LA JOLLA PHARMACEUTICAL CO
Form 10-Q
November 03, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016
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: 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 x 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 x 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)
Large accelerated filer o Accelerated filer x
Non-accelerated filer o Smaller reporting company o
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x
As of October 31, 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)

	September 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 85,035	$ 126,467
Restricted cash	200	237
Prepaid clinical expenses	105	223
Prepaid expenses and other current assets	1,396	618
Total current assets	86,736	127,545
Property and equipment, net	2,566	1,732
Other assets	219	70
Total assets	$ 89,521	$ 129,347
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,998	$ 2,506
Accrued expenses	3,917	1,224
Accrued payroll and related expenses	1,321	1,090
Total current liabilities	7,236	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 September 30, 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 September 30, 2016 and December 31, 2015, and liquidation preference of $3,906 at September 30, 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 September 30, 2016 and December 31, 2015, and liquidation preference of $2,737 at September 30, 2016 and December 31, 2015	2,737	2,737
Additional paid-in capital	657,464	646,408
Accumulated deficit	(581,824)	(528,526)
Total shareholders' equity	82,285	124,527
Total liabilities and shareholders' equity	$ 89,521	$ 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue				
Contract revenue - related party	$44	$647	$531	$647
Total revenue	44	647	531	647
Expenses				
Research and development	16,992	7,781	42,111	19,637
General and administrative	4,349	3,353	11,868	11,122
Total expenses	21,341	11,134	53,979	30,759
Loss from operations	(21,297)	(10,487)	(53,448)	(30,112)
Other income, net	46	13	150	33
Net loss	$(21,251)	$(10,474)	$(53,298)	$(30,079)
Basic and diluted net loss per share	$(1.23)	$(0.70)	$(3.10)	$(1.99)
Shares used in computing basic and diluted net loss per share	17,211	14,899	17,211	15,129

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$(53,298)	$(30,079)
Adjustments to reconcile net loss to net cash used for operating activities:		
Share-based compensation expense	10,804	9,330
Third party share-based compensation expense	167	1,013
Depreciation expense	510	209
Loss on disposal of equipment	75	—
Changes in operating assets and liabilities:		
Restricted cash	37	(200)
Prepaid clinical expenses	118	1,168
Prepaid expenses and other current assets	(778)	(347)
Other assets	(149)	(57)
Accounts payable	(508)	1,837
Accrued expenses	2,693	219
Accrued payroll and related expenses	231	205
Net cash used for operating activities	(40,098)	(16,702)
Investing activities		
Purchase of property and equipment	(1,419)	(1,681)
Net cash used for investing activities	(1,419)	(1,681)
Financing activities		
Net proceeds from the issuance of common stock	—	104,596
Net proceeds from the exercise of stock options for common stock	85	287
Net cash provided by financing activities	85	104,883
Net decrease in cash and cash equivalents	(41,432)	86,500
Cash and cash equivalents at beginning of period	126,467	48,555
Cash and cash equivalents at end of period	$85,035	$135,055
Supplemental disclosure of cash flow information		
Non-cash investing and financing activity:		
Conversion of Series C-1[2] Convertible Preferred Stock into common stock	$—	$11
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)

September 30, 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 synthetic human 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 September 30, 2016, the Company’s cash used in operating activities was $85.0 million. The Company had available cash and cash equivalents of $85.0 million at September 30, 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 and nine months ended September 30, 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 September 30, 2016, the condensed consolidated statements of operations for the three and nine months ended September 30, 2016, and the condensed consolidated statement of cash flows for the nine months ended September 30, 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. Certain amounts previously reported in the financial statements have been reclassified to conform to the current presentation. Such

reclassifications did not affect net loss, shareholders' equity or cash flows. The results of operations for the three and nine months ended September 30, 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 and nine months ended September 30, 2016 was $21.3 million and $53.3 million, respectively, and for the three and nine months ended September 30, 2015 was $10.5 million and $30.1 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, excluding unvested restricted stock awards. Diluted net loss per share is calculated using the weighted-average number of common shares outstanding plus common stock 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 excluded from the calculation of diluted net loss per share when their effect is anti-dilutive. As of September 30, 2016 and September 30, 2015, there were common stock equivalents of 11.2 million shares and 9.1 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 for the year ending December 31, 2016. The adoption of this standard has no 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 781): 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 trial design and management for projects undertaken. In exchange for providing such services, the Company is entitled to receive 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 and nine months ended September 30, 2016, the Company recognized approximately $44,000 and $531,000, respectively, 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 and nine months ended September 30, 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 and nine months ended September 30, 2016 and 2015 was comprised of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development:				
Stock options	$1,678	$636	$4,154	$1,609
Restricted stock	—	240	30	1,452
Warrants	10	15	25	40
Research and development share-based compensation expense	1,688	891	4,209	3,101
General and administrative:				
Stock options	1,666	1,443	4,934	2,950
Restricted stock	516	545	1,645	3,719
Warrants	56	182	183	573
General and administrative share-based compensation expense	2,238	2,170	6,762	7,242
Total share-based compensation expense included in expenses	$3,926	$3,061	$10,971	$10,343

As of September 30, 2016, $33.2 million 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 3.0 years. As of September 30, 2016, $0.9 million 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 5 months.

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 of non-employee stock options is based on 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:

	Nine Months Ended September 30,			
	2016		2015	
Expected volatility	141	%	147	%
Expected life (years)	5.74 years		4.91 years	
Risk-free interest rate	1.3	%	1.4	%
Dividend yield	—		—	

Stock Option Activity

The Company's 2013 Equity Incentive Plan stock option activity for the nine months ended September 30, 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	364,500	$ 17.59
Exercised	(10,000)	$ 8.52
Forfeited	(47,700)	$ 25.76
Outstanding at September 30, 2016	2,625,485	$ 21.38

As of September 30, 2016, there were 1,969,725 shares available for future grants under the 2013 Equity Incentive Plan.

Restricted Stock Award Activity

The Company's restricted stock award activity for the nine months ended September 30, 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 September 30, 2016	1,042,679	$ 13.22

Warrants

At September 30, 2016, the Company had 68,000 warrants outstanding. During the nine months ended September 30, 2016, the Company issued 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 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 and nine months ended September 30, 2016 to the results for the three and nine months ended September 30, 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 synthetic human 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 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 trial of LJPC-501 for the treatment of CRH, called the ATHOS (Angiotensin II for the Treatment of High-Output Shock) 3 Phase 3 trial, in March 2015. Prior to commencing the ATHOS 3 Phase 3 trial, 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 trial. In accordance with the SPA,

the primary efficacy endpoint for the ATHOS 3 Phase 3 registration trial is increase in blood pressure at three hours. The ATHOS 3 Phase 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 trial 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. We expect to report top-line results from the ATHOS 3 Phase 3 trial in the first quarter of 2017.

LJPC-401

LJPC-401 is our novel formulation of synthetic human hepcidin. Hepcidin, an endogenous peptide hormone, is the body's naturally occurring regulator of iron absorption and distribution. In healthy individuals, 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 characterized by a genetic deficiency in hepcidin. 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.

In September 2016, we reported positive results from a Phase 1 trial of LJPC-401 in patients at risk of iron overload suffering from HH, thalassemia and SCD. Single, escalating doses of LJPC-401 were associated with a dose-dependent, statistically significant reduction in serum iron. LJPC-401 was well tolerated with no dose-limiting toxicities. Injection-site reactions were the most commonly reported adverse event. These were all mild or moderate in severity, self-limiting, and fully resolved.

Also in September 2016, we announced that we reached agreement with the European Medicines Agency (EMA) on the design of a pivotal trial of LJPC-401. The pivotal trial will be a randomized, controlled, multicenter trial in beta thalassemia patients suffering from iron overload, a major unmet need in an orphan patient population. The primary endpoint will be a clinically relevant measurement directly related to iron overload. We plan to initiate this trial in mid-2017. In 2015, the EMA Committee Orphan Medicinal Products (COMP) designated LJPC-401 as an orphan medicinal product for the treatment of beta thalassemia intermedia and major, and, in 2016, the EMA COMP issued an opinion recommending LJPC-401 for designation as an orphan medicinal product for the treatment of SCD.

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 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 and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Contract revenue - related party	$44	$647	$531	$647
Research and development expense	(16,992)	(7,781)	(42,111)	(19,637)
General and administrative expense	(4,349)	(3,353)	(11,868)	(11,122)
Other income, net	46	13	150	33
Net loss	$(21,251)	$(10,474)	$(53,298)	$(30,079)

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 trial design and management for projects undertaken. Contract revenue is a function of our available resources and the availability of potential projects identified by our customer. As such, this revenue may be significantly reduced in future periods, as has happened year-over-year for the three months ended September 30, 2016 and 2015. 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 and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Clinical development costs	$9,438	$3,097	$22,740	$9,137
Personnel and related costs	3,690	1,857	9,067	4,131
Share-based compensation expense	1,688	891	4,209	3,101
Technology in-licensing costs	199	404	384	439
Other research and development costs	1,977	1,532	5,711	2,829

Total research and development expense	$16,992	$7,781	$42,111	$19,637

For the three and nine months ended September 30, 2016, research and development expense increased to $17.0 million and $42.1 million, respectively, from $7.8 million and $19.6 million for the same periods in 2015, respectively. The increase was primarily due to increased clinical development costs associated with the Phase 3 trial of LJPC-501 for the treatment of CRH, clinical development costs associated with the Phase 1 trial of LJPC-401 in patients at risk of iron overload and preclinical costs associated with the LJPC-30S program. Increases in personnel costs and share-based compensation

expense associated with the support of our increased development activities also contributed to the increase in research and development expense. We anticipate research and development expense to increase during the remainder of 2016, due to planned increases in personnel to support the continuation of our ongoing clinical trial of LJPC-501 and the ongoing development of our product candidates.

General and Administrative Expense

The following summarizes our general and administrative expense for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Personnel and related costs	$1,008	$598	$2,707	$1,831
Share-based compensation expense	2,238	2,170	6,762	7,242
Other general and administrative expense	1,103	585	2,399	2,049
Total general and administrative expense	$4,349	$3,353	$11,868	$11,122

During the three and nine months ended September 30, 2016, general and administrative expense increased to $4.3 million and $11.9 million, respectively, from $3.4 million and $11.1 million for the same periods in 2015, respectively. The increase was primarily due to increased personnel costs associated with the support of our increased development activities, partially offset by decreased share-based compensation expense. We anticipate total general and administrative expense, excluding share-based compensation expense, to increase during the remainder of 2016, as the result of year-over-year increases in personnel to support the ongoing development of our product candidates.

Liquidity and Capital Resources

Since January 2012, when La Jolla was effectively restarted with new assets and a new management team, through September 30, 2016, our cash used in operating activities was $85.0 million. From inception through September 30, 2016, we have incurred a cumulative net loss of $581.8 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, 2016, we have raised $586.1 million in net proceeds from the sales of equity securities.

As of September 30, 2016, we had $85.0 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 nine months ended September 30, 2016 was $40.1 million, compared to $16.7 million for the same period in 2015. The increase was primarily due to increased research and development activities. For the nine months ended September 30, 2016, we used $1.4 million of cash for investing activities related to purchases of property and equipment, compared to $1.7 million for the same period in 2015. At September 30, 2016, we had positive working capital of $79.5 million, compared to positive working capital of $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.

Based on our cash and working capital as of September 30, 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,

as well as the overall condition of capital markets, including capital markets for development-stage and clinical-stage biopharmaceutical companies. 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 provide assurance 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 material changes to our market risks in the nine months ended September 30, 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

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, we are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

No material changes to risk factors have occurred as previously disclosed in Item 1A 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

		Incorporated by Reference Herein	
Exhibit Number	Description	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: November 3, 2016 /s/ George F. Tidmarsh
George F. Tidmarsh, M.D., Ph.D.
President, Chief Executive Officer and Secretary
(Principal Executive Officer)

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