

LA JOLLA PHARMACEUTICAL CO
Form 10-Q
October 24, 2018

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 September 30, 2018

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.)

4550 Towne Centre Court, 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, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "non-accelerated filer," "smaller reporting company" and "emerging growth company," in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 October 19, 2018, La Jolla Pharmaceutical Company had 26,233,631 shares of common stock outstanding.

LA JOLLA PHARMACEUTICAL COMPANY
FORM 10-Q
QUARTERLY REPORT

TABLE OF CONTENTS

PART I — FINANCIAL INFORMATION

ITEM 1. Condensed Consolidated Financial Statements

Condensed Consolidated Balance Sheets as of September 30, 2018 (Unaudited) and December 31, 2017 1

Unaudited Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2018 and 2017 2

Unaudited Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017 3

Notes to Unaudited Condensed Consolidated Financial Statements 4

ITEM 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations 9

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk 15

ITEM 4. Controls and Procedures 15

PART II — OTHER INFORMATION

ITEM 1. Legal Proceedings 17

ITEM 1A. Risk Factors 17

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds 17

ITEM 3. Defaults upon Senior Securities 17

ITEM 4. Mine Safety Disclosures 17

ITEM 5. Other Information 17

ITEM 6. Exhibits 18

SIGNATURES 19

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, 2018	December 31, 2017
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 204,337	\$ 90,915
Accounts receivable, net	1,537	—
Inventory	1,101	—
Prepaid expenses and other current assets	5,847	3,147
Total current assets	212,822	94,062
Property and equipment, net	23,339	24,568
Restricted cash	909	909
Total assets	\$ 237,070	\$ 119,539
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,570	\$ 11,484
Accrued expenses	10,995	703
Accrued payroll and related expenses	4,922	4,995
Deferred rent, current portion	1,370	1,370
Total current liabilities	23,857	18,552
Deferred rent, less current portion	13,895	12,785
Deferred royalty obligation, net	124,324	—
Total liabilities	162,076	31,337
Shareholders' equity:		
Common Stock, \$0.0001 par value; 100,000,000 shares authorized, 26,226,955 and 22,167,529 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	3	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, 2018 and December 31, 2017; and liquidation preference of \$3,906 at September 30, 2018 and December 31, 2017	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, 2018 and December 31, 2017; and liquidation preference of \$2,737 at September 30, 2018 and December 31, 2017	2,737	2,737
Additional paid-in capital	943,913	803,071
Accumulated deficit	(875,565)	(721,514)
Total shareholders' equity	74,994	88,202
Total liabilities and shareholders' equity	\$ 237,070	\$ 119,539

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		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenue				
Net product sales	\$3,470	\$—	\$5,872	\$—
Total revenue	3,470	—	5,872	—
Operating expenses				
Cost of product sales	256	—	443	—
Research and development	30,439	19,093	89,735	57,666
Selling, general and administrative	21,139	7,390	66,319	18,915
Total operating expenses	51,834	26,483	156,497	76,581
Loss from operations	(48,364)	(26,483)	(150,625)	(76,581)
Interest (expense) income, net	(2,381)	195	(3,426)	324
Net loss	\$(50,745)	\$(26,288)	\$(154,051)	\$(76,257)
Net loss per share, basic and diluted	\$(1.93)	\$(1.19)	\$(6.15)	\$(3.65)
Weighted-average common shares outstanding, basic and diluted	26,226	22,125	25,055	20,900

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,	
	2018	2017
Operating activities		
Net loss	\$(154,051)	\$(76,257)
Adjustments to reconcile net loss to net cash used for operating activities:		
Share-based compensation expense	29,126	15,176
Depreciation expense	3,245	899
Loss on disposal of equipment	236	—
Interest expense	4,421	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,537) —
Inventory	(1,101) —
Prepaid expenses and other current assets	(2,700) (267
Other assets	—	219
Accounts payable	(4,914) (413
Accrued expenses	5,906	(234
Accrued payroll and related expenses	(73) 1,151
Deferred rent	1,110	—
Net cash used for operating activities	(120,332) (59,726
Investing activities		
Purchase of property and equipment	(2,252) (4,288
Net cash used for investing activities	(2,252) (4,288
Financing activities		
Net proceeds from royalty financing	124,289	—
Net proceeds from the issuance of common stock	109,809	117,480
Proceeds from the exercise of stock options for common stock	1,908	2,359
Net cash provided by financing activities	236,006	119,839
Net increase in cash, cash equivalents and restricted cash	113,422	55,825
Cash, cash equivalents and restricted cash at beginning of period	91,824	65,926
Cash, cash equivalents and restricted cash at end of period	\$205,246	\$121,751
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	\$204,337	\$120,840
Restricted cash, current portion	—	911
Restricted cash, less current portion	909	—
Total cash, cash equivalents and restricted cash	\$205,246	\$121,751

See accompanying notes to the condensed consolidated financial statements.

LA JOLLA PHARMACEUTICAL COMPANY

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Business

La Jolla Pharmaceutical Company (collectively with its wholly-owned 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.

GIAPREZA™ (angiotensin II), formerly known as LJPC-501, was approved by the U.S. Food and Drug Administration (FDA) on December 21, 2017 as a vasoconstrictor to increase blood pressure in adults with septic or other distributive shock. LJPC-401 (synthetic human hepcidin), a clinical-stage investigational product, is being developed for the potential treatment of conditions characterized by iron overload, such as hereditary hemochromatosis, beta thalassemia, sickle cell disease and myelodysplastic syndrome.

As of September 30, 2018, the Company had \$204.3 million in cash and cash equivalents, compared to \$90.9 million in cash and cash equivalents as of December 31, 2017. Based on the Company's current operating plans and projections, the Company expects that its cash and cash equivalents as of September 30, 2018 will be sufficient to fund its operations at least into the second half of 2020.

2. Basis of Presentation and Summary of Significant Accounting Policies

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 U.S. Securities and Exchange Commission (SEC) Regulation S-X. Accordingly, they should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 22, 2018 (the Form 10-K). 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 as of September 30, 2018, the condensed consolidated statements of operations for the three and nine months ended September 30, 2018 and the condensed consolidated statement of cash flows for the nine months ended September 30, 2018.

The preparation of the Company's unaudited condensed consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in the Company's unaudited condensed consolidated financial statements and the accompanying notes. Actual results may differ materially from these estimates. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the full year or any future interim periods. The accompanying condensed consolidated balance sheet as of December 31, 2017 has been derived from the audited consolidated balance sheet as of December 31, 2017 contained in the Form 10-K.

Summary of Significant Accounting Policies

During the nine months ended September 30, 2018, there have been no changes to the Company's significant accounting policies as described in the Form 10-K, except as described below.

Accounts Receivable

Accounts receivable are recorded net of customers' allowances for prompt-pay discounts, chargebacks and doubtful accounts. Allowances for prompt-pay discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. As of September 30, 2018, the Company did not have any allowances for doubtful accounts.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value on a first-in, first-out (FIFO) basis. The Company periodically analyzes its inventory levels and writes down inventory as cost of product sales when: inventory has become obsolete; inventory has a cost basis in excess of its estimated net realizable value; or inventory quantities are in excess of expected product sales. As of September 30, 2018, the Company had \$1.1 million of inventory, which consisted of work in process of \$0.4 million and finished goods of \$0.7 million.

Revenue Recognition

The Company adopted the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 606 – Revenue from Contracts with Customers (ASC 606) at the time of its first commercial shipment of GIAPREZA in the first quarter of 2018. The Company had no revenue from product sales prior to the first quarter of 2018.

Under ASC 606, the Company recognizes revenue when distributors (customers) obtain control of the Company's product, which typically occurs on delivery. Revenue is recognized in an amount that reflects the consideration that the Company expects to receive in exchange for those goods. To determine revenue recognition for contracts with customers within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Revenue from product sales is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns and other allowances offered to customers. Variable consideration is estimated using the most-likely amount method, which is the single-most likely outcome under a contract and is typically at the stated contractual rate. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary materially from the Company's estimates, the Company will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted.

Chargebacks. Chargebacks are discounts the Company provides to distributors in the event that the sales prices to end users are below the distributors' acquisition price. Chargebacks are estimated based on known chargeback rates and recorded as a reduction of revenue upon delivery to the Company's customers.

Discounts. The Company offers customers various forms of incentives and consideration, including prompt-pay discounts, service fees and other contract fees. The Company estimates discounts and fees primarily based on contractual terms. These discounts and fees are recorded as a reduction of revenue upon delivery to the Company's customers.

Returns. The Company offers customers a limited right of return, generally for damaged or expired product. The Company estimates returns based on an internal analysis, which includes actual experience and a review of comparable companies. The estimates for returns are recorded as a reduction of revenue upon delivery to the Company's customers.

The Company will continue to assess its estimates of variable consideration as it accumulates additional historical data and will adjust these estimates accordingly.

Interest Expense

Interest expense and the amortization of debt issuance costs related to the deferred royalty obligation (see Note 5) are recognized over the expected repayment term of the deferred royalty obligation using the effective interest method. The assumptions used in determining the expected repayment term of the deferred royalty obligation require the Company to make estimates that could impact the effective interest rate. Each reporting period, the Company estimates the expected repayment term of the deferred royalty obligation based on forecasted net product sales of GIAPREZA. Changes in interest expense resulting from changes in the effective interest rate, if any, are recorded on a prospective basis.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash. The Company maintains its cash in checking and money market savings accounts at federally insured financial institutions in excess of federally insured limits.

Three of the Company's customers each represented approximately one-third of the Company's net product sales for the three and nine months ended September 30, 2018, and each represented one-third of the Company's accounts receivable balance at September 30, 2018.

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 based on the weighted-average number of common shares outstanding plus common stock equivalents. Convertible preferred stock, stock options and warrants 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, 2018 and 2017, there were 14.3 million shares and 11.9 million shares, respectively, of common stock equivalents, which were excluded from the calculation of diluted net loss per share because their effect was anti-dilutive.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In the first quarter of 2018, the Company adopted Accounting Standard Update (ASU) 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The standard clarifies the presentation of restricted cash and cash equivalents and requires companies to include restricted cash and cash equivalents in the beginning and ending balances of cash and cash equivalents on the statement of cash flows. The standard also requires additional disclosures to describe the amount and detail of the restriction by balance sheet line item. Accordingly, restricted cash is included as a component of cash, cash equivalents and restricted cash in the unaudited condensed consolidated statement of cash flows for all periods presented, and we have disclosed the amount and detail of the restriction by balance sheet line item.

Not Yet Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting. The standard expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods and services. The provisions of this standard are effective for annual periods beginning after December 15, 2018, and for interim periods within those years. Early adoption is permitted. The Company will adopt the standard in the first quarter of 2019. The Company is currently evaluating the impact of this standard on its consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The standard requires lessees to recognize right-of-use assets and lease liabilities on the balance sheet for most leases and provide enhanced disclosures. The provisions of this standard are effective for annual periods beginning after December 15, 2018, and for interim periods within those years. Early adoption is permitted. In July 2018, the FASB issued additional guidance for companies to elect transition using either (1) a modified retrospective approach for leases that exist upon adoption and in the comparative periods presented, or (2) an optional approach to initially apply the new lease guidance upon the adoption date, without adjusting the comparative periods presented. The Company plans to elect the optional transition approach and will adopt the standard beginning in fiscal 2019. The Company is in the process of evaluating the overall accounting impacts of adoption of the standard, including whether to elect the available practical expedients. The Company currently believes the most significant changes will be related to the recognition of a new right-of-use asset and lease liability on the balance sheet for its 10-year operating lease agreement for its corporate headquarters, which commenced October 30, 2017.

3. Balance Sheet Account Details

Restricted Cash

Restricted cash as of September 30, 2018 and December 31, 2017 represents a standby letter of credit for the Company's building lease in lieu of a security deposit during the term of such lease. There is a requirement to maintain \$0.9 million of cash collateral in an account pledged as security for such letter of credit.

6

Accrued Expenses

Accrued expenses consist of the following for each of the periods below (in thousands):

	September 30, December 31,	
	2018	2017
Accrued interest expense	\$ 4,386	\$ —
Accrued clinical trials	3,082	577
Accrued other	3,527	126
Total accrued expenses	\$ 10,995	\$ 703

4. Shareholders' Equity

2017 Common Stock Offering

In March 2017, the Company offered and sold 3,731,344 shares of common stock in an underwritten public offering at a price of \$33.50 per share for gross proceeds of approximately \$125.0 million. The Company received proceeds of approximately \$117.5 million, net of approximately \$7.5 million in underwriting commissions, discounts and other issuance costs.

2018 Common Stock Offering

In March 2018, the Company offered and sold 3,910,000 shares of common stock in an underwritten public offering at a price of \$29.50 per share for gross proceeds of approximately \$115.3 million. The Company received proceeds of approximately \$109.8 million, net of approximately \$5.5 million in underwriting commissions, discounts and other issuance costs.

Stock Option Activity

The Company's stock option activity under its option plans was comprised of the following for the nine months ended September 30, 2018:

	Shares	Weighted-
	Underlying	average
	Stock	Exercise Price
	Options	per Share
Outstanding at December 31, 2017	6,037,302	\$ 24.19
Granted	1,130,700	\$ 29.48
Exercised	(106,370)	\$ 17.95
Forfeited	(293,368)	\$ 26.94
Outstanding at September 30, 2018	6,768,264	\$ 25.05

As of September 30, 2018, there were 1,038,400 shares of common stock available for future grants under its option plans, and the Company has reserved an additional 6,768,264 shares of common stock for future issuance upon exercise of all outstanding stock options granted under its option plans.

During the nine months ended September 30, 2018, stock options to purchase 106,370 shares of common stock were exercised with an intrinsic value of \$1.4 million.

Share-based Compensation Expense

Total share-based compensation expense related to all share-based awards was comprised of the following for each of the periods below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Research and development	\$5,895	\$3,092	\$16,992	\$8,141
Selling, general and administrative	3,985	2,390	12,134	7,035
Total share-based compensation expense	\$9,880	\$5,482	\$29,126	\$15,176

As of September 30, 2018, \$89.1 million of total unrecognized share-based compensation expense related to unvested stock options remains and is expected to be recognized over a weighted-average period of 2.9 years.

2018 Employee Stock Purchase Plan

In July 2018, the Company adopted the La Jolla Pharmaceutical Company 2018 Employee Stock Purchase Plan (ESPP) in order to provide a means for eligible employees to accumulate shares of the Company's common stock over time through regular payroll deductions. Under the ESPP, eligible employees of the Company may purchase shares of the Company's common stock twice per month at a price equal to 85% of the closing price of the Company's common stock on the date of each purchase. Eligible employees purchasing shares of common stock under the ESPP are subject to an annual cap equal to the lesser of \$25,000 or 10% of the employee's annual cash compensation. Shares of common stock purchased under the ESPP cannot be sold for a period of one-year following the purchase date (or such shorter period of time if the participating employee's employment terminates before this one-year anniversary).

As of September 30, 2018, there were 750,000 shares of common stock reserved for issuance under the ESPP, and no shares were issued under the ESPP.

Warrants

As of September 30, 2018, the Company had outstanding warrants to purchase 10,000 shares of common stock. In March 2018, the Company issued 43,056 shares of common stock in a cashless exercise of 83,013 warrants to a third-party warrant holder.

5. Deferred Royalty Obligation

On May 10, 2018, the Company closed a \$125.0 million royalty financing agreement (the Royalty Agreement) with HealthCare Royalty Partners (HCR). Under the terms of the Royalty Agreement, the Company received \$125.0 million in exchange for tiered royalty payments on worldwide net product sales of GIAPREZA. HCR is entitled to receive quarterly royalties on worldwide net product sales of GIAPREZA beginning April 1, 2018. Payments to HCR under the Royalty Agreement start annually at a maximum royalty rate, with step-downs based on the achievement of annual net product sales thresholds. Through December 31, 2021, the royalty rate will be a maximum of 10%. Starting January 1, 2022, the maximum royalty rate may increase by 4% if an agreed-upon, cumulative sales threshold has not been met, and, starting January 1, 2024, the maximum royalty rate may increase by an additional 4% if a different agreed-upon, cumulative sales threshold has not been met. The Royalty Agreement is subject to maximum aggregate royalty payments to HCR of 180% of the \$125.0 million to be received by the Company, at which time the payment obligations under the Royalty Agreement would expire. The Royalty Agreement was entered into by the Company's wholly owned subsidiary, La Jolla Pharma, LLC, and HCR has no recourse under the Royalty Agreement against La Jolla Pharmaceutical Company or any assets other than GIAPREZA.

On receipt of the \$125.0 million payment from HCR, the Company recorded a deferred royalty obligation of \$125.0 million, net of debt issuance costs of \$0.7 million. For the three and nine months ended September 30, 2018, the Company recognized interest expense, including amortization of the debt discount, of \$3.0 million and \$4.6 million, respectively. The carrying value of the deferred royalty obligation as of September 30, 2018 was \$124.3 million, net of unamortized debt discount of \$0.7 million, and was classified as non-current. Accrued interest expense of \$4.4 million is included in accrued expenses in the condensed consolidated balance sheet as of September 30, 2018. For the three and nine months ended September 30, 2018, the Company made royalty payments to HCR of \$0.2 million.

In the event of certain material breaches of the Royalty Agreement, HCR would have the right to terminate the Royalty Agreement and demand payment of an amount equal to either \$125.0 million, minus aggregate royalties paid to HCR, or \$225.0 million, minus aggregate royalties paid to HCR. The Company concluded that certain of these material breaches are embedded derivatives that require bifurcation from the deferred royalty obligation and fair value recognition. The Company determined the fair value of each derivative by assessing the probability of each event occurring, as well as the potential repayment amounts and timing of such repayments that would result under various scenarios. As a result of this assessment, the Company determined that the fair value of the embedded derivatives is immaterial as of September 30, 2018. Each reporting period, the Company estimates the fair value of the embedded derivatives until the features lapse and/or the termination of the Royalty Agreement. Any change in the fair value of the embedded derivatives will be recorded as either a gain or loss on the consolidated statements of operations.

6. Subsequent Events

On October 18, 2018, the Company effected a Company-wide realignment to increase its focus and efficiency on achieving its corporate goals. The Company's highest priorities remain the effective commercialization of GIAPREZA and development of its product pipeline, including LJPC-401 for multiple indications. As a result of the realignment, the Company expects that its cash and cash equivalents as of September 30, 2018 will be sufficient to fund its operations at least into the second half of 2020. The Company estimates that it will incur and pay restructuring charges of approximately \$8.3 million in connection with the realignment in the fourth quarter of 2018.

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, including La Jolla Pharma, LLC, on a consolidated basis.

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 on forward-looking statements as predictions of future events. Forward-looking statements include, but are not limited to, statements regarding risks relating to: our ability to successfully commercialize, market and achieve market acceptance of GIAPREZA™ (angiotensin II) and our product candidates; our ability to meet the demand for GIAPREZA in a timely manner; potential market sizes for our products and product candidates, including the market for the treatment of septic or distributive shock; the cost of producing GIAPREZA; unforeseen safety issues from the administration of GIAPREZA and our product candidates in patients; the timing and prospects for approval of GIAPREZA by the European Medicines Agency (EMA) or other regulatory authorities; expected impact of the New Technology Add-on Payment (NTAP) designation for GIAPREZA; the extent to which hospitals will take advantage of the NTAP program; the scope of product label(s) and potential market sizes, as well as the broader commercial opportunity for GIAPREZA and our product candidates; the impact of pharmaceutical industry regulation and healthcare legislation in the United States; the success of future development activities; potential indications for which the Company's product candidates may be developed; the timing, costs, conduct and outcome of clinical studies; the anticipated treatment of future clinical data by the U.S. Food and Drug Administration (FDA), EMA and other regulatory authorities, including whether such data will be sufficient for approval; and the expected duration over which the Company's 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 the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" sections contained in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the U.S. Securities and Exchange

Commission (SEC) on February 22, 2018, and in other reports and registration statements that we file with the SEC. 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 an overview of GIAPREZA and LJPC-401.
- **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, 2018 to the results for the three and nine months ended September 30, 2017.
- **Liquidity and Capital Resources.** This section provides an analysis of our historical cash flows, as well as our future capital requirements.

Business Overview

We are 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. GIAPREZA™ (angiotensin II), formerly known as LJPC-501, was approved by the U.S. Food and Drug Administration (FDA) on December 21, 2017 as a vasoconstrictor to increase blood pressure in adults with septic or other distributive shock. LJPC-401 (synthetic human hepcidin), a clinical-stage investigational product, is being developed for the potential treatment of conditions characterized by iron overload, such as hereditary hemochromatosis, beta thalassemia, sickle cell disease and myelodysplastic syndrome.

Program Overview

GIAPREZA™ (angiotensin II)

GIAPREZA™ (angiotensin II), injection for intravenous infusion, was approved by the FDA on December 21, 2017 as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. Angiotensin II is a major bioactive component of the renin-angiotensin-aldosterone system (RAAS). The RAAS is one of three central regulators of blood pressure. In March 2018, we announced the commercial availability of GIAPREZA. GIAPREZA is available in 1 mL single-dose vials, each containing 2.5 mg of angiotensin II (as a sterile liquid) through authorized specialty distributors.

Over 1 million Americans are affected by shock on an annual basis, with 1 in 3 patients being treated for shock in the intensive care unit. Distributive shock is the most common type of shock in the inpatient setting with approximately 800,000 distributive shock cases in the U.S. each year. Of these cases, an estimated 90% are septic shock patients. Approximately 300,000 do not achieve adequate blood pressure response with standard of care vasopressor therapy (catecholamines and vasopressin). The inability to achieve or maintain adequate blood pressure results in inadequate blood flow to the body's organs and tissue and is associated with a mortality rate exceeding most acute conditions requiring hospitalization. In the European Union, the annual incidence of sepsis in adults is estimated to be more than 500,000, with more than 170,000 progressing to septic shock.

The GIAPREZA clinical development program included a Phase 3 study of GIAPREZA in adult patients with septic or other distributive shock who remain hypotensive despite fluid and vasopressor therapy, known as the ATHOS-3 (Angiotensin II for the Treatment of High-Output Shock) Phase 3 study. In ATHOS-3, patients were randomized in a 1:1 fashion to receive either: (i) GIAPREZA plus standard-of-care vasopressors; or (ii) placebo plus standard-of-care vasopressors. ATHOS-3 completed enrollment of 344 patients in the fourth quarter of 2016. In February 2017, we reported positive top-line results from ATHOS-3, and, in May 2017, the results of ATHOS-3 were published by The New England Journal of Medicine.

The analysis of the primary efficacy endpoint, defined as the percentage of patients achieving a pre-specified target blood pressure response, was highly statistically significant: 23% of the 158 placebo-treated patients had a blood pressure response compared to 70% of the 163 GIAPREZA-treated patients ($p < 0.00001$). In addition, there was a consistent trend

toward longer survival over the 28-day study period: 22% reduction in mortality risk through day 28 [hazard ratio=0.78 (0.57-1.07), p=0.12] for GIAPREZA-treated patients.

In this critically ill patient population: 92% of placebo-treated patients compared to 87% of GIAPREZA-treated patients experienced at least one adverse event, and 22% of placebo-treated patients compared to 14% of GIAPREZA-treated patients discontinued treatment due to an adverse event.

Additional analyses from the ATHOS-3 trial have been published:

In September 2017, an analysis was presented during the 30th European Society of Intensive Care Medicine Annual Congress, entitled “Baseline angiotensin levels and ACE effects in patients with vasodilatory shock treated with angiotensin II.” The pre-specified analysis showed that a relatively low angiotensin II state (as measured by the ratio of angiotensin I to angiotensin II) predicted increased mortality in patients with vasodilatory shock, suggesting that a low angiotensin II state is a negative prognostic indicator of outcomes. Furthermore, the analysis showed a statistically significant treatment effect of GIAPREZA compared to placebo on mortality in these patients with a relatively low angiotensin II state (relative risk reduction of 36%; HR=0.64; 95% CI: 0.41-1.00; p=0.047).

In February 2018, an abstract was presented at the Society of Critical Care Medicine’s (SCCM) 47th Critical Care Congress, entitled “Effect of Disease Severity on Survival in Patients Receiving Angiotensin II for Vasodilatory Shock.” The abstract, which was published in the January Supplement of Critical Care Medicine, includes results from a pre-specified analysis from the ATHOS-3 Phase 3 study of GIAPREZA in patients with high severity of illness, defined as an APACHE II (Acute Physiology and Chronic Health Evaluation II) score > 30 or baseline MAP < 65 mmHg, despite treatment with high-dose vasopressors. The authors presented data showing a lower 28-day mortality rate in patients with baseline APACHE II scores > 30 in the GIAPREZA group versus the placebo group: 28-day mortality was 51.8% (n = 58) for the GIAPREZA group compared to 70.8% (n = 65) for the placebo group (hazard ratio=0.62 [95% CI: 0.39, 0.98; p=0.037]). In patients with a baseline MAP < 65 mmHg, a trend towards improved 28-day mortality was seen in the GIAPREZA group compared to the placebo group: 28-day mortality was 54.2% (n = 52) for the GIAPREZA group compared to 70.4% (n = 50) for the placebo group (hazard ratio=0.66 [95% CI: 0.40, 1.09; p=0.10]).

In March 2018, an analysis was presented at the 23rd International Conference on Advances in Critical Care Nephrology AKI & CRRT 2018, entitled “Outcomes in Patients with Acute Kidney Injury Receiving Angiotensin II for Vasodilatory Shock.” The manuscript of this analysis, entitled “Outcomes in patients with vasodilatory shock and renal replacement therapy treated with intravenous angiotensin II,” was published online in Critical Care Medicine. The presentation and manuscript detail the outcomes of patients with acute kidney injury (AKI) and vasodilatory shock enrolled in the ATHOS-3 study of GIAPREZA. In this post-hoc analysis, the data from 105 AKI patients (GIAPREZA n=45; placebo n=60) requiring renal replacement therapy (RRT) at study drug initiation were analyzed. Survival through day 28 was 53% (95% CI: 38%-67%) for the GIAPREZA group compared to 30% (95% CI: 19%-41%) for the placebo group (p = 0.012). By day 7, 38% (95% CI: 25%-54%) of patients treated with GIAPREZA discontinued RRT compared to 15% (95% CI: 8%-27%) of patients treated with placebo (p = 0.007). Mean arterial pressure (MAP) response at hour 3 was achieved in 53% (95% CI: 38%-68%) of patients treated with GIAPREZA compared to 22% (95% CI: 12%-34%) of patients treated with placebo (p = 0.001).

In June 2018, we announced that the Marketing Authorization Application (MAA) for GIAPREZA was validated by the EMA. Validation of the MAA confirms that the submission is complete and starts the EMA’s centralized review process. This followed our announcement in September 2017, in which we reported that the EMA’s Committee for Medicinal Products for Human Use (CHMP) issued favorable Scientific Advice regarding the European Union (EU) regulatory pathway for GIAPREZA. If approved, GIAPREZA could be available for marketing in the EU in the second half of 2019.

LJPC-401, a clinical-stage investigational product, is our proprietary formulation of synthetic human hepcidin. Hepcidin, an endogenous peptide hormone, is the body's naturally occurring regulator of iron absorption and distribution. Low levels of hepcidin production in disease states such as hereditary hemochromatosis and thalassemia may lead to abnormal 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 primary iron overload diseases

such as hereditary hemochromatosis (HH), or secondary iron overload diseases such as beta thalassemia (BT), 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. There are no FDA approved therapies for HH and the current standard treatment for HH is a blood removal procedure known as phlebotomy. Each phlebotomy procedure, which is usually conducted at a hospital, medical office or blood center, typically involves the removal of approximately one pint of blood. The required frequency of procedures varies by patient but often ranges from one to two times per week for an initial period after diagnosis and once every one to three months for life. Since most of the body's iron is stored in red blood cells, chronic removal of blood can effectively lower iron levels if a phlebotomy regimen is adhered to. However, phlebotomy procedures may cause and may be associated with pain, bruising and scarring at the venous puncture site, joint pain, fatigue and dizziness during and following the procedure and disruption of daily activities. Furthermore, phlebotomy is not appropriate in patients with poor venous access, anemia or heart disease.

BT, SCD and MDS are genetic diseases of blood cells 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 2015, the EMA Committee for Orphan Medicinal Products (COMP) designated LJPC-401 as an orphan medicinal product for the treatment of beta thalassemia intermedia and major. In 2016, the EMA COMP designated LJPC-401 as an orphan medicinal product for the treatment of SCD.

In September 2016, we reported positive results from a Phase 1 study of LJPC-401 in patients at risk of iron overload suffering from HH, thalassemia and SCD. In this study, 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 and were all mild or moderate in severity, self-limiting and fully resolved.

In June 2018, two presentations on LJPC-401 were given at the 23rd Congress of the European Hematology Association (EHA). The first was an oral presentation, entitled "A Phase 1, Open-Label Study to Determine the Safety, Tolerability, and Pharmacokinetics of Escalating Doses of LJPC-401 (Synthetic Human Hepcidin) in Patients with Iron Overload." The second was a poster presentation, entitled "A Phase 1, Placebo-Controlled Study to Determine the Safety, Tolerability, and Pharmacokinetics of Escalating Subcutaneous Doses of LJPC-401 (Synthetic Human Hepcidin) in Healthy Adults."

LJPC-401 is currently the subject of two clinical studies, LJ401-HH01 in patients with HH and LJ401-BT01 in patients with BT.

LJ401-HH01

In December 2017, we announced the initiation of LJ401-HH01, a Phase 2 clinical study of LJPC 401 in patients with HH. LJ401-HH01 is a multinational, multicenter, randomized, Phase 2 study that is designed to evaluate the safety and efficacy of LJPC-401 as a treatment for HH. The primary efficacy endpoint of the study is the change in transferrin saturation, a standard measurement of iron levels in the body and one of the two key measurements used to detect iron overload, from baseline to end of treatment. Secondary efficacy endpoints include: (i) the change in serum ferritin, the other key measurement used to detect iron overload, from baseline to end of treatment; and (ii) the requirement for and frequency of phlebotomy procedures used during the study.

LJ401-BT01

In September 2016, we announced that we reached agreement with the EMA on the design of a pivotal study of LJPC-401 for the treatment of BT patients suffering from iron overload, a major unmet need in an orphan patient population. In December 2017, we announced the initiation of LJ401-BT01, a pivotal, multinational, multicenter, randomized, controlled study that is designed to evaluate the safety and efficacy of LJPC-401 as a treatment for BT patients who, despite chelation therapy, have cardiac iron levels above normal. The primary efficacy endpoint of this study is the change in iron content in the heart after 6 months, as measured by cardiac magnetic resonance imaging (MRI). If this study is successful, we would anticipate filing an MAA for LJPC-401 in the EU.

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 (GAAP). 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, 2017, which was filed on February 22, 2018, except for the newly adopted accounts receivable, inventory, revenue recognition and interest expense policies disclosed in Note 2 to the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

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 each of the periods below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net product sales	\$3,470	\$—	\$5,872	\$—
Cost of product sales	(256)	—	(443)	—
Research and development expense	(30,439)	(19,093)	(89,735)	(57,666)
Selling, general and administrative expense	(21,139)	(7,390)	(66,319)	(18,915)
Interest (expense) income, net	(2,381)	195	(3,426)	324
Net loss	\$(50,745)	\$(26,288)	\$(154,051)	\$(76,257)

Net Product Sales

For the three months ended September 30, 2018, GIAPREZA net product sales were \$3.5 million. This compares to \$1.6 million for the three months ended June 30, 2018 and \$0.8 million for the three months ended March 31, 2018. La Jolla launched GIAPREZA in the U.S. in March 2018. For the nine months ended September 30, 2018, GIAPREZA net product sales were \$5.9 million.

Cost of Product Sales

For the three and nine months ended September 30, 2018, we recognized cost of product sales of \$0.3 million and \$0.4 million, respectively, for sales of GIAPREZA, primarily related to royalty, labeling, shipping and distribution costs. Prior to the approval of GIAPREZA by the FDA, approximately \$0.6 million of direct material costs to manufacture GIAPREZA were recorded to research and development expense in 2017.

Research and Development Expense

The following summarizes our research and development expense for each of the periods below (in thousands):

	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Clinical development costs	\$ 10,937	\$ 6,744	\$ 32,369	\$ 24,895
Personnel and related costs	8,413	6,955	26,757	17,659
Share-based compensation expense	5,895	3,092	16,992	8,141
Other research and development costs	5,194	2,302	13,617	6,971
Total research and development expense	\$ 30,439	\$ 19,093	\$ 89,735	\$ 57,666

During the three and nine months ended September 30, 2018, research and development expense increased to \$30.4 million and \$89.7 million, respectively, from \$19.1 million and \$57.7 million for the same periods in 2017, respectively. The increase was primarily due to increased personnel and related costs, share-based compensation expense and clinical development costs to support the advancement of GIAPREZA and the development of LJPC-401 and our other product candidates.

In October 2018, we effected a Company-wide realignment to increase our focus and efficiency on achieving our corporate goals. Our highest priorities remain the effective commercialization of GIAPREZA and development of our product pipeline, including LJPC-401 for multiple indications. We anticipate research and development expense to remain consistent for the remainder of 2018 and to decrease in future periods as a result of effecting our Company-wide realignment.

Selling, General and Administrative Expense

The following summarizes our selling, general and administrative expense for each of the periods below (in thousands):

	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Personnel and related costs	\$ 9,232	\$ 1,971	\$ 28,375	\$ 4,765
Selling and marketing costs	5,706	1,417	19,080	2,524
Share-based compensation expense	3,985	2,390	12,134	7,035
General and administrative costs	2,216	1,612	6,730	4,591
Total selling, general and administrative expense	\$ 21,139	\$ 7,390	\$ 66,319	\$ 18,915

During the three and nine months ended September 30, 2018, selling, general and administrative expense increased to \$21.1 million and \$66.3 million, respectively, from \$7.4 million and \$18.9 million for the same periods in 2017, respectively. The increase was due to increased personnel and related costs, share-based compensation and commercialization and promotional activities to support the product launch of GIAPREZA. We anticipate selling, general and administrative expense to remain consistent for the remainder of 2018 and to decrease in future periods as a result of effecting our Company-wide realignment.

Interest (Expense) Income, Net

During the three and nine months ended September 30, 2018, net interest expense increased to \$2.4 million and \$3.4 million, respectively, from \$0.2 million and \$0.3 million for the same periods in 2017, respectively. The increase was primarily due to amounts accrued pursuant to our deferred royalty obligation balance outstanding during the three and nine months ended September 30, 2018.

Liquidity and Capital Resources

Since January 2012, when the Company was effectively restarted with new assets and a new management team, through September 30, 2018, our cash used in operating activities was \$308.8 million. From inception through September 30,

2018, we have incurred a cumulative net loss of \$875.6 million and have financed our operations through public and private offerings of securities, a royalty financing, revenues from collaborative agreements and net product sales, equipment financings and interest income on invested cash balances. As of September 30, 2018, we had \$204.3 million in cash and cash equivalents, compared to \$90.9 million of cash and cash equivalents at December 31, 2017.

Cash used for operating activities for the three and nine months ended September 30, 2018 was \$36.9 million and \$120.3 million, respectively, compared to \$18.5 million and \$59.7 million, respectively, for the same periods in 2017. The increase in cash used for operating activities was a result of the increase in our net loss, primarily offset by changes in working capital and increases in share-based compensation, depreciation expense and non-cash interest expense.

Cash used for investing activities for the nine months ended September 30, 2018, was \$2.3 million compared to \$4.3 million for the same period in 2017.

Cash provided by financing activities for the nine months ended September 30, 2018 was \$236.0 million, compared to \$119.8 million for the same period in 2017. The increase in cash provided by financing activities for the nine months ended September 30, 2018 was primarily the result of \$109.8 million of net proceeds from the March 2018 common stock offering and \$124.3 million of net proceeds from the May 2018 royalty financing.

On October 18, 2018, the Company effected a Company-wide realignment to increase its focus and efficiency on achieving its corporate goals. The Company's highest priorities remain the effective commercialization of GIAPREZA and development of its product pipeline, including LJPC-401 for multiple indications. As a result of the realignment, the Company expects that its cash and cash equivalents as of September 30, 2018 will be sufficient to fund its operations at least into the second half of 2020.

Contractual Obligations

On May 10, 2018, we closed a \$125.0 million royalty financing agreement (the Royalty Agreement) with HealthCare Royalty Partners (HCR). Under the terms of the Royalty Agreement, we received \$125.0 million in exchange for tiered royalty payments on worldwide net product sales of GIAPREZA. HCR is entitled to receive royalties on worldwide net product sales of GIAPREZA beginning April 1, 2018. Payments under the Royalty Agreement start annually at a maximum royalty rate, with step-downs based on the achievement of annual net product sales thresholds. Through December 31, 2021, the royalty rate will be a maximum of 10%. Starting January 1, 2022, the maximum royalty rate may increase by 4% if an agreed-upon, cumulative sales threshold has not been met, and, starting January 1, 2024, the maximum royalty rate may increase by an additional 4% if a different agreed-upon, cumulative sales threshold has not been met. The Royalty Agreement is subject to maximum aggregate royalty payments to HCR of 180% of the \$125.0 million to be received by us, at which time the payment obligations under the Royalty Agreement would expire. The Royalty Agreement was entered into by our wholly owned subsidiary, La Jolla Pharma, LLC, and HCR has no recourse under the Royalty Agreement against us or any assets other than GIAPREZA.

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, 2018, when compared to the disclosures in Item 7A of our Annual Report Form 10-K for the year ended December 31, 2017, filed with the SEC on February 22, 2018.

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 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.

During the three months ended September 30, 2018, there was no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. During the nine months ended September 30, 2018, we implemented controls in connection with the newly-adopted accounts receivable, inventory, revenue recognition and interest expense policies as disclosed in Note 2 to the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

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. As of the date of this report, we are not currently a party to any legal proceedings that we believe could have a material adverse effect on our business, financial condition or results of operations. However, litigation is inherently uncertain, and any judgment or injunctive relief entered against us or any adverse settlement could negatively affect our business, financial condition and results of operations.

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, 2017, filed with the SEC on February 22, 2018.

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

The disclosure set forth in Note 6 to the accompanying unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference.

ITEM 6. EXHIBITS

Exhibit Number	Description
<u>31.1</u>	<u>Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
<u>31.2</u>	<u>Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
<u>32.1</u>	<u>Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

18

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: October 24, 2018 /s/ George F. Tidmarsh
George F. Tidmarsh, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

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