

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): January 7, 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 January 7, 2019, La Jolla Pharmaceutical Company, issued a press release highlighting recent corporate progress, key objectives and preliminary unaudited financial results. 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.

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press release, dated January 7, 2019</a>

\* \* \*

**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: January 7, 2019

La Jolla Pharmaceutical Company

By: /s/ Dennis M. Mulroy

Name: Dennis M. Mulroy

Title Chief Financial Officer



## La Jolla Pharmaceutical Company Highlights Recent Corporate Progress and Key Objectives

*- Fourth-Quarter 2018 Net Sales of GIAPREZA Were Approximately \$4.2 Million, Up 20% from the Third Quarter of 2018 -*

*- Full-Year 2019 Net Sales Guidance for GIAPREZA of \$24 Million to \$28 Million -*

*- Decision on GIAPREZA MAA by EMA Expected in June of 2019 -*

*- NDA Planned for New Investigational Product, LJPC-0118, for the Treatment of Severe Malaria, in Fourth Quarter of 2019 -*

*- Topline Results of Phase 2 Study of LJPC-401 in Patients with Hereditary Hemochromatosis Expected in Second Half of 2019 -*

*- Topline Results of Pivotal Study of LJPC-401 in Patients with Beta Thalassemia Expected in Mid-2020 -*

SAN DIEGO, CA - January 7, 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 highlighted recent corporate progress and key objectives.

### Recent Corporate Progress and Key Objectives

#### *GIAPREZA™ (angiotensin II)*

- **Fourth-Quarter 2018 Net Sales:** Fourth-quarter 2018 net sales were approximately \$4.2 million, up 20% from the third quarter of 2018.
- **2018 Net Sales:** 2018 net sales were approximately \$10.1 million. GIAPREZA was launched in March 2018.
- **Full-Year 2019 Net Sales Guidance:** La Jolla expects full-year 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.
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- **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).

As of December 31, 2018, La Jolla had approximately \$172 million in cash and cash equivalents and no debt. In 2019, La Jolla expects that its net cash used in operating activities will be \$89 million to \$94 million.

“We are excited to have launched GIAPREZA, our first commercial product, in 2018. We believe that GIAPREZA has the potential to help many patients suffering from septic or other distributive shock, and we have 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 announce a planned NDA submission for LJPC-0118, our new investigational product for the treatment of severe malaria, in the fourth quarter of 2019.”

#### **About GIAPREZA**

In December 2017, GIAPREZA™ (angiotensin II) was approved by the U.S. Food and Drug Administration (FDA) as a vasoconstrictor 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](http://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](http://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

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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. Heparidin, 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) and myelodysplastic syndrome (MDS). 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 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 and myelodysplastic syndrome. For more information, please visit [www.ljpc.com](http://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 expectation for 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, preliminary results subject to audit by their independent registered public accounting firm, 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](http://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 future development activities; 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.

**Company Contacts**

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*and*

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