LA JOLLA PHARMACEUTICAL CO
Form 8-K
January 06, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 4, 2009
La Jolla Pharmaceutical Company
(Exact name of registrant as specified in its charter)

Delaware	000-24274	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)	(Zip Code)

Registrant s telephone number, including area code: (858) 452-6600
N/A

(Former name or former address, if changed since last report)

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))

Item 1.01 Entry into a Material Definitive Agreement.

On January 4, 2009 (the Effective Date), La Jolla Pharmaceutical Company (the Company) entered into a development and commercialization agreement (the Development Agreement) with BioMarin CF Limited (BioMarin CF), a wholly-owned subsidiary of BioMarin Pharmaceutical Inc. (BioMarin Pharma), granting BioMarin CF co-exclusive rights to develop and commercialize Riquent (and certain potential follow-on products) (collectively, Riquent) in the Territory, and the non-exclusive right to manufacture Riquent anywhere in the world, as more fully described below. The Territory includes all countries of the world except the Asia-Pacific Territory (i.e., all countries of East Asia, Southeast Asia, South Asia, Australia, New Zealand, and other countries of Oceania). Riquent is comprised of a lupus disease-specific epitope attached to a carrier platform and is currently in a Phase 3 clinical trial (known as the ASPEN study) for the treatment of systemic lupus erythematosus.

Under the terms of the Development Agreement, BioMarin CF will pay the Company a non-refundable commencement payment of $7.5 million and will purchase, through BioMarin Pharma, $7.5 million of a newly designated series of preferred stock (the Series B Preferred Stock), pursuant to a securities purchase agreement described more fully below.

At each of the two predefined interim efficacy analyses to be conducted by an independent data monitoring board (the DMB) during the course of the ASPEN study or when the ASPEN study comes to a successful completion, BioMarin CF may decide to exercise its full license rights by making required payments under the Development Agreement. Further, BioMarin CF must decide to fully participate following achievement of the nominal p-value for the primary end point in the ASPEN study, otherwise the Development Agreement will automatically terminate. Prior to the decision to participate fully, BioMarin CF may not exercise its rights or license (nor grant any sublicenses under such rights), except such rights as are necessary for manufacturing Riquent.

Depending on the outcomes (non-futile or achievement of p-value $p<0.001$) of the two interim efficacy analyses in the ASPEN study, as well as the final results of the ASPEN study, BioMarin CF will pay the Company up to an additional $47.5 million to $92.5 million in clinical milestone and full participation payments prior to FDA approval. Up to $20 million of these pre-approval clinical milestone payments can be structured as additional equity purchases of the Company s Series B Preferred Stock. If the first interim efficacy analysis results in a non-futile determination by the DMB, BioMarin CF will pay a milestone payment of $15 million to maintain its license option. If the second interim efficacy analysis results in a non-futile determination by the DMB, BioMarin CF will pay a milestone payment of $22.5 million to continue its license option, up to $5 million of which may be used to purchase additional Series B Preferred Stock of the Company. Depending upon (i) when BioMarin CF decides to exercise its right to participate fully following the first interim efficacy analysis, the second interim efficacy analysis or successful completion of the ASPEN study and (ii) the payments that BioMarin CF has made to the Company in accordance with the Development Agreement prior to its decision to participate fully, BioMarin CF must make an additional payment to the Company of between $15 million and $55 million (up to $15 million of which may be used to purchase additional Series B Preferred Stock) in order to participate fully and exercise all of the rights and licenses granted by the Company.

If the DMB indicates after the first or second interim efficacy analyses that the ASPEN study no longer has meaningful potential to meet its primary endpoint with statistical significance, or the nominal p-value for the primary end point is not achieved following the end of the ASPEN study, then the Company and BioMarin CF may agree to certain limitations on the development costs to be shared prior to FDA approval and BioMarin CF may delay its decision to participate fully until the receipt of FDA approval. Under this scenario, an additional payment of $55 million (up to $15 million of which may be used to purchase additional Series B Preferred Stock) will be due to the Company following FDA approval in order for BioMarin CF to participate fully and exercise all of its rights and license to develop and commercialize Riquent in the Territory.

The Company will also be eligible to receive additional payments of up to $181 million based on the receipt of regulatory approvals and the achievement of certain commercial milestones. Furthermore, upon commercialization of Riquent, if approved by the FDA, the Company will receive 50% of the net profits generated from sales of Riquent in the Territory.

The Company retains all rights to develop and commercialize Riquent in the Asia-Pacific Territory. In addition, in the event the Company wishes to enter into a license agreement with a third party with respect to Riquent for a country within the Asia-Pacific Territory, the Development Agreement provides BioMarin CF with a right to match such third party s offer.

Under the Development Agreement, the Company retains the right to manufacture Riquent for use in the Territory, subject to certain conditions and limitations relating to quantity and price. If the Company does not retain rights to manufacture Riquent for the Territory, BioMarin CF will have the right to manufacture Riquent for the use or sale of Riquent in the Territory. BioMarin CF and the Company will also work collaboratively to maximize supply chain and process efficiencies.

In addition, under the Development Agreement, the Company retains responsibility for completion of the ongoing Phase 3 clinical trial for Riquent as well as for planning and implementing a planned dosing study. The Company will also remain responsible for preparing and filing a New Drug Application for Riquent in the United States, and BioMarin CF will assume all regulatory responsibilities for Riquent if such New Drug Application is approved. If approved, the Company and BioMarin CF will jointly commercialize Riquent in the United States and the Company has the right to deploy up to approximately half of the total sales and marketing headcount for Riquent in the United States. In other countries of the Territory, BioMarin CF will be exclusively responsible for the commercialization of Riquent. A joint steering committee will be formed to oversee, review and coordinate the activities of the Company and BioMarin CF under the Development Agreement.

The Development Agreement terminates automatically if BioMarin CF does not make the payments that are due upon the occurrence of certain clinical development milestones prior to BioMarin CF deciding to participate fully, or if BioMarin CF does not decide to participate fully pursuant to the terms set forth in the Development Agreement. BioMarin CF has the right to terminate the Development Agreement for convenience upon 180 days prior written notice to

the Company and, prior to deciding to participate fully, BioMarin CF has the right to terminate the Development Agreement upon thirty days written notice to the Company.

If the Development Agreement is terminated due to breach, including the occurrence of certain events related to the other party s financial distress, the party who terminated the agreement has the right to purchase the other party s interests in Riquent in the Territory in return for the payment of either (i) a reasonable royalty, subject to certain limitations; or (ii) a lump sum payment equal to eighty percent (80%) of the fair value of the rights, provided that BioMarin CF shall only have this right if the Company s stockholders approve this term. If BioMarin CF terminates the Development Agreement due to the Company s breach and the Company has not obtained stockholder approval for the BioMarin CF purchase right, then BioMarin CF has the right to require the Company to purchase all of BioMarin CF s interest in Riquent in the Territory for an amount equal to the higher of (i) the fair value of the rights, or (ii) three times all payments (other than equity purchases) made by BioMarin CF to the Company under the Development Agreement.

In connection with the Development Agreement, the Company also entered into a securities purchase agreement, dated as of January 4, 2009 (the Purchase Agreement) with BioMarin Pharma. The Purchase Agreement provides that the Company will issue to BioMarin Pharma 3,391,035 shares of Series B Preferred Stock at a price per share of $2.21171 and may, as described below, issue additional shares of Series B Preferred Stock in consideration of certain milestone payments due under the Development Agreement. The sale of the shares is expected to close on January 20, 2009. The Series B Preferred Stock is non-voting, has a liquidation preference that is senior to the Company s common stock and is convertible into common stock at a rate of three to one (i.e., three shares of common stock for every one Series B Share).

Further, the Company may be required to issue additional shares of Series B Preferred Stock to BioMarin CF in exchange for up to $20 million of contingent milestone payments described above. If issued, the Series B Preferred Stock will be issued at a price per common share equivalent equal to the greater of (a) one hundred ten percent (110%) of the average closing price of the Company s common stock over a 10-day day period prior to the Company s public announcement of the event triggering the milestone payment or (b) $0.73724 per common equivalent share.

Finally, under the Purchase Agreement, BioMarin Pharma has a limited preemptive right to participate in future sales or issuances of common stock, or other securities or rights convertible into common stock, by the Company, subject to certain exceptions.

Item 8.01. Other Events.

About La Jolla Pharmaceutical Company and Riquent.

We are a biopharmaceutical company dedicated to improving and preserving human life by developing innovative pharmaceutical products. Our leading product in development, Riquent, is designed to treat lupus renal (kidney) disease by preventing or delaying renal flares. Lupus renal disease is a life-threatening, antibody-mediated disease in which disease-causing antibodies damage the kidneys. Renal flares are periods of extreme, acute kidney inflammation in patients

suffering from lupus renal disease. Riquent is currently in a Phase 3 clinical trial under a Special Protocol Assessment and has been granted Fast Track designation by the FDA. This study is an event-driven trial requiring us to accrue a specified number of renal flares to complete the study.

Lupus renal disease is a chronic illness that can lead to irreversible renal damage, renal failure and the need for dialysis, and is a leading cause of death in lupus patients. Lupus is an antibody-mediated disease caused by autoantibodies, of which antibodies to double-stranded DNA (dsDNA) are an important subgroup. Riquent is designed to prevent or delay renal flares by lowering the levels of circulating antibodies to dsDNA, which are believed to cause lupus renal disease. Current treatments for this autoimmune disorder often address only symptoms of the disease, or nonspecifically suppress the entire immune system, which can result in severe, negative side effects and hospitalization. We believe that Riquent has the potential to treat lupus renal disease without these severe, negative side effects. We believe that 40% to 45% of lupus patients will develop renal disease.

In 2008, we announced positive 12-month interim antibody data from our ongoing double-blind, placebo-controlled, randomized Phase 3 study of Riquent referred to as the Phase 3 ASPEN study (Abetimus Sodium in Patients with a History of Lupus Nephritis). Analyses of 12-month interim antibody data in the first 125 patients randomized in the study indicate that for all patients treated with 900 mg, 300 mg or 100 mg of Riquent per week compared with placebo, there were significantly greater reductions in antibodies to dsDNA ($p < 0.0001$).

The data show a dose-response curve for antibody reduction and also show that the 300 mg and 900 mg doses appear to be near the top of the antibody-related dose-response curve, thus supporting the choice of doses for this study. Antibody levels in the placebo-treated group remained around baseline levels throughout the 12 months. The rate at which antibody levels were maximally reduced appeared to be more rapid in the 900 mg dose group than in the 300 mg or the 100 mg dose groups. Each individual dose group was significantly different from placebo ($p < 0.0001$). An area under the curve (AUC) analysis, which reflects the effect of the drug on antibody levels over time, showed significantly greater antibody-lowering effects for the 300 mg and 900 mg dose groups compared with the placebo group (decreases of 26.9% for 100 mg, 35.5% for 300 mg and 37.7% for 900 mg, compared with an increase of 7.5% for placebo). The AUC analysis provides additional evidence that the higher doses of Riquent suppressed antibodies further than the 100 mg dose group. The proportion of patients achieving a 50% or greater AUC reduction was 0.0% in the placebo and 100 mg groups, 23% in the 300 mg group, and 30% in the 900 mg group. Antibody levels were measured every two weeks for the first 16 weeks of the study and then monthly for the remaining 36 weeks. All demographics and baseline characteristics were comparable across dosing groups.

As of January 1, 2009, more than 170 clinical trial sites were active and more than 900 patients have been enrolled in the ASPEN trial. The DMB has completed four reviews of the safety data and has not indicated any safety issues. The study is an event-driven trial designed to be completed when 128 renal flares have occurred. The current overall renal flare rate is lower than the original trial assumption. As a result, in an effort to shorten the time to achieve the required number of renal flares, we have extended the treatment period beyond 12 months and continue to

enroll patients beyond the initially targeted 740 patients. Based on these changes, we expect the trial to complete in the second half of 2009.

In early November 2008, we voluntarily temporarily suspended the dosing of patients in the ASPEN trial as a precautionary measure due to the discovery of minute particulates in certain vials used in the trial. The particulates were the result of vial delamination occurring in certain vials, containing either drug or placebo, used in the trial. We promptly reported the finding to the FDA and investigated the matter. After the quality of the drug and placebo was assured and, following discussions with the FDA and clinical investigators, dosing was resumed, with the allowance of the use of syringe filters for administering the placebo and Riquent as an added assurance of patient safety. Multiple sites in several countries resumed dosing of patients approximately two and a half weeks later and, as of the date of this filing, approximately 88% of patients currently enrolled and who were being treated when this issue first arose have been re-dosed. Any patients who do not resume dosing before having missed nine doses will be replaced. We do not believe that this delamination issue has, to date, adversely affected, or will in the future adversely affect, the timing or cost to complete the ASPEN trial, nor is it expected to affect the outcome of the trial.

During the temporary dosing interruption, patients continued with their protocol-defined physician visits. This temporary interruption of dosing was discussed with the FDA and is not expected to either result in any impediment to FDA approval or have any negative impact on the integrity of the study.

The Phase 3 ASPEN study also includes two interim efficacy analyses, each with target p values of $p < 0.001$ and a final p value of $p < 0.05$ at the end of the study. We have added a futility analysis to each interim efficacy analysis. The first interim efficacy analysis is expected to occur in early 2009, and the second interim efficacy analysis is expected to occur approximately midway between the first analysis and the expected end of the study.

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.

La Jolla Pharmaceutical Company

Date: January 6, 2009

By: /s/ Gail A. Sloan
Gail A. Sloan
Vice President of Finance and Secretary