LA JOLLA PHARMACEUTICAL CO
Form 10-Q
May 10, 2018

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 March 31, 2018
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.)
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 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 (§232.405 of this chapter) 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, a smaller reporting company or an emerging growth company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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 7(a)(2)(B) of the Securities Act.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 April 23, 2018, La Jolla Pharmaceutical Company had 26,154,439 shares of common stock outstanding.

LA JOLLA PHARMACEUTICAL COMPANY
FORM 10-Q
QUARTERLY REPORT

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LA JOLLA PHARMACEUTICAL COMPANY
Condensed Consolidated Balance Sheets
(in thousands, except share and par value amounts)

	March 31, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 154,408	$ 90,915
Inventory	820	—
Prepaid expenses and other current assets	6,326	3,147
Total current assets	161,554	94,062
Property and equipment, net	24,438	24,568
Restricted cash	909	909
Total assets	$ 186,901	$ 119,539
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,321	$ 11,484
Accrued clinical and other expenses	4,280	703
Accrued payroll and related expenses	3,044	4,995
Deferred rent, current portion	1,370	1,370
Total current liabilities	16,015	18,552
Deferred rent, less current portion	13,473	12,785
Total liabilities	29,488	31,337
Shareholders' equity:		
Common Stock, $0.0001 par value; 100,000,000 shares authorized, 26,154,439 and 22,167,529 shares issued and outstanding at March 31, 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 March 31, 2018 and December 31, 2017, and liquidation preference of $3,906 at March 31, 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 March 31, 2018 and December 31, 2017, and liquidation preference of $2,737 at March 31, 2018 and December 31, 2017	2,737	2,737
Additional paid-in capital	922,809	803,071
Accumulated deficit	(772,042)	(721,514)
Total shareholders' equity	157,413	88,202
Total liabilities and shareholders' equity	$ 186,901	$ 119,539

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2018	2017
Revenue		
Net product sales	$809	$—
Total revenue	809	—
Operating expenses		
Cost of product sales	58	—
Research and development	28,429	17,765
Selling, general and administrative	23,016	5,503
Total operating expenses	51,503	23,268
Loss from operations	(50,694)	(23,268)
Other income, net	166	28
Net loss	$(50,528)	$(23,240)
Net loss per share, basic and diluted	$(2.22)	$(1.26)
Weighted-average common shares outstanding, basic and diluted	22,742	18,410

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2018	2017
Operating activities		
Net loss	$(50,528)	$(23,240)
Adjustments to reconcile net loss to net cash used for operating activities:		
Share-based compensation expense	9,402	4,983
Depreciation expense	992	281
Loss on disposal of equipment	132	—
Changes in operating assets and liabilities:		
Inventory	(820)	—
Prepaid expenses and other current assets	(3,179)	(182)
Other assets	—	199
Accounts payable	(4,163)	(2,479)
Accrued clinical and other expenses	3,577	(439)
Accrued payroll and related expenses	(1,951)	(1,167)
Deferred rent	688	—
Net cash used for operating activities	(45,850)	(22,044)
Investing activities		
Purchase of property and equipment	(994)	(750)
Net cash used for investing activities	(994)	(750)
Financing activities		
Net proceeds from the issuance of common stock	109,809	117,480
Proceeds from the exercise of stock options for common stock	528	2,074
Net cash provided by financing activities	110,337	119,554
Net increase in cash, cash equivalents and restricted cash	63,493	96,760
Cash, cash equivalents and restricted cash at beginning of period	91,824	65,926
Cash, cash equivalents and restricted cash at end of period	$155,317	$162,686
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalent	$154,408	$162,382
Restricted cash, current portion	—	304
Restricted cash, less current portion	909	—
Total cash, cash equivalent and restricted cash	$155,317	$162,686

See accompanying notes to the condensed consolidated financial statements.

LA JOLLA PHARMACEUTICAL COMPANY

Notes to Condensed Consolidated Financial Statements
(Unaudited)

March 31, 2018

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. 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 March 31, 2018, the Company had $154.4 million in cash and cash equivalents, compared to $90.9 million in cash and cash equivalents as of December 31, 2017. On a pro-forma basis, adjusting for the net proceeds from the May 2018 royalty financing (see Note 5), the Company's cash and cash equivalents as of March 31, 2018 were $279 million. Based on the Company's current operating plans and projections, management believes that available cash and cash equivalents are sufficient to fund operations for at least one year from the date this Quarterly Report on Form 10-Q is filed with the U.S. Securities and Exchange Commission (SEC). The Company was incorporated in 1989 as a Delaware corporation and reincorporated in California in 2012.

2. Summary of Significant Accounting Policies

During the three months ended March 31, 2018, there have been no changes to the Company's significant accounting policies as described in the Annual Report on Form 10-K for the year ended December 31, 2017, except as described below.

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 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 accompanying unaudited condensed consolidated financial statements include the accounts of La Jolla Pharmaceutical Company and its wholly-owned subsidiaries. All significant inter-company transactions and balances have been eliminated in consolidation. The unaudited condensed consolidated financial statements contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the condensed consolidated balance sheet of the Company at March 31, 2018, the condensed consolidated statement of operations for the three months ended March 31, 2018 and the condensed consolidated statement of cash flows for the three months ended March 31, 2018. Estimates were made relating to useful lives of inventory, fixed assets, return and valuation allowances, impairment of assets, share-based compensation expense and accruals for clinical studies and research and development expense. 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 months ended March 31, 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 at December 31, 2017 has been derived from the audited consolidated balance sheet at December 31, 2017 contained in the above referenced Annual Report on Form 10-K.

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 sales.

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 (our 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 our 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' price they acquire the product from the Company. The accrual for distributor chargebacks is estimated based on known chargeback rates. Estimates for chargebacks are recorded as a reduction of revenue and accounts receivable 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 and accounts receivable upon delivery to the Company's customers.

Returns. The Company offers customers a limited right of return, generally for damaged or expired product. To date, there have been no product returns. The Company estimates returns based on an analysis of comparable companies. The estimates for returns are recorded as a reduction of revenue and accounts receivable 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.

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 based on 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 March 31, 2018 and

2017, there were 14.1 million shares and 11.4 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 May 2017, the FASB issued Accounting Standard Update (ASU) 2017-09, Compensation - Stock Compensation (Topic 718), Scope of Modification Accounting. The standard clarifies when to account for a change in the terms or conditions of a share-based payment award as a modification. The standard is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2017. The Company adopted the standard in the first quarter of 2018. Adoption of the standard did not have a material impact on the Company’s financial position or results of operations.

In November 2016, the FASB issued 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. The standard is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2017. The Company adopted the standard in the first quarter of 2018. 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.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). The 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. Since its initial release, the FASB has issued several amendments to the standard, which include clarification of accounting guidance related to identification of performance obligations and principal versus agent considerations. The Company adopted the standard in the first quarter of 2018. Refer to the revenue recognition disclosure above.

Not Yet Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The 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 with modified retrospective application for the Company’s 10-year lease agreement for its corporate headquarters, which commenced October 30, 2017. This lease will be recognized on the balance sheet as a lease liability with a corresponding right-of-use asset, which will require modified retrospective application back to the fourth quarter of 2017 and for all of 2018. All of the Company’s other leases will have ended by the first quarter of 2019 and, therefore, will not require modified retrospective disclosures applied within the consolidated financial statements upon adoption of the standard.

3. Cash, Cash Equivalents and Restricted Cash

Restricted cash as of March 31, 2018 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 a $0.9 million collateral cash account pledged as security for such letter of credit. Restricted cash as of March 31, 2017 represents collateral cash pledged for the Company’s credit card arrangements of $0.2 million and a standby letter of credit for the Company’s prior lease in lieu of a security deposit during the term of the lease of $0.1 million.

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 for the three months ended March 31, 2018 was comprised of the following:

	Shares Underlying Stock Options	Weighted-average Exercise Price per Share
Outstanding at December 31, 2017	6,037,302	$ 24.19
Granted	701,900	$ 30.02
Exercised	(33,854)	$ 15.62
Forfeited	(84,178)	$ 24.77
Outstanding at March 31, 2018	6,621,170	$ 24.84

As of March 31, 2018, there were 1,258,010 shares of common stock available for future grants under its option plans, and the Company has reserved an additional 6,621,170 shares of common stock for future issuance upon exercise of all outstanding stock options granted under its option plans.

During the three months ended March 31, 2018, stock options to purchase 33,854 shares of common stock were exercised with an intrinsic value of $0.5 million.

Share-based Compensation Expense

Total share-based compensation expense related to all share-based awards for the three months ended March 31, 2018 and 2017 was comprised of the following (in thousands):

	Three Months Ended March 31,	
	2018	2017
Research and development:		
Stock options	$5,386	$2,453
Warrants	10	17
Research and development share-based compensation expense	5,396	2,470
Selling, general and administrative:		
Stock options	4,006	1,955
Restricted stock	—	409
Warrants	—	149
Selling, general and administrative share-based compensation expense	4,006	2,513
Total share-based compensation expense	$9,402	$4,983

As of March 31, 2018, $103.7 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 3.2 years.

Warrants

As of March 31, 2018, the Company had outstanding warrants to purchase 10,000 shares of common stock. During the three months ended March 31, 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. Subsequent Events

On May 10, 2018, the Company closed a $125 million royalty financing agreement with HealthCare Royalty Partners (HCR). Under the terms of the agreement, the Company will receive $125 million in exchange for tiered royalty payments on worldwide net sales of GIAPREZA. Payments under the agreement start annually at a maximum royalty rate, with step-downs based on the achievement of annual net 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 agreement is subject to maximum aggregate royalty payments to HCR of 180% of the $125 million to be received by the Company, at which time the payment obligations under the agreement would expire. The agreement was entered into by the Company's wholly owned subsidiary, La Jolla Pharma, LLC, and HCR has no recourse under the agreement against the Company or any assets other than GIAPREZA.

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 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 other 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 other product candidates in patients; the timing and prospects for approval of GIAPREZA by the European Medicines Agency (EMA) or other regulatory authorities; risks relating to the scope of product label(s) and potential market sizes, as well as the broader commercial opportunity for GIAPREZA and our other 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 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 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, 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 a current status overview for each of our product candidates in development.
- Critical Accounting Policies and Estimates. This section provides a description of our significant accounting policies, including the critical accounting policies and estimates, which are summarized in Note 2 to the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.
- Results of Operations. This section provides an analysis of our results of operations presented in the accompanying unaudited condensed consolidated statements of operations by comparing the results for the three months ended March 31, 2018 to the results for the three months ended March 31, 2017.

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. 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. In March 2018, we announced the commercial availability of GIAPREZA. 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.

There are 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 patients do not achieve adequate blood pressure response with initial vasopressor therapy and require additional therapy for low blood pressure. The Center for Disease Control estimates that approximately 250,000 people in the U.S. die each year from septic shock. 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 March 2015, we initiated 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. Randomized patients received their assigned treatment via continuous IV infusion for up to 7 days. The primary efficacy endpoint was the percentage of patients with a MAP ≥ 75 mmHg or a 10 mmHg increase from baseline MAP at three hours following the initiation of study treatment without an increase in standard-of-care vasopressors.

The ATHOS-3 Phase 3 study completed enrollment of 344 patients in the fourth quarter of 2016. In February 2017, we reported positive top-line results from ATHOS-3. 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, a trend toward longer survival was observed: 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.

In September 2017, an analysis from ATHOS-3, entitled "Baseline angiotensin levels and ACE effects in patients with vasodilatory shock treated with angiotensin II," was presented during the 30th European Society of Intensive Care Medicine Annual Congress. 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 September 2017, we reported that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued favorable Scientific Advice regarding the EU regulatory pathway for GIAPREZA. Based on this Advice, we intend to submit a Marketing Authorization Application (MAA) for GIAPREZA in the third quarter of 2018.

In December 2017, GIAPREZA™ (angiotensin II) was approved by the FDA to increase blood pressure in adults with septic or other distributive shock.

In February 2018, an abstract, entitled "Effect of Disease Severity on Survival in Patients Receiving Angiotensin II for Vasodilatory Shock," was presented at the Society of Critical Care Medicine's (SCCM) 47th Critical Care Congress. 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, entitled “Outcomes in Patients with Acute Kidney Injury Receiving Angiotensin II for Vasodilatory Shock,” was presented at the 23rd International Conference on Advances in Critical Care Nephrology AKI & CRRT 2018. 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 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).

LJPC-401

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. 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 primary iron overload diseases such as hereditary hemochromatosis (HH), or secondary iron overload diseases such as 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. 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, 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.

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 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 September 2016, we reached agreement with the EMA on the design of a pivotal study of LJPC-401 for the treatment of beta thalassemia patients suffering from iron overload, a major unmet need in an orphan patient population. This study, which we refer to as LJ401-BT01, was initiated in December 2017. LJ401-BT01 is designed to enroll approximately 100 patients across 9 countries, including the U.S. Patients will be randomized 1:1 to receive either: (i) weekly subcutaneous injections of LJPC 401, while continuing standard-of-care chelation therapy (LJPC 401 treatment arm); or (ii) a continuation of standard-of-care chelation therapy only (observation arm). After 6 months of treatment, patients randomized to the observation arm will cross over to receive LJPC 401 (plus standard-of-care chelation therapy) for 6 months, while patients randomized to the LJPC-401 treatment arm will continue with LJPC-401 (plus standard-of-care chelation therapy) for an additional 6 months (for a total of one year). 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 Europe.

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, placebo-controlled, double-blind, Phase 2 study that is designed to evaluate the safety and efficacy of LJPC-401 as a treatment for HH. Approximately 60 patients will be randomized to receive weekly subcutaneous injections of either LJPC 401 or placebo for 12 weeks. 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.

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, 2017, which was filed on February 22, 2018, except for the newly adopted inventory and revenue recognition 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 the three months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	2017
Net product sales	$809	$—
Cost of product sales	(58)	—
Research and development expense	(28,429)	(17,765)
Selling, general and administrative	(23,016)	(5,503)
Other income, net	166	28
Net loss	$(50,528)	$(23,240)

Revenue

In March 2018, we announced the commercial availability of GIAPREZA.

Cost of Product Sales

For the three months ended March 31, 2018, we recognized cost of product sales of $58,000 for sales of GIAPREZA, primarily related to royalty, labeling, shipping and distribution costs. A portion of the cost to manufacture GIAPREZA was recorded to research and development expense prior to the approval of GIAPREZA by the FDA.

Research and Development Expense

The following summarizes our research and development expense for the three months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	2017
Clinical development costs	$9,793	$7,994
Personnel and related costs	9,164	5,271
Share-based compensation expense	5,396	2,470
Technology in-licensing costs	119	253
Other research and development costs	3,957	1,777
Total research and development expense	$28,429	$17,765

During the three months ended March 31, 2018, research and development expense increased to $28.4 million, compared to $17.8 million for the three months ended March 31, 2017. The increase was primarily due to increased personnel and related costs and share-based compensation expense as a result of increased headcount associated with the development of GIAPREZA and LJPC-401. We anticipate research and development expense to increase throughout 2018 due to the continuation of our clinical development of GIAPREZA and LJPC-401, the initiation of additional clinical studies and ongoing development of other product candidates.

Selling, General and Administrative Expense

The following summarizes our selling, general and administrative expense for the three months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	2017
Personnel and related costs	$9,586	$1,354
Share-based compensation expense	4,006	2,513
Other selling, general and administrative expense	9,424	1,636
Total selling, general and administrative expense	$23,016	$5,503

During the three months ended March 31, 2018, selling, general and administrative expense increased to $23.0 million, compared to $5.5 million for the three months ended March 31, 2017. 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 and the development of other product candidates. We anticipate selling, general

and administrative expense to increase throughout 2018 due to commercial activities related to GIAPREZA and ongoing development of other product candidates.

Liquidity and Capital Resources

Since January 2012, when the Company was effectively restarted with new assets and a new management team, through March 31, 2018, our cash used in operating activities was $234.4 million. From inception through March 31, 2018, we

have incurred a cumulative net loss of $772.0 million and have financed our operations through public and private offerings of securities, revenues from collaborative agreements, equipment financings and interest income on invested cash balances. From inception through March 31, 2018, we have raised $816.1 million in net proceeds from the sales of equity securities.

As of March 31, 2018, we had $154.4 million in cash and cash equivalents, compared to $90.9 million of cash and cash equivalents at December 31, 2017. On a pro-forma basis, adjusting for the net proceeds from the May 2018 royalty financing, the Company’s cash and cash equivalents as of March 31, 2018 were $279 million. Cash used for operating activities for the three months ended March 31, 2018 was $45.9 million, compared to $22.0 million for the same period 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 and depreciation expense. For the three months ended March 31, 2018, we used $1.0 million of cash for investing activities, compared to $0.8 million for the same period in 2017. The increase in cash used for investing activities was a result of purchases of property and equipment. Cash provided by financing activities for the three months ended March 31, 2018 was $110.3 million, compared to $119.6 million for the same period in 2017. The cash provided by financing activities for the three months ended March 31, 2018 was due to $109.8 million of proceeds from the March 2018 common stock offering and $0.5 million of proceeds from the exercise of stock options for common stock.

Based on the cash and cash equivalent resources available as of March 31, 2018, management believes that the Company has sufficient resources to fund operations for at least one year from the date this Quarterly Report on Form 10-Q is filed with the SEC.

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 three months ended March 31, 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.

Other than controls implemented in connection with the newly adopted inventory and revenue recognition 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, 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. 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

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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

SIGNATURES

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

La Jolla Pharmaceutical Company

Date: May 10, 2018 /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)