

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): November 23, 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))

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

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

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.

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**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On November 23, 2019, George Tidmarsh, M.D., Ph.D. resigned as the President and Chief Executive Officer of La Jolla Pharmaceutical Company (the “Company”) and as a member of the Company’s Board of Directors (the “Board”). Also, on November 23, 2019, Jennifer Carver resigned as the Company’s Chief Operating Officer.

Dr. Tidmarsh had served as the Company’s “*principal executive officer*,” as such term is defined under the Securities Exchange Act of 1934, as amended. Following Dr. Tidmarsh’s resignation, Dennis Mulroy, the Company’s Chief Financial Officer, was appointed to serve as the Company’s “*principal executive officer*,” pending further action from the Board.

**Item 8.01. Other Events.**

On November 25, 2019, the Company issued a press release regarding its intent to reassess continued development of LJPC-401 (synthetic human hepcidin) based on recent mixed clinical results. A copy of this press release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release dated November 25, 2019</a>

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**SIGNATURE**

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: November 29, 2019

**La Jolla Pharmaceutical Company**

By: /s/ Dennis M. Mulroy

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Dennis M. Mulroy

Chief Financial Officer



## La Jolla to Reassess Continued Development of LJPC-401 Based on Recent Clinical Results

SAN DIEGO, CA - November 25, 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 that it will reassess continued development of LJPC-401 (synthetic human hepcidin) based on recent mixed clinical results.

The Company plans to discontinue Study LJ401-BT01 due to lack of efficacy. Study LJ401-BT01 is a pivotal, multinational, multicenter, randomized, controlled study with a target enrollment of approximately 100 patients that is designed to evaluate the safety and efficacy of LJPC-401 as a treatment for iron overload in beta thalassemia (BT) patients who, despite chelation therapy, have cardiac iron levels above normal. The primary endpoint of this study is the change in cardiac iron levels, as measured by cardiac T2\* magnetic resonance imaging (MRI), from baseline to 6 months following treatment. The Company recently conducted an interim analysis that included approximately one-half of the target-enrolled patients. There were no significant differences in the primary endpoint or key secondary endpoints between patients on the treatment arm and patients on the control arm.

Topline results of Study LJ401-HH01 are also now available. Study LJ401-HH01 is a multinational, multicenter, randomized, placebo-controlled, double-blind, Phase 2 study with a target enrollment of approximately 60 patients that is designed to evaluate the safety and efficacy of LJPC-401 as a treatment for patients with hereditary hemochromatosis (HH). Topline results from this study are consistent with the interim results reported in June 2019. The change in TSAT from baseline to the end of treatment (16 weeks), the primary efficacy endpoint of the study, was statistically significant: LJPC-401-treated patients had a mean reduction in TSAT of 33% compared to placebo-treated patients who had a mean reduction of 3% ( $p < 0.0001$ ). The requirement for and frequency of phlebotomy procedures, a key secondary endpoint of the study, was statistically significant: LJPC-401-treated patients had 0.10 phlebotomies per month compared to placebo-treated patients who had 0.50 phlebotomies per month ( $p < 0.0001$ ). 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.

The Company expects to re-evaluate its current operating plan in light of the mixed results of these studies and to make adjustments as appropriate to manage the Company's available cash resources. The Company's near-term focus is to: (1) maximize sales of GIAPREZA™ (angiotensin II) as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock in the U.S., where it was launched by La Jolla in the first quarter of 2018; (2) maximize the value of GIAPREZA 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 in Europe, where it was approved by the European Commission in August 2019; and (3) seek U.S. Food and Drug Administration (FDA) approval of LJPC-0118 (artesunate) for the treatment of severe malaria, for which the Company recently submitted a New Drug Application.

### About LJPC-401

LJPC-401 (synthetic human hepcidin) is La Jolla's investigational product for the potential treatment of conditions characterized by iron overload. 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 has been 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.

### 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. 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 (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 (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. 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. We caution investors that forward-looking statements are based on management's expectations and assumptions as of the date of this press release 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, European Medicines Agency 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 press release 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.

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## **Company Contacts**

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