LA JOLLA PHARMACEUTICAL CO
Form 8-K
January 28, 2005

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

FORM 8-K

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

Date of report (Date of earliest event reported): January 28, 2005

LA JOLLA PHARMACEUTICAL COMPANY

(Exact name of registrant as specified in its charter)

Delaware	0-24274	33-0361285
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6455 Nancy Ridge Drive
San Diego, California 92121
(Address of principal executive offices, including zip code)

(858) 452-6600
(Registrant s telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 1.01 Entry Into A Material Definitive Agreement.

On November 26, 2002, La Jolla Pharmaceutical Company (the Company) filed, pursuant to Rule 415 under the Securities Act of 1933, as amended (the Securities Act), a registration statement on Form S-3 (File No. 333-101499), including a prospectus, which, as amended, was declared effective on December 12, 2002 (the Registration Statement).

On January 28, 2005, the Company entered into an underwriting agreement (the Underwriting Agreement) with Pacific Growth Equities, LLC (the Underwriter), pursuant to which the Company agreed to sell 12,250,000 shares of its common stock (the Shares) in an underwritten public offering. The price to the public is $1.40 per Share. According to the terms of the Underwriting Agreement, the Underwriter will receive an underwriting discount equal to $0.084 per Share. The Underwriting Agreement contains representations, warranties and agreements of the Company, customary conditions to closing, indemnification rights and obligations of the parties and termination provisions. A copy of the Underwriting Agreement is filed as Exhibit 1.1 hereto and is herein incorporated by reference. The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the Underwriting Agreement.

On January 28, 2005, the Company filed a prospectus supplement pursuant to Rule 424 of the Securities Act, dated January 28, 2005 (the Prospectus Supplement), relating to the underwritten public offering of the Shares as described above. The sale of the Shares is expected to close on February 2, 2005. The aggregate net proceeds to the Company from the offering are estimated to be approximately $15.8 million.

Item 8.01 Other Events.

On January 28, 2005, the Company issued two separate press releases announcing (i) its intent to offer 12,250,000 shares of the Company s common stock in a public offering and (ii) the pricing of the underwritten public offering of the Shares. A copy of the Company s press releases are filed with this Form 8-K as Exhibits 99.1 and 99.2 hereto.

In addition, the Company is providing herein an update regarding its recent developments and risk factors as set forth in the Prospectus Supplement and provided below.

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Recent Developments

On February 16, 2004, we announced that our New Drug Application (NDA) for Riquent® (abetimus sodium), our clinical drug candidate for the treatment of lupus renal disease, had been accepted for review by the United States Food and Drug Administration (the FDA). Our NDA submission was prepared based on our understanding that the FDA could approve Riquent on the basis of our clinical trial results or under Subpart H. Under Subpart H, drugs in development for serious, life-threatening diseases with an unmet medical need can be approved on an accelerated basis if the FDA determines that the effect of the drug on a surrogate endpoint is reasonably likely to predict clinical benefit and that a post-marketing clinical trial can be successfully completed following drug approval which confirms the clinical benefit. As previously announced, in our Phase 3 and Phase 2/3 trials, patients treated with Riquent had significantly reduced levels of antibodies to double-stranded DNA (dsDNA) compared with patients treated with placebo.

On August 2, 2004, we announced that we had reached a written agreement with the Cardio-Renal Division of the FDA under a special protocol assessment concerning a trial that is designed to meet the requirements of a Phase 4 post-marketing clinical trial which would have to be conducted if Riquent were to be approved under Subpart H and that we had initiated the trial. The special protocol assessment process is a formal procedure that results in a written agreement between a company and the FDA that documents the design and planned analysis of a study used in support of a regulatory submission. Agreements reached under the special protocol assessment process are generally binding except in circumstances where public health concerns are raised or when there are significant changes in medical science or practice.

Based on the date that we submitted our NDA to the FDA, we expected that the FDA would notify us in mid-October of its decision regarding the approvability of Riquent. On October 14, 2004, we announced that we had received a letter from the FDA indicating that Riquent is approvable, but that an additional, randomized, double-blind study demonstrating the clinical benefit of Riquent would need to be completed prior to approval. The FDA letter indicated that the successful completion of the clinical trial that we initiated in August 2004 would appear to satisfy this requirement.

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On November 23, 2004, we provided an update on our clinical and regulatory activities concerning Riquent. We announced that the clinical trial that we initiated in August 2004 was evaluating doses of 100 mg and 300 mg of Riquent over a 12-month period in lupus patients with a history of renal disease. As of January 27, 2005, we are recruiting patients in 35 of 60 planned U.S. clinical trial sites in 20 states. We also announced that we were conducting an additional study to evaluate higher doses of Riquent for use in the multi-dose study. To date, this additional study, conducted in healthy volunteers, has evaluated single doses of 600 mg in one group and 1200 mg in another group treated with Riquent or placebo. Both dose levels of Riquent appeared to be well tolerated and we may test additional dose levels in connection with this trial. Based on previous studies of Riquent, we believe that some lupus patients may benefit from higher doses of Riquent. Once the dosing study is completed, we plan to review the data from the study with the FDA and may choose to study additional doses of Riquent in the trial that we initiated in August 2004.

Our November 2004 announcement also provided that we had met with the European Agency for the Evaluation of Medicinal Products (the EMEA) which had designated two countries to lead the review of our European regulatory filing and that, due to the efforts involved in our ongoing discussions with the FDA, we anticipated a delay in filing our Marketing Authorization Application (MAA) for Riquent in Europe. We also announced that, while our discussions with the FDA were ongoing, we had taken steps to control certain costs associated with our research, development and other activities. Finally, we announced that, since receiving the approvable letter from the FDA in October 2004, we and the FDA had met twice to discuss the approvable letter and data concerning Riquent and that we had two additional meetings scheduled.

Since our November 2004 announcement, we completed three additional meetings with the FDA regarding the approvable letter and whether the FDA would approve Riquent under Subpart H. During our discussions with the FDA, we have provided the FDA with additional evidence in support of the potential efficacy of Riquent and with information that we believe supports a determination that antibodies to dsDNA are a surrogate endpoint for lupus renal disease and that the magnitude of the effect of Riquent on antibodies to dsDNA is reasonably likely to predict clinical benefit, which is the requirement for any potential approval under Subpart H. While we are in discussions with the FDA regarding the possibility of approval under Subpart H, we continue to conduct the clinical study that we initiated in August 2004 in order to satisfy the additional trial requirement set forth in the FDA s October 2004 approvable letter. In the event that the FDA approves Riquent under Subpart H, we expect that we would continue the ongoing trial as a Phase 4 post-marketing trial, which we would need to complete after approval.

We currently expect to continue our discussions with the FDA regarding Subpart H approval, although there can be no guarantee that any future meetings with the FDA can be held in a timely manner, or at all, or that our meetings with the FDA will eliminate or change the current FDA requirement that we conduct an additional trial for Riquent prior to any further consideration of possible approval.

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RISK FACTORS

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

In order to complete our ongoing clinical trial of Riquent, we will need additional funding. If we are unable to successfully complete the trial, our business and financial condition will be adversely affected and it may be difficult or impossible for us to survive.

We will need to successfully complete the trial that we commenced in August 2004. We expect that the ongoing trial will involve approximately 500 to 600 patients, cost at least $60 million, and take several years to complete. In order to complete this trial, we will require significant additional funding, in addition to the funds raised in this offering. There is no guarantee that we will be able to obtain additional funds from the sale of additional securities, from a collaborative partner, or otherwise. If we are unable to timely raise additional funding, we will not have the financial resources to complete the ongoing trial or to continue the research and development of Riquent, and it may be difficult or impossible for us to survive.

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

We expect that the ongoing clinical trial of Riquent will involve approximately 500 to 600 patients, which is significantly more than were involved in our Phase 3 trial. In order to complete this trial, we will need to locate and enroll a sufficient number of patients who meet the criteria for the trial. We may have difficulty enrolling patients because, among other matters, there are specific limitations on the medications that a patient may be taking upon entry into the trial. If we are unable to timely enroll a sufficient number of patients, we will not be able to complete successfully the ongoing trial. As a result, it may be difficult or impossible for us to survive.

If we do not obtain Subpart H approval for Riquent and we do not raise additional funds in the near future, we will need to take significant cost reducing measures.

Even after receiving the proceeds from this offering, if the FDA does not approve Riquent under Subpart H and we do not raise additional funds in the near future, either through the sale of additional securities or a collaborative agreement with a corporate partner, we will need to take significant additional cost cutting measures to continue our operations into the first quarter of 2006, including by, among other matters, ceasing the enrollment of additional patients in, or halting, the ongoing multi-dose trial that we initiated in August 2004, further reducing the expenses associated with our other current drug development programs, or significantly reducing our workforce. If we do not receive a final Subpart H decision from the FDA in the near term, we may elect to initiate some or all of these cost reducing efforts as early as the second quarter of 2005.

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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 is safe and effective. If Riquent is ultimately not found to be safe and effective, we would be unable to obtain regulatory approval to manufacture, market and sell Riquent. Although we have received an approvable letter from the FDA, the analysis of the data from our Phase 3 trial of Riquent showed that the trial did not reach statistical significance with respect to its primary endpoint, time to renal flare, or with respect to the secondary endpoint, time to treatment with high-dose corticosteroids or cyclophosphamide. We can provide no assurances that the FDA will ultimately approve Riquent or what Riquent s indication will be, if approved.

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 or any other potential drug candidates.

Our discussions with the FDA may not result in us obtaining accelerated approval for Riquent under the Subpart H regulation.

Although we and the FDA are currently discussing the possibility of obtaining accelerated approval for Riquent under Subpart H, 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 the demonstrated effect of Riquent on antibody levels, or any other results from our previous clinical trials, will be sufficient for the FDA to grant approval under Subpart H, or that we will be able to successfully complete any post-marketing clinical trial. The success of the clinical trial that we initiated in August 2004, whether conducted as part of a Subpart H approval process or otherwise, will depend, in part, on our ability to locate and enroll patients meeting the criteria specified for such a trial and the availability of a sufficient amount of funding. We may be required to complete patient enrollment milestones in the ongoing clinical trial prior to obtaining any approval under Subpart H. 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. The current clinical trial involves significantly more patients than were involved in the Phase 3 trial of Riquent and will require significant time to complete. Even if the FDA approves Riquent under Subpart H, we believe that it will take at least nine months from the date of approval for us to build our inventory and expand our operations in order to bring Riquent to market. In addition, 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 or any other potential drug candidates.

We will need additional funds to support our operations.

Our operations to date have consumed substantial capital resources, and we expect to 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

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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:

the scope and results of pre-clinical testing and clinical trials,

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 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 clinical trial, research, clinical development and manufacturing activities. If we ultimately receive regulatory approval for Riquent, or any of our other drug candidates, our manufacturing, marketing and sales activities are likely to substantially increase our expenses and our need for additional working capital. We anticipate that our existing cash, investments and interest earned thereon plus the proceeds that we expect to receive from the shares of common stock that we are offering pursuant to this prospectus supplement will be sufficient to fund our operations as currently planned into the first quarter of 2006. This projection is based on the assumption that we do not obtain Subpart H approval, that we do not raise any additional funds, either through the sale of additional securities or a collaborative agreement with a corporate partner, that we do not engage in any significant commercialization activities, and that we take one or more significant cost reducing measures, including ceasing the enrollment of additional patients in, or halting, the ongoing multi-dose trial of Riquent that we initiated in August 2004, further reducing the expenses associated with our other current drug development programs and/or significantly reducing our workforce. However, the amounts we expend 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.

Our business is highly cash-intensive. Therefore, regardless of whether we obtain Subpart H approval for Riquent, we will need to 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, reduce the size of our workforce, sell or license our technologies, or obtain funds through other arrangements with collaborative partners or others that require us to relinquish rights to our technologies or potential products. We also may 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

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investment in us will be diluted, and dilution can be particularly substantial when the price of our common stock is low.

We may be required to design and conduct additional trials.

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 current or earlier clinical trials, including the Phase 2/3 and Phase 3 trials of Riquent, a possible failure to conduct clinical trials in complete adherence to FDA good clinical practice standards and similar standards of foreign regulatory authorities, the identification of new clinical trial endpoints, or the need for additional data regarding the safety or efficacy of our drug candidates. It is possible that the FDA or foreign regulatory authorities may not ultimately approve Riquent or our other drug candidates for commercial sale in any jurisdiction, even if future clinical results are positive.

Current and future clinical trials may be delayed or halted.

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

the lack of available funding,

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

the products are not effective,

patients experience severe side effects during treatment,

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

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

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

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. Although the FDA has reviewed the blood assay as part of the approval process of Riquent, the FDA s review of the assay will not be complete until after Riquent is approved, if ever, and we and the FDA have agreed upon the label for Riquent. In addition, foreign regulatory agencies may require that the assay be reviewed as part of their approval process for Riquent. Even if Riquent and the assay are approved by the FDA or foreign regulatory agencies, we may have to conduct additional studies on the assay post-approval. The testing laboratory that will conduct the assay if Riquent is approved may also require additional regulatory approval. If the FDA or foreign regulatory agencies do not concur with the use of the assay to identify potential patients for treatment with Riquent, or if any of them requires additional studies on the assay or additional regulatory approval of the testing laboratory, the approval and possible commercialization of Riquent may be delayed or prevented, which would have a severe negative effect on our business.

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

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

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

For fiscal year 2005, we have currently budgeted a very limited amount of funds for our continued development of LJP 1082, our drug candidate for the treatment of antibody-mediated thrombosis. In addition, we have budgeted only a limited amount of funds for the development of small molecules for the treatment of autoimmune diseases and acute and chronic inflammatory disorders. As a result, significant progress with respect to drug candidates other than Riquent, if any, will be significantly delayed and our success and ability to survive depends on whether we obtain FDA approval to market Riquent.

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

In September 2000, the FDA granted us orphan drug designation for Riquent for the treatment of lupus kidney disease. The Orphan Drug Act potentially enables us to obtain research funding, tax credits for certain research expenses and a waiver of the application user fees. In addition, the Orphan Drug Act allows for seven years of exclusive marketing rights to a specific drug for a specific orphan indication. Exclusivity is conferred upon receipt of marketing approval from FDA. The marketing exclusivity prevents FDA approval during the seven year period of the same drug from another company for the same orphan indication. Two drugs with substantially similar characteristics are considered to be the same, and exclusivity granted to one drug will block approval of the subsequent drug for the same indication. However, one may overcome the exclusivity designation by demonstrating that, despite the similarity of the drugs, a subsequent drug is clinically superior in terms of increased effectiveness and adequate safety, increased safety and adequate effectiveness or represents a major contribution to patient care, and therefore is not barred by the exclusivity. In the course of the FDA s initial review of our NDA, the FDA indicated that the indication for Riquent proposed in our NDA may be broader than the indication identified in our orphan drug designation. Accordingly, we were required to pay the filing fee for the NDA for Riquent. However, we subsequently received 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.

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.

We have never operated a commercial manufacturing facility and we will be required to manufacture Riquent pursuant to applicable FDA good manufacturing practices. Our inexperience could result in manufacturing delays or interruptions and higher manufacturing costs. This could negatively affect our ability to produce products for clinical studies and, therefore, to introduce products into the market on a timely and competitive basis. The subsequent sales of our products, if any, and our profit margins may also be negatively affected. In addition, substantial capital investment in the expansion and build-out of our manufacturing facilities 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.

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

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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 and our other drug candidates in sufficient quantities for our clinical trials and possible commercialization, our suppliers will be required to provide us with an adequate supply of chemicals and reagents. Our ability to obtain these chemicals and reagents is subject to the following risks:

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

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

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

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

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

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

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

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.

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

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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, if any. For example, in certain foreign markets, pricing and profitability of prescription drugs are subject to government control. In the United States, we expect that there will continue to be a number of federal and state proposals to implement similar government controls. In addition, an increasing emphasis on managed care in the United States will continue to put pressure on drug manufacturers to reduce prices. Price control initiatives could reduce the revenue that we receive for any products we may develop and sell in the future.

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 $222.0 million as of September 30, 2004. We expect to incur substantial losses each year for at least the next several years as we conduct additional clinical trials of our drug candidates, seek regulatory approval, and continue our research, clinical development, and manufacturing activities. In addition, assuming we ultimately receive FDA approval for Riquent or our other drug candidates, we will be required to develop commercial manufacturing capabilities and marketing and sales programs which may result in substantial additional losses. To achieve profitability we must, among other matters, complete the development of our products, obtain all necessary regulatory approvals and establish commercial manufacturing, marketing and sales capabilities. The amount of losses and the time required by us to reach sustained profitability are highly uncertain and we may never achieve profitability. We do not expect to generate revenues from the sale of Riquent, if approved, or our other products, if any, in the near term, and we may never generate product revenues.

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

We depend on patents and other unpatented intellectual property to prevent others from improperly benefiting from products or technologies that we may have developed. As of December 31, 2004, we owned 100 issued patents and 85 pending patent applications covering various technologies and drug candidates including Riquent. There can be no assurance, however, that any additional patents will be issued, that the scope of any patent protection will be sufficient to protect us or our technology, or that any current or future issued patent will be held valid if subsequently challenged. There is a substantial backlog of biotechnology patent applications at the United States Patent and Trademark Office that may delay the review and issuance of any patents. The patent position of biotechnology firms like ours is highly uncertain and involves complex legal and factual questions, and no consistent policy has emerged regarding the breadth of claims covered in biotechnology patents or the protection afforded by these patents. 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 believed appropriate for patents covering both our products and processes. There can be no assurance that patents will be issued from any of these applications, or that the scope of any issued patents will protect our technology.

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

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candidates, including Riquent. However, upon our further investigation, there can be no assurance that these patent families or other patents will not ultimately be found to impact the advancement of our drug candidates, including Riquent. If the United States Patent and Trademark Office or any foreign counterpart issues or has issued patents containing competitive or conflicting claims, and if these claims are valid, the protection provided by our existing patents or any future patents that may be issued could be significantly reduced, and our ability to prevent competitors from developing products or technologies identical or similar to ours could be negatively affected. In addition, there can be no guarantee that we would be able to obtain licenses to these patents on commercially reasonable terms, if at all, or that we would be able to develop or obtain alternative technology. Our failure to obtain a license to a technology or process that may be required to develop or commercialize one or more of our drug candidates may have a material adverse effect on our business. In addition, we may have to incur significant expenses and management time in defending or enforcing our patents.

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

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

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

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

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

The technology underlying our products is uncertain and unproven.

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

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 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 Dr. Kenneth Heilbrunn, Bruce Bennett, and William Welch, to assist us with growth and expansion into areas requiring additional expertise, such as clinical trials, 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.

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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 potential products may be negatively affected because, for instance, the trials may not be conducted properly, or the manufacturing or sales of our products may be delayed. In addition, we rely upon 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 potential products. If a collaborative arrangement is established, the collaborative partner may discontinue funding any particular program or may, either alone or with others, pursue alternative technologies or develop alternative drug candidates for the diseases we are targeting. Competing products, developed by a collaborative partner or to which a collaborative partner has rights, may result in the collaborative partner withdrawing support as to all or a portion of our technology.

Without collaborative arrangements, we must fund our own 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 could 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. Our competitors may develop or obtain regulatory approval for products more rapidly than we do. If, before the FDA approves Riquent, if ever, the FDA were to approve a drug other than Riquent for the same indication that Riquent is designed to treat, and such drug therefore received marketing exclusivity under the Orphan Drug Act, the FDA may be prevented from approving Riquent. Also, the biotechnology and pharmaceutical industries are subject to rapid changes in technology. Our competitors may develop and market technologies and products that are more effective or less costly than those being developed by us, or that would render our technology and proposed products obsolete or noncompetitive.

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

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

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

Due to the nature of our manufacturing processes, we are subject to stringent federal, state and local laws governing the use, handling and disposal of certain materials and wastes. We may have to incur significant costs to comply with environmental regulations if and when our manufacturing increases to commercial volumes. Current or future environmental laws may significantly affect our operations because, for instance, our production process may be required to be altered, thereby increasing our production costs. In our research and manufacturing activities, we use radioactive and other materials that could be hazardous to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. The risk of accidental injury or contamination from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any resulting damages, and any such liability could exceed our resources. Although we maintain general liability insurance, we do not specifically insure against environmental liabilities.

II. Risk Factors Related Specifically To Our Stock

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. Recent corporate events have caused our stock price to be particularly 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 us or our stockholders,

developments concerning potential agreements with collaborators,

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comments by securities analysts and general market conditions, and

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

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

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 which is subject to change from time to time. Although we have since come back into compliance with this Nasdaq requirement, it is possible that we will fall out of compliance with this 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 our 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 January 20, 2005, there were:

Approximately 61,436,547 shares of common stock (excluding the shares offered hereby) that have been issued in registered offerings or were otherwise freely tradable in the public markets.

Approximately 72,303 shares of common stock eligible for resale in the public market pursuant to SEC Rule 144.

8,924,755 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 $4.43 per share.

Approximately 866,673 shares of common stock reserved for future issuance pursuant to awards granted 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. After giving effect to the offering of common stock under this prospectus supplement, we may offer up to an aggregate amount of $53,937,500 of our common stock.

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.

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Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

We are currently evaluating the effectiveness of our internal controls over financial reporting in order to comply with Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to evaluate annually the effectiveness of our internal controls over financial reporting as of the end of each fiscal year beginning in 2004, and to include a management report assessing the effectiveness of our internal controls over financial reporting in all annual reports beginning with our Annual Report on Form 10-K for the fiscal year ended December 31, 2004. Section 404 also requires our independent accountant to attest to, and report on, management s assessment of our internal controls over financial reporting. As a result of our evaluation of our internal controls over financial reporting to date, we made changes to our internal controls in order to better document the controls and we implemented changes to our information systems used in financial reporting. The changes made during the third and fourth quarters of 2004 did not have, individually or in the aggregate, a material effect on our internal controls over financial reporting. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. If we fail to achieve and maintain a system of effective internal controls, it could have a material adverse effect on our business and stock price.

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.

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Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit No.	Description
1.1	Underwriting Agreement, dated January 28, 2005, by and between the Company and Pacific Growth Equities, LLC
5.1	Opinion of Gibson, Dunn & Crutcher LLP regarding the legality of the shares
23.1	Consent of Gibson, Dunn & Crutcher LLP (included as part of Exhibit 5.1)
99.1	Press Release, dated January 28, 2005, announcing the Company s intent to offer 12,250,000 shares of its common stock in a public offering
99.2	Press Release, dated January 28, 2005, announcing the pricing of the public offering of shares

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 28, 2005

LA JOLLA PHARMACEUTICAL COMPANY

By: /s/ Steven B. Engle
Steven B. Engle
Chairman and Chief Executive Officer

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