

LA JOLLA PHARMACEUTICAL CO
Form 10-Q
May 06, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2016

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: 1-36282

LA JOLLA PHARMACEUTICAL COMPANY
(Exact name of registrant as specified in its charter)

California 33-0361285
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

10182 Telesis Court, 6th Floor, San Diego, CA 92121
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (858) 207-4264

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 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 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 definition 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

Non-accelerated filer 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

As of April 22, 2016, La Jolla Pharmaceutical Company had 18,254,009 shares of common stock, \$0.0001 par value per share, outstanding.

LA JOLLA PHARMACEUTICAL COMPANY
FORM 10-Q
QUARTERLY REPORT

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LA JOLLA PHARMACEUTICAL COMPANY

Condensed Consolidated Balance Sheets

(in thousands, except share and par value amounts)

	March 31, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 113,071	\$ 126,467
Restricted cash	200	237
Prepaid clinical expenses	64	223
Prepaid expenses and other current assets	1,408	618
Total current assets	114,743	127,545
Property and equipment, net	2,047	1,732
Other assets	217	70
Total assets	\$ 117,007	\$ 129,347
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,408	\$ 2,506
Accrued expenses	2,411	1,224
Accrued payroll and related expenses	352	1,090
Total current liabilities	5,171	4,820
Shareholders' equity:		
Common Stock, \$0.0001 par value; 100,000,000 shares authorized, 18,254,009 and 18,244,009 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	2	2
Series C-1 ² Convertible Preferred Stock, \$0.0001 par value; 11,000 shares authorized, 3,906 shares issued and outstanding at March 31, 2016 and December 31, 2015, and liquidation preference of \$3,906 at March 31, 2016 and December 31, 2015	3,906	3,906
Series F Convertible Preferred Stock, \$0.0001 par value; 10,000 shares authorized, 2,737 shares issued and outstanding at March 31, 2016 and December 31, 2015, and liquidation preference of \$2,737 at March 31, 2016 and December 31, 2015	2,737	2,737
Additional paid-in capital	650,198	646,408
Accumulated deficit	(545,007)	(528,526)
Total shareholders' equity	111,836	124,527
Total liabilities and shareholders' equity	\$ 117,007	\$ 129,347

See accompanying notes to the condensed consolidated financial statements.

LA JOLLA PHARMACEUTICAL COMPANY
 Unaudited Condensed Consolidated Statements of Operations
 (in thousands, except per share amounts)

	Three Months Ended March 31,	
	2016	2015
Revenue		
Contract revenue - related party	\$234	\$—
Total revenue	234	—
Expenses		
Research and development	12,694	5,170
General and administrative	4,053	3,796
Total expenses	16,747	8,966
Loss from operations	(16,513)	(8,966)
Other income, net	32	11
Net loss	\$(16,481)	\$(8,955)
Basic and diluted net loss per share	\$(0.96)	\$(0.59)
Shares used in computing basic and diluted net loss per share	17,210	15,242

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	\$(16,481)	\$(8,955)
Adjustments to reconcile net loss to net cash used for operating activities:		
Share-based compensation expense	3,623	2,906
Third party share-based compensation expense	82	496
Depreciation expense	142	11
Loss on disposal of equipment	21	—
Changes in operating assets and liabilities:		
Restricted cash	37	—
Prepaid clinical expenses	159	79
Prepaid expenses and other current assets	(790)	(485)
Other assets	(147)	(57)
Accounts payable	(98)	1,729
Accrued expenses	1,187	(809)
Accrued payroll and related expenses	(738)	(424)
Net cash used for operating activities	(13,003)	(5,509)
Investing activities		
Purchase of property and equipment	(478)	(391)
Net cash used for investing activities	(478)	(391)
Financing activities		
Net proceeds from the exercise of stock options for common stock	85	57
Net cash provided by financing activities	85	57
Net decrease in cash and cash equivalents	(13,396)	(5,843)
Cash and cash equivalents at beginning of period	126,467	48,555
Cash and cash equivalents at end of period	\$113,071	\$42,712
Supplemental disclosure of cash flow information		
Non-cash investing and financing activity:		
Conversion of Series F Convertible Preferred Stock into common stock	\$—	\$61

See accompanying notes to the condensed consolidated financial statements.

LA JOLLA PHARMACEUTICAL COMPANY

Notes to Condensed Consolidated Financial Statements (Unaudited)

March 31, 2016

1. Business

La Jolla Pharmaceutical Company (collectively with its subsidiaries, the Company) is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies intended to significantly improve outcomes in patients suffering from life-threatening diseases. The Company has several product candidates in development. LJPC-501 is the Company's proprietary formulation of angiotensin II for the potential treatment of catecholamine-resistant hypotension. LJPC-401 is the Company's novel formulation of hepcidin for the potential treatment of conditions characterized by iron overload, such as hereditary hemochromatosis, beta thalassemia, sickle cell disease and myelodysplastic syndrome. LJPC-30S is the Company's next-generation gentamicin derivative program that is focused on therapeutics for the potential treatment of serious bacterial infections as well as rare genetic disorders, such as cystic fibrosis and Duchenne muscular dystrophy. The Company was incorporated in 1989 as a Delaware corporation and reincorporated in California in 2012.

The Company has a history of incurring significant operating losses and negative cash flows from operations. Since January 2012, when the Company was effectively restarted with new assets and a new management team, through March 31, 2016, the Company's cash used in operating activities was \$57.9 million. The Company had available cash and cash equivalents of \$113.1 million at March 31, 2016. Based on current operating plans and projections, management believes that the available cash and cash equivalents will be sufficient to fund operations into 2018.

2. Summary of Significant Accounting Policies

During the three months ended March 31, 2016, there have been no changes to the Company's significant accounting policies as described in the Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Basis of Presentation and Use of Estimates

The accompanying unaudited condensed consolidated financial statements of 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 the Securities and Exchange Commission (SEC) Regulation S-X. Accordingly, they should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2015, included in the Company's Annual Report on Form 10-K filed with the SEC on February 25, 2016. The accompanying unaudited condensed consolidated financial statements include the accounts of La Jolla Pharmaceutical Company and its wholly-owned subsidiaries. All significant inter-company transactions and balances have been eliminated in consolidation. The unaudited condensed consolidated financial statements contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the condensed consolidated balance sheet of the Company at March 31, 2016, the condensed consolidated statements of operations for the three months ended March 31, 2016, and the condensed consolidated statement of cash flows for the three months ended March 31, 2016. Estimates were made relating to useful lives of fixed assets, valuation allowances, impairment of assets, share-based compensation expense and accruals for clinical trial and research and development expenses. Actual results could differ materially from those estimates. The results of operations for the three months ended March 31, 2016 are not necessarily indicative of the results to be expected for the full year or any future interim

periods.

Comprehensive Loss

Comprehensive loss for the periods reported was comprised solely of the Company's net loss. The comprehensive loss for the three months ended March 31, 2016 and March 31, 2015 was \$16.5 million and \$9.0 million, respectively. There were no other changes in equity that were excluded from net loss for all periods presented.

Net Loss Per Share

Basic net loss per share is calculated based on the weighted-average number of common shares outstanding. Diluted net loss per share is calculated using the weighted-average number of common shares outstanding plus common stock

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equivalents. Convertible preferred stock, stock options, warrants and unvested restricted stock awards are considered common stock equivalents and are included in the calculation of diluted net loss per share using the treasury stock method when their effect is dilutive. Common stock equivalents are not included in the computation of diluted net loss per share if the inclusion of these securities is anti-dilutive. As of March 31, 2016 and March 31, 2015, there were common stock equivalents of 9.9 million shares and 8.8 million shares, respectively. Common stock equivalents were excluded from the calculation of diluted net loss per share because they were anti-dilutive.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) 2016-09 Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard modifies multiple provisions intended to simplify various aspects of accounting for share-based payments including income tax consequences, accounting for forfeitures, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 will be effective for the Company beginning in the first quarter of 2017. The adoption of this standard will not have a material impact on the Company's financial position or results of operations.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new standard requires lessees to recognize most leases on their balance sheets as lease liabilities with corresponding right-of-use assets and eliminates certain real estate-specific provisions. ASU 2016-02 will be effective for the Company in the first quarter of 2019 and will be adopted on a modified retrospective transition basis for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The new standard requires management to assess, at each annual and interim reporting period, an entity's ability to continue as a going concern within one year after the date that the financial statements are issued and to provide related footnote disclosures. ASU 2014-15 will be effective for the Company beginning in the first quarter of 2017. The adoption of this standard will not have a material impact on the Company's financial position or results of operations.

In June 2014, the FASB issued ASU 2014-12, Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period. The new standard requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. The Company adopted ASU 2014-12 effective as of January 1, 2016, and the adoption of this standard had no impact on the Company's financial position or results of operations.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). The new standard is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 will be effective for the Company in the first quarter of 2018 and allows for full retrospective or a modified retrospective adoption approach. The adoption of this standard will not have a material impact on the Company's financial position or results of operations.

3. Contract Revenue - Related Party

During the year ended December 31, 2015, the Company entered into a services agreement with a related party. Pursuant to the services agreement, the Company provides certain services to this related party, including, but not limited to, research and development and clinical trial design and management for the project undertaken. In exchange for providing such services, the Company receives payments at a negotiated, arms-length rate. As a result, the consideration received by the Company for its services is considered to be no less favorable to the Company than comparable terms that the Company could obtain from an unaffiliated third party in an arms-length transaction. The services agreement may be canceled by either party upon 60-days' written notice to the other party. In addition, the Company has a non-voting profit interest in the related party, which provides the Company with the potential to receive a portion of the future distributions of profits, if any.

During the three months ended March 31, 2016, the Company recognized approximately \$0.2 million of contract revenue for services and costs provided under the services agreement.

4. Share-Based Compensation

Share-Based Compensation Expense

Share-based compensation expense recognized in the condensed consolidated statements of operations for the three months ended March 31, 2016 and 2015 is based on awards ultimately expected to vest.

Total share-based compensation expense related to all share-based awards for the three months ended March 31, 2016 and 2015 was comprised of the following (in thousands):

	Three Months Ended March 31, 2016 2015	
Research and development:		
Stock options	\$1,261	\$558
Restricted stock	30	478
Warrants	11	11
Research and development share-based compensation expense	1,302	1,047
General and administrative:		
Stock options	1,710	589
Restricted stock	619	1,579
Warrants	74	187
General and administrative share-based compensation expense	2,403	2,355
Total share-based compensation expense included in expenses	\$3,705	\$3,402

As of March 31, 2016, approximately \$35,436,000 of total unrecognized share-based compensation expense related to non-vested stock options remains and is expected to be recognized over a weighted-average period of approximately 3.3 years. As of March 31, 2016, approximately \$1,952,000 of total unrecognized share-based compensation expense related to non-vested restricted stock awards remains and is expected to be recognized over a weighted-average period of approximately 1.0 year.

Stock Option Valuation

The fair value of each stock option award is estimated on the grant date using a Black-Scholes option pricing model (Black-Scholes model), which uses the assumptions noted in the following table. Expected volatility is based on historical volatility of the Company's common stock. Expected life of employee stock options is determined using the "simplified" method. The expected life assumptions for non-employees were based upon the contractual term of the stock options. Risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the stock options in effect at the time of the grants. Dividend yield is based on the expectation of no future dividend payments by the Company.

The Company estimated the fair value of each stock option grant on the grant date using the Black-Scholes model with the following weighted-average assumptions:

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Three Months Ended

March 31,

2016 2015

Expected volatility	148	%	174	%
Expected life (years)	5.41 years		6.82 years	
Risk-free interest rate	1.4	%	1.8	%
Dividend yield	—		—	

Stock Options

The Company's 2013 Equity Plan stock option activity for the three months ended March 31, 2016 is comprised of the following:

	Outstanding Stock Options	
	Shares Underlying Stock Options	Weighted-Average Exercise Price per Share
Outstanding at December 31, 2015	2,318,685	\$ 22.01
Granted	79,800	\$ 17.59
Exercised	(10,000)	\$ 8.52
Forfeited	(27,666)	\$ 25.71
Outstanding at March 31, 2016	2,360,819	\$ 21.87

As of March 31, 2016, there were 734,391 shares available for future grants under the 2013 Equity Plan.

Restricted Stock Awards

The Company's restricted stock award activity for the three months ended March 31, 2016 is comprised of the following:

	Number of Shares	Weighted-Average Grant Date Fair Market Value
Unvested at December 31, 2015	1,072,899	\$ 13.00
Vested	(30,220)	\$ 5.53
Unvested at March 31, 2016	1,042,679	\$ 13.22

Warrants

At March 31, 2016, the Company had 68,000 warrants outstanding. During the three months ended March 31, 2016, the Company awarded a warrant to purchase up to 17,000 shares of the Company's common stock to an outside third party at a price equal to the fair market value of the Company's common stock on the grant date.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In this report, all references to "we," "our," "us," "La Jolla" and the "Company" refer to La Jolla Pharmaceutical Company, a California corporation, and its subsidiaries.

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, which 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. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Forward-looking statements include, but are not limited to, statements regarding our expectations around timing of commencement and completion of future clinical trials, the ability to successfully develop drug candidates, our ability to obtain orphan drug status or other regulatory approvals, and the expected duration over which our cash balances will fund our operations. The outcomes of the events described in these forward-looking statements are subject to the risks, uncertainties and other factors described in this "Management's Discussion and Analysis of Financial Condition and Results of Operations," in the "Risk Factors" section contained in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission, or SEC, on February 25, 2016, and in other reports and registration statements that we file with the SEC from time to time. We expressly disclaim any intent to update forward-looking statements.

Introduction

Management's discussion and analysis of financial condition and results of operations is provided as a supplement to the accompanying unaudited condensed consolidated financial statements and notes, which are included in Item 1 of this Quarterly Report on Form 10-Q, to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. Our discussion is organized as follows:

- **Business Overview.** This section provides a general description of our business and significant events and transactions that we believe are important in understanding our financial condition and results of operations.
- **Program Overview.** This section provides a current status overview for each of our product candidates in development.
- **Critical Accounting Policies and Estimates.** This section provides a description of our significant accounting policies, including the critical accounting policies and estimates, which are summarized in Note 2 to the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.
- **Results of Operations.** This section provides an analysis of our results of operations presented in the accompanying unaudited condensed consolidated statements of operations by comparing the results for the three months ended March 31, 2016 to the results for the three months ended March 31, 2015.
- **Liquidity and Capital Resources.** This section provides an analysis of our historical cash flows, as well as our future capital requirements.

Business Overview

La Jolla Pharmaceutical Company is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies intended to significantly improve outcomes in patients suffering from life-threatening diseases. We have several product candidates in development. LJPC-501 is our proprietary formulation of angiotensin II for the potential treatment of catecholamine-resistant hypotension. LJPC-401 is our novel formulation of hepcidin for the potential treatment of conditions characterized by iron overload, such as

hereditary hemochromatosis, beta thalassemia, sickle cell disease and myelodysplastic syndrome. LJPC-30S is our next-generation gentamicin derivative program that is focused on therapeutics for the potential treatment of serious bacterial infections as well as rare genetic disorders, such as cystic fibrosis and Duchenne muscular dystrophy.

Program Overview

LJPC-501

LJPC-501 is our proprietary formulation of angiotensin II. Angiotensin II, the major bioactive component of the renin-angiotensin system, serves as one of the body's central regulators of blood pressure. We are developing LJPC-501 for the treatment of catecholamine-resistant hypotension (CRH), which is an acute, life-threatening condition in which blood pressure drops to dangerously low levels in patients who respond poorly to current treatments. Angiotensin II has been shown to raise blood pressure in a randomized, placebo-controlled clinical trial in CRH, which was recently published in the journal *Critical Care*. We have conducted preclinical pharmacology studies that have demonstrated that catecholamine resistance may be in part a result of reduced endogenous production of angiotensin II. In October 2014, we presented positive data from a preclinical study of LJPC-501 for the treatment of CRH.

We initiated a Phase 3 clinical trial with LJPC-501 for the treatment of CRH, called the ATHOS (Angiotensin II for the Treatment of High-Output Shock) 3 trial, in March 2015. In February 2015, we reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for this multicenter, randomized, double-blind, placebo-controlled, Phase 3 clinical trial. In accordance with the SPA, the primary efficacy endpoint for the ATHOS 3 registration trial is increase in blood pressure at three hours. The ATHOS 3 trial is designed to enroll approximately 315 patients. Patients are to be randomized in a 1:1 fashion to receive either: (i) LJPC-501 plus standard-of-care vasopressors; or (ii) placebo plus standard-of-care vasopressors. Randomized patients are to receive their assigned treatment via continuous IV infusion for up to seven days. The primary efficacy endpoint in the study is to compare the change in mean arterial pressure in patients with CRH who receive an IV infusion of LJPC-501 plus standard-of-care vasopressors to those that receive an IV infusion of placebo plus standard-of-care vasopressors. Secondary endpoints include comparison of changes in cardiovascular Sequential Organ Failure Assessment (SOFA) scores and the safety and tolerability of LJPC-501 in patients with CRH. Results from ATHOS 3 are expected by the end of 2016.

LJPC-401

LJPC-401 is our novel formulation of hepcidin. Hepcidin, an endogenous peptide hormone, is the body's naturally occurring regulator of iron absorption and distribution. Hepcidin prevents excessive iron accumulation in vital organs, such as the liver and heart, where it can cause significant damage and even result in death.

We are developing LJPC-401 for the potential treatment of iron overload, which occurs as a result of diseases such as hereditary hemochromatosis (HH), beta thalassemia, sickle cell disease (SCD) and myelodysplastic syndrome (MDS). HH is a disease caused by a genetic deficiency in hepcidin that results in excessive iron accumulation. HH is the most common genetic disease in Caucasians and causes liver cirrhosis, liver cancer, heart disease and/or failure, diabetes, arthritis and joint pain. Beta thalassemia, SCD and MDS are genetic diseases of the blood that can cause life-threatening anemia and usually require frequent and life-long blood transfusions. These blood transfusions cause excessive iron accumulation in the body, which is toxic to vital organs, such as the liver and heart. In addition, the underlying anemia causes excessive iron accumulation independent of blood transfusions.

LJPC-401 has been shown to be effective in reducing serum iron in preclinical testing. In October 2015, we initiated a Phase 1 clinical trial of LJPC-401 in patients at risk of iron overload due to conditions such as HH, beta thalassemia, SCD and MDS. In January 2016, we reported interim results from this study that suggested a dose-dependent reduction in serum iron following a single dose of LJPC-401. We expect to report complete results from our Phase 1 clinical trial in the second half of 2016.

During 2015, the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) designated LJPC-401 an orphan medicinal product for the treatment of beta thalassemia intermedia and major.

LJPC-30S

LJPC-30S is our next-generation gentamicin derivative program. Despite kidney toxicity, gentamicin has become one of the most commonly prescribed hospital antibiotics due to its broad spectrum of antimicrobial efficacy. Gentamicin consists primarily of a mixture of four distinct but closely related chemical entities that may contribute differentially to the product's toxicity profile.

Our LJPC-30S program is focused on therapeutics derived from purified components of the currently marketed gentamicin product that retain the biologic activity of gentamicin, yet appear to lack the traditional kidney toxicity associated

with its use. This program includes the development of potential treatments for serious bacterial infections as well as rare genetic disorders, such as cystic fibrosis and Duchenne muscular dystrophy.

In the area of rare genetic disorders, we believe that gentamicin's ability to induce a lack of fidelity in gene transcription, intrinsic to its antimicrobial mechanism of action, can also be leveraged in the correction of certain human genetic mutations that are the hallmark of diseases such as cystic fibrosis and Duchenne muscular dystrophy. In spite of favorable short-term clinical proof-of-efficacy data in cystic fibrosis, development of gentamicin as a chronic treatment for these genetic diseases has been limited by its toxicity profile.

Following a pre-investigational new drug (IND) meeting with the FDA, we have received guidance that we may proceed with a proposed Phase 1 clinical trial following the submission of an IND application.

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 U.S. generally accepted accounting principles. The preparation of these unaudited condensed 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. 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.

There have been no material changes to the critical accounting policies as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, which was filed on February 25, 2016.

Recent Accounting Pronouncements

Recent accounting pronouncements are disclosed in Note 2 to the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on form 10-Q.

Results of Operations

The following summarizes the results of our operations for the three months ended March 31, 2016 and 2015 (in thousands):

	Three Months Ended March 31,	
	2016	2015
Contract revenue - related party	\$234	\$—
Research and development expense	(12,694)	(5,170)
General and administrative expense	(4,053)	(3,796)
Other income, net	32	11
Net loss	\$(16,481)	\$(8,955)

Contract Revenue - Related Party

During the year ended December 31, 2015, we entered into a services agreement with a related party. Pursuant to the services agreement, we provide certain services to this related party, including, but not limited to, research and

development and clinical trial design and management for the project undertaken. In exchange for providing such services, we receive payments at a negotiated, arms-length rate. As a result, the consideration received by us for our services is considered to be no less favorable to us than comparable terms that we could obtain from an unaffiliated third party in an arms-length transaction. The services agreement may be canceled by either party upon 60-days' written notice to the other party. In addition, we have a non-voting profit interest in the related party, which provides us with the potential to receive a portion of the future distributions of profits, if any.

Research and Development Expense

The following summarizes our research and development expense for the three months ended March 31, 2016 and 2015 (in thousands):

	Three Months Ended March 31,	
	2016	2015
Clinical development costs	\$6,991	\$2,924
Personnel and related costs	2,516	886
Share-based compensation expense	1,302	1,047
Technology in-licensing costs	185	29
Other research and development costs	1,700	284
Total research and development expense	\$12,694	\$5,170

For the three months ended March 31, 2016, we incurred \$12.7 million in research and development expense compared to \$5.2 million for the three months ended March 31, 2015. The increase was primarily due to increased clinical development costs associated with the Phase 3 clinical trial of LJPC-501 for the treatment of CRH, clinical development costs associated with the Phase 1 clinical trial of LJPC-401 in patients at risk of iron overload and preclinical costs associated with the LJPC-30S program. Increases in personnel and related costs and share-based compensation expense, which were mainly due to the hiring of additional personnel to support the increased development activities noted above, also contributed to the increase in research and development expense. We anticipate research and development expense to increase throughout 2016, due to planned increases in personnel to support the continuation of our ongoing clinical trials of LJPC-501 and LJPC-401, the initiation of additional clinical trials and ongoing development of our product candidates and additional programs that we have acquired.

General and Administrative Expense

The following summarizes our general and administrative expense for the three months ended March 31, 2016 and 2015 (in thousands):

	Three Months Ended March 31,	
	2016	2015
Personnel and related costs	\$920	\$531
Share-based compensation expense	2,403	2,355
Other general and administrative expense	730	910
Total general and administrative expense	\$4,053	\$3,796

During the three months ended March 31, 2016, we incurred \$4.1 million in general and administrative expense compared to \$3.8 million for the three months ended March 31, 2015. The increase was primarily due to increased personnel and related costs, which was mainly due to the hiring of additional personnel to support the development activities discussed above. We anticipate general and administrative expense to increase throughout 2016, as the result of year-over-year increases in personnel to support our operations in light of the additional programs that we have acquired or are developing.

Liquidity and Capital Resources

Since January 2012, when La Jolla was effectively restarted with new assets and a new management team, through March 31, 2016, our cash used in operating activities was \$57.9 million. From inception through March 31, 2016, we have incurred a cumulative net loss of approximately \$545.0 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 March 31, 2016, we have raised approximately \$586.1 million in net proceeds from the sales of equity securities.

As of March 31, 2016, we had \$113.1 million in cash and cash equivalents, compared to \$126.5 million of cash and cash equivalents at December 31, 2015. Cash used in operating activities for the three months ended March 31, 2016 was

\$13.0 million, compared to \$5.5 million for the same period in 2015. The increase was primarily due to increased research and development activities. For the three months ended March 31, 2016, we used approximately \$0.5 million of cash for investing activities related to purchases of property and equipment, compared to \$0.4 million for the three months ended March 31, 2015. At March 31, 2016, we had positive working capital of approximately \$109.6 million, compared to positive working capital of approximately \$122.7 million at December 31, 2015. The decrease in our cash and cash equivalents and working capital was primarily due to cash used for operating and investing activities, partially offset by cash provided by financing activities for the three months ended March 31, 2016.

Based on our cash and working capital as of March 31, 2016 and our current operating plans and projections, we believe that the available cash and cash equivalents will be sufficient to fund operations into 2018. To fund future operations to the point where we are able to generate positive cash flow from the sales or out-licensing of our drug candidates, we will need to raise additional capital. The amount and timing of future funding requirements will depend on many factors, including the timing and results of our ongoing development efforts, the potential expansion of our current development programs, potential new development programs and related general and administrative support. We anticipate that we will seek to fund our operations through public and private equity and debt financings or other sources, such as potential collaboration agreements. We cannot assure you that anticipated additional financing will be available to us on favorable terms, or at all. Although we have previously been successful in obtaining financing through equity securities offerings, there can be no assurance that we will be able to do so in the 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 financial condition, changes in our financial condition, expenses, results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to financial market risks, including changes in interest rates. There were no substantial changes to our market risks in the three months ended March 31, 2016, when compared to the disclosures in Item 7A of our Annual Report Form 10-K for the year ended December 31, 2015, filed with the SEC, on February 25, 2016.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports, filed under the Securities Exchange Act of 1934, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by the SEC Rule 13a-15(b), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

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ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we may face various claims brought by third parties. Any of these claims could subject us to costly litigation. However, as of the date of this report, management believes the outcome of currently identified potential claims and lawsuits will not have a material adverse effect on our financial condition or results of operations.

ITEM 1A. RISK FACTORS

No material changes to risk factors have occurred as previously disclosed in Item IA of our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on February 25, 2016.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith	
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith	
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith	
101.INS	XBRL Instance Document	Filed herewith	
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith	

SIGNATURES

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

La Jolla Pharmaceutical Company

Date: May 6, 2016 /s/ George F. Tidmarsh
George F. Tidmarsh, M.D., Ph.D.
President, Chief Executive Officer and Secretary

/s/ Dennis M. Mulroy
Dennis M. Mulroy
Chief Financial Officer
(As Principal Financial and Accounting Officer)