

LA JOLLA PHARMACEUTICAL CO

Form 10-Q

November 09, 2007

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2007**

**OR**

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

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

**Commission file number: 0-24274**

**LA JOLLA PHARMACEUTICAL COMPANY**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**33-0361285**

(I.R.S. Employer  
Identification No.)

**6455 Nancy Ridge Drive  
San Diego, CA**

(Address of principal executive offices)

**92121**

(Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of shares of the registrant's common stock, \$0.01 par value per share, outstanding at November 1, 2007 was 39,606,515.

**LA JOLLA PHARMACEUTICAL COMPANY**  
**FORM 10-Q**  
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(in thousands)

	September 30, 2007 (Unaudited)	December 31, 2006 (See Note)
<b><u>ASSETS</u></b>		
Current assets:		
Cash and cash equivalents	\$ 5,169	\$ 3,829
Short-term investments	44,902	39,080
Prepays and other current assets	953	1,004
Total current assets	51,024	43,913
Property and equipment, net	1,304	2,333
Patent costs and other assets, net	3,033	3,279
Total assets	\$ 55,361	\$ 49,525
<b><u>LIABILITIES AND STOCKHOLDERS EQUITY</u></b>		
Current liabilities:		
Accounts payable	\$ 1,866	\$ 2,125
Accrued clinical/regulatory expenses	3,932	1,530
Accrued expenses	1,516	1,137
Accrued payroll and related expenses	1,011	1,265
Current portion of obligations under notes payable	95	183
Total current liabilities	8,420	6,240
Noncurrent portion of obligations under notes payable	186	196
Commitments		
Stockholders' equity:		
Common stock	396	327
Additional paid-in capital	384,775	342,519
Other comprehensive income	17	
Accumulated deficit	(338,433)	(299,757)
Total stockholders' equity	46,755	43,089
Total liabilities and stockholders' equity	\$ 55,361	\$ 49,525

Note: The condensed consolidated balance sheet at December 31, 2006 has been derived from the audited consolidated financial statements as of that date but does not include all of the information and disclosures required by U.S. generally accepted accounting principles.

See accompanying notes.

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**LA JOLLA PHARMACEUTICAL COMPANY**  
**Condensed Consolidated Statements of Operations**

(Unaudited)

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Expenses:				
Research and development	\$ 11,448	\$ 7,687	\$ 34,009	\$ 23,764
General and administrative	2,585	1,546	6,677	7,171
 Total expenses	 14,033	 9,233	 40,686	 30,935
 Loss from operations	 (14,033)	 (9,233)	 (40,686)	 (30,935)
Interest income	752	701	2,084	2,211
Interest expense	(8)	(6)	(74)	(27)
 Net loss	 \$ (13,289)	 \$ (8,538)	 \$ (38,676)	 \$ (28,751)
 Basic and diluted net loss per share	 \$ (0.34)	 \$ (0.26)	 \$ (1.04)	 \$ (0.88)
 Shares used in computing basic and diluted net loss per share	 39,577	 32,534	 37,215	 32,510

See accompanying notes.

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**LA JOLLA PHARMACEUTICAL COMPANY**  
**Condensed Consolidated Statements of Cash Flows**  
(Unaudited)  
(in thousands)

	Nine Months Ended September 30,	
	2007	2006
Operating activities:		
Net loss	\$ (38,676)	\$ (28,751)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	1,300	1,507
Loss on write-off/disposal of patents and property and equipment	691	172
Share-based compensation expense	3,715	4,170
Accretion of interest income, net	(140)	46
Change in operating assets and liabilities:		
Prepays and other current assets	51	(177)
Accounts payable	(259)	749
Accrued clinical/regulatory expenses	2,402	560
Accrued expenses	379	149
Accrued payroll and related expenses	(254)	(163)
Net cash used for operating activities	(30,791)	(21,738)
Investing activities:		
Purchases of short-term investments	(47,415)	(16,700)
Sales of short-term investments	41,750	40,050
Additions to property and equipment	(117)	(316)
Increase in patent costs and other assets	(599)	(362)
Net cash (used for) provided by investing activities	(6,381)	22,672
Financing activities:		
Net proceeds from issuance of common stock	38,610	192
Proceeds from issuance of notes payable	75	
Payments on obligations under notes payable	(173)	(451)
Net cash provided by (used for) financing activities	38,512	(259)
Net increase in cash and cash equivalents	1,340	675
Cash and cash equivalents at beginning of period	3,829	6,411
Cash and cash equivalents at end of period	\$ 5,169	\$ 7,086

Supplemental disclosure of cash flow information:

Interest paid	\$	74	\$	27
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Supplemental schedule of noncash investing and financing activities:

Net unrealized gains on available-for-sale investments	\$	17	\$	
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See accompanying notes.

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**LA JOLLA PHARMACEUTICAL COMPANY**  
**Notes to Condensed Consolidated Financial Statements**  
(Unaudited)  
**September 30, 2007**

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of La Jolla Pharmaceutical Company and its wholly-owned subsidiary (the Company) have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals and the severance accrual see Note 3 for further details) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for other quarters or the year ended December 31, 2007. For more complete financial information, these condensed consolidated financial statements, and the notes thereto, should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2006 included in the Company's Form 10-K filed with the Securities and Exchange Commission.

**2. Accounting Policies**

**Principles of Consolidation**

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

**Use of Estimates**

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and disclosures made in the accompanying notes to the condensed consolidated financial statements. Actual results could differ materially from those estimates.

**Recent Accounting Pronouncement**

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of SFAS 157 relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company does not currently believe that the adoption of SFAS 157 will have a material impact on its consolidated results of operations and financial condition. In February 2007, FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact of SFAS 159 on its consolidated results of operations and financial condition.

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**Net Loss Per Share**

Basic and diluted net loss per share is computed using the weighted-average number of common shares outstanding during the periods in accordance with SFAS No. 128, *Earnings per Share*, and Staff Accounting Bulletin No. 98. Basic earnings per share ( EPS ) is calculated by dividing the net income or loss by the weighted-average number of common shares outstanding for the period, without consideration for common share equivalents. Diluted EPS is computed by dividing the net income or loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options, common stock subject to repurchase by the Company, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted EPS when their effect is dilutive.

Because the Company has incurred a net loss for all periods presented in the condensed consolidated statements of operations, stock options, common stock subject to repurchase and warrants are not included in the computation of net loss per share because their effect is anti-dilutive. The shares used to compute basic and diluted net loss per share represent the weighted-average common shares outstanding, reduced by the weighted-average unvested common shares subject to repurchase. There were no unvested common shares subject to repurchase for the three and nine months ended September 30, 2007. The number of weighted-average unvested common shares subject to repurchase for the three and nine months ended September 30, 2006 were 64,398 and 61,724, respectively.

**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 \$13,272,000 and \$8,538,000 for the three-month periods ended September 30, 2007 and 2006, respectively, and \$38,659,000 and \$28,751,000 for the nine-month periods ended September 30, 2007 and 2006, respectively.

**3. Severance Charges**

On March 17, 2006, the Company entered into a separation agreement with its former Chairman and Chief Executive Officer following his resignation on March 14, 2006. In March 2006, the Company recorded total severance charges of approximately \$915,000 in connection with the separation agreement, which was included in general and administrative expense. In accordance with the separation agreement, the Company had paid \$907,000 as of September 30, 2007.

**4. Stockholders' Equity**

**Share-Based Compensation**

In 1994, the Company adopted the La Jolla Pharmaceutical Company 1994 Stock Incentive Plan (the 1994 Plan ), under which, as amended, 1,640,000 shares of common stock were authorized for issuance. The 1994 Plan expired in June 2004 and there remained 956,535 options outstanding under the 1994 Plan as of September 30, 2007.

In 2004, the Company adopted the La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (the 2004 Plan ), under which, as amended, 5,000,000 shares of common stock have been authorized for issuance. The 2004 Plan provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to employees, directors, consultants and advisors of the Company with up to a 10-year contractual life and various vesting periods as determined by the Company's Compensation Committee or the board of directors, as well as automatic fixed grants to non-employee directors of the Company. As of September 30, 2007, there were a total of 3,837,038 options outstanding under the 2004 Plan and 884,796 shares remained available for future grant.

In 1995, the Company adopted the La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (the ESPP ), under which, as amended, 700,000 shares of common stock are reserved for sale to eligible employees, as defined in the ESPP. Employees may purchase common stock under the ESPP

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every three months (up to but not exceeding 10% of each employee's base salary or hourly compensation, and any cash bonus paid) over the offering period at 85% of the fair market value of the common stock at specified dates. The offering period may not exceed 24 months. As of September 30, 2007, 505,941 shares of common stock have been issued under the ESPP and 194,059 shares of common stock are available for future issuance.

On January 1, 2006, the Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R). Under SFAS 123R, the estimated fair value of share-based compensation, including stock options and restricted stock granted under the 2004 Plan and discounted purchases of common stock by employees under the ESPP, is recognized as compensation expense. The estimated fair value of stock options and restricted stock is expensed on a straight-line basis over the vesting term. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock for each quarterly purchase during the two-year offering period and the purchase discount.

Expenses allocable to options or stock awards issued to non-employees, other than non-employee directors, have been determined in accordance with Emerging Issues Task Force 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Deferred charges for options granted to such non-employees are periodically remeasured as the options vest.

Share-based compensation expense recognized under SFAS 123R for the three-month periods ended September 30, 2007 and 2006 was \$1,134,000 and \$1,142,000, respectively, and \$3,713,000 and \$4,168,000, for the nine-month periods ended September 30, 2007 and 2006, respectively. As of September 30, 2007 and 2006, there was \$7,971,000 and \$9,244,000, respectively, of total unrecognized compensation cost related to non-vested share-based payment awards granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize this compensation cost over a weighted-average period of 1.2 years.

The following table summarizes share-based compensation expense related to employee and director stock options, restricted stock and ESPP purchases under SFAS 123R by expense category (in thousands):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Research and development	\$ 378	\$ 446	\$ 1,560	\$ 1,590
General and administrative	756	696	2,153	2,578
Share-based compensation expense included in operating expenses	\$ 1,134	\$ 1,142	\$ 3,713	\$ 4,168

The Company determines the fair value of share-based payment awards on the date of grant using the Black-Scholes option-pricing model, which is affected by the Company's stock price as well as assumptions regarding a number of highly complex and subjective variables. Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Because stock options granted by the Company have characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, in management's opinion, the existing valuation models may not provide an accurate measure of fair value of the stock options granted by the Company. Although the fair value of the employee and director stock options granted by the Company is determined in accordance with SFAS 123R using an option-pricing model, that value may not be indicative of the fair value observed in a willing-buyer/willing-seller market transaction.

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The Company estimated the fair value of each option grant and ESPP purchase right on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

<b>Options:</b>	<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>
Risk-free interest rate	4.7%	4.9%
Dividend yield	0.0%	0.0%
Volatility	118.5%	113.9%
Expected life (years)	5.5 - 6.1	5.5 - 6.1

<b>ESPP:</b>	<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>
Risk-free interest rate	4.8%	4.8%
Dividend yield	0.0%	0.0%
Volatility	72.1%	46.0%
Expected life	3 months	3 months

The weighted-average fair values of options granted were \$3.68 and \$3.08 for the three months ended September 30, 2007 and 2006, respectively, and \$3.73 and \$3.97 for the nine months ended September 30, 2007 and 2006, respectively. For the ESPP, the weighted-average purchase prices were \$2.74 and \$3.07 for the three months ended September 30, 2007 and 2006, respectively, and \$2.69 and \$3.07 for the nine months ended September 30, 2007 and 2006, respectively.

A summary of the Company's stock option activity and related data for the nine months ended September 30, 2007 follows:

	<b>Outstanding Options</b>	
	<b>Number of Shares</b>	<b>Weighted-Average Exercise Price</b>
Balance at December 31, 2006	4,302,379	\$ 9.83
Granted	971,973	\$ 4.32
Exercised	(165,922)	\$ 3.01
Forfeited or expired	(314,857)	\$ 15.20
Balance at September 30, 2007	4,793,573	\$ 8.59

In March 2007, the Company awarded 3,600 shares of common stock to the Chairman of the Board in accordance with the Chairman Compensation Policy approved by the Board of Directors on March 14, 2006 regarding the tax liability associated with the restricted stock issued on March 15, 2006 and vested on March 15, 2007. The newly awarded shares immediately vested on the date of issuance, and the Company recorded compensation expense of approximately \$25,000 for the fair value of the award.

**5. Income Taxes**

On January 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS 109. FIN 48 prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken in a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing

authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures and transition.

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At January 1, 2007, the Company had net deferred tax assets of \$131,496,000. The deferred tax assets are primarily composed of federal and state tax net operating loss ( NOL ) carryforwards and federal and state research and development ( R&D ) credit carryforwards. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the Company's net deferred tax assets. Additionally, the future utilization of the Company's NOL and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to ownership changes that have occurred previously or that could occur in the future. The Company has not yet determined whether such an ownership change has occurred, however, the Company plans to complete a Section 382 analysis regarding the limitation of the carryforwards for NOL and R&D credits. When this project is completed, the Company plans to update the unrecognized tax benefits under FIN 48. Therefore, the Company expects that the unrecognized tax benefits may change within 12 months of this reporting date. At this time, the Company cannot estimate how much the unrecognized tax benefits may change. Any carryforwards that will expire prior to their utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. Upon adoption of FIN 48 on January 1, 2007, the Company did not record any interest or penalties related to income tax matters.

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years are subject to examination for 1991 and forward by the U.S. tax authorities and for 1989 and forward by the California tax authorities due to the carryforward of unutilized NOL and R&D credits.

**6. Changes in Securities**

In April 2007, the Company sold an aggregate of 6,670,000 shares of common stock in a public offering for net proceeds to the Company of approximately \$37,911,000.

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Forward-Looking Statements**

The forward-looking statements in this report involve significant risks, assumptions and uncertainties, and a number of factors, both foreseen and unforeseen, could cause actual results to differ materially from our current expectations. Forward-looking statements include those that express a plan, belief, expectation, estimation, anticipation, intent, contingency, future development or similar expression. The analyses of clinical results of Riquent® (abetimus sodium), previously known as LJP 394, our drug candidate for the treatment of systemic lupus erythematosus (lupus), and any other drug candidate that we may develop, including the results of any trials or models that are ongoing or that we may initiate in the future, could result in a finding that these drug candidates are not effective in large patient populations, do not provide a meaningful clinical benefit, or may reveal a potential safety issue requiring us to develop new candidates. The analysis of the data from our previous Phase 3 trial of Riquent showed that the trial did not reach statistical significance with respect to its primary endpoint, time to renal flare, or with respect to its secondary endpoint, time to treatment with high-dose corticosteroids or cyclophosphamide. The results from our clinical trials of Riquent, including the results of any trials that are ongoing or that we may initiate in the future, may not ultimately be sufficient to obtain regulatory clearance to market Riquent either in the United States or any other country, and we may be required to conduct additional clinical studies to demonstrate the safety and efficacy of Riquent in order to obtain marketing approval. There can be no assurance, however, that we will have the necessary resources to complete any current or future trials or that any such trials will sufficiently demonstrate the safety and efficacy of Riquent. Our ability to develop and sell our products in the future may be adversely affected by the intellectual property rights of third parties or the validity or enforceability of our intellectual property rights, including the ability of the recently issued European composition of matter patent to survive any opposition proceedings. Additional risk factors include the uncertainty and timing of: obtaining required

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regulatory approvals, including delays associated with any approvals that we may obtain; the availability of sufficient financial resources; the timely supply of drug product for clinical trials; our ability to pass all necessary regulatory inspections; 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. Accordingly, you should not rely upon forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements are subject to the risks, uncertainties and other factors described in Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Quarterly Report on Form 10-Q, in the Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2006, and in other reports and registration statements that we file with the Securities and Exchange Commission from time to time.

**Developments in 2007**

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

On March 8 and March 20, 2007, we announced positive interim antibody results from our ongoing double-blind, placebo-controlled randomized Phase 3 trial of Riquent. Analyses of interim antibody data indicate that patients treated with 900 mg or 300 mg per week doses of Riquent had greater reductions in antibodies to double-stranded DNA ( dsDNA ) than patients treated with 100 mg per week or placebo. The results showed a significant dose response when comparing all Riquent-treated patients to placebo-treated patients ( $p = 0.0001$ ), and each Riquent dose group to the placebo dose group ( $p < 0.0032$  for 100 mg,  $p < 0.0001$  for 300 mg and 900 mg).

On March 29, 2007, we announced the pricing of an underwritten public offering of 5,800,000 shares of our common stock at \$6.00 per share. In connection with this offering, we granted the underwriters an option to purchase up to an additional 870,000 shares to cover over-allotments. On April 10, 2007, we announced that we had completed the public offering for total net proceeds of approximately \$37.9 million, including the proceeds from the over-allotment shares.

On April 26, 2007, we announced that composition of matter patents covering Riquent have issued in both Europe and in the People's Republic of China. If the full five years of patent term extension under a Supplemental Protection Certificate are granted, the term of the European patent would extend to December 2, 2018. The Chinese patent will be in effect until September 8, 2014.

On May 10, 2007, we announced that Niv E. Caviar had joined the Company as Executive Vice President, Chief Business Officer and Chief Financial Officer.

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On May 24, 2007, we announced that we had presented three papers related to Riquent at the 8th International Congress on SLE. The first presentation reviewed recently announced safety and interim antibody data from the current Phase 3 study which highlighted the statistically significant dose response observed between the 100 mg, 300 mg and 900 mg doses of Riquent compared with placebo ( $p=0.0001$ ). The second presentation reviewed the safety and drug levels of Riquent at doses up to 2,400 mg in healthy volunteers and the third, cardiovascular safety in healthy volunteers.

### **Overview**

Since our inception in May 1989, we have devoted substantially all of our resources to the research and development of technology and potential drugs to treat antibody-mediated diseases. We have never generated any revenue from product sales and have relied on public and private offerings of securities, revenue from collaborative agreements, equipment financings and interest income on invested cash balances for our working capital. We expect that our research and development expenses will increase significantly in the future. For example, we have initiated a Phase 3 clinical trial of Riquent, which the FDA has indicated appears to satisfy the requirement that we conduct an additional randomized, double-blind study. This study is expected to involve approximately 700 patients and take several years to complete. We expect to expend substantial amounts of capital resources for the clinical development and manufacturing of Riquent. We may also devote substantial additional capital resources to establish commercial-scale manufacturing capabilities and to market and sell potential products. These expenses may be incurred prior to or after any regulatory approvals that we may receive. In addition, our research and development expenses may increase if we initiate any additional clinical studies of Riquent or if we increase our activities related to any additional drug candidates. Even with the net proceeds of approximately \$37.9 million from the fundraising that we completed in April 2007, we expect that we will need additional funds to complete the Phase 3 trial and to continue the development of Riquent. Our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and the financial information included in this report are not necessarily indicative of our future operating results or financial condition.

We expect our net loss to fluctuate from quarter to quarter as a result of the timing of expenses incurred and the revenues earned from any potential collaborative arrangements we may establish. Some of these fluctuations may be significant. As of September 30, 2007, our accumulated deficit was approximately \$338.4 million.

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

### **Critical Accounting Policies and Estimates**

#### *Impairment and useful lives of long-lived assets*

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





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Costs related to successful patent applications are amortized using the straight-line method over the lesser of the remaining useful life of the related technology or the remaining patent life, commencing on the date the patent is issued. Legal costs and expenses incurred in connection with pending patent applications have been capitalized. We expense all costs related to abandoned patent applications. If we elect to abandon any of our currently issued or unissued patents, the related expense could be material to our results of operations for the period of abandonment. The estimation of useful lives for long-lived assets requires judgment and assumptions that could differ materially from the actual results. In addition, our results of operations could be materially impacted if we begin amortizing the costs related to unissued patents. We have expensed approximately \$0.7 million for the nine months ended September 30, 2007 primarily for the write-off of selected pending patent applications for technologies not related to Riquent or our small molecule SSAO inhibitors that are no longer being pursued. There were no significant patent write-offs recognized for the nine months ended September 30, 2006.

**Recent Accounting Pronouncements**

For information on the recent accounting pronouncements impacting our business, see Note 2 of the notes to condensed consolidated financial statements included in Item 1.

**Results of Operations**

For the three and nine months ended September 30, 2007, research and development expenses increased to \$11.4 million and \$34.0 million, respectively, from \$7.7 million and \$23.8 million, respectively, for the same periods in 2006. These increases were primarily attributable to increased activity in the Phase 3 clinical trial of Riquent.

Research and development expenses of \$11.4 million and \$34.0 million for the three and nine months ended September 30, 2007, respectively, consisted primarily of costs related to the Phase 3 clinical trial of Riquent, including fees for clinical research organizations, labs, investigators, drug production costs and salaries for manufacturing, clinical and research personnel, as well as share-based compensation expense of approximately \$0.4 million and \$1.6 million, respectively.

We expect that our research and development expense will increase significantly in the future. For example, our Phase 3 clinical trial of Riquent, which the FDA has indicated appears to satisfy the requirement that we conduct an additional randomized, double-blind study, is expected to involve approximately 700 patients and take several years to complete. As patient enrollment expands, we will be required to manufacture more Riquent and our manufacturing expenses will increase. Additionally, our research and development expenses may increase significantly if we initiate any additional clinical studies of Riquent or if we increase our activities related to the development of additional drug candidates.

For the three months ended September 30, 2007, general and administrative expense increased to \$2.6 million from \$1.5 million for the same period in 2006 and decreased to \$6.7 million for the nine months ended September 30, 2007, from \$7.2 million for the same period in 2006. The increase for the three months ended September 30, 2007 was primarily due to the write-off of selected pending patent applications for technologies not related to Riquent or our small molecule SSAO inhibitors that are no longer being pursued and an increase in consulting expenses for market research. The decrease for the nine months ended September 30, 2007 was primarily due to a decrease in termination benefits, mainly severance of approximately \$0.9 million and additional expense of approximately \$0.8 million for accelerated stock option vesting related to the former Chairman and Chief Executive Officer's departure in the first quarter of 2006. This decrease was partially offset by the write-off of selected pending patent applications noted above.

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

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Interest income, net remained consistent at \$0.7 million for the three months ended September 30, 2007 and for the same period in 2006 and decreased to \$2.0 million for the nine months ended September 30, 2007 from \$2.2 million for the same period in 2006. The decrease for the nine months ended September 30, 2007 was due primarily to lower average balances of cash, cash equivalents and short-term investments as compared to 2006.

**Liquidity and Capital Resources**

From inception through September 30, 2007, we have incurred a cumulative net loss of approximately \$338.4 million and have financed our operations through public and private offerings of securities, revenues from collaborative agreements, equipment financings and interest income on invested cash balances. From inception through September 30, 2007, we have raised approximately \$375.6 million in net proceeds from sales of equity securities.

At September 30, 2007, we had \$50.1 million in cash, cash equivalents and short-term investments, as compared to \$42.9 million at December 31, 2006. Our working capital at September 30, 2007 was \$42.6 million, as compared to \$37.7 million at December 31, 2006. The increase in cash, cash equivalents and short-term investments resulted from the net proceeds of \$37.9 million from the sale of 6.7 million shares of our common stock in April 2007 offset by the use of our financial resources to fund our clinical trial and manufacturing activities, research and development efforts and for other general corporate purposes. We invest our cash in United States government-backed securities, debt instruments of entities with strong credit ratings and money market funds. As of September 30, 2007, we classified all of our investments as available-for-sale securities because we expect to sell them in order to support our current operations regardless of their maturity dates. As of September 30, 2007, available-for-sale securities and cash equivalents of \$9.8 million have stated maturity dates of one year or less and \$38.0 million have maturity dates after one year. Securities that have a maturity date greater than one year have their interest rate reset periodically within time periods not exceeding 92 days.

As of September 30, 2007, approximately \$0.7 million of equipment (\$0.3 million net of depreciation) is financed under notes payable obligations. In December 2006, we entered into a credit facility to fund equipment purchases of up to \$1.8 million until the end of the second quarter of 2008. In addition, we lease our office and laboratory facilities and certain equipment under operating leases. We have also entered into non-cancelable purchase commitments for an aggregate of \$1.3 million with third-party manufacturers of materials to be used in the production of Riquent, approximately \$1.2 million of which is included in the consolidated balance sheet as of September 30, 2007. We intend to use our current financial resources to fund our obligations under these purchase commitments. In the future, we may increase our investments in property and equipment if we expand our research and development and manufacturing facilities and capabilities.

The following table summarizes our contractual obligations at September 30, 2007 (in thousands). Long-term debt obligations include interest.

	Total	Payment due by period			More than 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
Long-Term Debt Obligations	\$ 323	\$ 118	\$ 205	\$	\$
Operating Lease Obligations	1,645	822	823		
Purchase Obligations	1,303	1,303			
Total	\$3,271	\$2,243	\$1,028	\$	\$

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

Riquent, the outcome of our meetings with regulatory authorities, the timing of any regulatory applications and approvals, and technological developments. Expenditures also will depend on any establishment of collaborative arrangements and contract research as well as the availability of other funding or financings.

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We anticipate that our existing cash, cash investments, including the net proceeds of approximately \$37.9 million that we received from the sale of common stock in April 2007, and the interest earned thereon, will be sufficient to fund our operations as currently planned into the third quarter of 2008. This projection is based on the assumption that we do not raise any additional funds, either through the sale of additional securities or a collaborative agreement with a corporate partner and that we do not engage in any significant commercialization activities or significant activities in our other research programs.

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

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

### **ITEM 3. 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 92 days. We currently do not invest in any securities that are materially and directly affected by foreign currency exchange rates or commodity prices.

### **ITEM 4. CONTROLS AND PROCEDURES**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2007. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ( Exchange Act ), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of

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September 30, 2007, our principal executive officer and principal financial officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 6. EXHIBITS**

**Exhibit**

<b>Number</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (2)
4.1	Rights Agreement, dated as of December 3, 1998, between the Company and American Stock Transfer & Trust Company (3)
4.2	Amendment No. 1 to the Rights Agreement, dated as of July 21, 2000, between the Company and American Stock Transfer & Trust Company (4)
4.3	Amendment No. 2 to the Rights Agreement, dated as of December 14, 2005, between the Company and American Stock Transfer & Trust Company (5)
4.4	Amendment No. 3 to the Rights Agreement, dated as of March 1, 2006, between the Company and American Stock Transfer & Trust Company (1)
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
(1)	Previously filed with the Company's Current Report on Form 8-K filed March 1, 2006 and incorporated by reference herein.
(2)	Previously filed with the Company's Quarterly Report on Form

10-Q for the quarter ended September 30, 2000 and incorporated by reference herein.

(3) Previously filed with the Company's Registration Statement on Form 8-A (Registration No. 000-24274) filed December 4, 1998 and incorporated by reference herein.

(4) Previously filed with the Company's Current Report on Form 8-K filed January 26, 2001 and incorporated by reference herein. The changes effected by the Amendment are also reflected in the Amendment to Application for Registration on Form 8-A/A filed on January 26, 2001.

(5) Previously filed with the Company's Current Report on Form 8-K filed

December 16,  
2005 and  
incorporated by  
reference  
herein.



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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 thereunto duly authorized.

La Jolla Pharmaceutical Company

Date: November 8, 2007

/s/ Deirdre Y. Gillespie  
Deirdre Y. Gillespie, M.D.  
President and Chief Executive Officer  
(On behalf of the Registrant)

/s/ Niv E. Caviar  
Niv E. Caviar  
Executive Vice President, Chief Business  
Officer  
and Chief Financial Officer  
(As Principal Financial Officer)

/s/ Gail A. Sloan  
Gail A. Sloan  
Vice President of Finance and Secretary  
(As Principal Accounting Officer)

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**LA JOLLA PHARMACEUTICAL COMPANY  
INDEX TO EXHIBITS**

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