LA JOLLA PHARMACEUTICAL CO Form 10-Q November 16, 2009

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

#### **FORM 10-O**

(Mark One)

**DESCRIPTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934** 

For the quarterly period ended September 30, 2009

OR

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

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

Commission file number: 0-24274 LA JOLLA PHARMACEUTICAL COMPANY

(Exact name of registrant as specified in its charter)

Delaware 33-0361285

(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

4365 Executive Drive, Suite 300 San Diego, CA

92121

(Address of principal executive offices)

(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 b No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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 definition of large accelerated filer accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer b Non-accelerated filer o Smaller reporting company o

(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 o No b

The number of shares of the registrant s common stock, \$0.01 par value per share, outstanding at November 12, 2009 was 65,722,648.

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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)

ASSETS	•	ember 30, 2009 audited)	cember 31, 2008 see Note)
Current assets:			
Cash and cash equivalents	\$	5,830	\$ 9,447
Short-term investments		746	10,000
Prepaids and other current assets		746	785
Total current assets		6,576	20,232
Property and equipment, net			357
Patent costs and other assets, net			250
Total assets	\$	6,576	\$ 20,839
LIABILITIES AND STOCKHOLDERS EQUITY			
Current liabilities:			
Accounts payable	\$	692	\$ 4,626
Accrued clinical/regulatory expenses			3,957
Accrued expenses		235	1,008
Accrued payroll and related expenses		98	1,549
Credit facility			5,933
Current portion of obligations under notes payable			152
Current portion of obligations under capital leases			11
Total current liabilities		1,025	17,236
Noncurrent portion of obligations under notes payable			179
Noncurrent portion of obligations under capital leases			34
Commitments			
Stockholders equity:			
Common stock		657	555
Additional paid-in capital		427,574	418,522
Accumulated deficit		(422,680)	(415,687)
Total stockholders equity		5,551	3,390

Total liabilities and stockholders equity

\$

6,576

\$

20,839

Note: The condensed consolidated balance sheet at December 31, 2008 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, 2009 2008			Nine Months Ended September 30, 2009 2008		
Revenue from collaboration agreement	\$	\$		\$ 8,125	\$	
Expenses: Research and development General and administrative	(240) 992		14,099 2,791	9,567 5,602		38,170 6,766
Total expenses	752		16,890	15,169		44,936
Loss from operations	(752)		(16,890)	(7,044)		(44,936)
Interest and other income Interest expense Realized loss on investments, net	54		163 (12) (395)	64 (13)		653 (71) (1,352)
Net loss	\$ (698)	\$	(17,134)	\$ (6,993)	\$	(45,706)
Basic and diluted net loss per share	\$ (0.01)	\$	(0.31)	\$ (0.11)	\$	(0.96)
Shares used in computing basic and diluted net loss per share	65,723		55,327	62,555		47,764
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,			
		2009		2008
Operating activities: Net loss	\$	(6,993)	\$	(45,706)
Adjustments to reconcile net loss to net cash used for operating activities:	ψ	(0,993)	Ψ	(43,700)
Depreciation and amortization		116		758
(Gain) loss on write-off/disposal of patents and property and equipment		(326)		193
Share-based compensation expense		2,344		3,400
Expense reduction from settlement of vendor obligations		(2,645)		-,
Realized loss on investments, net		, , ,		1,352
Amortization of premium on investments				341
Change in operating assets and liabilities:				
Prepaids and other current assets		39		33
Accounts payable and accrued liabilities		(6,019)		491
Accrued payroll and related expenses		(1,451)		29
Net cash used for operating activities		(14,935)		(39,109)
Investing activities:				
Sales of short-term investments		10,000		24,665
Net proceeds from sale of patents and property and equipment		841		43
Additions to property and equipment		(18)		(484)
Increase in patent costs and other assets		(6)		(179)
Net cash provided by investing activities		10,817		24,045
Financing activities:				
Net proceeds from issuance of common stock				28,263
Net proceeds from issuance of preferred stock		6,810		20,200
Payments on credit facility		(5,933)		
Payments on obligations under notes payable		(331)		(112)
Payments on obligations under capital leases		(45)		(6)
Net cash provided by financing activities		501		28,145
Net (decrease) increase in cash and cash equivalents		(3,617)		13,081
Cash and cash equivalents at beginning of period		9,447		4,373
		- ,		.,

Cash and cash equivalents at end of period

\$ 5,830

\$ 17,454

See accompanying notes.

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#### LA JOLLA PHARMACEUTICAL COMPANY

**Notes to Condensed Consolidated Financial Statements** 

(Unaudited)

## **September 30, 2009**

#### 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, including restructuring costs and settlement of liabilities) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2009. 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, 2008 included in the Company s Form 10-K filed with the Securities and Exchange Commission on March 31, 2009. In February 2009, the Company announced that an Independent Monitoring Board for the Riquent ® Phase 3 ASPEN study had completed its review of the first interim efficacy analysis and determined that continuing the study was futile. Based on these results, the Company immediately discontinued the Riquent Phase 3 ASPEN study and the development of Riquent. The Company had previously devoted substantially all of its research, development and clinical efforts and financial resources toward the development of Riquent. In connection with the termination of the clinical trials for Riquent, the Company subsequently initiated steps to significantly reduce its operating costs, including a reduction in force, which was effected in April 2009 (see Note 6), and ceased all Riquent manufacturing and regulatory activities.

In July 2009, the Company announced that, in light of the current alternatives available to the Company, a wind down of the Company s business would be in the best interests of the Company and its stockholders. Although the Board of Directors (the Board ) approved a Plan of Complete Liquidation and Dissolution (the Plan of Dissolution ) in September 2009, it is subject to approval by holders of at least a majority in voting power of the Company s outstanding shares. The Company has called a special meeting of stockholders to vote on the Plan of Dissolution, however to date, the majority of the Company s stockholders have failed to return their proxy cards or otherwise indicate their votes with respect to this proposal.

The Company has not changed its basis of accounting as a result of the Board s adoption of the Plan of Dissolution, given that the Plan of Dissolution cannot be implemented without stockholder approval. Should the dissolution of the Company pursuant to the Plan of Dissolution be approved by the required vote of its stockholders, the Company would then change its basis of accounting from the going concern basis to the liquidation basis. If the Company s stockholders do not approve the dissolution of the Company pursuant to the Plan of Dissolution, the Board will explore what, if any, alternatives are available for the future of the Company.

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 this 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 or should the

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dissolution of the Company pursuant to the Plan of Dissolution be approved by the Company s stockholders. Certain assets, such as prepaid insurance (which represents a significant component of prepaids and other current assets), could have significantly lower values, or no value, under the liquidation basis of accounting. While the basis of presentation remains that of a going concern, the Company has a history of recurring losses from operations, and as of September 30, 2009, the Company had an accumulated deficit of \$422,680,000, available cash and cash equivalents of \$5,830,000 and working capital of \$5,551,000. These factors, as well as the Company s current inability to generate future cash flows and the potential stockholder approval of the Plan of Dissolution, raise substantial doubt about the Company s ability to continue as a going concern.

## 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. La Jolla Limited was formally dissolved during October 2009 with no resulting accounting consequences.

#### **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**

In June 2009, the Financial Accounting Standards Board (FASB) approved the FASB Accounting Standards Codification (the Codification) when it issued Statement of Financial Accounting Standards No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, which is included in *The Accounting Standards Codification* (ASC) *Topic of Generally Accepted Accounting Principles* (the Topic). All existing accounting standard documents, such as FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force and other related literature, excluding guidance from the Securities and Exchange Commission (SEC), have been superseded by the Codification. All other non-grandfathered, non-SEC accounting literature not included in the Codification has become non-authoritative. The Codification did not change GAAP, but instead introduced a new structure that combines all authoritative standards into a comprehensive, topically-organized online database. The Topic is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Topic impacts the Company's financial statement disclosures as all future references to authoritative accounting literature will be referenced in accordance with the Codification. As a result of the implementation of the Codification during the quarter ended September 30, 2009, previous references to accounting standards and literature are no longer applicable.

Effective April 1, 2009, the Company implemented *The ASC Topic of Subsequent Events*. This guidance establishes general standards of accounting for and disclosure of events that occur after the balance sheet date and requires companies to disclose the date through which subsequent events have been evaluated, as well as whether that date is the date the financial statements were issued or the date the financial statements were available to be issued. *The ASC Topic of Subsequent Events* became effective for interim or annual periods ending after June 15, 2009 and did not have a material impact on the Company sunaudited condensed consolidated financial statements for the three and nine months ended September 30, 2009.

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#### **Revenue Recognition**

On January 4, 2009, the Company entered into a development and commercialization agreement (the Development Agreement ) with BioMarin CF Limited (BioMarin CF), a wholly-owned subsidiary of BioMarin Pharmaceutical Inc. (BioMarin Pharma). The Development Agreement was terminated on March 27, 2009 following the failure of the Phase 3 ASPEN trial. See Note 4 for further details related to the Development Agreement.

The Company considers a variety of factors in determining the appropriate method of revenue recognition under collaborative arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

## **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. 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**

Unrealized gains and losses on available-for-sale securities are included in other comprehensive income (loss). There were no unrealized gains or losses on available-for-sale securities for the three or nine months ended September 30, 2009, and therefore net loss is equal to comprehensive loss for these periods. The Company s comprehensive net loss was \$17,133,000 and \$45,719,000 for the three and nine months ended September 30, 2008, respectively.

## Impairment of Long-Lived Assets and Assets to Be Disposed Of

If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through the undiscounted future operating cash flows.

As a result of the futility determination in the Phase 3 ASPEN trial, the Company discontinued the Riquent Phase 3 ASPEN study and the development of Riquent. Based on these events, the future cash flows from the Company s Riquent-related patents are no longer expected to exceed their carrying values and the assets became impaired as of December 31, 2008. This rendered substantially all of the Company s laboratory equipment, as well as a large portion of its furniture and fixtures and computer equipment and software, impaired as of December 31, 2008.

The Company recorded a non-cash charge for the impairment of long-lived assets of \$2,810,000 for the year ended December 31, 2008 to write down the value of the Company s long-lived assets to their estimated fair values. The Company sold, disposed of, or wrote off all of its remaining long-lived assets during the nine months ended September 30, 2009 for a gain of \$326,000.

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#### 3. Fair Value of Financial Instruments

Fair value is defined under *The ASC Topic of Fair Value Measurements and Disclosures* 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 *The ASC Topic of Fair Value Measurements and Disclosures* 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 which are the following:

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.

As of September 30, 2009, cash and cash equivalents were comprised of cash in checking accounts. The Company held no investments as of September 30, 2009.

As of December 31, 2008, cash and cash equivalents were comprised of short-term, highly liquid investments with maturities of 90 days or less from the date of purchase. Investments were comprised of available-for-sale securities recorded at estimated fair value determined using level 3 inputs. Unrealized gains and losses associated with the Company s investments, if any, were reported in stockholders equity.

At December 31, 2008, short-term investments were comprised of \$10,000,000 invested in auction rate securities, which were sold to UBS at par value in January 2009 pursuant to an Auction Rate Securities Agreement executed in November 2008.

## 4. Development and Stock Purchase Agreements

On January 4, 2009, the Company entered into the Development Agreement with BioMarin CF, a wholly-owned subsidiary of BioMarin Pharma, granting BioMarin CF co-exclusive rights to develop and commercialize Riquent (and certain potential follow-on products) (collectively, Riquent ) in the Territory, and the non-exclusive right to manufacture Riquent anywhere in the world. The Territory includes all countries of the world except the Asia-Pacific Territory (i.e., all countries of East Asia, Southeast Asia, South Asia, Australia, New Zealand, and other countries of Oceania).

Under the terms of the Development Agreement, BioMarin CF paid the Company a non-refundable commencement payment of \$7,500,000 and purchased, through BioMarin Pharma, \$7,500,000 of a newly designated series of preferred stock (the Series B-1 Preferred Stock), pursuant to a related securities purchase agreement described more fully below.

Following the futile results of the first interim efficacy analysis of Riquent received in February 2009, BioMarin CF elected not to exercise its full license rights to the Riquent program under the Development Agreement. Thus, the Development Agreement between the parties terminated on March 27, 2009 in accordance with its terms. All rights to Riquent were returned to the Company.

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Accordingly, the \$7,500,000 non-refundable commencement payment received in connection with this Development Agreement was recorded as revenue in the quarter ended March 2009.

In connection with the Development Agreement, the Company also entered into a securities purchase agreement, dated as of January 4, 2009 with BioMarin Pharma. In accordance with the terms of the agreement, on January 20, 2009, the Company sold 339,104 shares of Series B-1 Preferred Stock at a price per share of \$22.1171 and received \$7,500,000. On March 27, 2009, in connection with the termination of the Development Agreement, the Series B-1 Preferred Stock converted into 10,173,120 shares of Common Stock pursuant to the terms of the securities purchase agreement. The total sales price included a premium over the fair value of the stock issued of \$625,000, which was recorded as revenue in the quarter ended March 31, 2009.

## 5. Stockholders Equity

## **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 499,935 options outstanding under the 1994 Plan as of September 30, 2009. 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, 2009, there were a total of 3,315,958 options outstanding under the 2004 Plan and 2,804,822 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, 2009, 833,023 shares of common stock have been issued under the ESPP and 16,977 shares of common stock are available for future issuance. Options or stock awards issued to non-employees, other than non-employee directors, are periodically remeasured as the options vest.

Share-based compensation expense recognized for the three months ended September 30, 2009 and 2008 was \$311,000 and \$1,119,000, respectively, and \$2,344,000 and \$3,409,000 for the nine months ended September 30, 2009 and 2008, respectively. As of September 30, 2009, there was \$941,000 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 1.1 years.

The following table summarizes share-based compensation expense related to employee and director stock options, restricted stock and ESPP purchases by expense category:

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	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2	2009	:	2008		2009	:	2008
Research and development General and administrative	\$	311	\$	563 556	\$	632 1,712	\$	1,565 1,844
Share-based compensation expense included in operating expenses	\$	311	\$	1,119	\$	2,344	\$	3,409

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 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:

	I nree Moi Septem	September 30,		
Options:	2009	2008	2009	2008
Risk-free interest rate		3.3%	0.6%	3.2%
Dividend yield		0.0%	0.0%	0.0%
Volatility		106.4%	295.0%	115.2%
Expected life (years)		5.6	1.0	5.6

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Nine Months Ended

	Three Months Ended September 30,		Nine Mon Septem	ths Ended lber 30,
ESPP:	2009	2008	2009	2008
Risk-free interest rate		1.6%		1.7%
Dividend yield		0.0%		0.0%
Volatility		54.5%		65.8%
Expected life (months)		3.0		3.0

There were no purchases under the ESPP for the three or nine months ended September 30, 2009.

There were no options granted in the three months ended September 30, 2009. The weighted-average fair values of options granted was \$1.18 for the three months ended September 30, 2008. The weighted-average fair values of options granted were \$1.72 and \$1.71 for the nine months ended September 30, 2009 and 2008, respectively. For the ESPP, the weighted-average purchase prices were \$0.95 and \$1.29 for the three and nine months ended September 30, 2008, respectively.

A summary of the Company s stock option activity and related data for the nine months ended September 30, 2009 follows:

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	Outstanding Options Weighted-			
	Number of	A	Average Exercise	
	Shares		Price	
Balance at December 31, 2008	5,626,960	\$	6.80	
Granted	691,875	\$	1.73	
Exercised		\$		
Forfeited or expired	(2,502,942)	\$	5.23	
Balance at September 30, 2009	3,815,893	\$	6.91	

#### 6. Restructuring Costs

In connection with the termination of the clinical trials for Riquent, the Company ceased all manufacturing and regulatory activities related to Riquent and initiated steps to significantly reduce its operating costs, including a reduction of force, resulting in the termination of 74 employees who received notification in February 2009 and were terminated in April 2009. The Company recorded a charge of approximately \$1,048,000 in the quarter ended March 31, 2009, of which \$668,000 was included in research and development and \$380,000 was included in general and administrative expense. The \$1,048,000 was paid in May 2009.

#### 7. Commitments and Contingencies

The Company leased two adjacent buildings in San Diego, California covering a total of approximately 54,000 square feet. Both building leases expired in July 2009. Pursuant to one of the leases, the Company was responsible for completing modifications to the leased building prior to lease expiration. In July 2009, approximately \$315,000 was paid in accordance with the lease provisions upon lease expiration and exit of the buildings.

The Company renewed certain of its liability insurance policies in March 2009 covering future periods. In addition, the Company early terminated its operating leases during the quarter ended June 30, 2009, and as a result paid a termination fee of \$100,000 in September 2009. There were no operating leases remaining as of September 30, 2009.

#### 8. Settlement of Liabilities

During the nine months ended September 30, 2009, the Company negotiated settlements related to accounts payable obligations and accrued liabilities with a majority of its vendors. These negotiations resulted in reductions to accounts payable obligations and accrued liabilities from those amounts originally invoiced and accrued of approximately \$765,000 and \$2,645,000 for the three and nine months ended September 30, 2009, respectively, which were recorded as expense reductions upon the execution of the settlement agreements. As a result of these settlements, during the quarter ended September 30, 2009 there were decreases of \$711,000 and \$54,000 to research and development and general and administrative expenses, respectively. During the nine months ended September 30, 2009 there were decreases of \$2,499,000 and \$146,000 to research and development and general and administrative expenses, respectively.

In April 2009, the Company settled its notes payable obligations at face value.

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#### 9. Subsequent Events

No events subsequent to September 30, 2009 that require disclosure have occurred. The Company evaluated subsequent events for disclosure through the time of filing on November 13, 2009, which represents the date the financial statements were issued.

# 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 analysis of the data from our Phase 3 ASPEN trial of Riquent showed that the trial did not reach statistical significance with respect to its primary endpoint, delaying time to renal flare or for either secondary endpoint, improvement in proteinuria or time to major SLE flare and we decided to stop the study as well as the further development of Riquent. 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 in the Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2008, and 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.

## **Overview and Recent Developments**

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.

On January 4, 2009, we entered into a development and commercialization agreement (the Development Agreement) with BioMarin CF Limited (BioMarin CF), a wholly-owned subsidiary of BioMarin Pharmaceutical Inc. (BioMarin

with BioMarin CF Limited (BioMarin CF), a wholly-owned subsidiary of BioMarin Pharmaceutical Inc. (BioMarin Pharma). Under the terms of the Development Agreement, BioMarin CF was granted co-exclusive rights to develop and commercialize Riquent in the United States, Europe and all other territories of the world, excluding the Asia Pacific region, and the non-exclusive right to manufacture Riquent anywhere in the world. In connection with the Development Agreement, we also entered into a securities purchase agreement with BioMarin Pharma. In January 2009, BioMarin CF paid us a non-refundable commencement payment of \$7.5 million pursuant to the Development Agreement and BioMarin Pharma paid us \$7.5 million in exchange for a newly designated series of our preferred stock pursuant to the securities purchase agreement. As described below, the Development Agreement was terminated on March 27, 2009.

In February 2009, we were informed by an Independent Monitoring Board for the Riquent Phase 3 ASPEN study that the monitoring board completed its review of the first interim efficacy analysis of Riquent and determined that continuing the study was futile. We subsequently unblinded the data and found that there was no statistical difference in the primary endpoint, delaying time to renal flare, between the Riquent-treated group and the placebo-treated group, although there was a significant difference in the reduction of antibodies to double-stranded DNA.

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Based on these results, we immediately discontinued the Riquent Phase 3 ASPEN study and the further development of Riquent. We had previously devoted substantially all of our research, development and clinical efforts and financial resources toward the development of Riquent. In connection with the termination of our clinical trials for Riquent, we subsequently initiated steps to significantly reduce our operating costs, including a reduction in force, which was effected in April 2009. We also ceased the manufacture of Riquent at our former facility in San Diego, California, as well as all regulatory activities associated with Riquent. We recorded a charge of approximately \$1.1 million in the quarter ended March 31, 2009, of which \$0.7 million was included in research and development and \$0.4 million was included in general and administrative expense. This amount was paid in May 2009.

Following the futile results of the first interim efficacy analysis of Riquent, BioMarin CF elected to not exercise its full license rights to the Riquent program under the Development Agreement. Thus, the Development Agreement between the parties terminated on March 27, 2009 in accordance with its terms. Pursuant to the Securities Purchase Agreement between us and BioMarin Pharma, the Company s Series B-1 preferred shares purchased by BioMarin Pharma were automatically converted into 10,173,120 shares of common stock upon the termination of the Development Agreement. Additionally, all rights to Riquent were returned to us.

In January 2009, we sold all of our auction rate securities to our broker-dealer, UBS A.G. (UBS) at par value of \$10.0 million. As of December 31, 2008, we had previously recognized a total impairment charge of \$2.3 million as a result of the illiquidity of these securities, which was fully offset by a realized gain of \$2.3 million from UBS s repurchase agreement that provided for a put option on these securities. Following the sale of these investments, we no longer hold any auction-rate securities.

In July 2009, we announced that, in light of the current alternatives available to us, a wind down of our business would be in the best interests of our stockholders. Although the Board of Directors (the Board) approved a Plan of Complete Liquidation and Dissolution (the Plan of Dissolution) in September 2009, it is subject to approval by holders of at least a majority in voting power of our outstanding shares. We have called a special meeting of stockholders to vote on the Plan of Dissolution however, to date, the majority of our stockholders failed to return their proxy cards or otherwise indicate their votes with respect to this proposal prior to the start of these stockholders meetings.

We have not changed our basis of accounting as a result of the Board s adoption of the Plan of Dissolution, given that the Plan of Dissolution cannot be implemented without stockholder approval. Should the dissolution of the Company pursuant to the Plan of Dissolution be approved by the required vote of our stockholders, we would then change our basis of accounting from the going concern basis to the liquidation basis. If our stockholders do not approve the dissolution of the Company pursuant to the Plan of Dissolution, the Board will explore what, if any, alternatives are available for the future of the Company.

During September 2009, Thomas H. Adams, Ph.D., James N. Topper, M.D., Ph.D. and Martin P. Sutter each resigned from our Board and all committees and related positions thereof. The resignations of Drs. Adams and Topper and Mr. Sutter from the Board did not involve any disagreement with the Company.

During September 2009, the Board approved the termination of the Amended and Restated Rights Agreement, dated December 2, 2008, by and between the Company and American Stock Transfer & Trust Co., LLC, as amended (the Rights Agreement ) effective as of September 23, 2009. The Rights Agreement was terminated in connection with the Board s approval of the liquidation and dissolution of the Company.

During September 2009, we received a notice from the Nasdaq Stock Market indicating that we are not in compliance with Nasdaq Marketplace Rule 5550(a)(2) (the Minimum Bid Price Rule ) because, for 30 consecutive days, the bid price of our common stock has closed below the

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minimum level of \$1.00 per share. In accordance with Nasdaq Marketplace Rules, we have been provided 180 calendar days, or until March 15, 2010, to regain compliance with the Minimum Bid Price Rule. Although this notification has no effect on the current listing of our common stock, if we do not regain compliance with the Minimum Bid Price Rule by March 15, 2010, Nasdaq will notify us that our common stock will be delisted from the Nasdaq Stock Market.

## **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. 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 stock-based compensation. 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).

#### Revenue Recognition

We consider a variety of factors in determining the appropriate method of revenue recognition under collaborative arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

## 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. For the year ended December 31, 2008, as a result of the futility determination in the ASPEN trial, we recorded a non-cash charge for the impairment of long-lived assets of \$2.8 million to write down the value of our long-lived assets to their estimated fair values. We disposed of or wrote off all of our remaining long-lived assets during the nine months ended September 30, 2009 for a gain of \$0.3 million.

## Share-Based Compensation

Share-based compensation expense was approximately \$2.3 million and \$3.4 million for the nine months ended September 30, 2009 and 2008, respectively. As of September 30, 2009, there was approximately \$0.9 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 1.1 years.

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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 using an option-pricing model that value may not be indicative of the fair value observed in a willing-buyer/willing-seller market transaction.

## **Recent Accounting Pronouncements**

In June 2009, the Financial Accounting Standards Board (FASB) approved the FASB Accounting Standards Codification (the Codification) when it issued Statement of Financial Accounting Standards No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, which is included in *The Accounting Standards Codification* (ASC) *Topic of Generally Accepted Accounting Principles* (the Topic). All existing accounting standard documents, such as FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force and other related literature, excluding guidance from the Securities and Exchange Commission (SEC), have been superseded by the Codification. All other non-grandfathered, non-SEC accounting literature not included in the Codification has become non-authoritative. The Codification did not change GAAP, but instead introduced a new structure that combines all authoritative standards into a comprehensive, topically organized online database. The Topic is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of the Topic impacts our financial statement disclosures as all future references to authoritative accounting literature will be referenced in accordance with the Codification. As a result of the implementation of the Codification during the quarter ended September 30, 2009, previous references to accounting standards and literature are no longer applicable.

Effective April 1, 2009, we implemented *The ASC Topic of Subsequent Events*. This guidance established general standards of accounting for and disclosure of events that occur after the balance sheet date and requires companies to disclose the date through which subsequent events have been evaluated, as well as whether that date is the date the financial statements were issued or the date the financial statements were available to be issued. *The ASC Topic of Subsequent Events* became effective for interim or annual periods ending after June 15, 2009 and did not have a material impact on our unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2009.

## **Results of Operations**

For the nine months ended September 30, 2009, revenue increased to \$8.1 million as a result of the Development Agreement entered into with BioMarin CF in January 2009. The Development Agreement was terminated in March 2009 following the negative results from our Riquent Phase 3 ASPEN study. There were no revenues for the three months ended September 30, 2009 and 2008 or the nine months ended September 30, 2008. During the nine months ended September 30, 2009, we negotiated settlements related to accounts payable obligations and accrued liabilities with a majority of our vendors to preserve our remaining cash and other assets. These negotiations resulted in a reduction of approximately \$2.6 million to accounts payable obligations and accrued liabilities from amounts originally invoiced and accrued, which were recorded upon the execution of the settlement agreements. As a result of these settlements, during the nine months ended September 30, 2009, there were decreases of \$2.5 million and \$0.1 million to research and development and general and administrative expenses, respectively.

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For the three and nine months ended September 30, 2009, research and development expenses decreased to (\$0.2) million and \$9.6 million, respectively, from \$14.1 million and \$38.2 million, respectively, for the same periods in 2008 as a result of the discontinuation of the Riquent Phase 3 ASPEN study, salary and benefits decreases due to the termination of all research personnel and the settlement of accounts payable obligations and accrued liabilities noted above. For the nine months ended September 30, 2009, this decrease was partially offset by an increase in termination expense, mainly relating to severance, of approximately \$0.7 million recorded as of March 31, 2009, as a result of the termination of 64 research and development personnel in April 2009. We expect minimal research and development expenditures going forward as we wind down our operations.

For the three and nine months ended September 30, 2009, general and administrative expenses decreased to \$1.0 million and \$5.6 million, respectively, from \$2.8 million and \$6.8 million for the same periods in 2008. The decreases in general and administrative expenses are primarily the result of decreases in consulting and legal expense for the three and nine months ended September 30, 2009 of \$1.2 million and \$0.9 million, respectively. In addition, during April 2009, 10 general and administrative personnel were terminated, resulting in salary and benefits decreases for the three and nine months ended September 30, 2009 of \$0.7 million and \$0.6 million, respectively. The decrease in general and administrative expense for the nine months ended September 30, 2009 was partially offset by an increase in termination expense recorded as of March 31, 2009 relating to severance of approximately \$0.3 million as a result of the termination of personnel in April 2009. We expect decreased general and administrative expenditures going forward as we wind down our operations.

Interest and other income, net, decreased to less than \$0.1 million for the three and nine months ended September 30, 2009, from \$0.2 million and \$0.6 million, respectively, for the same periods in 2008. These decreases are primarily due to moving all short-term investments to non-interest bearing cash accounts during the quarter ended March 31, 2009.

Realized loss on investments, net, of \$0.4 million and \$1.4 million for the three and nine months ended September 30, 2008 primarily consisted of the other-than-temporary impairment loss on our auction rate securities recorded during the nine months ended September 30, 2008. These securities were sold to UBS at par value in January 2009 with no realized loss on investments.

#### **Liquidity and Capital Resources**

From inception through September 30, 2009, we have incurred a cumulative net loss of approximately \$422.7 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, 2009, we have raised approximately \$410.8 million in net proceeds from sales of equity securities. At September 30, 2009, we had \$5.8 million in cash and cash equivalents as compared to \$19.4 million of cash, cash equivalents and short-term investments at December 31, 2008. Our working capital at September 30, 2009 was \$5.6 million, as compared to \$3.0 million at December 31, 2008. The decrease in cash, cash equivalents and short-term investments resulted from the use of our financial resources to fund our clinical trial and manufacturing activities until their termination in 2009 and for other general corporate purposes. This decrease was partially offset by the non-refundable commencement payment of \$7.5 million received from BioMarin CF under the Development Agreement and the proceeds of \$7.5 million from the sale of 339,104 shares of our preferred stock to BioMarin Pharma under the Securities Purchase Agreement in January 2009.

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At September 30, 2009, all of our contractual obligations have been either paid in full or settlement amounts have been accrued as of September 30, 2009. We expect to pay all remaining outstanding obligations by December 31, 2009.

On July 31, 2009, our two building leases expired. Pursuant to the lease for one of these buildings, we were responsible for completing modifications to the leased building prior to lease expiration. In July 2009, approximately \$315,000 was paid in accordance with the lease provisions. We exited the buildings upon the expiration of the leases in July 2009.

As discussed above, we have presented a plan of liquidation and dissolution to our stockholders in our Proxy distributed to our stockholders on or about October 7, 2009. As noted in the Proxy, if the dissolution of the Company pursuant to the Plan of Dissolution is approved by the stockholders and implemented, we project that there will be between \$0.028 and \$0.045 per share available for distribution to stockholders.

## **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. OUANTITATIVE AND OUALITATIVE DISCLOSURES ABOUT MARKET RISK

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.

At September 30, 2009, all of our cash and cash equivalents consisted of cash. At December 31, 2008, all of our investment securities, which consisted of money market funds, U.S. Treasury bills and asset-backed student loan auction rate securities, were classified as available-for-sale and were therefore reported on the balance sheet at market value.

#### 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, 2009. 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, 2009, 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.

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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, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### **ITEM 1.A. 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, 2008 have occurred, other than those set forth in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2009 and June 30, 2009, our proxy statement filed with the Securities and Exchange Commission on October 1, 2009 and as set forth below.

#### II. RISK FACTORS RELATED SPECIFICALLY TO OUR STOCK.

Our common stock is at risk of being delisted from The Nasdaq Stock Market. If it is delisted, our stock price and the liquidity of our common stock would be impacted.

In September 2009, we received a notice from the Nasdaq Stock Market indicating that the Company is not in compliance with Nasdaq Marketplace Rule 5550(a)(2) (the Minimum Bid Price Rule ) because, for 30 consecutive days, the bid price for our common stock has closed below the minimum level of \$1.00 per share. Our stock continues to trade below \$1.00 per share, resulting in a strong likelihood that Nasdaq will commence delisting proceedings. Delisting from the Nasdaq Stock Market would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock.

#### ITEM 6. EXHIBITS

Evhibit

EXHIBIT	
Number	Description
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

<sup>\*</sup> Filed herewith.

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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 13, 2009 /s/ Deirdre Y. Gillespie

Deirdre Y. Gillespie, M.D.

President and Chief Executive Officer

(On behalf of the Registrant)

/s/ Gail A. Sloan

Gail A. Sloan

Vice President of Finance and Secretary (As Principal Financial and Accounting

Officer)

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# LA JOLLA PHARMACEUTICAL COMPANY INDEX TO EXHIBITS

Exhibit	
Number	Description
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
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