renal function. Patients with impaired renal function were defined as those who had a serum creatinine level of > 1.5 mg/dL at baseline. In general, patients with impaired renal function are at greater risk of progressing to renal flare, kidney failure and dialysis.

The primary endpoint in the trial was time to renal flare. A renal flare was defined as a significant, reproducible increase in serum creatinine, urine protein or blood in the urine. The secondary endpoint was time to treatment with HDCC. Treatment with HDCC was defined as any dose of cyclophosphamide or an increase in prednisone of 15 mg/day or higher resulting in a final dose greater than 20 mg/day for greater than two days or any dose greater than 200 mg/day.

Other prospectively defined outcomes included time to Major SLE flare, treatment associated maintenance and/or improvement in HRQOL, decreases in antibodies to dsDNA and associated increases in complement C3 levels. A Major SLE flare was defined as the occurrence of any one of the following due to manifestations of active SLE: treatment with HDCC or initiation or increase in treatment with other immunosuppressive agents, including azathioprine, mycophenolate mofetil, methotrexate, cyclosporin and leflunomide; hospitalization; or death. This definition of Major SLE flare was designed to capture serious events where patients were treated for manifestations of active SLE as well as renal disease or where treatment, hospitalization or death could have preceded the occurrence of a documented renal flare.

Complement protein changes were evaluated by determining the mean change from baseline in the complement protein C3 that indicates overall complement consumption due to active inflammation. Antibody changes were evaluated by determining the mean percent change of antibodies to dsDNA from baseline. Patients’ assessments of disease activity and HRQOL were measured on a regular basis, including at the time of, and seven days following, a documented renal flare.

In February 2003, we announced our preliminary findings from the Phase 3 trial. The study results indicated 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, in a statistically significant manner when compared with placebo through the end of the study. There were 298 patients in the intent-to-treat population of high-affinity patients, 145 on Riquent and 153 on placebo. Patients were treated for up to 92 weeks with a median of 46 weeks.

In the intent-to-treat population, there were fewer renal flares, fewer treatments with HDCC and fewer Major SLE flares in Riquent-treated patients compared with placebo-treated patients. The estimated median time to renal flare was 123 months in the Riquent-treated group and 89 months in the placebo-treated group. There were 41 renal flares, 17 (12%) in Riquent-treated patients and 24 (16%) in placebo-treated patients. There were 68 treatments with HDCC, 32 (22%) in the Riquent-treated group and 36 (24%) in the placebo-treated group. There were 82 Major SLE flares in the trial, 35 (24%) in patients on Riquent and 47 (31%) in patients on placebo. None of these differences were statistically significant.

There was a statistically significant reduction in antibodies to dsDNA in the Riquent-treated group compared with the placebo-treated group ($p<0.001$). Antibodies to dsDNA are believed to result in renal flares and other clinical manifestations of lupus. Riquent was designed

to reduce antibodies to dsDNA and this effect has been demonstrated in all clinical studies of Riquent to date.

In the Phase 3 trial, reductions in antibodies to dsDNA strongly correlated with increases in complement C3 levels ($p<0.001$). Inverse correlations between antibody levels and complement C3 were observed in the previous Phase 2/3 trial ($p=0.0001$). Complement C3 levels below normal at baseline (hypocomplementemia) correlated with an increased risk of renal flare ($p<0.001$) in the Phase 3 trial although a statistically significant correlation was not demonstrated in the Phase 2/3 trial. Together, these data support the pathogenic nature of these antibodies to dsDNA in lupus patients.

A review of the Phase 3 trial results for time to renal flare and for the increases in antibody levels showed that the Riquent and placebo groups were separating in favor of Riquent until weeks 46 to 48. In the first 46 weeks, 22 of 24 (90%) renal flares occurred in the study in the placebo patients compared with 10 of 17 (59%) in the Riquent-treated patients. At weeks 44, 46, and 48, the incidence of renal flares in the placebo-treated group compared with the Riquent-treated group (placebo-treated: Riquent-treated) was: 20:10 ($p=0.085$), 22:10 ($p = 0.041$) and 22:11 ($p = 0.067$), respectively, in favor of Riquent. At weeks 44, 46 and 48, the incidence of renal and/or Major SLE flares was 43:27 ($p=0.057$), 46:28 ($p=0.033$) and 46:29 ($p=0.061$), respectively, in favor of Riquent.

In a prospectively defined subpopulation with impaired renal function at baseline, defined as a serum creatinine level of 1.5 mg/dl at baseline, there were 43 patients, 20 on Riquent and 23 on placebo. Riquent-treated patients had fewer renal flares, treatments with HDCC and Major SLE flares compared with patients on placebo, but the number of patients was small and the differences were not statistically significant. There were eight renal flares, two (10%) in patients on Riquent and six (26%) in patients on placebo. There were nine treatments with HDCC, three (15%) in patients on Riquent and six (26%) in patients on placebo. There were 11 Major SLE flares, four (20%) in patients on Riquent and seven (30%) in patients on placebo. There were 14 renal flares and/or Major SLE flares, five (25%) in patients on Riquent and nine (39%) in patients on placebo. Similar results in the same group were observed for renal flares in the Phase 2/3 trial: no renal flares (0%) were observed in the 11 Riquent-treated high-affinity patients compared with six of 11 (55%) of the placebo – treated high-affinity patients. We believe that a delay in time to, or a decrease in, the incidence of renal flares and/or Major SLE flares in this high-risk population would be considered by experts in the lupus field to be medically meaningful.

The results from the Phase 3 trial appear to support the use of our high-affinity assay to identify patients who may respond well to Riquent.

Additional findings from the Phase 3 and Phase 2/3 trials

On March 31, 2003, we announced additional analyses of data from our Phase 3 and Phase 2/3 trials of Riquent. The data showed a statistically significant correlation between reductions in antibodies to dsDNA and a reduced risk of renal flare in lupus patients (Phase 3: $p < 0.0001$; Phase 2/3: $p = 0.0004$). These results were presented at the Biomarkers for the Assessment of Systemic Lupus Erythematosus Conference in March 2003.

In the Phase 3 trial, 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. In both the Phase 3 and Phase 2/3 trials, patients with sustained reductions were defined as those who had at least a 10% reduction in antibodies to dsDNA from baseline for at least two-thirds of all measurements of antibodies to dsDNA during the trial, unless they were treated with high-dose corticosteroids and/or cyclophosphamide. Because HDCC suppresses antibodies to dsDNA, antibody values subsequent to HDCC treatment were adjusted to have a

value equivalent to baseline. Patients meeting the criteria for sustained reductions in antibodies to dsDNA are also referred to as "responders." The analyses on sustained reductions were conducted after the trial was unblinded.

In the Phase 3 trial, renal flares occurred in only 4% of patients (five of 121) with sustained reductions whereas renal flares occurred in 20% of patients (36 of 177) who did not experience sustained reductions ($p<0.0001$). Twice as many Riquent-treated patients had sustained reductions (80 of 145, or 55%) compared with placebo-treated patients (41 of 153, or 27%).

In the Phase 2/3 trial, renal flares occurred in only 3% of patients (two of 67) with sustained reductions whereas renal flares occurred in 21% of patients (26 of 122) who did not experience sustained reductions ($p=0.0004$). Four times as many Riquent-treated patients had sustained reductions (54 of 92, or 59%) compared with placebo-treated patients (13 of 97, or 13%).

The results from both studies also confirm the correlation between increasing levels of antibodies to dsDNA and the occurrence of renal flares in lupus patients (Phase 3: $p < 0.0001$; Phase 2/3: $p < 0.0007$).

The number of Major SLE flares was also significantly reduced in patients with sustained reductions in antibodies to dsDNA in the Phase 3 and Phase 2/3 trials. Patients with sustained reductions in antibodies to dsDNA had a 70% reduction in the risk of Major SLE flare in the Phase 3 trial and a 75% reduction in risk in the Phase 2/3 trial when compared with patients who did not have sustained reductions ($p < 0.0001$ for each trial).

The majority of Major SLE flares were observed in patients who did not have a sustained reduction in antibodies to dsDNA. This group included 68 of 82 (83%) total Major SLE flares in the Phase 3 trial and 55 of 63 (87%) total Major SLE flares in the Phase 2/3 trial.

On November 17, 2003, we presented additional analyses at the American Society of Nephrology Annual Meeting of data using Cox's Proportional Hazards Regression Model that predicts that a 50% reduction in antibodies to dsDNA from baseline is 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 ($p<0.0001$). These findings are consistent with previously released data showing that patients with sustained reductions in antibodies to dsDNA had fewer renal flares.

On March 11, 2004, we announced additional analyses of data from our Phase 3 and Phase 2/3 trials of Riquent. The data showed 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 of renal disease. These results were presented at the SG Cowen 24th Annual Healthcare Conference on March 11, 2004.

In patients who had 24-hour urine protein measured at both baseline and at week 52 during the Phase 3 trial, 41% (26 of 63) of patients in the Riquent-treated group with high-affinity antibodies to Riquent achieved a 50% or greater reduction from baseline in the amount of protein in their urine at week 52, compared with 28% (23 of 81) of patients in the placebo-treated group with high-affinity antibodies (nominal $p = 0.047$). In patients who had 24-hour urine protein measured at both baseline and at approximately week 52 during the Phase 2/3 trial, 44% (23 of 52) of patients in the Riquent-treated group with high-affinity antibodies had a 50% or greater reduction from baseline in the amount of protein in their urine at approximately week 52, compared with 18% (11 of 61) of patients in the placebo-treated group with high-affinity antibodies

(nominal p = 0.002). The measurement of 24-hour urine protein was specified in each protocol at defined time points, but the analysis of the reduction in proteinuria was conducted on a retrospective basis.

Health-related quality of life

Results from the Phase 3 and Phase 2/3 trials were consistent among patients who were "responders." As discussed above, patients were considered to be "responders" if they had sustained reductions in antibodies to dsDNA. Responders reported improved HRQOL compared with patients without sustained reductions in antibodies to dsDNA, regardless of treatment group. Similar analyses within each treatment group demonstrated that responders reported improved HRQOL compared with non-responders. This evidence supports that decreases in levels in antibodies to dsDNA result in improvements in patient-reported HRQOL, assessed by SF-36, whether sustained reductions in antibodies to dsDNA are due to spontaneous improvement or to treatment with Riquent. In the Phase 2/3 trial, responders at visit 18 (week 16) showed improvement in all domains relative to non-responders. In the Phase 3 trial, responders at visit 27 (week 24) and 51 (week 48) showed improvement in all domains relative to non-responders and in six of eight domains at their last visit.

In the Phase 2/3 trial, approximately four times as many patients in the Riquent-treated group were responders than in the placebo group. In the Phase 3 trial, approximately twice as many patients in the Riquent-treated group were responders than in the placebo group.

Although the sample size was small, a potentially important finding in the Riquent-treated group was that, following a renal flare, compared to pre-flare assessments, patients reported improvement or less deterioration in all domain scores compared with no change or deterioration in the placebo-treated group. These findings were also seen when seven patients receiving HDCC prior to a flare were excluded, suggesting that deterioration in reported HRQOL due to administration of HDCC did not account for the differences between the treatment groups. In an analysis of SF-36 scores pre- and post-renal flare in the Phase 3 trial (41 patients), Riquent-treated patients reported less deterioration than placebo-treated patients in six of eight domains. When eight patients receiving HDCC prior to renal flare were excluded, Riquent-treated patients reported less deterioration than placebo-treated patients in five of eight domains, suggesting that deterioration in reported HRQOL due to administration of HDCC did not account for the differences between treatment groups.

The differences in HRQOL between the Riquent-treated and placebo-treated groups were not significantly different during the Phase 3 trial, and mirror the renal flare results reported for the Phase 3 trial. The lack of significance may have been due to changes in medical practice during the trial and a loss of susceptible patients as discussed in detail in our February 18, 2003 press release.

Comments on trial data

Several observations may help to explain the results from the recent Phase 3 trial. These observations are preliminary and they will all require review by appropriate regulatory agencies and medical experts.

There appear to have been changes in medical practice since the completion of the Phase 2/3 trial as evidenced by a difference in prescribing regimens for immunosuppressive drugs. In particular, it appears there were differences in baseline treatments in the patient population in the Phase 3 trial compared with the Phase 2/3 trial. A higher percentage of patients were receiving immunosuppressive treatments at study entry: 73 of 145 (50%) in the Riquent-treated group versus 63 of 153 (41%) in the placebo-treated group in the Phase 3 trial compared to 35 of 114

(31%) in the Riquent-treated group versus 40 of 116 (34%) in the placebo-treated group in the Phase 2/3 trial. The sample size selected for the Phase 3 trial was based on the Phase 2/3 trial.

In addition, the definition of HDCC may not have captured all of the potential events in the Phase 3 trial because the definition did not include some of the newer immunosuppressive drugs that are increasingly used instead of cyclophosphamide. Although these newer drugs have a better side effect profile than cyclophosphamide, they are still broadly immunosuppressive.

Reviewing a graph of the Phase 3 trial results showed that the Riquent and placebo lines for time to renal flare and for the changes in antibody levels were separating until weeks 46 to 48. After weeks 46 to 48, the placebo flare rate decreased significantly. In the placebo-treated group, those who remained in the study after weeks 44 to 48 showed a reduction in antibodies to dsDNA compared with levels observed in the prior weeks.

We believe that the high-affinity antibody blood test we developed identifies lupus patients who are most likely to respond to Riquent treatment. The FDA and other regulatory agencies may require screening of patients for high-affinity antibodies with this test prior to treatment with Riquent. We have filed a patent application for this blood test.

Orphan drug designation for Riquent

In September 2000, the FDA granted us orphan drug designation for Riquent for the treatment of lupus kidney disease. The Orphan Drug Act provides for seven years of marketing exclusivity in the United States and enables us to obtain research funding, tax credits for certain research expenses and a waiver of the application user fees. In the course of the FDA's initial review of our NDA, the FDA has indicated that the indication for Riquent proposed in our NDA may be broader than the indication identified in our orphan drug designation. Accordingly, the FDA has indicated that we will be required to pay the filing fee for the NDA for Riquent at this time, even though the FDA's final approved indication, if any, may be within the original orphan drug designation. We intend to seek, and believe that we qualify for, a refund of the full filing fee under the FDA's small business regulations. Whether we will be able to take advantage of the benefits afforded by the orphan drug designation will ultimately be determined by the FDA only after further review of our NDA. If the FDA approves Riquent for a broader indication, we believe that we will be able to market Riquent to a larger number of patients, although, in such case, we would not be able to take advantage of the orphan drug designation for market exclusivity, research funding and certain tax credits.

In November 2001, the European Commission granted us orphan medicinal product designation in the European Union for Riquent on the recommendation of the Committee on Orphan Medical Products. 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, marketing authorization and inspections.

Continuing risks

The continued development of Riquent involves a number of risks and uncertainties. There can be no assurance that any previous clinical results can be replicated in further clinical testing or that Riquent will be effective in inducing and sustaining antibody suppression; will prove to be clinically safe or effective; will receive required regulatory approvals; or will not require further FDA or other regulatory mandated clinical testing. In addition, there can be no assurances that regulatory authorities will accept as evidence of efficacy the retrospective analyses that are contained within the NDA and that are a key part of the arguments for FDA approval. If the continued development of Riquent is significantly delayed or if additional trials produce negative or inconclusive results, our business and financial condition will be adversely

affected and it may be difficult or impossible for us to survive. Our blood test to measure the binding affinity for Riquent is experimental, has not been validated by independent laboratories and will likely be reviewed as part of the Riquent approval process.

Antibody-Mediated Thrombosis, Including Stroke, Heart Attack, Deep Vein Thrombosis and Recurrent Fetal Loss

Researchers believe that antibodies called "antiphospholipid" antibodies promote arterial and venous blood clots, which can cause a variety of recurring and potentially life-threatening medical problems. For example, blood clots that lodge in the brain may cause stroke and those that lodge in the legs may cause deep vein thrombosis. There are multiple conditions associated with these antibodies that we collectively refer to as antibody-mediated thrombosis: antibody-mediated stroke, heart attack, deep vein thrombosis, recurrent fetal loss and complications following cardiovascular surgery. We believe that our program to develop a Toleragen to treat antibody-mediated thrombosis could be helpful in preventing these problems. We estimate that there are up to 2,000,000 patients in the United States and Europe with antibody-mediated thrombosis.

Stroke is a leading cause of death in the United States. In 2002, there were approximately 4,000,000 stroke patients in the United States and approximately 750,000 new episodes are expected to occur each year. In 2002, approximately 160,000 people died from stroke in the United States. This debilitating condition results from acute neurological injury caused by the blockage or rupture of blood vessels in the brain. Many of the blockages are caused by thromboses, or blood clots, which many clinicians believe may be caused by a number of factors, including antiphospholipid antibodies. We believe that these antibodies contributed to approximately 10% of strokes in the United States. Antibody-mediated stroke is thought to occur in younger individuals and with greater frequency than non-antibody-mediated stroke. The cost of treatment to provide hospitalization and home nursing care for a survivor of a serious stroke is approximately $30,000 per year for life.

Antibody-mediated thrombosis is also associated with recurrent fetal loss, a syndrome of repeated miscarriage. Published clinical reports estimate that many women with elevated antiphospholipid antibody levels experience multiple miscarriages, delayed fetal development or premature childbirth. Recent academic research suggests that elevated levels of these antibodies are also found in approximately 10% to 30% of patients with other clotting disorders, including myocardial infarction (heart attack), deep vein thrombosis and cardiac valve lesion, as well as in approximately 30% of lupus patients. In myocardial infarction, recent research suggests the relative risk of a thrombotic event or death is approximately twice as high in people with high antiphospholipid antibodies, and this risk is independent of other risk factors. In deep vein thrombosis, research indicates antiphospholipid antibody-positive patients have recurring deep vein thromboses about twice as often as antiphospholipid antibody-negative patients.

Current treatments for antibody-mediated thrombosis involve the use of chronic, potentially life-long anticoagulant therapy with drugs such as heparin or warfarin to prevent the formation of blood clots. Patients must be carefully monitored to minimize serious bleeding episodes that can occur because of the therapy. If patients are removed from anticoagulant therapy, they are at an increased risk of stroke or another thrombotic episode. Warfarin is not recommended in the treatment of recurrent fetal loss because it is toxic to the developing fetus.

We believe that a Toleragen to treat antibody-mediated thrombosis would be a major step forward in specifically targeting the cause of this clotting disorder, thereby minimizing or avoiding the side effects of current therapies.

Our research supports the finding that specific antibodies in antibody-mediated thrombosis enhance blood-clot formation by interfering with the natural breakdown of a blood component — Factor Va — that accelerates clotting. The true target of these clot-promoting antibodies is not cardiolipin, but a region on a blood protein called beta 2-glycoprotein I ("beta 2 GPI"). To date, our scientists have shown that approximately 90% of patients studied with antibody-mediated thrombosis have antibodies that bind to this region. The identification of a disease target for antibody-mediated thrombosis has allowed us to begin building new drug candidates that bind to these antibodies with high-affinity and are designed to tolerize, or shut down, the B cells that produce them.

We have synthesized a family of candidate antibody-mediated thrombosis Toleragens for testing. We have also developed a mouse model of the disease in which animals produce antibodies to beta 2 GPI. In this animal model, several candidate molecules have been shown to reduce the production of antibodies to beta 2 GPI, a key step in the development of a drug to treat this disorder.

LJP 1082 Clinical Trial History

In July 2000, we selected LJP 1082 as our clinical drug candidate for the treatment of antibody-mediated thrombosis. Based on positive pre-clinical results in mice, rats and primates, we chose this candidate for toxicology studies required for the filing of an Investigational New Drug application. In September 2000, at the 9th International Symposium on Antiphospholipid Antibodies in Tours, France, we presented results that showed LJP 1082 reduced disease-causing antibodies and the B cells involved in antibody-mediated thrombosis in an animal model of the disease.

In September 2001, we announced that we had filed an Investigational New Drug application with the FDA to begin a Phase 1/2 clinical trial of LJP 1082. In November 2001, we announced the initiation of the Phase 1/2 clinical trial. The objective of the study was to evaluate the safety of LJP 1082 and its ability to reduce disease-causing antibody levels in patients with antibody-mediated thrombosis. The Phase 1/2 trial was a randomized, placebo-controlled dose escalating study designed to evaluate the safety and activity of a single dose of LJP 1082 in a small group of patients. In the Phase 1/2 trial, five different groups, each consisting of four or five patients, were treated with a single intravenous dose of LJP 1082 of 1, 3, 10, 50 or 200 mg and then monitored for 30 days. One patient in each group received placebo. In order to participate in the trial, patients were required to have elevated levels of antibodies to beta 2 GPI, the target of the antibodies involved in antibody-mediated thrombosis.

In October 2002, we announced preliminary results from the Phase 1/2 clinical trial. Based on an initial assessment of the trial data, the drug appeared to be well tolerated at the five dose levels used in the study. LJP 1082 had an elimination half-life of at least 12 hours following intravenous administration. Following treatment with a single 50 mg or 200 mg dose, antibodies to LJP 1082 appeared to be reduced in some patients. In total, 20 patients with a history of antibody-mediated thrombosis participated in the trial period.

Standard safety assessments, including physical exams, lab values and vital signs, and immunology specific measurements were taken during the 30 days following a single dose of LJP 1082. All adverse events observed were categorized as mild to moderate and were deemed to have no or an unlikely relationship to LJP 1082. The adverse event profiles appeared similar between drug-treated and placebo-treated groups. There were no serious adverse events reported. We observed no significant increase in circulating immune complexes, changes in complement protein C3 or activation of patient T cells following drug treatment.

This study is the first of several that may be required to establish appropriate dose regimens and the observed reductions may not be large enough to affect patient health or reduce antibodies to beta 2 GPI in a majority of patients. Additional analyses are ongoing. Potential drug interference in some of the antibody assays is also being evaluated. This study was not designed to evaluate the ability of LJP 1082 to tolerize B cells that produce antibodies to beta 2 GPI and additional studies will be needed for this purpose.

SSAO Inflammation Program

On December 2, 2003, we announced the discovery of novel, orally-active small molecules for the treatment of autoimmune diseases and acute and chronic inflammatory disorders. Our scientists have generated highly selective inhibitors of semicarbazide-sensitive amine oxidase ("SSAO"), an enzyme that has been implicated in inflammatory responses in many tissues and organs. SSAO, also know 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 and acute inflammation have shown that treatment with the 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. We expect to continue to explore the potential to use inhibitors of SSAO to provide a novel approach to treating a number of debilitating diseases. These results were presented at the 2nd International Inflammatory & Immune Diseases World Summit on March 8-10, 2004 in Baltimore, Maryland.

Other Antibody-Mediated Diseases

We believe our Tolerance Technology may be applicable to additional diseases and conditions caused by the production of disease-causing antibodies, including xenotransplantation, myasthenia gravis and Rh hemolytic disease in newborns.

Xenotransplantation, the use of animals as a source of donor organs for human transplantation, has become an area of significant interest due to the worldwide shortage of human organs available for transplantation. According to the American Society of Transplant Physicians, approximately 100,000 patients in the United States are currently on waiting lists for organ transplants. More than 5,000 patients die annually, many of whom are too sick to qualify for waiting lists.

Hyper acute rejection, or the immediate destruction of the transplanted animal organ by the recipient's antibodies, is a major barrier to xenotransplantation. Human antibodies recognize and bind to an epitope called alpha galactose found on the tissues of transplanted animal organs. This binding causes massive blood clots that block the blood supply to the transplanted organ, destroying it within minutes.

Myasthenia gravis is a form of muscular paralysis in which neuromuscular receptors are attacked by antibodies, which can lead to a wasting of muscles, progressive loss of strength and life-threatening respiratory arrest. This disease currently affects an estimated 20,000 people in the United States.

Rh hemolytic disease in newborns is a life-threatening fetal condition characterized by the hemolysis, or destruction, of fetal red blood cells. This condition occurs in Rh-incompatible pregnancies in which maternal antibodies to Rh cross the placenta, bind to fetal red blood cells and cause their destruction. Each year approximately 500,000 women in the United States have Rh-incompatible pregnancies. We believe that a Toleragen that binds to the appropriate maternal B cells will suppress Rh antibody production, and that once the level of antibodies to Rh(+) red blood cells is reduced, the risk of life-threatening hemolysis will be reduced.

Collaborative Arrangements

As part of our business strategy, we attempt to pursue collaborations with pharmaceutical companies in an effort to access their research, drug development, manufacturing, marketing and financial resources. In December 1996, we entered into a collaborative relationship with Abbott for the worldwide development and commercialization of Riquent. This agreement was terminated in September 1999 following the initial analysis of the Phase 2/3 lupus trial, and all rights to Riquent were returned 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. There can be no assurance that we will be able to negotiate arrangements with any collaborative partner on acceptable terms, if at all. Once a collaborative relationship is established, there can be no assurance that the collaborative partner will continue to fund any particular program or 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 of ours, 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 exceed 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, which, based on our current projections, we believe would be sufficient to treat approximately 20,000 patients 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/or engaging third party contract manufacturers.

We are required to comply with the FDA's and other regulatory agencies' Good Manufacturing Practices ("GMPs") when we manufacture our drug candidates for clinical trials. We will also be required to comply with the GMPs if Riquent, or our other drug candidates, are manufactured for commercial purposes. We have limited manufacturing experience and the FDA has never conducted a pre-approval inspection of our manufacturing facility. We can

provide no assurance that we will pass the FDA's pre-approval inspection or that we will be able to successfully transition to commercial production if Riquent is approved.

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. 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 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 our drug candidates, including Riquent. In order to manufacture Riquent, LJP 1082 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. 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 initially who can 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 in Europe, we currently expect to market Riquent ourselves or seek a marketing collaboration with a European partner. We believe that the majority of European patients are treated at around 300 major hospitals and, as is the case in the United States, that a specialty pharmaceutical sales force could successfully market Riquent to the majority of these sites.

In order to commercialize Riquent in Europe through a partner, we would need to enter into marketing arrangements with one or more pharmaceutical or biotechnology companies. These collaborative arrangements may be exclusive or nonexclusive and may provide for marketing rights for a geographic region or for specified countries. 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 currently 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 payors.

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 101 issued patents and have 84 pending patent applications covering various technologies and drug candidates, including our Tolerance Technology, our lupus and antibody-mediated stroke drug candidates (Toleragens), and our carrier platform and linkage technologies for our Toleragens. Our issued patents include:

- four issued United States patents, one issued Australian patent, 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, one granted Finnish patent and one granted Irish patent concerning our lupus Toleragens (expiring in 2010, 2011, 2013, 2014, 2007, 2013, 2011, 2011, 2011, 2011 and 2011, respectively);

- two 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 patent**s**, one granted South Korean patent and one granted Irish patent concerning our Tolerance Technology (expiring in 2011, 2011, 2008, 2012, 2012, 2012, 2012, 2012 and 2012, respectively);

- seven issued United States patents, five issued Australian patents, one granted European patent (which has been unbundled as 15 European national patents), three issued Japanese patents, one granted Hong Kong patent, one granted Portuguese patent, one granted South Korean patent, and one granted Irish patent concerning carrier platform and linkage technologies for our Toleragens (expiring in 2012, 2014, 2015, 2015, 2015, 2016**,** 2019, 2014, 2014, 2012, 2012, 2017, 2012, 2012, 2012, 2012, 2012, 2014**,** 2014 and 2012 respectively); and

- two issued United States patents and one issued Australian patent concerning our antibody-mediated stroke drug candidates (expiring in 2016, 2015 and 2016, respectively).

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, thrombosis and other antibody-mediated diseases.

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 being developed by us or that would render our technology and proposed products obsolete or noncompetitive.

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, 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. We expect that competition among products approved for marketing 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/or the Public Health Service Act govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of 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”); 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 current Good Manufacturing Practices (“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/or to patients diagnosed with the condition for which the drug is being tested under the supervision of a qualified clinical investigator. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the Investigational New Drug application. Each clinical trial is conducted under the auspices of an independent Institutional Review Board (“IRB”). The IRB 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. In Phase 1, the phase in which the drug is initially introduced into healthy human subjects, 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.

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 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 profitability of the drug product. 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. 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 or the related NDA or BLA.

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 substantial 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 or the related NDA or BLA could be withdrawn. 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 product withdrawal.

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 can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes 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 9, 2004, we employed 128 full-time employees (including 17 people who have a Ph.D. and two people who have an M.D.), 104 of whom are involved full-time in research, development and manufacturing activities. All of our management has 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.

Executive Officers of the Registrant

Our executive officers and key employees and their ages are set forth below.

Name	Age	Title
Steven B. Engle	49	Chairman of the Board and Chief Executive Officer
Matthew D. Linnik, Ph.D.	44	Chief Scientific Officer, Executive Vice President of Research and Assistant Secretary
Bruce K. Bennett, Jr.	52	Vice President of Manufacturing
Kenneth R. Heilbrunn, M.D.	46	Vice President of Clinical Development
Paul C. Jenn, Ph.D.	53	Vice President of Product Development
Theodora Reilly	54	Vice President of Human Resources
Gail A. Sloan, CPA	41	Vice President of Finance, Controller and Secretary
William J. Welch	42	Vice President of Sales and Marketing
Andrew Wiseman, Ph.D.	55	Senior Director of Business Development and Investor Relations

Steven B. Engle, Chairman of the Board and Chief Executive Officer, joined the Company in 1993 as Executive Vice President and Chief Operating Officer. He assumed the offices of President, Director and Secretary in 1994, became Chief Executive Officer in 1995, and Chairman of the Board in 1997. From 1991 to 1993, Mr. Engle served as Vice President of Marketing at Cygnus Inc., a publicly held company that develops drug-delivery systems for therapeutic drugs, including Nicotrol®, a smoking cessation transdermal patch. From 1987 to 1991, he was Chief Executive Officer of Quantum Management Company, a privately held management consulting firm serving pharmaceutical and other industries. From 1984 to 1987, he was Vice President of Marketing and Divisional General Manager for Micro Power Systems, Inc., a privately held company that manufactures high technology products, including medical devices. From 1979 to 1984, he was a management consultant at Strategic Decisions Group and SRI International, where he advised pharmaceutical, high technology and other companies. Mr. Engle is a former Chairman of BIOCOM, a regional trade association for the biotechnology and medical

devices industries. Mr. Engle holds an M.S.E.E. and a B.S.E.E. with a focus in biomedical engineering from the University of Texas.

Matthew D. Linnik, **Ph.D.,** Chief Scientific Officer, Executive Vice President of Research and Assistant Secretary, joined the Company in 1998 as Director of Research and Development, was promoted to Vice President of Research in February 1999, to Executive Vice President of Research in June 1999 and to Chief Scientific Officer and Executive Vice President of Research in 2002. He was appointed Assistant Secretary in 1999. Prior to joining the Company, from 1989 to 1998, Dr. Linnik served as Senior Pharmacologist, Scientist, Research Scientist and Project Leader for Hoechst Marion Roussel, formerly Marion Merrell Dow and Marion Laboratories, a publicly held pharmaceutical company. From 1996 to 1998, he also served as Adjunct Associate Professor of Neurosurgery at the University of Cincinnati School of Medicine. From 1986 to 1988, he served as Postdoctoral Fellow, then Instructor, in the Departments of Neurology and Neurosurgery at Massachusetts General Hospital and Harvard Medical School. Dr. Linnik holds a B.A. in Physiology from Southern Illinois University and a Ph.D. in Physiology and Pharmacology from Southern Illinois University School of Medicine.

Bruce K. Bennett, Jr., Vice President of Manufacturing, joined the Company in January 2002. Prior to joining the Company, from 2000 to 2001, Mr. Bennett was Vice President of Operations at Provasis Therapeutics, Inc., a privately held medical device company. From 1997 to 2000, he served as Vice President of Operations, Regulatory Affairs/Quality Assurance and Commercial Development at VIA Medical Corporation, a privately held medical device company. From 1995 to 1996, he was Vice President of Manufacturing at Mulay Plastic, Inc., a privately held injection molding company. From 1992 to 1995, Mr. Bennett served as Vice President of Operations at Cygnus Therapeutic Systems, Inc., a publicly held company that develops drug-delivery systems for therapeutic drugs. From 1989 to 1992, he was Vice President of Manufacturing at Progress Lighting, a privately held manufacturer of decorative lighting fixtures. From 1987 to 1989, he was Vice President of Manufacturing at Sulzer Intermedics, Inc., a publicly held medical device company. From 1986 to 1987, Mr. Bennett served as Director of Manufacturing at Kendall Respiratory Care, Inc., a medical device division of Kendall — a subsidiary of Colgate-Palmolive Company. From 1979 to 1986, he was Operations Director at Kendall McGaw Laboratories, a medical device division of Kendall, and held several other positions. Mr. Bennett holds a B.S. in Industrial Technology from California State University, Long Beach and an M.B.A. from Pepperdine University.

Kenneth R. Heilbrunn, M.D., Vice President of Clinical Development, joined the Company in June 2002. Prior to joining the Company, from 1998 to 2002, he progressed to Vice President of Clinical Research at Advanced Tissue Sciences, Inc., a publicly held tissue engineering company, where he was responsible for a multicenter Phase 3 clinical trial which led to the FDA approval of Dermagraft®, a bioengineered human tissue. From 1997 to 1998, Dr. Heilbrunn served as Vice President of Medical Affairs at Hepatix, Inc., a privately held company engaged in the development of a bioengineered liver (extracorporeal liver assist device). From 1994 to 1996, he served as Staff Vice President of Medical Affairs at C.R. Bard, Inc., a publicly held manufacturer of healthcare products. From 1989 to 1994, he served as Medical Affairs Director for Cardiovascular and Pulmonary Drugs at Ciba-Geigy Pharmaceuticals Division, a manufacturer of health-care products, where he participated in the launch of the nicotine patch, Habitrol®, and the antihypertensive drug, Lotensin®. From 1986 to 1989, Dr. Heilbrunn served as Staff Internist and, ultimately, Director of the Critical Care unit at the 31st Tactical Air Force Hospital in Homestead, Florida. Dr. Heilbrunn completed his residency in internal medicine at Baystate Medical Center in Springfield, Massachusetts after receiving his M.D. from New York Medical College and his B.A. from Brown University.

Paul C. Jenn, **Ph.D.**, Vice President of Product Development, joined the Company in 1994 as Associate Director of Production and Process Development. Dr. Jenn was promoted to

Director of Operations in 1999, Senior Director of Operations in 2000, Vice President of Operations in 2001, and Vice President of Product Development in 2002. Prior to joining the Company, from 1992 to 1994, Dr. Jenn was Director of Peptide Manufacturing at Telios Pharmaceuticals, Inc., a publicly held pharmaceutical company, and held several other positions. From 1988 to 1992, he served as Senior Research Associate at Mallinckrodt Specialty Chemicals Company, a publicly held specialty chemical company. From 1984 to 1988, Dr. Jenn served as a Research Scientist at International Minerals and Chemical Corporation, a publicly held chemical company. From 1982 to 1984, he performed his post-doctoral research at the Lawrence Berkeley Laboratory at the University of California, Berkeley. Dr. Jenn holds a B.S. in Chemistry from Fu-Jen Catholic University, Taipei, Taiwan and a Ph.D. in Chemistry from State University of New York at Buffalo.

Theodora Reilly, Vice President of Human Resources, joined the Company in 1998 as Director of Human Resources and was promoted to Vice President of Human Resources in 2001. Prior to joining the Company, from 1997 to 1998, Ms. Reilly was Director of Human Resources at ThermoLase Corporation, a public subsidiary of Thermo Electron Corporation, which developed laser-based systems for laser-based skin resurfacing. From 1994 to 1997, Ms. Reilly served as Director of Human Resources at Solectek Corporation, a privately held high tech manufacturer of wireless interconnectivity products. Ms. Reilly received a B.S. in Psychology from the Christian Bible College and Seminary located in Independence, Missouri.

Gail A. Sloan, **CPA**, Vice President of Finance, Controller and Secretary, joined the Company in 1996 as Assistant Controller, was promoted to Controller in 1997, Senior Director of Finance in 2002 and Vice President of Finance in 2004. She was appointed Secretary in 1999. Prior to joining the Company, from 1993 to 1996, Ms. Sloan served as Assistant Controller at Affymax Research Institute, a publicly held drug-discovery research company and a part of the Glaxo Wellcome Group. From 1985 to 1993, she progressed to the position of Audit Manager with Ernst & Young LLP. Ms. Sloan holds a B.S. in Business Administration from California Polytechnic State University, San Luis Obispo and is a Certified Public Accountant.

William J. Welch, Vice President of Sales and Marketing, joined the Company in 1998 as Vice President of Business Development. After leaving the Company in 1999, he rejoined the Company in 2001 as Vice President of Marketing and was promoted to his current position in 2002. Prior to rejoining the Company, Mr. Welch was Vice President of Global Marketing at Dade Behring, a privately held global diagnostic company. From 1993 until 1998, Mr. Welch worked for Abbott Laboratories, a publicly held global healthcare company, as General Manager of Abbott Ambulatory Infusion Systems, Senior Marketing Manager of Abbott Renal Care and as Manager of Strategic Planning, Corporate Planning and Development. From 1991 to 1993, Mr. Welch was Director of Business Development for In-Process Technology, a privately held company that manufactured processing systems for the pharmaceutical industry. From 1989 to 1991, Mr. Welch was Senior Associate for D'Accord, Inc., a global investment banking company. Mr. Welch holds a B.S. in Chemical Engineering from the University of California, Berkeley and an M.B.A. from Harvard University.

Andrew Wiseman, **Ph.D.**, Senior Director of Business Development and Investor Relations, joined the Company in 1989 as Director of Business Development and was one of the Company's original founders. Dr. Wiseman has also served as head of investor relations since 1994. From 1983 to 1989, Dr. Wiseman held several positions with Quidel Corporation, a publicly held manufacturer of diagnostic tests, including Manager of Business Development, Project Manager in Diagnostic Research and Development and Senior Research Scientist. Dr. Wiseman was an Assistant Professor at the Medical Biology Institute and an Assistant Member at the Scripps Clinic and Research Foundation. He received a B.S. in Zoology and a Ph.D. in Genetics from Duke University.

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 as soon as reasonably practicable after we electronically file or furnish the reports with or to the Securities and Exchange Commission.

RISK FACTORS

I. Risk Factors Relating To La Jolla Pharmaceutical And The Industry In Which We Operate

If the continued development of Riquent is significantly delayed, our business and financial condition will be adversely affected and it may be difficult or impossible for us to survive.

The data from our Phase 2/3 and Phase 3 clinical trials of Riquent indicated that treatment with Riquent did not increase length of time to renal flare in the intent-to-treat population, the primary endpoint for the trials, in a statistically significant manner when compared with placebo. As a result, our ability to obtain regulatory clearance to market Riquent either in the United States or in Europe is uncertain, and we may be required to conduct additional clinical trials to demonstrate the safety and efficacy of Riquent. The uncertainty regarding the future development of Riquent may negatively affect our ability to raise necessary additional funding in the future. If the continued development of Riquent is significantly delayed for any reason, and if we are unable to timely raise additional funding, we may not have the financial resources to continue research and development of Riquent, LJP 1082, our drug candidate for the treatment of antibody-mediated thrombosis, or any other potential drug candidates, and it may be difficult or impossible for us to survive.

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

Our drug candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. In order to sell our products that are 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 other 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 or LJP 1082 are safe and effective after we complete our clinical trials. If Riquent or LJP 1082 are ultimately not found to be safe and effective, we would be unable to obtain regulatory approval to manufacture, market and sell these drugs. Currently, we have orphan drug designation for Riquent. In the course of the FDA's initial review of our NDA, the FDA has indicated that the indication for Riquent proposed in our NDA may be broader than the indication identified in our orphan drug designation. Accordingly, the FDA has indicated that we will be required to pay the filing fee for the NDA for Riquent at this time, even though the FDA's final approved indication, if any, may be within the original orphan drug designation. We intend to seek, and believe that we qualify for, a refund of the full filing fee under the FDA's small business regulations. Whether we will be able to take advantage of the benefits afforded by the orphan drug designation will ultimately be determined by the FDA only after further review of our NDA. Although our NDA for Riquent has been accepted for review by the FDA, we can provide no assurances that the FDA will approve Riquent.

We may be required to design and conduct additional studies to further demonstrate the safety and efficacy of our drug candidates, 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 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 the safety or efficacy of our drug candidates. It is possible that the FDA or foreign regulatory authorities may not ultimately approve Riquent, LJP 1082 or our other drug candidates for commercial sale in any jurisdiction, even if future clinical results are positive.

Because Riquent is our only drug candidate for which we have completed a Phase 3 clinical trial, and because there is no guarantee that we would be able to develop an alternate drug candidate, our inability to obtain regulatory approval of Riquent would have a severe negative effect on our business, and we may not have the financial resources to continue research and development of Riquent, LJP 1082 or any other potential drug candidates.

We may be unsuccessful in obtaining accelerated approval for Riquent under the Subpart H regulation.

Although we may pursue accelerated FDA approval for Riquent under the Subpart H regulation, there can be no assurance that reductions in levels of antibodies to dsDNA will be deemed by the FDA to be a surrogate endpoint that is reasonably likely to predict clinical benefit, that we will be able to agree with the FDA about the design and timing of a post-marketing clinical trial, or that we will be able to successfully complete any post-marketing clinical trial. The success of any future clinical trial that we may be required to conduct as part of a Subpart H approval process will depend, in part, on our ability to locate and enroll patients meeting the criteria specified for such a trial. We may be required to commence patient enrollment or to complete patient enrollment milestones for a post-marketing clinical trial prior to any regulatory approval that we may receive. The enrollment process may take a significant amount of time and may require significant funding. Any delay in meeting patient enrollment requirements may impact our ability to obtain timely regulatory approval for Riquent, if at all. A post-marketing efficacy trial may involve significantly more patients than were involved in the Phase 3 trial of Riquent and may require significant time to complete. Even if the FDA approves Riquent under Subpart H, if we fail to successfully complete a post-marketing clinical trial, the FDA would have the authority to remove Riquent from the market. Because Riquent is our only drug candidate for which we have completed a Phase 3 clinical trial, and because there is no guarantee that we would be able to develop an alternate drug candidate, our inability to obtain or maintain regulatory approval of Riquent would have a severe negative effect on our business, and we may not have the financial resources to continue research and development of Riquent, LJP 1082 or any other potential drug candidates.

Our blood test to measure the binding affinity for Riquent has not been validated by independent laboratories and is likely to require regulatory review as part of the Riquent approval process.

In 1998, we developed a blood test that we believe can identify the lupus patients who are most likely to respond to Riquent. The blood test is designed to measure the strength of the binding between Riquent and a patient's antibodies. This affinity assay was used to identify, prospectively in the 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 clinical trials of Riquent may not be observed in the broader lupus patient population. In addition, regulatory agencies will likely require that the assay be reviewed as part of the approval process of Riquent. The testing laboratory that will conduct the assay if Riquent is approved may also require additional regulatory approval. If additional regulatory approval of the testing laboratory is required, or if regulatory agencies do not concur with the use of the assay to identify potential patients for treatment with Riquent, the approval and possible commercialization of Riquent may be delayed or prevented.

If we are to obtain regulatory approval of Riquent, we must pass FDA inspection of our manufacturing facilities and processes.

In addition to demonstrating the safety and efficacy of Riquent in clinical trials, we must also pass FDA inspection of our manufacturing facilities in order to obtain FDA approval for the commercial use of Riquent. Before we can manufacture commercial product, we must validate our manufacturing facilities and processes to the satisfaction of the FDA. We have never operated a manufacturing facility that has passed an FDA pre-approval inspection. If we are unable to pass the necessary inspections, the FDA will not approve Riquent for commercial use.

We will need additional funds to support our operations.

Our operations to date have consumed substantial capital resources, and we may expend substantial amounts of capital resources for additional research, product development, pre-clinical testing and clinical trials of drug candidates. 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. We will need to raise additional funds to finance our future operations. Our future capital requirements will depend on many factors, including:

- our ability to obtain regulatory approval for Riquent,
- continued scientific progress in our research and development programs,
- the size and complexity of our research and development programs,
- the scope and results of pre-clinical testing and clinical trials,
- the time and costs involved in applying for regulatory approvals,
- 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 research, clinical development, manufacturing and marketing activities. If we ultimately receive regulatory approval for Riquent, LJP 1082 or our other drug candidates, our manufacturing, marketing and sales activities are likely to substantially increase our expenses and

our need for additional working capital. We anticipate that our existing cash and cash investments, including the net proceeds of $29.5 million we received from the recent sale of 10.0 million shares of common stock, and interest earned thereon, will be sufficient to fund our operations as currently planned into the second quarter of 2005, assuming that we do not engage in any significant clinical trial or commercialization activities and further assuming that we do not enter into an agreement with a collaborative partner or engage in any other fundraising activities. However, the amounts expended by us may vary significantly, and it is possible that our cash requirements will exceed current projections and that we will therefore need additional financing sooner than currently expected. In the future, it is possible that we will not have adequate resources to support continuation of our business activities.

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

We actively seek additional funding, including through public and private financings and collaborative arrangements. Our choice of financing alternatives may vary from time to time depending on various factors, including the market price of our securities, conditions in the financial markets and the interest of other entities in strategic transactions with us. There can be no guarantee that additional financing will be available on favorable terms, if at all, whether through issuance of securities, collaborative arrangements, or otherwise. If adequate funds are not available, we may be required to delay, scale back or eliminate one or more of our research and development programs or obtain funds through arrangements with collaborative partners or others that require us to relinquish rights to our technologies or potential products. We also may be required to 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, your investment in us will be diluted, and dilution can be particularly substantial when the price of our common stock is low.

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

Substantial capital investment in the expansion and build-out of our manufacturing facilities will be required to enable us to manufacture Riquent, if approved, in significant commercial quantities. We have limited manufacturing experience, and we may be unable to successfully transition to commercial production. In addition, we have never operated a manufacturing facility that has passed an FDA pre-approval inspection, 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 introduce products into the market on a timely and competitive basis and the subsequent sales of our products and our profit margins 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 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 our finished products, 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, the introduction of our products into the market and the subsequent

sales of these products would be negatively affected, and our profit margins and our ability to develop and deliver products on a timely and competitive basis may be negatively affected.

Our suppliers may not be able to provide us with sufficient quantities of materials that we may 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, LJP 1082 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 inspection or 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 may be 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, the introduction of any products into the market and the subsequent sales of any products would be negatively affected, and our profit margins and our ability to develop and deliver products on a timely and competitive basis may 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.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and review.

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 be required to adhere to regulations setting forth current good manufacturing practices. 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 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.

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 approximately 1,000,000 and that those with renal impairment, which Riquent is designed to treat, is approximately 300,000. With respect to antibody-mediated thrombosis, which LJP 1082 is designed to treat, we estimate that there are approximately 1,000,000 to 2,000,000 patients in the United States and Europe. For example, within the estimated antibody-mediated thrombosis patient population, we believe that antiphospholipid antibodies contributed to approximately 10% of the approximate 4,000,000 strokes in the United States in 2002. 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 our drug candidates will be observed in broader patient populations, and the number of patients who may benefit from our drug candidates may be significantly smaller than the estimated patient populations. Furthermore, management of patients with renal disease by specialists other than nephrologists and immunologists is likely to reduce our ability to access patients who may benefit from Riquent.

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 any of our 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.

Our drugs may not achieve market acceptance.

Even if Riquent or our other drug candidates receive regulatory approval, patients and physicians may not readily 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, 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 may experience delays and expenditures and have difficulty in gaining market acceptance of 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.

We may not earn as much income 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 income that we can generate from sales of future products. 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.

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 $192.4 million as of December 31, 2003. We expect to incur substantial losses each year for at least the next several years as we seek regulatory approval, conduct additional clinical trials of our drug candidates, and continue our research, clinical development, and manufacturing and marketing activities. In addition, assuming we ultimately receive favorable clinical results and FDA approval for Riquent, LJP 1082 or our other drug candidates, we will be required to develop commercial manufacturing capabilities and sales and marketing 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, LJP 1082 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. As of December 31, 2003, we owned 101 issued patents and 84 pending patent applications covering various technologies and drug candidates, including Riquent and LJP 1082. 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 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. Currently, we have a number of patent applications pending in the United States relating

to our technology, as well as foreign counterparts to some of our United States patent applications. We intend to continue to file applications as we believe 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. We are aware of one family of United States patents that contains claims covering subject matter that may conflict with some of our key patents and patent applications, and any such conflict may affect our ability to manufacture and sell our products in the future. If the United States Patent and Trademark Office or any foreign counterpart issues or has issued patents containing 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 will not have 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 in defending suits 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. Riquent and LJP 1082 have not been proven to be safe and effective in humans, and the technology on which they are based has been used only in our pre-clinical tests and clinical trials. Application of our technology to antibody-mediated diseases other than lupus and antibody-mediated thrombosis is in earlier research stages. Clinical trials of Riquent and LJP 1082 may be viewed as a test of our entire approach to developing therapies for antibody-mediated diseases. If Riquent or LJP 1082 does not work as intended, or if the data from our clinical trials indicates that Riquent or LJP 1082 is not safe and effective, the applicability of our technology for 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.

Future clinical trials may be delayed or halted.

Future clinical trials of Riquent or LJP 1082, trials of drugs related to these drugs, or clinical trials of other drug candidates may be delayed or halted. During the development of Riquent, our Phase 2/3 clinical study, in collaboration with Abbott Laboratories, was terminated before planned patient enrollment was completed. Future trials may be delayed or halted for various reasons, including:

- the products are not effective,
- patients experience severe side effects during treatment,
- the trials are not conducted in accordance with applicable clinical practices,
- patients do not enroll in the studies at the rate we expect, or
- supplies of drug product are not sufficient to treat the patients in the studies.

If any future trials are delayed or halted, we may incur significant additional expenses, which could have a severe negative effect on our business.

Our research and development and operations depend in part on key employees. Losing these employees would have a negative effect on our product development and operations.

We are highly dependent on the principal members of our scientific and management staff, the loss of whose services would delay the achievement of our research and development objectives. This is because our key personnel, including Steven Engle, Dr. Matthew Linnik, Dr. Paul Jenn and Dr. Andrew Wiseman, have been involved in the development of Riquent, LJP 1082 and other drug candidates for several years and have unique knowledge of our drug candidates and of the technology on which they are based. In addition, we will be required to rely on other key members of our senior management team, including Bruce Bennett, Dr. Kenneth Heilbrunn, and William Welch, to assist us with growth and expansion into areas requiring additional expertise, such as clinical trials, regulatory approvals, manufacturing, marketing and sales. We expect that we will continue to require additional management personnel, and that our existing management personnel will be required to develop additional expertise.

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

Retaining our current key personnel and recruiting additional qualified personnel to perform research and development, clinical development, manufacturing, marketing and sales will be critical to our success. Because competition for experienced scientific, clinical, manufacturing, 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 and to develop and sell our 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 research and development, clinical, regulatory, manufacturing, 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.

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 seek to collaborate with pharmaceutical companies to gain access to their research, drug development, manufacturing, marketing, sales and financial 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 the sales of our 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 research, development, manufacturing, marketing and sales activities, which would accelerate the depletion of our cash and require us to develop our own manufacturing, 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 would experience a material adverse effect on our ability to develop products and, if developed and approved, to manufacture, market and sell them successfully.

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 which 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 and thrombosis. Our competitors may develop or obtain regulatory approval for products more rapidly than we do. 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 being developed by us, or that would render our technology and proposed products obsolete or noncompetitive.

The use of Riquent, LJP 1082 and 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, LJP 1082 and other potential products may expose us to legal liability and generate 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, and 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 reputation 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 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

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:

- actions or decisions by the FDA and other comparable agencies,
- our clinical trial results,
- 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 existing stockholders,
- developments concerning potential agreements with collaborators,
- comments by securities analysts and general market conditions, and
- government regulation.

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.

In the future, our stock may be removed from listing on the Nasdaq quotation system and may not qualify for listing on any stock exchange, in which case it may be difficult to find a market in our stock.

If our stock is no longer traded on a national trading market, it may be more difficult for you to sell shares that you own, and the price of the stock may be negatively affected. Currently, our securities are traded on the Nasdaq National Market. Nasdaq has several continued listing requirements, including a minimum-trading price. Previously, we have received notice from Nasdaq that our stock price fell below this minimum trading price. Although we have since come back into compliance with this Nasdaq requirement, it is possible that we will fall out of compliance with this and/or other Nasdaq continued listing criteria at some point in the future. Failure to comply with any one of several Nasdaq requirements may cause our stock to be removed from listing on Nasdaq. Should this happen, we may not be able to secure listing on other exchanges or quotation systems. This would have a negative effect on the price and liquidity of our stock.

Future sales of our stock by existing stockholders could negatively affect the market price of our stock and make it more difficult for us to sell stock in the future.

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 and make it more difficult for us to complete future equity financings on acceptable terms, if at all. As of December 31, 2003, there were:

- Approximately 51,052,185 shares of common stock that have been issued in registered offerings or were otherwise freely tradable in the public markets.
- Approximately 72,348 shares of common stock eligible for resale in the public market pursuant to SEC Rule 144.
- 7,476,645 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 $4.79 per share.
- Approximately 9,200,000 shares of common stock reserved under our incentive stock option 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 December 31, 2003, there was $102,587,500 of our common stock available for future issuance. After giving effect to the recent sale of 10.0 million shares of our common stock, there is an aggregate amount of $71,087,500 of our common stock available for future issuance pursuant to the registration statement.

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 institutional 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.

Anti-takeover devices may prevent changes in our 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.

We do not pay dividends and this may negatively affect the price of our stock.

We have not paid any cash dividends since our inception and do not anticipate paying any cash dividends in the foreseeable future. The future price of our common stock may be negatively affected by the fact that we have not paid dividends.

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 2004. Each lease includes an option to extend the term of the lease for an additional five years and each is subject to an escalation clause that provides for annual rent increases. We have exercised our option to extend the lease for an additional five years on the corporate offices and warehouse lease and anticipate that we will exercise the option to extend on the other lease as well. We also lease approximately 1,500 square feet of laboratory space in San Diego, California for research and development purposes. This lease, which was extended in August 2003, expires in May 2004. We anticipate that we will extend the lease term through the end of 2004. 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.

No matters were submitted to a vote of security holders during the three-month period ended December 31, 2003.

PART II

Item 5. Market For Registrant's Common Equity and Related Stockholder Matters.

Information About Our Common Stock

Our common stock trades on the Nasdaq National 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.

	Prices	
	High	Low
Year Ended December 31, 2003		
First Quarter	$8.88	$1.12
Second Quarter	4.31	1.45
Third Quarter	5.21	2.80
Fourth Quarter	4.50	2.82
Year Ended December 31, 2002		
First Quarter	$9.42	$5.42
Second Quarter	7.58	3.85
Third Quarter	6.13	4.05
Fourth Quarter	7.05	3.40

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 10, 2004 was approximately 337.

Information About Our Equity Compensation Plans

Information regarding the securities authorized for issuance under our equity compensation plans required by Item 5 is incorporated by reference from our definitive proxy statement for the 2004 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year ended December 31, 2003.

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 below and the financial statements of the Company and related notes thereto beginning at page F-1 of this report.

	Years Ended December 31,				
	1999	2000	2001	2002	2003
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue from collaborative agreements – related party	$ 4,690	$ —	$ —	$ —	$ —
Expenses:					
Research and development	11,686	12,933	23,228	37,696	32,385
General and administrative	2,944	2,706	4,268	6,944	6,908
Loss from operations	(9,940)	(15,639)	(27,496)	(44,640)	(39,293)
Interest expense	(20)	(6)	(30)	(51)	(210)
Interest income	811	1,846	2,843	1,373	665
Net loss	$ (9,149)	$(13,799)	$(24,683)	$(43,318)	$(38,838)
Basic and diluted net loss per share	$ (0.45)	$ (0.53)	$ (0.71)	$ (1.03)	$ (0.85)
Shares used in computing basic and diluted net loss per share	20,135	26,138	34,604	42,046	45,804
Balance Sheet Data:					
Working capital	$10,661	$ 37,215	$ 44,387	$ 46,490	$ 28,914
Total assets	$14,043	$ 43,016	$ 51,686	$ 61,864	$ 41,944
Noncurrent portion of obligations under capital leases and notes payable	$ 44	$ —	$ —	$ 1,111	$ 1,341
Stockholders' equity	$12,793	$ 39,742	$ 48,545	$ 53,799	$ 36,427

Quarterly Results of Operations

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2003 and 2002 (in thousands except per share data):

	Quarters Ended			
	Mar. 31,	Jun. 30,	Sept. 30,	Dec. 31,
2003				
Expenses:				
Research and development	$ 11,920	$ 8,417	$ 5,633	$ 6,415
General and administrative	1,801	1,598	1,413	2,096
Loss from operations	(13,721)	(10,015)	(7,046)	(8,511)
Interest expense	(43)	(50)	(57)	(60)
Interest income	223	142	169	131
Net loss	$(13,541)	$ (9,923)	$ (6,934)	$ (8,440)
Basic and diluted net loss per share	$ (0.32)	$ (0.23)	$ (0.15)	$ (0.17)
Shares used in computing basic and diluted net loss per share	42,480	42,569	47,089	50,970
2002				
Expenses:				
Research and development	$ 7,244	$ 9,661	$ 9,448	$ 11,343
General and administrative	1,413	1,788	1,656	2,087
Loss from operations	(8,657)	(11,449)	(11,104)	(13,430)
Interest expense	(6)	(9)	(7)	(29)
Interest income	548	100	425	300
Net loss	$ (8,115)	$(11,358)	$(10,686)	$(13,159)
Basic and diluted net loss per share	$ (0.20)	$ (0.27)	$ (0.25)	$ (0.31)
Shares used in computing basic and diluted net loss per share	40,979	42,356	42,402	42,427

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Recent Developments

On February 18, 2003, we announced initial results from our Phase 3 clinical trial of Riquent, our clinical drug candidate for the treatment of lupus renal disease. Although the trial did not reach statistical significance for its primary endpoint, time to renal flare, the Phase 3 trial results demonstrated that lupus patients treated with Riquent had significantly lower levels of antibodies to dsDNA than patients treated with a placebo. Data from the Phase 3 and Phase 2/3 studies demonstrated that lupus patients with sustained reductions in antibodies to dsDNA experienced fewer renal flares. In these two studies, two and four times as many Riquent-treated patients had sustained reductions compared with placebo-treated patients.

On May 5, 2003, we announced that, based on our discussions with the FDA, we planned to complete an NDA for Riquent around the end of 2003.

In addition to closing our Riquent-related clinical trials, in May 2003 we reduced the size of our organization by 24 positions, including certain management positions. We began to realize the cost savings from these actions in the third quarter of 2003.

On June 16, 2003, we announced the HRQOL results from our Phase 3 clinical trial of Riquent. Patients in our Phase 3 trial with sustained reductions in antibodies to dsDNA reported improved HRQOL and had a lower risk of Major SLE flare compared with patients who did not have sustained reductions. A Major SLE flare was defined as the occurrence of any one of the following events due to the manifestation of active SLE: treatment with HDCC or initiation or increase in treatment with other identified immunosuppressive agents; hospitalization; or death. Similar results were also seen in our Phase 2/3 trial. We believe that these results support the pathogenicity or disease-causing ability of antibodies to dsDNA in lupus patients.

On July 24, 2003, we announced that, based on recent discussions with the FDA, we may pursue an accelerated approval for Riquent under the Subpart H regulation. 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 announced, 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. We believe that data from our clinical trials and the relevant medical literature would support the use of the level of antibodies to dsDNA as a surrogate endpoint that would be reasonably likely to predict clinical benefit.

On August 13, 2003, we announced that we had completed a public offering of 8,150,000 shares of our common stock. The net proceeds that we received from the offering, after expenses, were approximately $20.9 million.

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 ("semicarbazide-sensitive amine oxidase"), an enzyme that has been implicated in inflammatory responses in many tissues and organs. Preclinical studies in animal models of multiple sclerosis, rheumatoid arthritis and acute inflammation have shown that treatment with our inhibitors both maintained function and reduced disease activity compared with placebo treatment.

On December 16, 2003, we announced that we had submitted our NDA for Riquent with the FDA.

On February 16, 2004, we announced that our NDA for Riquent had been accepted for review by the FDA. The acceptance of the NDA by the FDA indicates that the NDA is sufficiently complete to permit a substantive review of the application. Further discussions with the FDA will be needed to clarify whether any additional supportive information or studies will be required to support the approval of the NDA. The FDA will determine whether to approve Riquent, either on the basis of our clinical trial results or under Subpart H, and the conditions of any approval, after it has reviewed our NDA. We are currently in discussion with the FDA about the design and timing of a post-marketing clinical trial that would be required if Subpart H approval is pursued. We also are currently meeting with European regulatory authorities to discuss potential next steps for Riquent in Europe. There can be no guarantee that meetings with the FDA and other regulatory agencies can be held in a timely manner, or at all, or that our meetings with them will result in our being able to continue to develop Riquent. If for any reason our development efforts as to Riquent are terminated, it would have a material adverse effect on our business and future prospects.

On February 26, 2004, we announced that we had completed a public offering of 8,695,653 shares of our common stock. The net proceeds that we received from the offering, after expenses, were approximately $25.6 million.

On March 5, 2004, we announced that the underwriter for the recently completed public offering purchased an additional 1,304,347 shares at the initial offering price per share pursuant to the over-allotment option granted to the underwriter in connection with the offering. The net proceeds that we received from the sale of the over-allotment shares were approximately $3.9 million.

On March 11, 2004, we announced additional analyses of data from our Phase 3 and Phase 2/3 trials of Riquent. The data showed 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. Additional details regarding this announcement can be found under the heading “Additional findings from the Phase 3 and Phase 2/3 trials,” on page 12 of this report.

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 private and public investors, revenue from collaborative agreements, equipment financings, and interest income on invested cash balances for our working capital. Depending on the outcome of the FDA’s review of our NDA, our discussions with the FDA and other regulatory agencies and our continuing analysis of the data from our clinical trials of Riquent, our research and development expenses may increase significantly in the future if we are required to conduct additional clinical studies to demonstrate the safety and efficacy of Riquent or if we increase our commercialization activities of Riquent, development of LJP 1082, or efforts to develop additional drug candidates. 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 revenues earned from any potential collaborative arrangements we may establish. Some of these fluctuations may be significant. As of December 31, 2003, our accumulated deficit was approximately $192.4 million.

Our business is subject to significant risks including, but not limited to, the risks inherent in research and development efforts, including clinical trials, uncertainties associated with both obtaining and enforcing patents and with the potential enforcement of the patent rights of others, the lengthy, expensive and uncertain process of seeking regulatory approvals, uncertainties regarding government reforms and of product pricing and reimbursement levels, technological change and competition, manufacturing uncertainties, our lack of marketing experience and the uncertainty of receiving future revenue from product sales or other sources such as collaborative relationships, the uncertainty of future profitability and the clear need for additional financing. 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 accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to patent costs and income taxes. 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 policy affects the significant judgments and estimates used in the preparation of our consolidated financial statements (see note 1 to our financial statements).

Impairment and useful lives of long-lived assets.

We regularly review long-lived assets for impairment. Our long-lived assets include costs incurred to file our patent applications. We evaluate the recoverability of long-lived assets by measuring the carrying amount of the assets against the estimated undiscounted future cash flows associated with them. At the time such evaluations indicate that the future undiscounted cash flows of certain long-lived assets are not sufficient to recover the carrying value of such assets, the assets are adjusted to their fair values. The estimation of the undiscounted future cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from the actual results. 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, and accordingly we have not recognized any impairment losses through December 31, 2003.

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 when we begin amortizing the costs related to unissued patents.

Results of Operations

Years Ended December 31, 2003, 2002 and 2001

Research and Development Expense. Our research and development expense decreased to $32.4 million for the year ended December 31, 2003 from $37.7 million in 2002 and increased from $23.2 million in 2001. The decrease in research and development expenses in 2003 from 2002 was primarily due to a decrease in expenses related to the Phase 3 clinical trial of Riquent which was completed in December 2002, the open-label follow-on clinical trial of Riquent which was initiated in July 2002 and closed in April 2003, and the Phase 1/2 clinical trial of LJP 1082 which was completed in October 2002. This decrease was partially offset by an increase in personnel costs, including the restructuring charges recorded in May 2003 of $0.3 million for 19 research and development employees. The increase in research and development expense in 2003 from 2001 was primarily due to the cost of the open-label follow-on clinical trial for Riquent which was initiated in July 2002 and closed in April 2003, as well as an increase in personnel costs as discussed above.

Research and development expense of $32.4 million for the year ended December 31, 2003 consisted of $27.1 million for lupus research and development related expense, $3.1 million for thrombosis research and development related expense and $2.2 million for other research and development related expense. Total lupus related research and development expense consisted primarily of salaries and other costs related to research, manufacturing and clinical personnel, clinical research organization fees, investigator fees, contract clinical research associate fees, clinical lab fees and fees for consulting and professional outside services. Total thrombosis related research and development expense consisted primarily of salaries for research and development personnel, raw materials for the production of LJP 1082 for research purposes and depreciation expense. Total other research and development expense consisted primarily of salaries for research and development personnel, research supplies and lease expense.

Our research and development expense may increase significantly in the future if we are required to initiate an additional clinical trial of Riquent, initiate commercialization activities for Riquent, increase our development activities of LJP 1082 or increase our development of additional drug candidates.

General and Administrative Expense. Our general and administrative expense of $6.9 million for the year ended December 31, 2003 remained consistent with 2002 and increased from $4.3 million in 2001. The increase in general and administrative expense in 2003 as compared to 2001 was due to an increase in headcount and administrative infrastructure to support increased clinical trial, manufacturing and research and development activities. General and administrative expense may increase in the future to support possible increases in commercialization, clinical trial, manufacturing and research and development activities.

Interest Income and Expense. Our interest income decreased to $0.7 million for the year ended December 31, 2003 from $1.4 million in 2002 and $2.8 million in 2001. The decrease in interest income in 2003 was due to lower average interest rates on our investments and lower average balances of cash and short-term investments as compared to 2002 and 2001. Interest

expense increased to $210,000 for the year ended December 31, 2003 from $51,000 in 2002 and $30,000 in 2001. The higher interest expense in 2003 as compared to 2002 and 2001 was due to new notes payable obligations entered into in 2003 to finance equipment purchases.

Net Operating Loss and Research Tax Credit Carryforwards. At December 31, 2003, we had available net operating loss carryforwards and research tax credit carryforwards of approximately $182.9 million and $10.0 million, respectively, for federal income tax purposes, which will begin to expire in 2005 unless utilized. Approximately $1.4 million of the federal net operating loss carryforward is set to expire in 2005 unless utilized and approximately $0.1 million of the federal research tax credit carryforward is set to expire in 2005 unless utilized. At December 31, 2003, we had available net operating loss carryforwards and research tax credit carryforwards of approximately $67.1 million and $5.0 million, respectively, for California income tax purposes, which will begin to expire in 2004 unless utilized. Approximately $0.3 million of the California net operating loss carryforward is set to expire in 2004 and approximately $0.7 million is set to expire in 2005, unless utilized.

Liquidity and Capital Resources

From inception through December 31, 2003, we have incurred a cumulative net loss of approximately $192.4 million and have financed our operations through private and public offerings of securities, revenues from collaborative agreements, equipment financings and interest income on invested cash balances. From inception through December 31, 2003, we had raised $228.1 million in net proceeds from sales of equity securities.

At December 31, 2003, we had $32.1 million in cash, cash equivalents and short-term investments, as compared to $52.7 million at December 31, 2002. Our working capital at December 31, 2003 was $28.9 million, as compared to $46.5 million at December 31, 2002. The decrease in cash, cash equivalents and short-term investments resulted from the use of our financial resources to fund our clinical trials, research and development efforts, manufacturing activities and for other general corporate purposes, partially offset by net proceeds of $20.9 million we received from the sale of 8,150,000 shares of our common stock in August 2003. We invest our cash in corporate and United States government-backed debt instruments. As of December 31, 2003, 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 date. As of December 31, 2003, available-for-sale securities of $14.6 million have stated maturity dates of one year or less and $16.1 million have maturity dates after one year.

As of December 31, 2003, we had acquired an aggregate of $13.3 million in property and equipment, of which $0.2 million and $3.0 million of equipment is financed under capital lease and notes payable obligations, respectively. In addition, we lease our office and laboratory facilities and certain equipment under operating leases. We have also entered into a $1.4 million purchase commitment with a potential third party manufacturer of materials for Riquent. The purpose of the agreement is to qualify the manufacturer as a manufacturer that we could use in the commercial production of Riquent if we obtain regulatory approval. The agreement includes a cancellation fee of $0.4 million. We intend to use our current financial resources to fund our obligation under this purchase commitment. In the future, we may have additional increases to 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 at December 31, 2003, and the effect such obligations are expected to have on our liquidity and cash flows in future periods:

	Payment due by period (in thousands)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-Term Debt Obligations	$2,317	$ 901	$ 1,392	$ 24	$ —
Capital Lease Obligations	100	70	30	—	—
Operating Lease Obligations	887	776	111	—	—
Purchase Obligations	1,370	1,370	—	—	—
Total	$4,674	$ 3,117	$ 1,533	$ 24	$ —

We intend to use our financial resources to fund our research and development efforts, to fund possible further clinical trials, manufacturing and commercialization activities of Riquent, and for working capital and other general corporate purposes. The amounts actually expended for each purpose may vary significantly depending on numerous factors, including the timing of any regulatory applications and approvals, the outcome of our meetings with regulatory authorities, the continued analysis of the Phase 3 clinical trial data, results from future clinical trials, and technological developments. Expenditures also will depend on any establishment and progress of collaborative arrangements and contract research as well as the availability of other funding or financings. There can be no assurance that future funds will be available on acceptable terms, if at all.

We anticipate that our existing cash and cash investments, including the net proceeds of $29.5 million we received from the recent sale of 10.0 million shares of common stock, and interest earned thereon, will be sufficient to fund our operations as currently planned into the second quarter of 2005, assuming that we do not engage in any significant clinical trial or commercialization activities and further assuming that we do not enter into an agreement with a collaborative partner or engage in any other financing activities. Our future capital requirements will depend on many factors, including the FDA's review of our NDA for Riquent, the outcome of meetings with regulatory authorities, the time and costs involved in applying for any regulatory approvals, the continued analysis of data from the Phase 3 clinical trial of Riquent and the Phase 1/2 clinical trial of LJP 1082, the scope and results of future clinical trials, continued scientific progress in our research and development programs, the size and complexity of these 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 relationships, and the cost of possible manufacturing and commercialization activities. We expect to incur significant net operating losses each year for at least the next several years as we continue our current research and development efforts, including possible additional clinical trials, manufacturing and commercialization activities of Riquent, and incur general and administrative expenses to support these efforts. It is possible that our cash requirements will exceed current projections and that we will therefore need additional financing sooner than currently expected.

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, could 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 appropriate means, including issuance of our securities and establishment of additional collaborative arrangements. However, there can be no assurance that additional financing will be available 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.

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 which 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 49 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 can be found above under the caption “Quarterly Results of Operations” on page 41 and at the end of this report beginning on page F-1.

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

None.

Item 9A. Controls and Procedures.

(a) As of the end of the period covered by this annual report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our principal executive officer and principal financial officer have concluded that these disclosure controls and procedures are effective in timely alerting them to material information relating to La Jolla Pharmaceutical Company required to be included in our periodic SEC filings.

(b) There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. Directors and Executive Officers of the Registrant.

Except for information concerning our executive officers which is included under the caption “Executive Officers of the Registrant” beginning on page 23 of this report, the information required by Item 10 is incorporated by reference to our definitive proxy statement for the 2004 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2003.

Item 11. Executive Compensation.

The information required by Item 11 is incorporated by reference to our definitive proxy statement for the 2004 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2003.

Item 12. Security Ownership of Certain Beneficial Owners and Management.

The information required by Item 12 is incorporated by reference to our definitive proxy statement for the 2004 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2003.

Item 13. Certain Relationships and Related Transactions.

None.

Item 14. Principal Accountant Fees and Services.

The information required by Item 14 is incorporated by reference to our definitive proxy statement for the 2004 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2003.

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

(a) Documents filed as part of this report.

1. Financial Statements.

The following financial statements of La Jolla Pharmaceutical Company are included in Item 8:

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 financial statements or notes thereto.

3. Exhibits.

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

(b) Reports on Form 8-K.

On October 17, 2003, we filed a current report on Form 8-K to report that certain directors and officers of La Jolla Pharmaceutical Company had amended previously reported trading plans. On October 28, 2003, we filed a current report on Form 8-K to report that Matthew Linnik, Ph.D., our Chief Scientific Officer and Executive Vice President of Research, and several of our clinical investigators reviewed previously released data from our clinical trials of Riquent and data regarding LJP 1082 at the American College of Rheumatology 67th Annual Scientific Meeting. On November 6, 2003, we filed a current report on Form 8-K pursuant to which we furnished a release regarding our third quarter financial results for 2003. On November 17, 2003, we filed a current report on Form 8-K to report that La Jolla Pharmaceutical Company had been selected to be added to the NASDAQ Biotechnology Index effective November 24, 2003 and that Matthew Linnik, Ph.D. and two of our principal investigators presented analyses showing associations between changes in levels of antibodies to double-stranded DNA and the relative risk of renal flare in our Phase 2/3 and Phase 3 trials of Riquent at the American Society of Nephrology Annual Meeting. On December 3, 2003, we filed a current report on Form 8-K to report the discovery of novel, orally-

active small molecules for the treatment of autoimmune diseases and acute and chronic inflammatory disorders. On December 16, 2003, we filed a current report on Form 8-K to report that we had submitted an NDA with the FDA for Riquent. On February 17, 2004, we filed a current report on Form 8-K to report that our NDA for Riquent was accepted for review by the FDA. On February 20, 2004, we filed a current report on Form 8-K to report that we had entered into an underwriting agreement, pursuant to which we agreed to sell 8,695,653 shares of our common stock in an underwritten public offering, that we had granted the underwriter an option, exercisable within 30 days of the date of the prospectus supplement, to purchase an additional 1,304,347 shares to cover over-allotments, and that we had filed a Prospectus Supplement with the Securities and Exchange Commission relating to the underwritten public offering of the shares. On February 26, 2004, we filed a current report on Form 8-K to report that we had completed our previously announced public offering. On March 2, 2004, we filed a current report on Form 8-K pursuant to which we furnished a release regarding our fourth quarter and annual financial results for 2003. On March 3, 2004, we filed a current report on Form 8-K to report that Steven Engle would present at the Lehman Brothers Seventh Annual Global Healthcare Conference. On March 8, 2004, we filed a current report on Form 8-K to report that the underwriter for our recently completed public offering of shares of common stock had purchased an additional 1,304,347 shares at the initial offering price per share pursuant to the over-allotment option granted to the underwriter in connection with the offering. On March 10, 2004, we filed a current report on Form 8-K to report that Steven Engle would present at the SG Cowen 24th Annual Healthcare Conference and that Gail Sloan was promoted to Vice President of Finance, Controller and Secretary. On March 11, 2004, we filed a current report on Form 8-K to report additional data from our Phase 3 and 2/3 clinical trials of Riquent.

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

By: /s/ Steven B. Engle

March 12, 2004

Steven B. Engle
Chairman of the Board and
Chief Executive Officer

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

Signature	Title	Date
/s/ Steven B. Engle Steven B. Engle	Chairman of the Board and Chief Executive Officer (Principal Executive Officer and Director)	March 12, 2004
/s/ Gail A. Sloan Gail A. Sloan	Vice President of Finance, Controller and Secretary (Principal Financial and Accounting Officer)	March 12, 2004
/s/ Thomas H. Adams Thomas H. Adams, Ph.D.	Director	March 12, 2004
/s/ William E. Engbers William E. Engbers	Director	March 12, 2004
/s/ Robert A. Fildes Robert A Fildes, Ph.D.	Director	March 12, 2004
/s/ Stephen M. Martin Stephen M. Martin	Director	March 12, 2004
/s/ William R. Ringo William R. Ringo	Director	March 12, 2004
/s/ W. Leigh Thompson W. Leigh Thompson, M.D., Ph.D.	Director	March 12, 2004

Report of Independent Auditors

The Board of Directors and Stockholders
La Jolla Pharmaceutical Company

We have audited the accompanying balance sheets of La Jolla Pharmaceutical Company as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of La Jolla Pharmaceutical Company at December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

ERNST & YOUNG LLP

San Diego, California
February 13, 2004
except for Note 9, as to which the date is February 25, 2004

La Jolla Pharmaceutical Company

Balance Sheets

(In thousands, except share and per share data)

	December 31,	
	2003	2002
Assets		
Current assets:		
Cash and cash equivalents	$ 4,021	$ 5,610
Short-term investments	28,112	47,115
Other current assets	957	719
Total current assets	33,090	53,444
Property and equipment, net	6,206	6,034
Patent costs and other assets, net	2,648	2,386
	$ 41,944	$ 61,864
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 278	$ 1,846
Accrued clinical/regulatory expenses	524	2,454
Accrued expenses	865	828
Accrued payroll and related expenses	1,692	1,332
Current portion of obligations under capital leases	66	60
Current portion of obligations under notes payable	751	434
Total current liabilities	4,176	6,954
Noncurrent portion of obligations under capital leases	29	—
Noncurrent portion of notes payable	1,312	1,111
Commitments:		
Stockholders' equity:		
Preferred stock, $.01 par value; 8,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $.01 par value; 100,000,000 shares authorized, 51,124,533 and 42,461,326 shares issued and outstanding at December 31, 2003 and 2002, respectively	511	425
Additional paid-in capital	228,394	206,905
Other comprehensive (loss) income	(73)	36
Accumulated deficit	(192,405)	(153,567)
Total stockholders' equity	36,427	53,799
	$ 41,944	$ 61,864

See accompanying notes.

La Jolla Pharmaceutical Company

Statements of Operations

(In thousands, except per share data)

	Years Ended December 31,		
	2003	2002	2001
Expenses:			
Research and development	$ 32,385	$ 37,696	$ 23,228
General and administrative	6,908	6,944	4,268
Total expenses	39,293	44,640	27,496
Loss from operations	(39,293)	(44,640)	(27,496)
Interest expense	(210)	(51)	(30)
Interest income	665	1,373	2,843
Net loss	$(38,838)	$(43,318)	$(24,683)
Basic and diluted net loss per share	$ (0.85)	$ (1.03)	$ (0.71)
Shares used in computing basic and diluted net loss per share	45,804	42,046	34,604

See accompanying notes.

La Jolla Pharmaceutical Company

Statements of Stockholders' Equity
(In thousands)
For the Years Ended December 31, 2001, 2002 and 2003

	Common stock		Additional paid-in capital	Accumulated deficit	Other comprehensive income (loss)	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2000	29,393	$294	$124,909	$(85,566)	$105	$39,742
Issuance of common stock, net	5,700	57	33,037	—	—	33,094
Issuance of common stock under Employee Stock Purchase Plan	145	2	226	—	—	228
Exercise of stock options	44	—	51	—	—	51
Net loss	—	—	—	(24,683)	—	(24,683)
Net unrealized gains on available-for-sale securities	—	—	—	—	113	113
Comprehensive loss						(24,570)
Balance at December 31, 2001	35,282	353	158,223	(110,249)	218	48,545
Issuance of common stock, net	7,000	70	48,230	—	—	48,300
Issuance of common stock under Employee Stock Purchase Plan	77	1	284	—	—	285
Exercise of stock options	102	1	168	—	—	169
Net loss	—	—	—	(43,318)	—	(43,318)
Net unrealized losses on available-for-sale securities	—	—	—	—	(182)	(182)
Comprehensive loss						(43,500)
Balance at December 31, 2002	42,461	425	206,905	(153,567)	36	53,799
Issuance of common stock, net	8,150	81	20,824	—	—	20,905
Issuance of common stock under Employee Stock Purchase Plan	313	3	462	—	—	465
Exercise of stock options	201	2	203	—	—	205
Net loss	—	—	—	(38,838)	—	(38,838)
Net unrealized losses on available-for-sale securities	—	—	—	—	(109)	(109)
Comprehensive loss						(38,947)
Balance at December 31, 2003	51,125	$ 511	$ 228,394	$(192,405)	$ (73)	$ 36,427

See accompanying notes.

La Jolla Pharmaceutical Company

Statements of Cash Flows
(In thousands)

	Years Ended December 31,		
	2003	2002	2001
Operating activities			
Net loss	$(38,838)	$(43,318)	$(24,683)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	1,918	1,391	684
Write-off of property and equipment	—	—	96
Write-off of patents	176	—	—
Accretion of interest income	74	426	117
Changes in operating assets and liabilities:			
Other current assets	(238)	(151)	22
Accrued clinical/regulatory expenses	(1,930)	1,751	(1,211)
Accounts payable and accrued expenses	(1,531)	854	792
Accrued payroll and related expenses	360	881	163
Net cash used for operating activities	(40,009)	(38,166)	(24,020)
Investing activities			
Purchases of short-term investments	(56,152)	(71,333)	(33,886)
Sales of short-term investments	69,385	29,942	3,488
Maturities of short-term investments	5,587	30,696	25,204
Additions to property and equipment	(1,809)	(5,143)	(1,341)
Increase in patent costs and other assets	(549)	(348)	(554)
Net cash provided by (used for) investing activities	16,462	(16,186)	(7,089)
Financing activities			
Net proceeds from issuance of common stock	21,575	48,754	33,373
Proceeds from issuance of notes payable	1,161	1,656	—
Payments on notes payable	(643)	(111)	—
Payments on obligations under capital leases	(135)	(269)	(393)
Net cash provided by financing activities	21,958	50,030	32,980
(Decrease) increase in cash and cash equivalents	(1,589)	(4,322)	1,871
Cash and cash equivalents at beginning of period	5,610	9,932	8,061
Cash and cash equivalents at end of period	$ 4,021	$ 5,610	$ 9,932
Supplemental disclosure of cash flow information:			
Interest paid	$ 210	$ 51	$ 30
Supplemental schedule of noncash investing and financing activities:			
Capital lease obligations incurred for property and equipment	$ 170	$ 162	$ 516
Other comprehensive (loss) income on investments	$ (109)	$ (182)	$ 113

See accompanying notes.

La Jolla Pharmaceutical Company
Notes to Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization and Business Activity

La Jolla Pharmaceutical Company (the "Company") is a biopharmaceutical company focused on the research and development of highly specific therapeutic products for the treatment of certain life-threatening antibody-mediated diseases. These diseases, including autoimmune conditions such as lupus and antibody-mediated thrombosis, are caused by abnormal B cell production of antibodies that attack healthy tissues. Current therapies for these autoimmune disorders address only symptoms of the disease, or nonspecifically suppress the normal operation of the immune system, which often results in severe, negative side effects and hospitalization. The Company believes that its drug candidates, called Toleragens®, will treat the underlying cause of many antibody-mediated diseases without these severe, negative side effects. The Company's clinical drug candidates are known as Riquent®, previously referred to as LJP 394, a drug for the treatment of lupus, and LJP 1082, a drug for the treatment of antibody-mediated thrombosis. The Company completed its Phase 3 clinical trial for Riquent in December 2002 and submitted an NDA with the FDA for Riquent on December 14, 2003, which was accepted for review by the FDA in February 2004. The Company completed its initial Phase 1/2 clinical trial for LJP 1082 in October 2002.

The Company actively seeks additional financing to fund its research and development efforts and to commercialize its technologies. There is no assurance such financing will be available to the Company when needed or that such financing would be available under favorable terms.

The Company believes that patents and other proprietary rights are important to its business. The Company's policy is to file patent applications to protect its technology, inventions and improvements to its inventions that are considered important to the development of its business. The patent positions of biotechnology firms, including those of the Company, are uncertain and involve complex legal and factual questions for which important legal principles are largely unresolved. There can be no assurance that any additional patents will be issued, that the scope of any patent protection will be sufficient, or that any current or future issued patent will be held valid if subsequently challenged.

Basis of Presentation

The accompanying 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 has incurred operating losses since its inception and has an accumulated deficit of $192.4 million at December 31, 2003. The Company believes its available cash, cash equivalents and short-term investments, including the net proceeds of $29.5 million received by the Company from the recent sale of 10.0 million shares of its common stock, and interest earned thereon, will be sufficient to fund its operations as currently planned into the second quarter of 2005, assuming that the Company does not engage in any significant clinical trial or commercialization activities and that the Company does not enter into an agreement with a collaborative partner or engage in any other fundraising activities. Prior to the commercialization of any of its products, substantial capital resources will be required to fund continuing operations related to the Company's research and development,

La Jolla Pharmaceutical Company
Notes to Financial Statements

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

manufacturing, clinical testing and business development activities. The Company believes there may be a number of alternatives available to meet the continuing capital requirements of its operations, such as collaborative agreements and public or private financings.

There can be no assurance that any of these financings will be consummated in the necessary time frames needed for continuing operations or on terms favorable to the Company. If adequate funds in the future are not available, the Company will be required to significantly curtail its operating plans and may have to sell or license out significant portions of the Company's technology or potential products.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Actual results could differ materially from those estimates.

Reclassification

Certain amounts in the 2001 and 2002 financial statements have been reclassified to conform to the 2003 presentation.

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 Financial Accounting Standards Board ("FASB") 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 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 are outstanding at December 31, 2003 have readily ascertainable market values; however, the carrying values are considered to approximate their fair values.

La Jolla Pharmaceutical Company
Notes to 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, money market funds and debt instruments of financial institutions and corporations with strong credit ratings. 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. While the Company's 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, and accordingly the Company has not recognized any impairment losses through December 31, 2003.

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 amortized on a straight-line basis over the shorter of the estimated useful life or the lease term.

La Jolla Pharmaceutical Company
Notes to Financial Statements

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

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

	December 31,	
	2003	2002
Laboratory equipment	$ 6,174	$ 5,383
Computer equipment and software	4,121	1,472
Furniture and fixtures	428	404
Leasehold improvements	2,559	2,125
Construction in progress	37	2,154
	13,319	11,538
Less: Accumulated depreciation and amortization	(7,113)	(5,504)
	$ 6,206	$ 6,034

Depreciation and amortization expense for the periods ending December 31, 2003, 2002 and 2001 was $1,807,000, $1,192,000 and $620,000, 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 cost and accumulated amortization were $2,905,000 and $488,000 at December 31, 2003 and $2,518,000 and $399,000 at December 31, 2002, respectively. Capitalized costs related to patent applications are charged to operations at the time a determination is made not to pursue such applications.

Stock-Based Compensation

As allowed under SFAS No. 123, *Accounting and Disclosure of Stock-Based Compensation* (“SFAS 123”), the Company has elected to continue to account for stock option grants in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (“APB 25”), and related interpretations. The Company generally grants stock options for a fixed number of shares to employees and directors with an exercise price equal to the fair value of the shares at the date of grant and therefore, under APB 25, recognized no compensation expense for such stock option grants.

Pro forma information regarding net loss and net loss per share is required by SFAS 123. SFAS 123 requires that the information be determined as if the Company has accounted for its employee stock plans granted after December 31, 1994 under the fair value method prescribed by SFAS 123 . The fair value of the options granted was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions for 2003, 2002 and 2001, respectively: risk-free interest rate

La Jolla Pharmaceutical Company
Notes to Financial Statements

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

of 3.3%, 3.0 % and 4.4%; volatility factor of the expected market price of the Company's common stock of 1.208, 1.056 and 1.109; a weighted-average expected life of 5.9 years, 4.9 years and 4.8 years; and a dividend yield of 0% for all three years presented.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is expensed over the options' vesting period. The Company's pro forma information follows (in thousands except for net loss per share information):

	Years Ended December 31,		
	2003	2002	2001
Pro forma net loss	$(45,884)	$(48,472)	$(27,919)
Pro forma basic and diluted net loss per share	$ (1.00)	$ (1.15)	$ (0.81)

The effects of applying SFAS 123 for either recognizing compensation expense or providing pro forma disclosures may not be representative of the effects on reported net loss for future years.

Options or stock awards issued to non-employees have been determined in accordance with SFAS 123 and 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 non-employees are periodically remeasured as the options vest. In both October 2003 and 2002, the Company granted a non-qualified stock option to purchase 5,000 shares of common stock to a consultant at an exercise price equal to fair market value of the stock at the date of each grant. The Company recognized approximately $14,000 and $3,000 in compensation expense for these stock option grants for the years ended December 31, 2003 and December 31, 2002, respectively.

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*. As the Company has incurred a net loss for all three years presented in the Statements of Operations, stock options are not included in the computation of net loss per share because their effect is anti-dilutive.

La Jolla Pharmaceutical Company
Notes to Financial Statements

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

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). The Company's comprehensive net loss totaled $38,947,000 and $43,500,000 for the years ended December 31, 2003 and 2002, respectively.

Segment Information

In accordance with SFAS No. 131, *Segment Information,* the Company has determined that it operates in one business segment.

Recently Issued Accounting Standards

In January 2003, FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of Accounting and Research Bulletin No. 51* ("FIN 46"). FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In December 2003, FASB issued FIN 46R, a revision to FIN 46. FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities to the first reporting period ending after March 15, 2004. The Company does not expect the adoption of FIN 46 to have a material impact upon its financial position, cash flows or results of operations.

In April 2003, FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities* ("SFAS 149"). SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities*. SFAS 149 is effective for contracts entered into or modified after June 30, 2003, and for hedging relationships designated after June 30, 2003. The adoption of this statement had no impact on the Company's financial statements.

In May 2003, FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ("SFAS 150"). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of such instruments were previously classified as equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of this statement had no impact on the Company's financial statements.

La Jolla Pharmaceutical Company
Notes to Financial Statements

2. Cash Equivalents and Short-term Investments

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2003				
Money market accounts	$ 8,613	$ —	$ —	$ 8,613
United States corporate debt securities	12,140	—	71	12,069
Government-asset-backed securities	9,005	—	—	9,005
United States Treasury securities and obligations of United States government agencies	1,006	—	2	1,004
	$30,764	$ —	$ 73	$30,691
December 31, 2002				
Money market accounts	$ 6,529	$ —	$ —	$ 6,529
United States corporate debt securities	17,148	43	20	17,171
Government-asset-backed securities	23,019	—	—	23,019
United States Treasury securities and obligations of United States government agencies	5,010	13	—	5,023
	$51,706	$ 56	$ 20	$51,742

The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization and accretion, interest income and realized gains and losses are included in interest income in the Statements of Operations. The cost of securities sold is based on the specific identification method. The net adjustment to unrealized holding gains (losses) on available-for-sale securities included in comprehensive income (loss) totaled ($109,000) and ($182,000) in 2003 and 2002, respectively. Included in cash and cash equivalents at December 31, 2003 and 2002 were $2,579,000 and $4,628,000, 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, 2003, available-for-sale securities of $14,613,000 mature in one year or less and $16,078,000 are due after one year.

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, which lease expires in July 2004. The lease is subject to an escalation clause that provides for annual increases based on the Consumer Price Index. The lease also contains an option to extend the lease term for an additional five years and a one-time cancellation option with the

La Jolla Pharmaceutical Company
Notes to Financial Statements

3. Commitments (continued)

payment of certain penalties. The Company anticipates that it will exercise its option to extend the lease for an additional five years. The rental payments for the renewal period, however, are not included in the table below because the annual rent is subject to negotiation.

In October 1996, the Company entered into an additional non-cancelable operating lease for additional office space. In November 2001, the Company extended the term of this lease to July 2004. The lease contains a provision for scheduled annual rent increases and an option to extend the lease term for an additional five years. In January 2004, the Company exercised its option to extend the lease for an additional five years. The rental payments for the renewal period, however, are not included in the table below because the annual rent is subject to negotiation.

In September 2002, the Company entered into an additional non-cancelable operating lease for additional research space. In August 2003, the Company extended the term of this lease to May 2004. The Company anticipates that it will extend the lease through the end of 2004. The rental payments for the extension period are not included in the table below because the rent is subject to negotiation.

In July 2003, the Company entered into a capital lease agreement for $111,000 to finance the purchase of certain property and equipment. The agreement is secured by the leased property and equipment, bears interest at 7.00% per annum, and is payable in quarterly installments of principal and interest of approximately $15,000 for eight quarters.

Annual future minimum lease payments as of December 31, 2003 are as follows (in thousands):

Years ended December 31,	Operating Leases	Capital Leases
2004	$ 776	$ 70
2005	88	30
2006	23	—
2007	—	—
Total	$ 887	100
Less amount representing interest		(5)
Present value of net minimum lease payments		95
Less current portion		(66)
Noncurrent portion of capital lease obligations		$ 29

Rent expense under all operating leases totaled $1,415,000, $1,718,000 and $2,330,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Equipment acquired under capital leases included in property and equipment totaled $134,000 and $65,000 (net of accumulated amortization of $45,000 and $99,000) at December 31, 2003 and 2002, respectively. Amortization expense associated with these assets is included in depreciation and amortization expense for each of the three years in the period ended December 31, 2003.

La Jolla Pharmaceutical Company
Notes to Financial Statements

4. Long-Term Debt

During 2002 and 2003, the Company entered into notes payable to finance the purchase of certain property and equipment. The following is a summary of the notes which are secured by the financed property and equipment:

Date of Note	Interest Rate (%)	Payments	Total Note Amount (in thousands)
September 27, 2002	9.45	$28,000 first 36 months; $17,000 last six months	$ 958
December 30, 2002	9.70	$20,000 first 36 months; $13,000 last six months	698
April 23, 2003	9.70	$17,000 first 36 months, $11,000 last six months	583
June 27, 2003	9.70	$10,000 first 36 months; $6,000 last six months	345
September 26, 2003	8.27	$4,000 for 42 months	150
December 18, 2003	8.27	$2,000 for 42 months	83
			$ 2,817

Annual future minimum notes payable payments as of December 31, 2003 are as follows (in thousands):

Years ended December 31,	Notes Payable
2004	$ 901
2005	951
2006	441
2007	24
2008	—
Total	2,317
Less amount representing interest	(254)
Present value of net minimum notes payable payments	2,063
Less current portion	(751)
Noncurrent portion of notes payable	$1,312

5. Restructuring Charges

In May 2003, the Company restructured its operations in order to reduce expenses and focus its resources on the further development of Riquent. In accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal* Activities, as of December 31, 2003, the Company recorded total restructuring charges of approximately $490,000 in connection with the termination of 24 employees. Approximately $305,000 of the total restructuring charges is included in research and development expense and approximately $185,000 is included in general and administrative expense. As of December 31, 2003, the Company had paid approximately $475,000 of the total restructuring charges, and the remaining $15,000 is payable in February 2004.

La Jolla Pharmaceutical Company
Notes to Financial Statements

6. Stockholders' Equity

Preferred Stock

As of December 31, 2003, the Company 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 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.

Stock Option Plans

In May 1989, the Company adopted the 1989 Stock Option Plan and the 1989 Nonstatutory Stock Option Plan (the "1989 Plan"), under which 904,000 shares of common stock have been authorized for issuance upon exercise of options granted by the Company. The 1989 Plan expired in 1999 and there were no options outstanding as of December 31, 2003.

In June 1994, the Company adopted the 1994 Stock Incentive Plan (the "1994 Plan"), under which 8,200,000 shares of common stock have been authorized for issuance upon exercise of options granted by the Company. The 1994 Plan provides for the grant of incentive and non-qualified stock options, as well as other stock-based awards, to employees, directors, consultants and advisors of the Company with various vesting periods as determined by the compensation committee, as well as automatic fixed grants to non-employee directors of the Company.

La Jolla Pharmaceutical Company
Notes to Financial Statements

6. Stockholders' Equity (continued)

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

	Options Available For Grant	Outstanding Options	
		Number of Shares	Weighted-Average Exercise Price
Balance at December 31, 2000	390,746	3,115,537	$ 3.47
Additional shares authorized	1,700,000	—	—
Expired	(2,260)	—	$ 1.00
Granted	(1,522,600)	1,522,600	$ 6.80
Exercised	—	(43,550)	$ 1.35
Cancelled	63,427	(63,427)	$ 6.61
Balance at December 31, 2001	629,313	4,531,160	$ 4.57
Additional shares authorized	1,900,000	—	—
Granted	(2,067,700)	2,067,700	$ 5.70
Exercised	—	(102,132)	$ 1.62
Cancelled	84,672	(84,672)	$ 6.70
Balance at December 31, 2002	546,285	6,412,056	$ 4.95
Additional shares authorized	1,100,000	—	—
Granted	(1,675,740)	1,675,740	$ 3.92
Exercised	—	(200,463)	$ 0.96
Cancelled	410,688	(410,688)	$ 5.58
Balance at December 31, 2003	381,233	7,476,645	$ 4.79

	Years Ended December 31,					
	2003		2002		2001	
	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price
Exercisable at end of year	4,796,296	$ 4.72	3,605,876	$ 4.08	2,770,587	$ 3.20
Weighted-average fair value of options granted during the year	$ 3.27		$ 4.41		$ 5.42	

La Jolla Pharmaceutical Company
Notes to Financial Statements

6. Stockholders' Equity (continued)

Exercise prices and weighted-average remaining contractual lives for the options outstanding as of December 31, 2003 follow:

Options Outstanding	Range of Exercise Prices	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price
921,533	$ 0.34 - $2.63	5.63	$ 1.15	918,325	$ 1.14
1,284,152	$ 2.97 - $3.69	7.66	$ 3.25	680,601	$ 3.49
1,570,502	$ 3.73 - $4.71	7.56	$ 4.48	738,293	$ 4.33
1,097,072	$ 4.75 - $5.80	7.14	$ 5.17	702,134	$ 5.17
1,281,436	$ 5.81 - $7.00	8.06	$ 6.30	801,883	$ 6.53
1,321,950	$7.03 - $12.06	7.70	$ 7.43	955,060	$ 7.46
7,476,645	$0.34 - $12.06	7.39	$ 4.79	4,796,296	$ 4.72

At December 31, 2003, the Company has reserved 7,857,878 shares of common stock for future issuance upon exercise of options granted or to be granted under the 1994 Plan.

Employee Stock Purchase Plan

Effective August 1, 1995, the Company adopted the 1995 Employee Stock Purchase Plan, as amended (the "Purchase Plan"). Under the amended Purchase Plan, a total of 1,000,000 shares of common stock are reserved for sale to employees, as defined. Employees may purchase common stock under the Purchase Plan every three months (up to but not exceeding 10% of each employee's earnings) over the offering period at 85% of the fair market value of the common stock at certain specified dates. The offering period may not exceed 24 months. For the year ended December 31, 2003, 312,744 shares of common stock were issued under the Purchase Plan (77,441 shares for the year ended December 31, 2002). To date, 910,958 shares of common stock have been issued under the Purchase Plan and 89,042 shares of common stock are available for issuance.

	Years Ended December 31, 2003	2002	2001
Weighted-average fair value of employee stock purchase plan purchases	$ 1.49	$ 4.21	$ 2.84

La Jolla Pharmaceutical Company
Notes to Financial Statements

6. Stockholders' Equity (continued)

Stockholder Rights Plan

The Company has adopted a Stockholder Rights Plan (the "Rights Plan") which was amended in July 2000. 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), the Rights permit the holders (other than the 15% holder, or, in the case of State of Wisconsin Investment Board, 20% 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 $.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.

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 is 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, 2003, the Company had federal and California income tax net operating loss carryforwards of approximately $182,935,000 and $67,116,000, 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 $10,029,000 and $5,023,000, respectively. The federal net operating loss and research tax credit carryforwards will begin to expire in 2005 unless previously utilized. The California net operating loss will begin to expire in 2004, 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.

La Jolla Pharmaceutical Company
Notes to Financial Statements

8. Income Taxes (continued)

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

	December 31, 2003	2002
Deferred tax assets:		
Net operating loss carryforwards	$ 67,886	$ 53,992
Research and development credits	13,294	9,976
Capitalized research and development	4,750	4,486
Total deferred tax assets	85,930	68,454
Deferred tax liability	—	—
	85,930	68,454
Valuation allowance for deferred tax assets	(85,930)	(68,454)
Net deferred tax assets	$ —	$ —

A valuation allowance of $85,930,000 has been recognized to offset the deferred tax assets as realization of such assets is uncertain.

9. Subsequent Event

On February 25, 2004, the Company sold 8,695,653 shares of common stock in a public offering for net proceeds of approximately $25,595,000 at a discounted per share value based on the reported last sale price of the common stock on the purchase date.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (1)
3.2	Amended and Restated Bylaws of the Company (2)
4.1	Rights Agreement dated as of December 3, 1998 between the Company and American Stock Transfer & Trust Company (3)
4.2	Certificate of Designation, Preferences and Rights of Series A Junior Participating Preferred Stock of the Company (4)
4.3	Amendment to Rights Agreement, effective as of July 21, 2001, between the Company and American Stock Transfer & Trust Company (5)
10.1	Stock Option Agreement dated February 4, 1993 entitling Joseph Stemler to purchase 35,000 shares of Common Stock (6)*
10.2	Steven B. Engle Employment Agreement (6)*
10.3	Amendment No. 1 to Steven B. Engle Employment Agreement (7)*
10.4	Amendment No. 2 to Steven B. Engle Employment Agreement (1)*
10.5	Amendment No. 3 to Steven B. Engle Employment Agreement (23)*
10.6	Form of Directors and Officers Indemnification Agreement (6)
10.7	Option and Collaborative Research Agreement, dated June 10, 1991, regarding certain compounds for potential treatment of muscular dystrophies or myasthenia gravis between the Company and CepTor Corporation (6)
10.8	Form of Employee Invention and Confidential Information Agreement (6)
10.9	Industrial Real Estate Lease (6)
10.10	La Jolla Pharmaceutical Company 1989 Incentive Stock Option Plan and 1989 Nonstatutory Stock Option Plan (6) *
10.11	Form of Stock Option Agreement under the 1989 Nonstatutory Stock Option Plan (6)*
10.12	La Jolla Pharmaceutical Company 1994 Stock Incentive Plan (Amended and Restated as of May 16, 2003) (23)*
10.13	La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (Amended and Restated as of May 22, 2002) (8)*
10.14	Letter of Agreement, dated June 7, 1993, between the Company and Vector Securities International regarding Vector's engagement as financial advisor to the Company with respect to potential corporate strategic alliances (6)
10.15	Second Amendment to Lease, dated June 30, 1994, by and between the Company and BRE Properties, Inc. (9)
10.16	Third Amendment to Lease, dated January 26, 1995, by and between the Company and BRE Properties, Inc. (10)
10.17	Master Lease Agreement, dated September 13, 1995, by and between the Company and Comdisco Electronics Group (11)
10.18	Agreement, dated September 22, 1995, between the Company and Joseph Stemler regarding option vesting (12) *
10.19	Building Lease Agreement, effective November 1, 1996, by and between the Company and WCB II-S BRD Limited Partnership (13)

Exhibit Number	Description
10.20	Master Lease Agreement, dated December 20, 1996, by and between the Company and Transamerica Business Credit Corporation (14)
10.21	License and Supply Agreement, dated December 23, 1996, by and between the Company and Abbott Laboratories (14) (15)
10.22	Stock Purchase Agreement, dated December 23, 1996, by and between the Company and Abbott Laboratories (14)
10.23	Waiver of Contractual Restrictions dated February 6, 2001 (16)
10.24	Master Lease Agreement No. 2, dated June 23, 1998, by and between the Company and Transamerica Business Credit Corporation (17)
10.25	Supplement to employment offer letter for Matthew Linnik, Ph.D. (18)*
10.26	Supplement to employment offer letter for William J. Welch (19)*
10.27	Supplement to employment offer letter for Theodora Reilly (19)*
10.28	Supplement to employment offer letter for Paul Jenn, Ph.D. (19)*
10.29	Supplement to employment offer letter for Bruce K. Bennett, Jr. (20)*
10.30	Supplement to employment offer letter for Kenneth R. Heilbrunn (8)*
10.31	Supplement to employment offer letter for Karen K. Church (21)*
10.32	Supplement to employment offer letter for David Duncan, Jr. (21)*
10.33	Master Security Agreement, effective September 6, 2002, between the Company and General Electric Capital Corporation (21)
10.34	Promissory Note, dated as of September 26, 2002, between the Company and General Electric Capital Corporation (21)
10.35	Amendment to Promissory Note, effective as of September 27, 2002, between the Company and General Electric Capital Corporation (21)
10.36	Promissory Note, dated as of December 30, 2002, between the Company and General Electric Capital Corporation (22)
10.37	Promissory Note, dated as of April 23, 2003, between the Company and General Electric Capital Corporation (22)
10.38	Promissory Note, dated as of June 27, 2003, between the Company and General Electric Capital Corporation (23)
10.39	Promissory Note, dated as of September 26, 2003, between the Company and General Electric Capital Corporation (24)
10.40	Promissory Note, dated as of December 18, 2003, between the Company and General Electric Capital Corporation
10.41	Lease Renewal Amendment, dated as of July 1, 2003, between the Company and General Electric Capital Corporation Successor In Interest to Comdisco, Inc. as of February 26, 2002 (24)
10.42	Underwriting Agreement, dated as of August 7, 2003, between the Company and Pacific Growth Equities, LLC (25)
10.43	Underwriting Agreement, dated as of February 19, 2004, between the Company and Pacific Growth Equities, LLC (27)
10.44	Form of Registration Rights Agreement, dated January 2002, between the Company and the initial purchasers (26)
10.45	Form of Stock Purchase Agreement, dated January 2002, between the Company and the initial purchasers (26)
10.46	Form of Registration Rights Agreement, dated February 5, 2001, between the Company and the initial purchasers (24)

Exhibit Number	Description
10.47	Form of Stock Purchase Agreement, dated February 5, 2001, between the Company and the initial purchasers (24)
10.48	Form of Registration Rights Agreement, dated July 19, 2000, between the Company and the initial purchasers (24)
10.49	Form of Stock Purchase Agreement, dated July 19, 2000, between the Company and the initial purchasers (24)
10.50	Form of Registration Rights Agreement, dated February 10, 2000, between the Company and the initial purchasers (24)
10.51	Form of Stock Purchase Agreement, dated February 10, 2000, between the Company and the initial purchasers (24)
23.1	Consent of Ernst & Young LLP, Independent Auditors
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 quarterly report on Form 10-Q for the quarter ended September 30, 1999 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 8-A (No. 000-24274) as filed with the Securities and Exchange Commission on December 4, 1998.

(4) Previously filed with the Company's quarterly report on Form 10-Q for the quarter ended June 30, 1999 and incorporated by reference herein.

(5) Previously filed with the Company's report on Form 8-K filed on 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 Registration Statement on Form S-1 (No. 33-76480) filed on March 16, 1994.

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

(8) Previously filed with the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2002 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 September 30, 1995 and incorporated by reference herein.

(12) Previously filed with the Company's annual report on Form 10-K for the fiscal year ended December 31, 1995 and incorporated by reference herein.

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

(14) Previously filed with the Company's annual report on Form 10-K for the fiscal year ended December 31, 1996 and incorporated by reference herein.

(15) Portions of the Exhibit 10.20 have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

(16) Previously filed with the Company's annual report on Form 10-K for the fiscal year ended December 31, 2000 and incorporated by reference herein.

(17) Previously filed with the Company's quarterly report on Form 10-Q for the quarter ended June 30, 1998 and incorporated by reference herein.

(18) 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.

(19) Previously filed with the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2001 and incorporated by reference herein.

(20) Previously filed with the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2002 and incorporated by reference herein.

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

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

(23) Previously filed with the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2003 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 Current Report on Form 8-K filed August 12, 2003 and incorporated by reference herein.

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

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

EXHIBIT 10.40

PROMISSORY NOTE

_____12/18/03_____

(DATE)

FOR VALUE RECEIVED, LA JOLLA PHARMACEUTICAL COMPANY a corporation located at the address stated below ("MAKER") promises, jointly and severally if more than one, to pay to the order of GENERAL ELECTRIC CAPITAL CORPORATION or any subsequent holder hereof (each, a "PAYEE") at its office located at 401 MERRITT 7 SUITE 23, NORWALK, CT 06851-1177 or at such other place as Payee or the holder hereof may designate, the principal sum of EIGHTY THREE THOUSAND ONE HUNDRED FORTY THREE AND 11/100 DOLLARS ($83,143.11), with interest on the unpaid principal balance, from the date hereof through and including the dates of payment, at a fixed interest rate of Eight and Twenty Seven Hundredths percent (8.27%) per annum, to be paid in lawful money of the United States, in Forty-Two (42) consecutive monthly installments of principal and interest as follows:

Periodic Installment	Amount
Thirty-Six (36)	$ 2,296.20
Five (5)	$ 2,095.98

each ("Periodic Installment") and a final installment which shall be in the amount of the total outstanding principal and interest. The first Periodic Installment shall be due and payable on 1/1/04 and the following Periodic Installments and the final installment shall be due and payable on the same day of each succeeding month (each, a "Payment Date"). Such installments have been calculated on the basis of a 360 day year of twelve 30-day months. Each payment may, at the option of the Payee, be calculated and applied on an assumption that such payment would be made on its due date.

The acceptance by Payee of any payment which is less than payment in full of all amounts due and owing at such time shall not constitute a waiver of Payee's right to receive payment in full at such time or at any prior or subsequent time.

The Maker hereby expressly authorizes the Payee to insert the date value is actually given in the blank space on the face hereof and on all related documents pertaining hereto.

This Note may be secured by a security agreement, chattel mortgage, pledge agreement or like instrument (each of which is hereinafter called a "SECURITY AGREEMENT").

Time is of the essence hereof. If any installment or any other sum due under this Note or any Security Agreement is not received within ten (10) days after its due date, the Maker agrees to pay, in addition to the amount of each such installment or other sum, a late payment charge of five percent (5%) of the amount of said installment or other sum, but not exceeding any lawful maximum. If (i) Maker fails to make payment of any amount due hereunder within ten (10) days after the same becomes due and payable; or (ii) Maker is in default under, or fails to perform under any term or condition contained in any Security Agreement, then the entire principal sum remaining unpaid, together with all accrued interest thereon and any other sum payable under this Note or any Security Agreement, at the election of Payee, shall immediately become due and payable, with interest thereon at the lesser of eighteen percent (18%) per annum or the highest rate not prohibited by applicable law from the date of such accelerated maturity until paid (both before and after any judgment).

Notwithstanding anything to the contrary contained herein or in the Security Agreement, Maker may not prepay in full or in part any indebtedness hereunder without the express written consent of Payee in its sole discretion.

It is the intention of the parties hereto to comply with the applicable usury laws; accordingly, it is agreed that, notwithstanding any provision to the contrary in this Note or any Security Agreement, in no event shall this Note or any Security Agreement require the payment or permit the collection of interest in excess of the maximum amount permitted by applicable law. If any such excess interest is contracted for, charged or received under this Note or any Security Agreement, or if all of the principal balance shall be prepaid, so that under any of such circumstances the amount of interest contracted for, charged or received under this Note or any Security Agreement on the principal balance shall exceed the maximum amount of interest permitted by applicable law, then in such event (a) the provisions of this paragraph shall govern and control, (b) neither Maker nor any other person or entity now or hereafter liable for the payment hereof shall be obligated to pay the amount of such interest to the extent that it is in excess of the maximum amount of interest permitted by applicable law, (c) any such excess which may have been collected shall be either applied as a credit against the then unpaid principal balance or refunded to Maker, at the option of the Payee, and (d) the effective rate of interest shall be automatically reduced to the maximum lawful contract rate allowed under applicable law as now or hereafter construed by the courts having jurisdiction thereof. It is further agreed that without limitation of the foregoing, all calculations of the rate of interest contracted for, charged or received under this Note or any Security Agreement which are made for the purpose of determining whether such rate exceeds the maximum lawful contract rate, shall be made, to the extent permitted by applicable law, by amortizing, prorating, allocating and spreading in equal parts during the period of the full stated term of the indebtedness evidenced hereby, all interest at any time contracted for, charged or received from Maker or otherwise by Payee in connection with such indebtedness; provided, however, that if any applicable state law is amended or the law of the United States of America preempts any applicable state law, so that it becomes lawful for the Payee to receive a greater interest per annum rate than is presently allowed, the Maker agrees that, on the effective date of such amendment or preemption, as the case may be, the lawful maximum hereunder shall be increased to the maximum interest per annum rate allowed by the amended state law or the law of the United States of America.

The Maker and all sureties, endorsers, guarantors or any others (each such person, other than the Maker, an "OBLIGOR") who may at any time become liable for the payment hereof jointly and severally consent hereby to any and all extensions of time, renewals, waivers or modifications of, and all substitutions or releases of, security or of any party primarily or secondarily liable on this Note or any Security Agreement or any term and provision of either, which may be made, granted or consented to by Payee, and agree that suit may be brought and maintained against any one or more of them, at the election of Payee without joinder of any other as a party thereto, and that Payee shall not be required first to foreclose, proceed against, or exhaust any security hereof in order to enforce payment of this Note. The Maker and each Obligor hereby waives presentment, demand for payment, notice of nonpayment, protest, notice of protest, notice of dishonor, and all other notices in connection herewith, as well as filing of suit (if permitted by law) and diligence in collecting this Note or enforcing any of the security hereof, and agrees to pay (if permitted by law) all expenses incurred in collection, including Payee's actual attorneys' fees. Maker and each Obligor agrees that fees not in excess of twenty percent (20%) of the amount then due shall be deemed reasonable.

THE MAKER HEREBY UNCONDITIONALLY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF, DIRECTLY OR INDIRECTLY, THIS NOTE, ANY OF THE RELATED DOCUMENTS, ANY DEALINGS BETWEEN MAKER AND PAYEE RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED BETWEEN MAKER AND PAYEE. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT (INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS.) THIS WAIVER IS IRREVOCABLE MEANING THAT IT MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING, AND THE WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS NOTE, ANY RELATED DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS

RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. IN THE EVENT OF LITIGATION, THIS NOTE MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

This Note and any Security Agreement constitute the entire agreement of the Maker and Payee with respect to the subject matter hereof and supercedes all

prior understandings, agreements and representations, express or implied.

No variation or modification of this Note, or any waiver of any of its provisions or conditions, shall be valid unless in writing and signed by an authorized representative of Maker and Payee. Any such waiver, consent, modification or change shall be effective only in the specific instance and for the specific purpose given.

Any provision in this Note or any Security Agreement which is in conflict with any statute, law or applicable rule shall be deemed omitted, modified or altered to conform thereto.

LA JOLLA PHARMACEUTICAL COMPANY

/s/ Lisa Peraza

(Witness)
Lisa Peraza
(Print name)
6455 Nancy Ridge Drive
San Diego, CA 92121
(Address)

By: /s/ Gail A. Sloan

Name: Gail A. Sloan

Title: Senior Director of Finance and Controller

Federal Tax ID #: 330361285

Address: 6455 Nancy Ridge Drive, San Diego, San Diego County, CA 92121

EXHIBIT 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-106060) pertaining to the La Jolla Pharmaceutical Company 1994 Stock Incentive Plan, the Registration Statement on Form S-8 (No. 333-89980) pertaining to the La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan and the Registration Statements on Form S-3 (Nos. 333-101499, 333-31142, 333-43066, 333-55370 and 333-81432) of La Jolla Pharmaceutical Company of our report dated February 13, 2004, except for Note 9 as to which the date is February 25, 2004, with respect to the financial statements of La Jolla Pharmaceutical Company included in its Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

ERNST & YOUNG LLP

San Diego, California
March 11, 2004

EXHIBIT 31.1

SECTION 302 CERTIFICATION

I, Steven B. Engle, certify that:

1. I have reviewed this annual report on Form 10-K of La Jolla Pharmaceutical Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statement made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2004

/s/ Steven B. Engle

Steven B. Engle
Chairman and Chief Executive Officer

EXHIBIT 31.2

SECTION 302 CERTIFICATION

I, Gail A. Sloan, certify that:

1. I have reviewed this annual report on Form 10-K of La Jolla Pharmaceutical Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statement made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2004

/s/ Gail A. Sloan

Gail A. Sloan
Vice President of Finance,
Controller and Secretary

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned, in his or her capacity as an officer of La Jolla Pharmaceutical Company (the "Registrant"), hereby certifies, for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- the annual report of the Registrant on Form 10-K for the year ended December 31, 2003 (the "Report"), which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Report fairly presents, in all material respects, the financial condition of the Registrant at the end of such year and the results of operations of the Registrant of such year.

Dated: March 12, 2004

/s/ Steven B. Engle

Steven B. Engle

Chairman and Chief Executive Officer

/s/ Gail A. Sloan

Gail A. Sloan

Vice President of Finance, Controller
and Secretary

Note: A signed original of this written statement required by Section 906 has been provided to La Jolla Pharmaceutical Company and will be retained by La Jolla Pharmaceutical Company and furnished to the Securities and Exchange Commission or its staff upon request.