

LA JOLLA PHARMACEUTICAL CO  
Form 10-Q  
November 10, 2008

**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, 2008**

**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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer <input checked="" type="checkbox"/>	Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>
<input type="checkbox"/>			

(Do not check if a smaller reporting company)

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 3, 2008 was 55,421,634.



**LA JOLLA PHARMACEUTICAL COMPANY**  
**FORM 10-Q**  
**QUARTERLY REPORT**  
**INDEX**

**PART I. FINANCIAL INFORMATION**

**ITEM 1. Condensed Consolidated Financial Statements    Unaudited**

Condensed Consolidated Balance Sheets as of September 30, 2008 and December 31, 2007 1

Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2008 and 2007 2

Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2008 and 2007 3

Notes to Condensed Consolidated Financial Statements 4

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 10

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk 18

ITEM 4. Controls and Procedures 18

**PART II. OTHER INFORMATION**

ITEM 1. Risk Factors 19

ITEM 6. Exhibits 19

SIGNATURES 21

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**PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS    UNAUDITED****LA JOLLA PHARMACEUTICAL COMPANY****Condensed Consolidated Balance Sheets**

(in thousands)

	September 30, 2008 (Unaudited)	December 31, 2007 (See Note)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 17,454	\$ 4,373
Short-term investments	8,615	34,986
Prepays and other current assets	985	1,018
Total current assets	27,054	40,377
Property and equipment, net	1,118	1,271
Patent costs and other assets, net	2,579	2,757
Total assets	\$ 30,751	\$ 44,405
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,933	\$ 2,203
Accrued clinical/regulatory expenses	4,664	6,282
Accrued expenses	1,043	664
Accrued payroll and related expenses	1,228	1,199
Current portion of obligations under notes payable	148	138
Current portion of obligations under capital leases	11	10
Total current liabilities	11,027	10,496
Noncurrent portion of obligations under notes payable	222	344
Noncurrent portion of obligations under capital leases	37	44
Commitments		
Stockholders' equity:		
Common stock	554	396
Additional paid-in capital	417,449	385,944
Other comprehensive income	1	14
Accumulated deficit	(398,539)	(352,833)
Total stockholders' equity	19,465	33,521

Total liabilities and stockholders' equity	\$	30,751	\$	44,405
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Note: The condensed consolidated balance sheet at December 31, 2007 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.

**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,	
	2008	2007	2008	2007
Expenses:				
Research and development	\$ 14,099	\$ 11,448	\$ 38,170	\$ 34,009
General and administrative	2,791	2,585	6,766	6,677
 Total expenses	 16,890	 14,033	 44,936	 40,686
 Loss from operations	 (16,890)	 (14,033)	 (44,936)	 (40,686)
 Interest income	 163	 752	 653	 2,084
Interest expense	(12)	(8)	(71)	(74)
Realized loss on investments, net	(395)		(1,352)	
 Net loss	 \$ (17,134)	 \$ (13,289)	 \$ (45,706)	 \$ (38,676)
 Basic and diluted net loss per share	 \$ (0.31)	 \$ (0.34)	 \$ (0.96)	 \$ (1.04)
 Shares used in computing basic and diluted net loss per share	 55,327	 39,577	 47,764	 37,215

See accompanying notes.

**LA JOLLA PHARMACEUTICAL COMPANY**  
**Condensed Consolidated Statements of Cash Flows**

(Unaudited)  
(in thousands)

	Nine Months Ended September 30,	
	2008	2007
Operating activities:		
Net loss	\$ (45,706)	\$ (38,676)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	758	1,300
Loss on write-off/disposal of patents and property and equipment	236	691
Share-based compensation expense	3,400	3,715
Realized loss on investments, net	1,352	
Amortization of premium (discount) on investments	341	(140)
Change in operating assets and liabilities:		
Prepays and other current assets	33	51
Accounts payable	1,730	(259)
Accrued clinical/regulatory expenses	(1,618)	2,402
Accrued expenses	379	379
Accrued payroll and related expenses	29	(254)
Net cash used for operating activities	(39,066)	(30,791)
Investing activities:		
Purchases of short-term investments		(47,415)
Sales of short-term investments	24,665	41,750
Additions to property and equipment	(484)	(117)
Increase in patent costs and other assets	(179)	(599)
Net cash provided by (used for) investing activities	24,002	(6,381)
Financing activities:		
Net proceeds from issuance of common stock	28,263	38,610
Proceeds from issuance of notes payable		75
Payments on obligations under notes payable	(112)	(173)
Payments on obligations under capital leases	(6)	
Net cash provided by financing activities	28,145	38,512
Net increase in cash and cash equivalents	13,081	1,340
Cash and cash equivalents at beginning of period	4,373	3,829

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Cash and cash equivalents at end of period	\$ 17,454	\$ 5,169
Supplemental disclosure of cash flow information:		
Interest paid	\$ 71	\$ 74
Supplemental schedule of noncash investing and financing activities:		
Net unrealized losses (gains) on available-for-sale investments	\$ 13	\$ (17)
See accompanying notes.		



**LA JOLLA PHARMACEUTICAL COMPANY**  
**Notes to Condensed Consolidated Financial Statements**

(Unaudited)

**September 30, 2008**

**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 realized impairment loss on investments 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, 2008 are not necessarily indicative of the results that may be expected for other quarters or the year ended December 31, 2008. For more complete financial information, these unaudited 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, 2007 included in the Company's Form 10-K filed with the Securities and Exchange Commission. The Company has a history of recurring losses from operations and has an accumulated deficit of \$398,539,000 as of September 30, 2008. As of September 30, 2008, the Company had available cash and cash equivalents totaling \$17,454,000 and working capital of \$16,027,000. As of September 30, 2008, there was insufficient demand at auction for each of the Company's four AAA rated asset-backed student loan auction rate securities, representing its short-term investments of approximately \$8,615,000 (net of a realized impairment loss of \$1,385,000 recorded in the first nine months of 2008). As a result of this insufficient demand, these four securities are currently not liquid. The Company expects that the current cash resources, excluding the value of its currently illiquid auction rate securities, will enable it to continue its operations as currently planned through December 31, 2008. Subsequent to September 30, 2008, the Company executed an agreement with its broker-dealer, UBS A.G., giving the Company the right to sell the auction rate securities to its broker-dealer at par value beginning in January 2009 (see Note 7). However, there is a substantial doubt about the Company's ability to continue as a going concern beyond fiscal 2008. The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company continues to seek additional funding, including through collaborative arrangements and debt or equity financings, to finance its continuing development efforts and to commercialize its technologies. The Company believes that additional funds can be obtained in the near future; however, there is no assurance such funds will be available to the Company when needed or that such funds would be available under favorable terms. In the event that the Company cannot obtain additional funds in the near future, the Company has the ability and intent to cut back on certain expenditures and/or reduce its operations, including halting its ongoing Phase 3 clinical trial of Riquent and significantly reducing its workforce, which would have an adverse impact on completing its development efforts in a timely manner.

**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 October 2004. There have been no significant transactions related to La Jolla Limited since its inception.

### **Use of Estimates**

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

### **Recent Accounting Pronouncements**

On January 1, 2008, the Company adopted the provisions of Financial Accounting Standards Board ( FASB ) 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. See Note 3 for further details on the impact of the adoption of SFAS 157 on the Company's unaudited condensed consolidated results of operations and financial condition for the three and nine months ended September 30, 2008.

On January 1, 2008, the Company adopted the provisions of FASB 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. At this time, the Company has not elected to account for any of its financial assets or liabilities using the provisions of SFAS 159. As such, the adoption of SFAS 159 did not have an impact on the Company's unaudited condensed consolidated results of operations and financial condition for the three and nine months ended September 30, 2008.

In June 2007, FASB ratified the consensus reached by the Emerging Issues Task Force ( EITF ) on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. On January 1, 2008 the Company adopted the provisions of EITF 07-3, which did not have an impact on the Company's unaudited condensed consolidated results of operations and financial condition for the three and nine months ended September 30, 2008.

### **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 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 unaudited condensed consolidated statements of operations, stock options 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.

### 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 was \$17,133,000 and \$13,272,000 for the three-month periods ended September 30, 2008 and 2007, respectively, and \$45,719,000 and \$38,659,000 for the nine-month periods ended September 30, 2008 and 2007, respectively.

### 3. Fair Value of Financial Instruments

Cash and cash equivalents are comprised of short-term, highly liquid investments with maturities of 90 days or less from the date of purchase. Investments are comprised of available-for-sale securities recorded at estimated fair value. Unrealized gains and losses associated with the Company's investments, if any, are reported in stockholders' equity in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*.

As of September 30, 2008, the Company's cash, cash equivalents and short-term investments total \$26,069,000. The Company's investment securities consist of U.S. Treasury bills, money market funds invested in U.S. Treasury bills and AAA rated asset-backed student loan auction rate securities. Although the credit ratings of the auction rate securities have not deteriorated, there has been insufficient demand at auction for all four of our auction rate securities during the nine months of 2008. As a result, these securities are currently not liquid. In the event the Company needs to access the funds that are in an illiquid state, it will not be able to do so without a loss of principal until a future auction on these auction rate securities is successful, the securities are settled at par by the broker-dealer or they are redeemed by the issuer. The Company may incur a loss of principal if the Company is required to sell or borrow against these securities in a privately negotiated transaction. As a result, the Company has recorded a realized impairment loss on these securities of \$1,385,000 in 2008. This realized loss was determined in accordance with SFAS 157, which was adopted by the Company on January 1, 2008. The Company's auction rate securities are classified as short-term investments, and the realized impairment loss is included in the Company's unaudited condensed consolidated statement of operations.

As a basis for considering market participant assumptions in fair value measurements, SFAS 157 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). Due to the lack of actively traded market data for the Company's student loan auction rate securities, the value of these securities and resulting realized impairment loss was determined using Level 3 hierarchical inputs. These inputs include management's assumptions of pricing by market participants, including assumptions about risk. In accordance with SFAS 157, the Company used the concepts of fair value based on estimated discounted future cash flows of interest income over a projected five-year period reflective of the length of time the Company anticipates it will take the securities to become liquid. Discount rates ranging from approximately 5% to 10% were utilized when preparing this model. The Company classified all of the student loan auction rate securities as short-term available-for-sale securities as the Company will need additional cash in the near term and may be required to liquidate these auction rate securities in order to continue operations. Because of the Company's inability to hold these securities until their maturity (which ranges between 20-30 years), the Company believes the impairment of these securities is other-than-temporary. The Company continues to seek additional funding, including through collaborative arrangements and debt or equity financings, to finance its continuing development efforts and to commercialize its technologies. See Note 1 for further details. Subsequent to September 30, 2008, the Company executed an agreement with its broker-dealer giving the Company the right to sell the auction rate securities to its broker-dealer at par value beginning in January 2009 (see Note 7).

The Company measures the following financial assets at fair value on a recurring basis. The fair value of these financial assets at September 30, 2008 (in thousands) are as follows:

Description	Balance at September 30, 2008	Fair Value Measurements at Reporting Date Using		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents	\$ 17,454	\$ 17,454	\$	\$
Short-term investments	8,615			8,615
Total	\$ 26,069	\$ 17,454	\$	\$ 8,615

The following table sets forth the change in estimated fair value for the Company's AAA rated asset-backed student loan auction rate securities (in thousands).

	Fair Value Measurement Using Significant Unobservable Inputs (Level 3)	
	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2008
Beginning balance	\$ 9,021	\$
Transfers in to Level 3		10,000
Changes in interest receivable balance	(11)	
Total realized/unrealized losses		
Included in net loss	(395)	(1,385)
Included in comprehensive loss		
Purchases, issuances and settlements		
Ending balance	\$ 8,615	\$ 8,615

During August 2008, the broker-dealer engaged by the Company entered into a settlement agreement with the Securities and Exchange Commission, among others, regarding the marketing and selling of auction rate securities. In connection with this settlement, the broker-dealer announced that it will offer to buy the auction rate securities it sold to its retail clients at par value. In October 2008, the Company received and executed a written agreement with the Company's broker-dealer giving the Company the right to sell its auction rate securities to the broker-dealer at par value beginning in January 2009. See Note 7 for further details.

#### 4. 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. The terms of the separation agreement were completed in March 2008 and the actual amounts paid under the separation agreement were approximately \$915,000.

## **5. Stockholders' Equity**

### **Common Stock**

On May 12, 2008, the Company sold 15,614,834 Units (the "Units," where each Unit consists of one share of common stock, \$0.01 par value per share (the "Common Stock") and a warrant to purchase 0.25 shares of Common Stock) in an underwritten public offering at a price per Unit of \$1.92125, for net proceeds totalling approximately \$28,033,000. The warrants, which represent the right to acquire a total of 3,903,708 shares of common stock, are exercisable at a price of \$2.15 per share and have a five-year

term. Certain of the Company's principal stockholders, including affiliates of certain of the Company's directors, purchased an aggregate of approximately \$24,300,000, or approximately 81%, of the Units sold.

### Share-Based Compensation

In June 1994, the Company adopted the La Jolla Pharmaceutical Company 1994 Stock Incentive Plan (the "1994 Plan"), under which, as amended, 1,640,000 shares of common stock were authorized for issuance. The 1994 Plan expired in June 2004 and there were 857,471 options outstanding under the 1994 Plan as of September 30, 2008.

In May 2004, the Company adopted the La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (the "2004 Plan"), under which, as amended, 6,400,000 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, 2008, there were a total of 4,899,839 options outstanding under the 2004 Plan and 1,220,942 shares remained available for future grant.

In August 1995, the Company adopted the La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (the "ESPP"), under which, as amended, 850,000 shares of common stock are reserved for sale to eligible employees, as defined in the ESPP. Employees may purchase common stock under the ESPP every three months (up to but not exceeding 10% of each employee's base salary or hourly compensation, and any cash bonus paid, subject to certain limitations) over the offering period at 85% of the fair market value of the common stock at specified dates. The offering period may not exceed 24 months. As of September 30, 2008, 705,129 shares of common stock have been issued under the ESPP and 144,871 shares of common stock are available for future issuance.

Share-based compensation expense recognized under SFAS 123R for the three-month periods ended September 30, 2008 and 2007 was \$1,119,000 and \$1,134,000, respectively, and \$3,409,000 and \$3,713,000 for the nine-month periods ended September 30, 2008 and 2007, respectively. As of September 30, 2008, there was \$5,734,000 of total unrecognized compensation cost related to non-vested share-based payment awards granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize this compensation cost over a weighted-average period of 1.4 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)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research and development	\$ 563	\$ 378	\$ 1,565	\$ 1,560
General and administrative	556	756	1,844	2,153
Share-based compensation expense included in operating expenses	\$ 1,119	\$ 1,134	\$ 3,409	\$ 3,713

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. 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.

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
<b>Options:</b>				
Risk-free interest rate	3.3%	4.6%	3.2%	4.7%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility	106.4%	108.6%	115.2%	118.5%
Expected life (years)	5.6	6.0 - 6.1	5.6	5.5 - 6.1

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
<b>ESPP:</b>				
Risk-free interest rate	1.6%	4.4%	1.7%	4.8%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility	54.5%	47.3%	65.8%	72.1%
Expected life (months)	3.0	3.0	3.0	3.0

The weighted-average fair values of options granted were \$1.18 and \$3.68 for the three months ended September 30, 2008 and 2007, respectively, and \$1.71 and \$3.73 for the nine months ended September 30, 2008 and 2007, respectively. For the ESPP, the weighted-average purchase prices were \$0.95 and \$2.74 for the three months ended September 30, 2008 and 2007, respectively, and \$1.29 and \$2.69 for the nine months ended September 30, 2008 and 2007, respectively.

Expenses allocable to options or stock awards issued to non-employees, other than non-employee directors, have been determined in accordance with EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Options granted to such non-employees are periodically remeasured as options vest.

A summary of the Company's stock option activity and related data for the nine months ended September 30, 2008 follows:

	Outstanding Options	
	Number of Shares	Weighted- Average Exercise Price
Balance at December 31, 2007	4,809,575	\$8.56
Granted	1,456,900	\$2.04
Exercised	(1,097)	\$2.51
Forfeited or expired	(508,068)	\$7.82
Balance at September 30, 2008	5,757,310	\$6.98

## 6. Income Taxes

On July 13, 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN 48 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, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption and there are no unrecognized tax benefits included in the unaudited condensed consolidated balance sheet at September 30, 2008, that would, if recognized, affect the effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's condensed consolidated balance sheets at September 30, 2008 and at December 31, 2007, and has not recognized interest and/or penalties in the unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2008 and 2007. The Company is subject to taxation in the United States and various state jurisdictions. The Company's tax years for 1993 and forward are subject to examination by the United States and California tax authorities due to the carry forward of unutilized net operating losses and research and development credits.

The Company is currently undergoing an analysis under Section 382/383 of the Internal Revenue Code, regarding the limitation of net operating loss and research and development credit carryforwards. When this analysis is finalized, the Company plans to update its unrecognized tax benefits under FIN No. 48. The Company expects the Section 382 analysis to be completed within the next twelve months. 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.

#### **7. Subsequent Event**

In October 2008, the Company received and executed a written agreement with UBS A.G., the broker-dealer that sold the auction rate securities to the Company, giving the Company the right to sell its auction rate securities to the broker-dealer at par value totaling \$10,000,000 beginning in January 2009. As such, the Company anticipates liquidating these investments at par value in January 2009, subject to the ability of the broker-dealer to consummate the transaction.

## **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. Additional risk factors include the uncertainty and timing of: our ability to raise additional capital; our ability to liquidate our auction rate securities; obtaining required regulatory approvals, including delays associated with any approvals that we may obtain; 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. 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 the Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2007, Quarterly Report on Form 10-Q for the period ended March 31, 2008, in other reports and registration statements that we file with the Securities and Exchange Commission from time to time, and as updated in Part II, Item 1.A. Risk Factors contained in this Quarterly Report on Form 10-Q. We expressly disclaim any intent to update forward-looking statements.

#### **Developments in 2008**

Based on our recent communications with the Food and Drug Administration ( FDA ), as well as the rate of occurrence of renal flares in our Phase 3 clinical study of Riquent, we currently expect the first interim efficacy analysis to occur some time during the first quarter of 2009. The Company currently has more than 160 active sites in approximately 30 countries and more than 880 patients enrolled in the study. We expect to enroll at least 900 patients in the study and to complete the trial in the third or fourth quarter of 2009.

#### **Previously Announced During 2008**

On February 11, 2008, we announced that we had made significant progress in our current double-blind, placebo-controlled randomized Phase 3 clinical study of Riquent, referred to as the Phase 3 ASPEN study (Abetimus Sodium in Patients with a History of Lupus Nephritis) in that we had enrolled 607 patients and 130 clinical trial sites were open to enroll patients in 23 countries.

On April 23, 2008, we announced the following information related to our current Phase 3 ASPEN study:

Positive 12-month interim antibody data analyses of 12-month interim antibody data in the first 125 patients randomized in the study indicated 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 double-stranded DNA ( $p < 0.0001$ );

Interim efficacy analyses two interim efficacy analyses are planned, each with target p values of  $p < 0.001$  and a final p value of  $p < 0.05$  at the end of the study. A futility analysis was added to each interim efficacy analysis. The first analysis was expected to occur around the fourth quarter of 2008 and the second is expected to occur about midway between the first analysis and the expected end of the study;

Progression of the trial more than 140 sites were active and more than 670 patients had been enrolled;

Extension of treatment period the treatment period was extended beyond 12 months until the required number of renal flares is achieved, which is 128 renal flares;

Increase in patient enrollment we estimated that at least 800 patients would be enrolled in the study and that the trial would be completed in the second half of 2009; and

Independent Data Monitoring Board ( DMB ) review the DMB had completed three reviews of the safety data and had not indicated any safety issues.



On May 12, 2008, we sold 15.6 million Units (the Units, where each Unit consists of one share of common stock, \$0.01 par value per share and a warrant to purchase 0.25 shares of Common Stock) in an underwritten public offering at a price per Unit of \$1.92125, for net proceeds totalling approximately \$28.0 million. The warrants, which represent the right to acquire a total of 3.9 million shares of common stock, will be exercisable at a price of \$2.15 per share and have a five-year term. Certain of our principal stockholders, including affiliates of certain of our directors, purchased an aggregate of approximately \$24.3 million, or approximately 81%, of the Units sold.

### **Overview**

Since our inception in May 1989, we have devoted substantially all of our resources to the research and development of technology and potential drugs to treat antibody-mediated diseases. We have never generated any revenue from product sales and have relied on public and private offerings of securities, revenue from collaborative agreements, equipment financings and interest income on invested cash balances for our working capital. We expect that our research and development expenses will increase significantly in the future. For example, we are conducting and expanding a Phase 3 clinical trial of Riquent, which the FDA has indicated appears to satisfy the requirement that we conduct an additional randomized, double-blind study. This study is an event-driven trial requiring us to accrue a specified number of renal flares to complete the study. We currently target enrolling at least 900 patients to achieve the required number of renal flares and the trial could take one to two years to complete. Therefore, we expect to expend substantial amounts of capital resources for the clinical development and manufacturing of Riquent. We may also devote substantial additional capital resources to establish commercial-scale manufacturing capabilities and to market and sell potential products. These expenses may be incurred prior to or after any regulatory approvals that we may receive. In addition, our research and development expenses may increase if we initiate any additional clinical studies of Riquent or if we increase our activities related to any other drug candidates. We will need additional funds to finance our future operations. Our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and the financial information included in this report are not necessarily indicative of our future operating results or financial condition.

We expect our net loss to fluctuate from quarter to quarter as a result of the timing of expenses incurred and the revenues earned from any potential collaborative arrangements that we may establish, if any. Some of these fluctuations may be significant. As of September 30, 2008, our accumulated deficit was approximately \$398.5 million.

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

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

The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles ( GAAP ). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to patent costs, clinical/regulatory expenses and, effective January 1, 2008, the fair value of our financial instruments. We base our

estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

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

*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. There were no impairment losses recognized on our long-lived assets for the nine-month periods ended September 30, 2008 and 2007.

Costs related to successful patent applications are amortized using the straight-line method over the lesser of the remaining useful life of the related technology or the remaining patent life, commencing on the date the patent is issued. Legal costs and expenses incurred in connection with pending patent applications have been capitalized. We expense all costs related to abandoned patent applications. If we elect to abandon any of our currently issued or unissued patents, the related expense could be material to our results of operations for the period of abandonment. The estimation of useful lives for long-lived assets requires judgment and assumptions that could differ materially from the actual results. In addition, our results of operations could be materially impacted if we begin amortizing the costs related to unissued patents.

*Accrued clinical/regulatory expenses*

We review and accrue clinical trial and regulatory-related expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, sites activated and other events. We follow this method because reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. Accrued clinical/regulatory costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development costs; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

*Share-Based Compensation*

We adopted Statement of Financial Accounting Standard ( SFAS ) No. 123R, *Share-Based Payments* ( SFAS 123R ), using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006. Share-based compensation expense recognized under SFAS 123R was approximately \$3.4 million and \$3.7 million for the nine-month periods ended September 30, 2008 and 2007, respectively. As of September 30, 2008, there was approximately \$5.7 million of total unrecognized compensation cost related to non-vested share-based payment awards granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. We currently expect to recognize the remaining unrecognized compensation cost over a weighted-average period of 1.4 years. Additional share-based compensation expense for any new share-based payment awards granted after September 30, 2008 under all equity compensation plans cannot be predicted at this time because it will depend on, among other matters, the amounts of share-based payment awards granted in the future.

Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Because the employee and director stock options granted by us have characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, in our opinion the existing valuation models may not provide an accurate measure of the fair value of the employee and director stock options granted by us. Although the fair value of the employee and director stock options granted by us 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.

#### *Fair Value of Financial Instruments*

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*. In February 2008, the Financial Accounting Standards Board ( FASB ) issued FASB Staff Position ( FSP ) No. SFAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one-year deferral of the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, we have adopted the provisions of SFAS 157 with respect to financial assets and liabilities only.

SFAS 157 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The adoption of this statement impacted our calculation of fair value associated with our investments, specifically our auction rate securities, which became illiquid during the first quarter of 2008. In accordance with SFAS 157, we valued these securities using Level 3 hierarchical inputs due to the lack of actively traded market data. These inputs include management's assumptions of pricing by market participants, including assumptions about risk. We based our fair value determination on estimated discounted future cash flows of interest income over a projected period reflective of the length of time we anticipate it will take the securities to become liquid. We considered any impairment on these investments to be other-than-temporary, thus any changes in fair value were recorded to the unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2008. Because we were required to value those securities using only Level 3 inputs, our valuation determinations are somewhat subjective and the actual fair values as determined at a later date or by a third party may be different than the fair values we have determined. Subsequent to September 30, 2008, we executed a written agreement with our broker-dealer giving us the right to sell our auction rate securities to our broker-dealer at par value beginning in January 2009 (see Note 7 to our unaudited condensed consolidated financial statements included in Part I).

#### **Recent Accounting Pronouncements**

On January 1, 2008, we adopted the provisions of 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. See Note 3 to our unaudited condensed consolidated financial statements included in Part I for further details on the impact of the adoption of SFAS 157 on our unaudited condensed consolidated results of operations and financial condition for the three and nine months ended September 30, 2008.

On January 1, 2008, we adopted the provisions of FASB 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. At this time, we have not elected to account for any of our financial assets or liabilities using the provisions of SFAS 159. As such, the adoption of SFAS 159 did not have an impact on our unaudited condensed consolidated results of operations and financial condition for the three and nine months ended September 30, 2008.

In June 2007, FASB ratified the consensus reached by the Emerging Issues Task Force ( EITF ) on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. On January 1, 2008 we adopted the provisions of EITF 07-3, which did not have an impact on our unaudited condensed consolidated results of operations and financial condition for the three and nine months ended September 30, 2008.

### **Results of Operations**

For the three and nine months ended September 30, 2008, research and development expenses increased to \$14.1 million and \$38.2 million, respectively, from \$11.4 million and \$34.0 million, respectively, for the same periods in 2007. Due to expansion of the Phase 3 clinical trial of Riquent®, shipping costs for drug and lab specimens and fees for clinical research organizations, investigators and labs increased by approximately \$1.6 million and \$6.6 million for the three and nine months ended September 30, 2008, respectively, as compared to the same periods in 2007. The increase in expenses for the nine months ended September 30, 2008 was offset by a decrease of approximately \$3.3 million for expenses associated with the manufacture of Riquent® for the nine months ended September 30, 2008 as compared to the same period in 2007. Adequate supplies of Riquent® were on hand for the first nine months of 2008, thereby reducing manufacturing expenses incurred for this period.

Subject to obtaining additional capital, we expect that our research and development expense will increase significantly in the future as our Phase 3 trial continues to expand and we initiate manufacturing scale-up activities. As patient enrollment expands, we may be required to manufacture more Riquent and our manufacturing expenses may 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 and nine months ended September 30, 2008, general and administrative expenses increased slightly to \$2.8 million and \$6.8 million, respectively, from \$2.6 million and \$6.7 million, respectively, for the same periods in 2007. We expect that our general and administrative expense will increase in the future to support our ongoing clinical trials as patient enrollment increases and the manufacturing of Riquent for clinical trials and scale-up increases. Additionally, general and administrative expense may increase in the future if there is an increase in research and development or commercialization activities.

Interest income, net of interest expense, decreased to \$0.2 million for the three months ended September 30, 2008 from \$0.7 million for the same period in 2007 and decreased to \$0.6 million for the nine months ended September 30, 2008 from \$2.0 million for the same period in 2007. The decreases for the three and nine months ended September 30, 2008 were due primarily to lower average balances of cash, cash equivalents and short-term investments and lower average interest rates as compared to the same periods in 2007.

Realized loss on investments, net, of \$0.4 million and \$1.4 million for the three and nine months ended September 30, 2008, respectively, consisted of the other-than-temporary impairment loss on our auction rate securities recorded in 2008, in connection with the adoption of SFAS 157. See Note 3 to our unaudited condensed consolidated financial statements included in Part I for further details.

### **Liquidity and Capital Resources**

From inception through September 30, 2008, we have incurred a cumulative net loss of approximately \$398.5 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, 2008, we have raised approximately \$403.9 million in net proceeds from sales of equity securities.

On May 12, 2008, we sold 15.6 million Units (the Units, where each Unit consists of one share of common stock, \$0.01 par value per share and a warrant to purchase 0.25 shares of Common Stock) in an underwritten public offering at a price per Unit of \$1.92125, for net proceeds totalling approximately \$28.0 million. The warrants, which represent the right to acquire a total of 3.9 million shares of common stock, are exercisable at a price of \$2.15 per share and have a five-year term. Certain of our principal stockholders, including affiliates of certain of our directors, purchased an aggregate of approximately \$24.3 million, or approximately 81%, of the Units sold.

At September 30, 2008, we had \$26.1 million in cash, cash equivalents and short-term investments, as compared to \$39.4 million at December 31, 2007. Our working capital at September 30, 2008 was \$16.0 million, as compared to \$29.9 million at December 31, 2007. The decrease in cash, cash equivalents and short-term investments is the result of our use of financial resources to fund our clinical trial and manufacturing activities and for other general corporate purposes as well as the \$1.4 million realized impairment loss on our auction rate securities recorded in 2008. This decrease is partially offset by net proceeds of approximately \$28.0 million from the sale of 15.6 million Units. We invest our cash in U.S. Treasury bills, money market funds invested in U.S. Treasury bills, and AAA rated asset-backed student loan auction rate securities. As of September 30, 2008, we classified all of our student loan auction rate securities as short-term available-for-sale securities as we will need additional cash in the near term and may be required to liquidate these auction rate securities in order to continue our operations. In the event we need to access the funds that are in an illiquid state, we will not be able to do so without a loss of principal until a future auction on these auction rate securities is successful, the securities are settled at par by the broker-dealer or they are redeemed by the issuer at par. As a result, we have recorded a realized impairment loss on investments in 2008 of approximately \$1.4 million. As of September 30, 2008, all of our short-term available-for-sale securities have stated maturity dates of more than one year, however, their interest rates are reset periodically within time periods not exceeding 92 days. Subsequent to September 30, 2008, we executed an agreement with our broker-dealer giving us the right to sell our auction rate securities to our broker-dealer at par value beginning in January 2009 (see Note 7 to the unaudited condensed consolidated financial statements included in Part I).

As of September 30, 2008, approximately \$0.7 million of equipment (\$0.5 million net of depreciation) is financed under notes payable and capital lease obligations. We lease our office and laboratory facilities and certain equipment under operating leases. We have also entered into non-cancelable purchase commitments for an aggregate of \$2.0 million with third-party manufacturers of materials to be used in the production of Riquent, approximately \$0.6 million of which is included in the unaudited condensed consolidated balance sheet as of September 30, 2008. 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, 2008 (in thousands). Long-term debt and capital lease obligations include interest.



		Payment due by period			
		Less than	1-3 Years	3-5 Years	More than
	Total	1 Year			5 Years
Long-Term Debt Obligations	\$ 422	\$ 177	\$ 245	\$	\$
Capital Lease Obligations	58	15	42	1	
Operating Lease Obligations	807	699	101	7	
Purchase Obligations	2,011	2,011			
Total	\$ 3,298	\$ 2,902	\$ 388	\$ 8	\$

We intend to use our financial resources to fund the current clinical studies of Riquent, possible future clinical trials, manufacturing activities, research and development efforts and for working capital and other general corporate purposes. The amounts that we actually spend for each purpose may vary significantly depending on a number of factors, including the results from current and future clinical trials, the continued analysis of the clinical trial data of Riquent, the outcome of our meetings with regulatory authorities, the timing of any regulatory applications and approvals, and technological developments. Expenditures also will depend on any establishment of collaborative arrangements and contract research as well as the availability of other funding or financings.

We anticipate that our existing liquid cash resources, consisting of cash and cash equivalents, and the interest earned thereon, will be sufficient to fund our operations as currently planned through December 31, 2008. This projection is based on the assumption that we do not raise any additional funds, including through the sale of additional securities, establishing a collaborative agreement with a corporate partner or obtaining debt financing, we do not liquidate our auction rate securities, and that we do not engage in any significant commercialization activities or significant activities in our other research programs. Subsequent to September 30, 2008, we executed an agreement with our broker-dealer giving us the right to sell our auction rate securities to our broker-dealer at par value beginning in January 2009 (see Note 7 to the unaudited condensed consolidated financial statements included in Part I).

We will continue to seek capital through any number of means, including by issuing our equity securities, establishing one or more collaborative arrangements, and by obtaining debt financing. However, there can be no assurance that additional financing will be available to us on acceptable terms, if at all, especially if the current depressed market conditions continue. 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.

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 and capital. Our other drug candidates are much less developed than Riquent. There can be no assurance that our product development efforts with respect to Riquent or any other drug candidate will be successfully completed, that required regulatory approvals will be obtained or that any product, if introduced, will be successfully marketed or achieve commercial acceptance. Accordingly, we must continue to rely on outside sources of financing to meet our capital needs for the foreseeable future.

#### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our consolidated financial condition, changes in our consolidated financial condition, expenses, consolidated results of operations, liquidity, capital expenditures or capital resources.

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

All of our investment securities are classified as available-for-sale and are therefore reported on the balance sheet at market value. Our investment securities consist of U.S. Treasury bills, money market funds invested in U.S. Treasury bills, and asset-backed student loan auction rate securities. As of September 30, 2008, our short-term investments consisted of \$8.6 million (net of a realized impairment loss of \$1.4 million) of AAA rated student loan auction rate securities. Our auction rate securities are debt instruments with long-term maturities and interest rates that reset in short intervals through auctions.

The recent conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to the security's predetermined rate. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature, which could be many years. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, the carrying value of the investment would be required to be adjusted through an impairment charge.

As of September 30, 2008, there was insufficient demand at auctions for all four of our AAA rated asset-backed student loan auction rate securities. As a result of this insufficient demand, these four securities are currently not liquid and the interest rates have been reset to each security's predetermined interest rate. To date, we have recognized a realized impairment loss of \$1.4 million on these securities. See Note 3 to our unaudited condensed consolidated financial statements in Part I for further information.

In the event we need to access the funds that are in an illiquid state, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful, they are settled by our broker-dealer at par or they are redeemed by the issuer at par. At this time the market for these investments is presently uncertain. The inability to liquidate these securities could potentially impact our current business plan as we will need the ability to access these funds in the near future. Subsequent to September 30, 2008, we executed an agreement with our broker-dealer giving us the right to sell our auction rate securities to our broker-dealer at par value beginning in January 2009, subject to the ability of our broker-dealer to consummate the transaction (see Note 7 to our unaudited condensed consolidated financial statements included in Part I).

### 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, 2008. 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 September 30, 2008, 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, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. RISK FACTORS**

No material changes to risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007 have occurred, other than those set forth in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, and as set forth below:

***The current volatility and disruption in the capital and credit markets may continue to exert downward pressure on our stock price and we may cease to be in compliance with the continued listing standards set forth by The Nasdaq Global Market. If we cease to be in compliance with the continued listing standards, The Nasdaq Global Market may commence delisting proceedings against us.***

The capital and credit markets have been experiencing extreme volatility and disruption for more than twelve months. In recent weeks, the volatility and disruption have reached unprecedented levels. Stock markets in general, and our stock prices in particular, have experienced significant price and volume volatility over the past year. Our stock is currently trading below \$1.00 per share and we could continue to experience further declines in our stock price. Our stock is currently trading below the minimum trading price, which is in violation of Nasdaq's continued listing requirements. Although Nasdaq has suspended the enforcement of rules requiring a minimum \$1.00 closing bid price and the rules requiring a minimum market value of publicly held shares, this suspension is currently only in effect through January 16, 2009. There is no guarantee that we will be in compliance with Nasdaq's continued listing requirements when this suspension is lifted. If our stock continues to trade below \$1.00 when the temporary suspension is lifted, Nasdaq may commence delisting procedures against us. If we were delisted, the market liquidity of our common stock could be adversely affected and the market price of our common stock could decrease. Such a delisting could also adversely affect our ability to obtain financing for the continuation of our operations and could result in a loss of confidence by investors, suppliers and employees. In addition, our stockholders' ability to trade or obtain quotations on our shares could be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask price for our common stock.

### **ITEM 6. EXHIBITS**

#### **Exhibit**

#### **Number Description**

- |     |  |
|-----|--|
| 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)  |
| 4.5 | Amendment No. 4, effective May 12, 2008, to Rights Agreement dated December 3, 1998, as amended, by and between La Jolla Pharmaceutical Company and American Stock Transfer & Trust Company, including |

the Summary of Rights to be distributed to stockholders (6)

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.

(6) Previously filed with the Company's Current Report on Form 8-K filed May 12, 2008 and incorporated by reference herein.

**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

21

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**LA JOLLA PHARMACEUTICAL COMPANY  
INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
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