

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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, 2019
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

(State or other jurisdiction of incorporation or organization)

33-0361285

(I.R.S. Employer Identification No.)

4550 Towne Centre Court, San Diego, CA

(Address of principal executive offices)

92121

(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, Par Value \$0.0001 per Share	LJPC	The Nasdaq Capital Market

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 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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 25, 2019, there were 27,157,205 shares of common stock outstanding.

LA JOLLA PHARMACEUTICAL COMPANY
FORM 10-Q
QUARTERLY REPORT

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2019	December 31, 2018
	(Unaudited)	
ASSETS		
Current assets:		
Cash	\$ 104,768	\$ 172,604
Accounts receivable, net	1,417	1,381
Inventory, net	1,910	2,020
Prepaid expenses and other current assets	4,783	5,111
Total current assets	112,878	181,116
Property and equipment, net	19,523	22,267
Right-of-use lease asset	15,829	—
Restricted cash	909	909
Total assets	\$ 149,139	\$ 204,292
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 5,338	\$ 8,572
Accrued expenses	9,351	8,485
Accrued payroll and related expenses	5,118	7,509
Lease liability, current portion	2,705	—
Deferred rent, current portion	—	1,370
Total current liabilities	22,512	25,936
Lease liability, less current portion	27,199	—
Deferred rent, less current portion	—	13,609
Deferred royalty obligation, net	124,366	124,323
Other noncurrent liabilities	10,233	4,503
Total liabilities	184,310	168,371
Shareholders' (deficit) equity:		
Common Stock, \$0.0001 par value; 100,000,000 shares authorized, 27,147,387 and 26,259,254 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	3	3
Series C-1 ² Convertible Preferred Stock, \$0.0001 par value; 11,000 shares authorized, 3,906 shares issued and outstanding at September 30, 2019 and December 31, 2018; and liquidation preference of \$3,906 at September 30, 2019 and December 31, 2018	3,906	3,906
Series F Convertible Preferred Stock, \$0.0001 par value; 10,000 shares authorized, 0 and 2,737 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively; and liquidation preference of \$0 and \$2,737 at September 30, 2019 and December 31, 2018, respectively	—	2,737
Additional paid-in capital	973,018	950,258
Accumulated deficit	(1,012,098)	(920,983)
Total shareholders' (deficit) equity	(35,171)	35,921
Total liabilities and shareholders' (deficit) equity	\$ 149,139	\$ 204,292

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue				
Net product sales	\$ 5,706	\$ 3,470	\$ 15,804	\$ 5,872
Total revenue	<u>5,706</u>	<u>3,470</u>	<u>15,804</u>	<u>5,872</u>
Operating expenses				
Cost of product sales	554	256	1,605	443
Research and development	21,182	30,439	64,469	89,735
Selling, general and administrative	10,782	21,139	34,425	66,319
Total operating expenses	<u>32,518</u>	<u>51,834</u>	<u>100,499</u>	<u>156,497</u>
Loss from operations	<u>(26,812)</u>	<u>(48,364)</u>	<u>(84,695)</u>	<u>(150,625)</u>
Other (expense) income				
Interest expense	(2,863)	(2,926)	(8,398)	(4,581)
Interest income	501	545	1,818	1,155
Total other expense, net	<u>(2,362)</u>	<u>(2,381)</u>	<u>(6,580)</u>	<u>(3,426)</u>
Net loss	<u>\$ (29,174)</u>	<u>\$ (50,745)</u>	<u>\$ (91,275)</u>	<u>\$ (154,051)</u>
Net loss per share, basic and diluted	<u>\$ (1.08)</u>	<u>\$ (1.93)</u>	<u>\$ (3.37)</u>	<u>\$ (6.15)</u>
Weighted-average common shares outstanding, basic and diluted	<u>27,135</u>	<u>26,226</u>	<u>27,093</u>	<u>25,055</u>

See accompanying notes to the condensed consolidated financial statements.

LA JOLLA PHARMACEUTICAL COMPANY
Condensed Consolidated Statements of Shareholders' (Deficit) Equity
(Unaudited)
(in thousands)

	Series C-1 ² Convertible Preferred Stock		Series F Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	4	\$ 3,906	3	\$ 2,737	26,259	\$ 3	\$ 950,258	\$ (920,983)	\$ 35,921
Share-based compensation expense	—	—	—	—	—	—	6,782	—	6,782
Issuance of common stock under ESPP	—	—	—	—	52	—	283	—	283
Issuance of common stock for conversion of Series F Preferred Stock	—	—	(3)	(2,737)	782	—	2,737	—	—
Cumulative-effect adjustment from adoption of ASU 2018-07	—	—	—	—	—	—	(160)	160	—
Net loss	—	—	—	—	—	—	—	(31,685)	(31,685)
Balance at March 31, 2019	4	3,906	—	—	27,093	3	959,900	(952,508)	11,301
Share-based compensation expense	—	—	—	—	—	—	6,321	—	6,321
Issuance of common stock under ESPP	—	—	—	—	32	—	201	—	201
Net loss	—	—	—	—	—	—	—	(30,416)	(30,416)
Balance at June 30, 2019	4	3,906	—	—	27,125	3	966,422	(982,924)	(12,593)
Share-based compensation expense	—	—	—	—	—	—	6,419	—	6,419
Issuance of common stock under ESPP	—	—	—	—	22	—	177	—	177
Net loss	—	—	—	—	—	—	—	(29,174)	(29,174)
Balance at September 30, 2019	4	\$ 3,906	—	\$ —	27,147	\$ 3	\$ 973,018	\$(1,012,098)	\$ (35,171)

	Series C-1 ² Convertible Preferred Stock		Series F Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	4	\$ 3,906	3	\$ 2,737	22,167	\$ 2	\$ 803,071	\$ (721,514)	\$ 88,202
Issuance of common stock for March 2018 financing	—	—	—	—	3,910	1	109,808	—	109,809
Share-based compensation expense	—	—	—	—	—	—	9,402	—	9,402
Exercise of stock options and warrants for common stock	—	—	—	—	77	—	528	—	528
Net loss	—	—	—	—	—	—	—	(50,528)	(50,528)
Balance at March 31, 2018	4	3,906	3	2,737	26,154	3	922,809	(772,042)	157,413
Share-based compensation expense	—	—	—	—	—	—	9,844	—	9,844
Exercise of stock options for common stock	—	—	—	—	65	—	1,188	—	1,188
Net loss	—	—	—	—	—	—	—	(52,778)	(52,778)
Balance at June 30, 2018	4	3,906	3	2,737	26,219	3	933,841	(824,820)	115,667
Share-based compensation expense	—	—	—	—	—	—	9,880	—	9,880
Exercise of stock options for common stock	—	—	—	—	8	—	192	—	192
Net loss	—	—	—	—	—	—	—	(50,745)	(50,745)
Balance at September 30, 2018	4	\$ 3,906	3	\$ 2,737	26,227	\$ 3	\$ 943,913	\$ (875,565)	\$ 74,994

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	2018
Operating activities		
Net loss	\$ (91,275)	\$ (154,051)
Adjustments to reconcile net loss to net cash used for operating activities:		
Share-based compensation expense	19,522	29,126
Depreciation expense	3,408	3,245
Loss on disposal of equipment	15	236
Non-cash interest expense	6,971	4,421
Non-cash rent expense	969	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(36)	(1,537)
Inventory, net	110	(1,101)
Prepaid expenses and other current assets	328	(2,700)
Accounts payable	(3,234)	(4,914)
Accrued expenses	(332)	5,906
Accrued payroll and related expenses	(2,391)	(73)
Lease liability	(1,873)	—
Deferred rent	—	1,110
Net cash used for operating activities	<u>(67,818)</u>	<u>(120,332)</u>
Investing activities		
Purchase of property and equipment	(679)	(2,252)
Net cash used for investing activities	<u>(679)</u>	<u>(2,252)</u>
Financing activities		
Proceeds from the issuance of common stock under ESPP	661	—
Net proceeds from royalty financing	—	124,289
Net proceeds from the issuance of common stock	—	109,809
Net proceeds from the exercise of stock options for common stock	—	1,908
Net cash provided by financing activities	<u>661</u>	<u>236,006</u>
Net (decrease) increase in cash and restricted cash	(67,836)	113,422
Cash and restricted cash at beginning of period	173,513	91,824
Cash and restricted cash at end of period	\$ 105,677	\$ 205,246
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of Series F Convertible Preferred Stock into common stock	\$ 2,737	\$ —
Cumulative-effect adjustment from adoption of ASU 2018-07	\$ (160)	\$ —
Initial recognition of right-of-use lease asset	\$ 16,798	\$ —
Reconciliation of cash and restricted cash to the condensed consolidated balance sheets		
Cash	\$ 104,768	\$ 204,337
Restricted cash	909	909
Total cash and restricted cash	\$ 105,677	\$ 205,246

See accompanying notes to the condensed consolidated financial statements.

LA JOLLA PHARMACEUTICAL COMPANY

Notes to the 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. In December 2017, GIAPREZA™ (angiotensin II) was approved by the U.S. Food and Drug Administration (“FDA”) as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. In August 2019, GIAPREZA was approved by the European Commission for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies. LJPC-0118 (artesunate) is La Jolla’s investigational product for the treatment of severe malaria. LJPC-401 (synthetic human hepcidin) is La Jolla’s investigational product for the potential treatment of conditions characterized by iron overload. LJPC-401 is being investigated in a pivotal study in beta thalassemia patients with iron overload and in a Phase 2 study in patients with hereditary hemochromatosis.

As of September 30, 2019, the Company had \$104.8 million in cash, compared to \$172.6 million in cash as of December 31, 2018. Based on the Company’s current operating plans and projections, the Company expects that its existing cash will be 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 (the “SEC”).

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 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, 2018 included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 4, 2019 (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, 2019, the condensed consolidated statements of operations for the three and nine months ended September 30, 2019, the condensed consolidated statement of shareholders’ (deficit) equity for the three and nine months ended September 30, 2019 and the condensed consolidated statement of cash flows for the nine months ended September 30, 2019.

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. Certain amounts previously reported in the financial statements have been reclassified to conform to the current year presentation. Such reclassifications did not affect net loss, shareholders’ equity or cash flows. The results of operations for the three and nine months ended September 30, 2019 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, 2018 has been derived from the audited consolidated balance sheet as of December 31, 2018 contained in the Form 10-K.

Summary of Significant Accounting Policies

During the nine months ended September 30, 2019, there have been no changes to the Company's significant accounting policies as described in the Form 10-K, except as described below.

Leases

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term. The Company calculates the present value of lease payments using the discount rate implicit in the lease, unless that rate cannot be readily determined. In that case, the Company uses its incremental borrowing rate, which is the rate of interest that the Company would have to pay to borrow on a collateralized basis an amount equal to the lease payments over the expected lease term. The Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement; and (ii) the right-of-use lease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

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 savings accounts at federally insured financial institutions in excess of federally insured limits.

The Company's products are distributed in the U.S. through authorized specialty distributors and select wholesalers (collectively, customers) that resell its products to hospitals, the end users. The following table includes the percentage of U.S. net product sales and accounts receivable balances for the Company's three major customers, each of which comprised 10% or more of its U.S. net product sales:

	U.S. Net Product Sales		Accounts Receivable
	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019	As of September 30, 2019
Customer A	32%	32%	27%
Customer B	38%	34%	35%
Customer C	30%	30%	38%
Total	100%	96%	100%

Revenue Recognition

The Company adopted the Financial Accounting Standards Board (the "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. There have been no contract assets or liabilities recorded to date relating to product revenue.

Under ASC 606, the Company recognizes revenue when its 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 5 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 the relevant performance obligations.

Revenue from product sales is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns and administrative fees. Variable consideration is estimated using the expected-value amount method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. 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. These items include:

- 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. This may occur due to a direct contract with a health system, a group purchasing organization ("GPO") agreement or a sale to a government facility. Chargebacks are estimated based on known chargeback rates and recorded as a reduction of revenue on delivery to the Company's customers.
- Discounts - The Company offers customers various forms of incentives and consideration, including prompt-pay and other discounts. The Company estimates discounts primarily based on contractual terms. These discounts are recorded as a reduction of revenue on 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 on delivery to the Company's customers.
- Administrative Fees - The Company pays administrative fees to GPOs for services and access to data. Additionally, the Company pays an Industrial Funding Fee as part of the U.S. General Services Administration's Federal Supply Schedules program. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the applicable GPO or government agency.

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 by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of potential common shares. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding plus potential common shares. Convertible preferred stock, stock options and warrants are considered potential common shares and are included in the calculation of diluted net loss per share using the treasury stock method when their effect is dilutive. Potential common shares are excluded from the calculation of diluted net loss per share when their effect is anti-dilutive. As of September 30, 2019 and 2018, there were 13.7 million and 14.3 million potential common shares, respectively, that were excluded from the calculation of diluted net loss per share because their effect was anti-dilutive.

Recent Accounting Pronouncements

In June 2018, the FASB issued Accounting Standards Update (“ASU”) No. 2018-07, Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting (“ASU 2018-07”). The standard expands the scope of Accounting Standards Codification (“ASC”) Topic 718 to include share-based payment awards granted to nonemployees in exchange for goods and services. ASU 2018-07 is effective for annual and interim reporting periods beginning after December 15, 2018.

In the first quarter 2019, the Company adopted ASU 2018-07. Prior to the adoption of ASU 2018-07, share-based payments awards granted to nonemployees were measured at fair value on their grant date, subject to periodic remeasurement, and share-based compensation expense was recognized on a straight-line basis over their vesting terms. After the adoption of ASU 2018-07, the fair value of share-based payment awards granted to nonemployees is not required to be remeasured periodically and share-based compensation expense will continue to be recorded on a straight-line basis over their vesting period, consistent with share-based payment awards granted to employees. As a result of the adoption of ASU 2018-07, the Company remeasured all of its outstanding nonemployee share-based payment awards at fair value and recognized a cumulative-effect adjustment of \$0.2 million to accumulated deficit as of January 1, 2019.

In February 2016, the FASB issued ASU No. 2016-02, Leases (“ASU 2016-02”). This guidance requires lessees to recognize operating leases with a term greater than one year on the balance sheet as a right-of-use asset and corresponding lease liability. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018. Although ASU 2016-02 is required to be adopted at the earliest period presented using a modified retrospective approach, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements (“ASU 2018-11”), which allows for an alternative transition method of adoption by recognizing a cumulative-effect adjustment, if any, to the opening balance of retained earnings in the period of adoption.

The Company adopted ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed under ASU 2018-11. As a result, the Company recorded a lease liability and right-of-use lease asset of \$31.8 million and \$16.8 million, respectively, on its balance sheet as of January 1, 2019. The lease liability represents the present value of the remaining lease payments of the Company’s corporate headquarters lease (see Note 4), discounted using the Company’s incremental borrowing rate as of January 1, 2019. The corresponding right-of-use lease asset is recorded based on the lease liability, adjusted for the unamortized lease incentives received and the cumulative difference between rent expense and amounts paid under the corporate headquarters lease. The adoption of ASU 2016-02 did not have a material impact on either the statement of operations or statement of cash flows for the three and nine months ended September 30, 2019.

3. Balance Sheet Details

Restricted Cash

Restricted cash as of September 30, 2019 and December 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 (see Note 4). There is a requirement to maintain \$0.9 million of cash collateral in an account pledged as security for such letter of credit.

Inventory, Net

Inventory, net consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Work-in-process	\$ 1,129	\$ 1,907
Finished goods	781	113
Total inventory, net	<u>\$ 1,910</u>	<u>\$ 2,020</u>

As of September 30, 2019 and December 31, 2018, total inventory is recorded net of \$0.1 million and \$0.8 million, respectively, of inventory reserves.

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued interest expense	\$ 3,458	\$ 2,260
Accrued clinical study costs	2,793	2,430
Accrued manufacturing costs	1,685	1,823
Accrued other	1,415	1,972
Total accrued expenses	<u>\$ 9,351</u>	<u>\$ 8,485</u>

4. Leases

On December 29, 2016, the Company entered into an agreement with BMR-Axiom LP to lease office and laboratory space as its corporate headquarters located at 4550 Towne Centre Court, San Diego, California (the "Lease") for a period of 10 years commencing on October 30, 2017. The Company has an option to extend the Lease for an additional 5 years at the end of the initial term.

The Company provided a standby letter of credit for \$0.9 million in lieu of a security deposit. This amount will decrease to \$0.6 million after year two of the lease term and decrease to \$0.3 million after year 5 of the lease term. The annual rent under the Lease is subject to escalation during the term. In addition to rent, the Lease requires the Company to pay certain taxes, insurance and operating costs relating to the leased premises. The Lease contains customary default provisions, representations, warranties and covenants. The Lease is classified as an operating lease.

Future minimum lease payments under the Lease as of September 30, 2019 are as follows (in thousands):

2019	\$ 1,000
2020	4,058
2021	4,174
2022	4,294
2023	4,417
Thereafter	18,134
Total future minimum lease payments	<u>36,077</u>
Less: discount	(6,173)
Total lease liability	<u>\$ 29,904</u>

The Company recorded a lease liability for the Lease based on the present value of the Lease payments over the expected Lease term, discounted using the Company's incremental borrowing rate. The Company recorded a corresponding right-of-use lease asset based on the lease liability, adjusted for incentives received prior to the Lease commencement date. The option to extend the Lease was not recognized as a part of either the Company's lease liability or right-of-use lease asset. Lease expense for each of the three and nine months ended September 30, 2019 and 2018 was \$0.7 million and \$2.1 million, respectively. Amortization for the right-of-use lease asset was \$0.4 million and \$1.0 million for the three and nine months ended September 30, 2019, respectively.

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. Quarterly payments to HCR under the Royalty Agreement start 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 received by the Company. The Royalty Agreement expires when the maximum aggregate royalty payments have been made or on January 1, 2031, whichever comes first. 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 issuance costs of \$0.7 million. For the three months ended September 30, 2019 and 2018, the Company recognized interest expense, including amortization of the obligation discount, of \$2.8 million and \$3.0 million, respectively. For the nine months ended September 30, 2019 and 2018, the Company recognized interest expense, including amortization of the obligation discount, of \$8.4 million and \$4.6 million, respectively. The carrying value of the deferred royalty obligation as of September 30, 2019 was \$124.4 million, net of unamortized obligation discount of \$0.6 million, and was classified as noncurrent. The related interest expense liability was \$13.7 million and \$6.8 million as of September 30, 2019 and December 31, 2018, respectively, of which \$10.2 million and \$4.5 million was classified as other noncurrent liabilities, respectively. During the three and nine months ended September 30, 2019, the Company made royalty payments to HCR of \$0.6 million and \$1.4 million, respectively, and, as of September 30, 2019, the Company recorded royalty obligations payable of \$0.6 million in accrued expenses. The deferred royalty obligation is classified as Level 3 in the ASC 820-10, Fair Value Measurements and Disclosures, three-tier fair value hierarchy, and its carrying value approximates fair value.

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, depending on the type of breach. The Company concluded that certain of these contract provisions that could result in an acceleration of amounts due under the Royalty Agreement 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, 2019. 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. Shareholders' (Deficit) Equity

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.

Preferred Stock

In January 2019, the Company issued 782,031 shares of common stock upon the conversion of 2,737 shares of Series F Convertible Preferred Stock. As of September 30, 2019, there were no shares of Series F Convertible Preferred Stock issued and outstanding.

Warrants

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. As of September 30, 2019, the Company had outstanding warrants to purchase 10,000 shares of common stock.

7. Equity Incentive Plans

2013 Equity Incentive Plan

A total of 8,100,000 shares of common stock have been reserved for issuance under the La Jolla Pharmaceutical Company 2013 Equity Incentive Plan (the "2013 Equity Plan"). As of September 30, 2019, 941,077 shares of common stock remained available for future grants under the 2013 Equity Plan.

2018 Employee Stock Purchase Plan

A total of 750,000 shares of common stock have been reserved for issuance under the La Jolla Pharmaceutical Company 2018 Employee Stock Purchase Plan (the "ESPP"). As of September 30, 2019, 611,599 shares of common stock remained available for future grants under the ESPP.

Equity Awards

The activity related to equity awards, which are comprised of stock options and inducement grants, during the nine months ended September 30, 2019 is summarized as follows:

	Equity Awards		Weighted-average Exercise Price per Share
Outstanding at December 31, 2018	6,466,214	\$	23.26
Granted ⁽¹⁾	1,982,402	\$	6.43
Cancelled/forfeited	(1,503,029)	\$	20.62
Outstanding at September 30, 2019	6,945,587	\$	19.03

(1) In March 2019, the Company issued a stock option grant to the Company's recently appointed Chief Commercial Officer to purchase 80,000 shares of common stock at an exercise price equal to the fair market value of the Company's common stock on the grant date. The grant was awarded as an inducement grant outside of the 2013 Equity Plan. On the first anniversary of the grant date, 25% of the underlying shares become exercisable with the remaining shares vesting on a monthly basis over the subsequent three years, subject to continued service during that time.

Share-based Compensation Expense

The classification of share-based compensation expense is summarized as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 4,169	\$ 5,895	\$ 12,062	\$ 16,992
Selling, general and administrative	2,250	3,985	7,460	12,134
Total share-based compensation expense	\$ 6,419	\$ 9,880	\$ 19,522	\$ 29,126

As of September 30, 2019, total unrecognized share-based compensation expense related to unvested equity awards was \$41.0 million, which is expected to be recognized over a weighted-average period of 2.4 years. As of September 30, 2019, there was no unrecognized share-based compensation expense related to shares of common stock issued under the ESPP.

8. Company-wide Realignment

On October 18, 2018, the Company effected a Company-wide realignment to increase its efficiency and focus on achieving its corporate goals. For the year ended December 31, 2018, total expense for these activities was \$4.0 million, with \$1.6 million included in research and development expense and \$2.4 million included in selling, general and administrative expense. Total expense was comprised of \$7.7 million for severance costs, offset by a \$3.7 million reversal of non-cash, share-based compensation expense related to forfeited, unvested equity awards. As of March 31, 2019, all severance costs had been paid. No expense for these activities was recorded during the three and nine months ended September 30, 2019.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and our audited financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the U.S. Securities and Exchange Commission (the “SEC”) on March 4, 2019 (the “Form 10-K”).

Forward-looking Statements

This Quarterly Report on Form 10-Q contains “forward-looking statements” as defined by the Private Securities Litigation Reform Act of 1995. We caution investors that forward-looking statements are based on management’s expectations and assumptions as of the date of this Quarterly Report on Form 10-Q and involve substantial risks and uncertainties that could cause the actual outcomes to differ materially from what we currently expect. These risks and uncertainties include, but are not limited to, those associated with: GIAPREZA™ (angiotensin II) sales; cash used in operating activities; regulatory actions relating to La Jolla’s products by the U.S. Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”) and/or other regulatory authorities; the outcomes of clinical studies of La Jolla’s products; and other risks and uncertainties identified in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements in this Quarterly Report on Form 10-Q apply only as of the date made, and we undertake no obligation to update or revise any forward-looking statements to reflect subsequent events or circumstances. 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 Form 10-K, and in other reports and registration statements that we file with the SEC.

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, LJPC-0118 and LJPC-401.
- *Critical Accounting Policies and Estimates.* This section provides a description of the material changes to 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, 2019 to the results for the three and nine months ended September 30, 2018.
- *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. In December 2017, GIAPREZA was approved by the FDA as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. In August 2019, GIAPREZA was approved by the European Commission (“EC”) for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies. LJPC-0118 (artesanate) is La Jolla’s investigational product for the treatment of severe malaria. LJPC-401 (synthetic human hepcidin) is La Jolla’s investigational product for the potential treatment of conditions characterized by iron overload. LJPC-401 is being investigated in a pivotal study in beta thalassemia patients with iron overload and in a Phase 2 study in patients with hereditary hemochromatosis.

Program Overview

GIAPREZA™ (angiotensin II)

GIAPREZA™ (angiotensin II), injection for intravenous infusion, was approved by the FDA in December 2017 as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock and by the EC in August 2019 for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies. Angiotensin II is a major bioactive component of the renin-angiotensin-aldosterone system (the “RAAS”). The RAAS is one of three central regulators of blood pressure. In March 2018, we announced the commercial availability of GIAPREZA in the U.S. 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 and select wholesalers.

More than 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 patients 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 “EU”), 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 remained hypotensive despite fluid and vasopressor therapy, known as ATHOS-3 (Angiotensin II for the Treatment of High-Output Shock). 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 ATHOS-3 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.

LJPC-0118

LJPC-0118 (artesunate) is an investigational product for the treatment of severe malaria. The active pharmaceutical ingredient in LJPC-0118, artesunate, was demonstrated to be superior to quinine in reducing mortality in patients with severe falciparum malaria infection in two randomized, controlled, clinical studies. Severe malaria is a serious and sometimes fatal disease caused by a parasite that commonly infects a certain type of mosquito, which feeds on humans. Symptoms include, but are not limited to: fever, chills, sweating, hypoglycemia and shock. Severe malaria is often complicated by central nervous system infections that may lead to delirium, which may progress to coma. Infections usually occur a few weeks after being bitten. In 2017, an estimated 219 million cases of malaria occurred worldwide, with an estimated 200 million of these cases occurring in the World Health Organization (the “WHO”) African Region, and, in 2013, the global annual incidence of severe malaria was estimated to be 2 million cases. In 2017, an estimated 435,000 people died from malaria worldwide.

In April 2019, the FDA granted Breakthrough Therapy designation for LJPC-0118. Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat serious or life-threatening diseases and for which preliminary clinical evidence indicates substantial improvement over available therapies on clinically significant endpoint(s).

In July 2019, the FDA granted Orphan Drug designation for LJPC-0118 for the treatment of malaria. Orphan Drug designation is designed to incentivize the development of drugs and biological products that treat rare diseases or conditions affecting fewer than 200,000 patients in the U.S. These incentives include: up to seven years of marketing exclusivity if the sponsor is the first to obtain regulatory approval from the FDA; tax credits related to clinical study expenses; an exemption from the FDA-user fee; and FDA assistance in clinical study design.

La Jolla plans to file a New Drug Application (“NDA”) with the FDA for LJPC-0118 for the treatment of severe malaria in the fourth quarter of 2019.

LJPC-401

LJPC-401 (synthetic human hepcidin) is La Jolla’s investigational product for the potential treatment of conditions characterized by iron overload. Heparin, 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 (“BT”), sickle cell disease (“SCD”), myelodysplastic syndrome (“MDS”) and polycythemia vera.

HH is the most common genetic disease in Caucasians. HH is characterized by a genetic mutation that causes excessive iron absorption and accumulation due to hepcidin deficiency or insensitivity. Without normal levels of hepcidin, excessive amounts of iron accumulate in the body. Symptoms of the disease include joint pain, abdominal pain, fatigue and weakness. If left untreated, HH can lead to liver cirrhosis, liver cancer, heart disease and/or failure and diabetes.

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 23^d Congress of the European Hematology Association (the “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 Heparin) 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 Heparin) 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, placebo-controlled, double-blind, Phase 2 study 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 (“TSAT”), 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 (16 weeks). Secondary efficacy endpoints include the requirement for and frequency of phlebotomy procedures during the study.

In June 2019, we announced positive results from the pre-specified interim analysis of LJ401-HH01. The interim analysis of efficacy included 26 patients who had reached the end of the 16-week treatment period (the efficacy population: 12 LJPC-401-treated patients; 14 placebo-treated patients), and the interim analysis of safety included 60 randomized patients (the safety population: 29 LJPC-401-treated patients; 31 placebo-treated patients). Results from the pre-specified interim analysis include the following:

- The change in TSAT from baseline to the end of treatment was statistically significant: LJPC-401-treated patients had a mean reduction in TSAT of 42% compared to placebo-treated patients who had a mean reduction of 6% ($p < 0.0001$).
- The requirement for and frequency of phlebotomy procedures was statistically significant: LJPC-401-treated patients had 0.06 phlebotomies per month compared to placebo-treated patients who had 0.41 phlebotomies per month ($p = 0.003$). There were 3 phlebotomies in 2 LJPC-401-treated patients and 24 phlebotomies in 9 placebo-treated patients.
- LJPC-401 was well tolerated. The most frequent treatment-emergent adverse events (“TEAEs”) were injection site reactions (“ISRs”), which occurred in 79% of LJPC-401-treated patients compared to 6% of placebo-treated patients. The ISRs were all mild or moderate in severity, and no ISRs resulted in treatment discontinuation. As of the interim analysis, there were no serious TEAEs reported.

We expect to announce top-line results of LJ401-HH01 in the fourth quarter of 2019.

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.

We expect to announce top-line results of LJ401-BT01 in the second half of 2020.

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, 2018, which was filed on March 4, 2019, except for the lease policy 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 table summarizes our results of operations for each of the periods below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net product sales	\$ 5,706	\$ 3,470	\$ 15,804	\$ 5,872
Cost of product sales	(554)	(256)	(1,605)	(443)
Research and development expense	(21,182)	(30,439)	(64,469)	(89,735)
Selling, general and administrative expense	(10,782)	(21,139)	(34,425)	(66,319)
Other expense, net	(2,362)	(2,381)	(6,580)	(3,426)
Net loss	\$ (29,174)	\$ (50,745)	\$ (91,275)	\$ (154,051)

Net Product Sales

For the three and nine months ended September 30, 2019, GIAPREZA U.S. net product sales were \$5.7 million and \$15.8 million, respectively, compared to \$3.5 million and \$5.9 million, respectively, for the same periods in 2018. La Jolla launched GIAPREZA in the U.S. in March 2018.

Cost of Product Sales

For the three and nine months ended September 30, 2019, we recognized cost of product sales of \$0.6 million and \$1.6 million, respectively, compared to \$0.3 million and \$0.4 million, respectively, for the same periods in 2018. Cost of product sales primarily included royalty and product manufacturing costs.

In 2017, prior to approval by the FDA, approximately \$0.6 million of direct material costs to manufacture GIAPREZA were recorded to research and development expense. As of September 30, 2019, inventory excludes approximately \$0.2 million of manufacturing costs that were recorded to research and development expense prior to FDA approval.

Research and Development Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Clinical development costs	\$ 7,097	\$ 10,937	\$ 20,982	\$ 32,369
Personnel and related costs	6,224	8,413	19,330	26,757
Share-based compensation expense	4,169	5,895	12,062	16,992
Other research and development costs	3,692	5,194	12,095	13,617
Total research and development expense	\$ 21,182	\$ 30,439	\$ 64,469	\$ 89,735

During the three months ended September 30, 2019, research and development expense decreased to \$21.2 million from \$30.4 million for the same period in 2018, or a decrease of \$9.2 million. Clinical development costs decreased by \$3.8 million due to a decrease of \$2.6 million in costs related to our clinical development program for LJPC-0118 and a decrease of \$2.0 million in clinical and regulatory activities for GIAPREZA. These decreases were partially offset by a \$0.8 million increase in costs related to our clinical development programs for LJPC-401. Personnel and related costs decreased by \$2.2 million primarily due to a Company-wide realignment to increase our efficiency and focus on achieving our corporate goals. Share-based compensation expense decreased by \$1.7 million due to a decrease in the weighted-average fair value of unvested share-based compensation awards outstanding. Other research and development costs decreased by \$1.5 million due to decreased costs to support our pre-clinical development programs.

During the nine months ended September 30, 2019, research and development expense decreased to \$64.5 million from \$89.7 million for the same period in 2018, or a decrease of \$25.2 million. Clinical development costs decreased by \$11.4 million primarily due to decreases in costs of: \$7.8 million related to clinical and regulatory activities for GIAPREZA; \$3.1 million related to our clinical development program for LJPC-0118; and \$2.0 million in other costs to support our clinical development programs. These decreases were partially offset by a \$1.5 million increase in costs related to our clinical development programs for LJPC-401. Personnel and related costs decreased by \$7.4 million primarily due to a Company-wide realignment to increase our efficiency and focus on achieving our corporate goals. Share-based compensation expense decreased by \$4.9 million due to a decrease in the weighted-average fair value of unvested share-based compensation awards outstanding. Other research and development costs decreased by \$1.5 million due to decreased costs to support our pre-clinical development programs.

We do not expect research and development expense to increase significantly in the near term.

Selling, General and Administrative Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Personnel and related costs	\$ 4,979	\$ 9,232	\$ 15,865	\$ 28,375
Share-based compensation expense	2,250	3,985	7,460	12,134
Selling and marketing costs	1,509	5,706	4,964	19,080
General and administrative costs	2,044	2,216	6,136	6,730
Total selling, general and administrative expense	\$ 10,782	\$ 21,139	\$ 34,425	\$ 66,319

During the three months ended September 30, 2019, selling, general and administrative expense decreased to \$10.8 million from \$21.1 million for the same period in 2018, or a decrease of \$10.3 million. Personnel and related costs decreased by \$4.3 million primarily due to a Company-wide realignment to increase our efficiency and focus on achieving our corporate goals. Selling and marketing costs decreased by \$4.2 million due to initial GIAPREZA-related launch initiatives in 2018. Share-based compensation expense decreased by \$1.7 million due to a decrease in the weighted-average fair value of unvested share-based compensation awards outstanding.

During the nine months ended September 30, 2019, selling, general and administrative expense decreased to \$34.4 million from \$66.3 million for the same period in 2018, or a decrease of \$31.9 million. Selling and marketing costs decreased by \$14.1 million due to initial GIAPREZA-related launch initiatives in 2018. Personnel and related costs decreased by \$12.5 million primarily due to a Company-wide realignment to increase our efficiency and focus on achieving our corporate goals. Share-based compensation expense decreased by \$4.7 million due to a decrease in the weighted-average fair value of unvested share-based compensation awards outstanding. Other general and administrative costs decreased by \$0.6 million.

We do not expect selling, general and administrative expense to increase significantly in the near term.

Other Expense, Net

During the three months ended September 30, 2019 and 2018, other expenses were \$2.4 million. During the nine months ended September 30, 2019, other expense increased to \$6.6 million from \$3.4 million for the same period in 2018. The increase in expense was due to an increase in interest accrued for our deferred royalty obligation, partially offset by an increase in interest income generated from cash held in savings accounts.

Liquidity and Capital Resources

Since January 2012, when the Company was effectively restarted with new assets and a new management team, through September 30, 2019, our cash used in operating activities was \$408.7 million. As of September 30, 2019, we had an accumulated deficit of \$1,012.1 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, 2019, we had \$104.8 million in cash, compared to \$172.6 million of cash at December 31, 2018. Based on our current operating plans and projections, we believe that our existing cash will be sufficient to fund operations for at least one year from the date this Quarterly Report on Form 10-Q is filed with the SEC.

Cash used for operating activities for the nine months ended September 30, 2019 was \$67.8 million, compared to \$120.3 million for the same period in 2018. The decrease in cash used for operating activities was a result of the decrease in our net loss, primarily offset by changes in non-cash expenses and working capital.

Cash used for investing activities for the nine months ended September 30, 2019 was \$0.7 million, compared to \$2.3 million for the same period in 2018. Net cash used in investing activities was the result of purchases of property and equipment.

Cash provided by financing activities for the nine months ended September 30, 2019 was \$0.7 million, compared to \$236.0 million for the same period in 2018. The decrease in cash provided by financing activities was primarily the result of the receipt of \$109.8 million of net proceeds from the March 2018 common stock offering and \$124.3 million of net proceeds from the royalty financing in May 2018 (see Note 5).

Contractual Obligations

In May 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 quarterly royalties on worldwide net product sales of GIAPREZA beginning April 1, 2018. Quarterly payments to HCR under the Royalty Agreement start 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 received by us. The Royalty Agreement expires when the maximum aggregate royalty payments have been made or on January 1, 2031, whichever comes first. 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 La Jolla Pharmaceutical Company or any assets other than GIAPREZA.

In December 2014, we entered into a patent license agreement with the George Washington University (“GW”), which the parties amended and restated on March 1, 2016 and we subsequently assigned to La Jolla Pharma, LLC in connection with its entry into the Royalty Agreement. Pursuant to the amended and restated license agreement, GW exclusively licensed to us certain intellectual property rights relating to GIAPREZA, including the exclusive rights to certain issued patents and patent applications covering GIAPREZA. Under the license agreement, we are obligated to use commercially reasonable efforts to develop, commercialize, market and sell GIAPREZA. We have paid a one-time license initiation fee, annual maintenance fees, an amendment fee, additional payments following the achievement of certain development and regulatory milestones, and royalty payments. As a result of the EC’s approval of GIAPREZA in August 2019, we will make a milestone payment to GW in the amount of \$0.5 million in the fourth quarter of 2019. Additional milestones may be payable to GW for additional indications for which GIAPREZA is approved, with each such additional indication resulting in potential milestone payments of up to \$1.1 million. Following the commencement of commercial sales of GIAPREZA, we are obligated to pay a 6% royalty on products covered by the licensed rights. The patents and patent applications covered by the GW license agreement are expected to expire between 2029 and 2038, and the obligation to pay royalties under this agreement extends through the last-to-expire patent covering 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 a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

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 is also 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 lease policy 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, 2018, filed with the SEC on March 4, 2019.

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
<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

SIGNATURES

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

Date: November 12, 2019

La Jolla Pharmaceutical Company

/s/ George Tidmarsh

George Tidmarsh, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Dennis Mulroy

Dennis Mulroy
Chief Financial Officer
(Principal Financial and Accounting Officer)

SECTION 302 CERTIFICATION

I, George Tidmarsh, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of La Jolla Pharmaceutical Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ George Tidmarsh

George Tidmarsh, M.D., Ph.D.
President, Chief Executive Officer and Secretary
(Principal Executive Officer)

SECTION 302 CERTIFICATION

I, Dennis Mulroy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of La Jolla Pharmaceutical Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Dennis Mulroy

Dennis Mulroy

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned, in his capacity as an officer of La Jolla Pharmaceutical Company (Registrant), hereby certifies, for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- the Quarterly Report of the Registrant on Form 10-Q for the quarter ended September 30, 2019 (Report), which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition of the Registrant at the end of such quarter and the results of operations of the Registrant for such quarter.

Date: November 12, 2019

/s/ George Tidmarsh

George Tidmarsh, M.D., Ph.D.
President, Chief Executive Officer and Secretary
(Principal Executive Officer)

/s/ Dennis Mulroy

Dennis Mulroy
Chief Financial Officer
(Principal Financial and Accounting Officer)

Note: A signed original of this written statement required by Section 906 has been provided to La Jolla Pharmaceutical Company and will be retained by La Jolla Pharmaceutical Company and furnished to the Securities and Exchange Commission or its staff upon request.