

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): March 4, 2019

LA JOLLA PHARMACEUTICAL COMPANY

(Exact name of registrant as specified in its charter)

California
(State or other jurisdiction of incorporation or
organization)

1-36282
(Commission
File Number)

33-0361285
(I.R.S. Employer
Identification No.)

4550 Towne Centre Court, San Diego, California 92121
(Address of Principal Executive Offices) (Zip Code)

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

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On March 4, 2019, La Jolla Pharmaceutical Company issued a press release announcing its financial results for the three and twelve months ended December 31, 2018. A copy of the press release is furnished as Exhibit 99.1.

The information in this Item 2.02 and in Exhibit 99.1 will not be treated as "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. This information will not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or into another filing under the Exchange Act, unless that filing expressly incorporates this information by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated March 4, 2019

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.

Date: March 4, 2019

La Jolla Pharmaceutical Company

By: /s/ Dennis Mulroy

Name: Dennis Mulroy

Title Chief Financial Officer



La Jolla Pharmaceutical Company Announces Financial Results for the Three and Twelve Months Ended December 31, 2018 and Highlights Recent Corporate Progress and Key Objectives

SAN DIEGO, CA - March 4, 2019 - [La Jolla Pharmaceutical Company](#) (Nasdaq: LJPC), a leader in the discovery, development and commercialization of innovative therapies intended to significantly improve outcomes in patients suffering from life-threatening diseases, today announced financial results for the three and twelve months ended December 31, 2018 and highlighted recent corporate progress and key objectives.

Recent Corporate Progress and Key Objectives

GIAPREZA™ (angiotensin II)

- **2018 Net Sales:** Fourth-quarter 2018 net sales were \$4.2 million, up 20% from the third quarter of 2018. 2018 net sales were \$10.1 million. GIAPREZA was launched in March 2018.
- **2019 Net Sales Guidance:** La Jolla expects 2019 net sales of \$24 million to \$28 million.
- **Decision on GIAPREZA MAA by EMA Expected in June of 2019:** La Jolla expects a decision on the GIAPREZA Marketing Authorisation Application (MAA) by the European Medicines Agency (EMA) in June of 2019.

Investigational Products Update

- **NDA Planned for New Investigational Product, LJPC-0118, for the Treatment of Severe Malaria, in Fourth Quarter of 2019:** La Jolla plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019 for LJPC-0118. LJPC-0118 is La Jolla's new investigational product for the treatment of severe malaria. The active pharmaceutical ingredient in LJPC-0118 was demonstrated to be superior to quinine in reducing mortality in patients with severe falciparum malaria infection in two randomized, controlled, clinical studies.
- **Topline Results of Phase 2 Study of LJPC-401 in Patients with Hereditary Hemochromatosis Expected in Second Half of 2019:** La Jolla expects topline results in the second half of 2019 for LJ401-HH01, a multinational, multicenter, randomized, Phase 2 study that is designed to evaluate the safety and efficacy of LJPC-401, La Jolla's proprietary formulation of synthetic human hepcidin, as a treatment for hereditary hemochromatosis (HH). The primary efficacy endpoint of the study is the change in transferrin saturation, a standard measurement of iron levels in the body and one of the two key measurements used to detect iron overload, from baseline to end of treatment.
- **Topline Results of Pivotal Study of LJPC-401 in Patients with Beta Thalassemia Expected in Mid-2020:** La Jolla expects topline results in mid-2020 for 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 beta thalassemia (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, La Jolla anticipates filing an MAA for LJPC-401 in the European Union (EU).

"We are excited to have launched GIAPREZA, our first commercial product, in 2018, and we look forward to executing on a number of initiatives that we believe will support its continued, increased adoption in 2019," said George Tidmarsh, M.D., Ph.D., La Jolla's President and Chief Executive Officer. "Our two randomized studies of LJPC-401 in BT and HH have the potential to demonstrate improved patient outcomes in these important diseases. Furthermore, we are excited to have recently announced a planned NDA submission for LJPC-0118, our new investigational product for the treatment of severe malaria, in the fourth quarter of 2019."

Financial Results

For the three months ended December 31, 2018, GIAPREZA net product sales were \$4.2 million. This compares to \$3.5 million for the three months ended September 30, 2018, \$1.6 million for the three months ended June 30, 2018 and \$0.8 million for the three months ended March 31, 2018. For the twelve months ended December 31, 2018, GIAPREZA net product sales were \$10.1 million. 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. La Jolla launched GIAPREZA in the U.S. in March 2018. La Jolla's net loss for the three and twelve months ended December 31, 2018 was \$45.4 million and \$199.5 million, or \$1.73 per share and \$7.85 per share, respectively, compared to \$38.5 million and \$114.8 million, or \$1.74 per share and \$5.41 per share, respectively, for the same periods in 2017.

As of December 31, 2018, La Jolla had \$172.6 million in cash and cash equivalents, compared to \$90.9 million as of December 31, 2017. The increase in cash and cash equivalents was the result of \$109.8 million of net proceeds from the March 2018 common stock offering and \$124.3 million of net proceeds from the May 2018 royalty financing, offset primarily by net cash used in operating activities. Net cash used in operating activities for the three and twelve months ended December 31, 2018 was \$32.0 million and \$152.4 million, respectively, compared to \$25.4 million and \$85.1 million, respectively, for the same periods in 2017. La Jolla had no debt as of December 31, 2018 and 2017. In 2019, La Jolla expects that its net cash used in operating activities will be \$89 million to \$94 million.

Conference Call Details

La Jolla will host a conference call and webcast today, March 4, 2019, at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time). The conference call can be accessed by dialing 877-359-9508 for domestic callers and 224-357-2393 for international callers. Please provide the operator with the conference ID number 1096371 to join the conference call or click [here](#) for the webcast. An archive of the conference call and webcast will be available on La Jolla's website for 30 days following the call.

About GIAPREZA

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. GIAPREZA mimics the body's endogenous regulatory peptide that is central to the renin-angiotensin-aldosterone system to increase blood pressure. Prescribing information for GIAPREZA is available at www.giapreza.com. GIAPREZA is marketed by La Jolla Pharmaceutical Company on behalf of La Jolla Pharma, LLC, its wholly owned subsidiary.

IMPORTANT SAFETY INFORMATION

Contraindications

None

Warnings and Precautions

There is a potential for venous and arterial thrombotic and thromboembolic events in patients who receive GIAPREZA. Use concurrent venous thromboembolism (VTE) prophylaxis.

Adverse Reactions

The most common adverse reactions that were reported in greater than 10% of GIAPREZA-treated patients were thromboembolic events.

Drug Interactions

Angiotensin converting enzyme (ACE) inhibitors may increase response to GIAPREZA. Angiotensin II receptor blockers (ARB) may reduce response to GIAPREZA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional information, please see [Full Prescribing Information](#).

About LJPC-0118

LJPC-0118 is La Jolla's investigational product for the treatment of severe malaria. The active pharmaceutical ingredient in LJPC-0118 was demonstrated to be superior to quinine in reducing mortality in patients with severe falciparum malaria infection in two randomized, controlled, clinical studies. La Jolla plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019 for LJPC-0118. 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 (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.

About LJPC-401

LJPC-401, a clinical-stage investigational product, is La Jolla's 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. La Jolla is 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), myelodysplastic syndrome (MDS) and polycythemia vera. The European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has designated LJPC-401 as an orphan medicinal product for the treatment of beta thalassemia intermedia and major and SCD.

About La Jolla Pharmaceutical Company

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 indicated to increase blood pressure in adults with septic or other distributive shock. LJPC-0118 is La Jolla's investigational product for the treatment of severe malaria. 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, myelodysplastic syndrome and polycythemia vera. For more information, please visit www.ljpc.com.

Forward-looking Statements

This press release contains forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements related to La Jolla's expectations regarding net sales and net cash used in operating activities for the full-year 2019, the expectations regarding future clinical and regulatory milestones, such as NDA submission and expected timing for commencement and completion of clinical studies. These statements relate to expectations regarding future events or La Jolla's future results of operations. These statements are only predictions or statements of current expectations and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those anticipated by the forward-looking statements. La Jolla cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they were made. Certain of these risks, uncertainties and other factors are described in greater detail in La Jolla's filings with the U.S. Securities and Exchange Commission (SEC), all of which are available free of charge on the SEC's website at www.sec.gov. These risks include, but are not limited to, risks relating to: our ability to successfully commercialize, market and achieve market acceptance of GIAPREZA; our ability to grow net sales of GIAPREZA; potential market sizes, including for septic or other distributive shock; the timing and prospects for approval of GIAPREZA by the European Medicines Agency (EMA) or other regulatory authorities; the scope of product label(s) and potential market sizes, as well as the broader commercial opportunity for GIAPREZA and our product candidates; the impact of pharmaceutical industry regulation and healthcare legislation in the United States; the success of development activities for LJPC-401, LJPC-0118 and other product candidates; potential indications for which La Jolla's product candidates may be developed; the timing, costs, conduct and outcome of clinical studies; risks relating to the development of drug candidates; the anticipated treatment of future clinical data by the U.S. Food and Drug Administration (FDA), EMA and other regulatory authorities, including whether such data will be sufficient for

approval; the expected duration over which La Jolla's cash balances will fund its operations; and other risks and uncertainties identified in our filings with the SEC. Forward-looking statements are presented as of the date of this press release, and La Jolla expressly disclaims any intent to update any forward-looking statements to reflect the outcome of subsequent events.

LA JOLLA PHARMACEUTICAL COMPANY

Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenue				
Net product sales	\$ 4,184	\$ —	\$ 10,056	\$ —
Total revenue	4,184	—	10,056	—
Operating expenses				
Cost of product sales	1,200	—	1,643	—
Research and development	27,567	26,909	117,302	84,575
Selling, general and administrative	18,843	11,937	85,162	30,852
Total operating expenses	47,610	38,846	204,107	115,427
Loss from operations	(43,426)	(38,846)	(194,051)	(115,427)
Other (expense) income				
Interest expense	(2,722)	—	(7,303)	—
Interest income	730	300	1,885	624
Total other (expense) income, net	(1,992)	300	(5,418)	624
Net loss	\$ (45,418)	\$ (38,546)	\$ (199,469)	\$ (114,803)
Net loss per share, basic and diluted	\$ (1.73)	\$ (1.74)	\$ (7.85)	\$ (5.41)
Weighted-average common shares outstanding, basic and diluted	26,242	22,151	25,422	21,215

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 172,604	\$ 90,915
Accounts receivable, net	1,381	—
Inventory, net	2,020	—
Prepaid expenses and other current assets	5,111	3,147
Total current assets	181,116	94,062
Property and equipment, net	22,267	24,568
Restricted cash	909	909
Total assets	\$ 204,292	\$ 119,539
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,572	\$ 11,484
Accrued expenses	12,988	703
Accrued payroll and related expenses	7,509	4,995
Deferred rent, current portion	1,370	1,370
Total current liabilities	30,439	18,552
Deferred rent, less current portion	13,609	12,785
Deferred royalty obligation, net	124,323	—
Total liabilities	168,371	31,337
Commitments and contingencies		
Shareholders' equity:		
Common Stock, \$0.0001 par value; 100,000,000 shares authorized, 26,259,254 and 22,167,529 shares issued and outstanding at December 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 December 31, 2018 and December 31, 2017, and a liquidation preference of \$3,906 at December 31, 2018 and 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 December 31, 2018 and December 31, 2017, and a liquidation preference of \$2,737 at December 31, 2018 and 2017	2,737	2,737
Additional paid-in capital	950,258	803,071
Accumulated deficit	(920,983)	(721,514)
Total shareholders' equity	35,921	88,202
Total liabilities and shareholders' equity	\$ 204,292	\$ 119,539

Company Contacts

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