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

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# FORM 8-K

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

**Date of report (Date of earliest event reported): August 1, 2019**

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# LA JOLLA PHARMACEUTICAL COMPANY

(Exact name of registrant as specified in its charter)

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| **California** | **1-36282** | **33-0361285** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (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.)

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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. ☐

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 |

**Item 2.02 Results of Operations and Financial Condition.**

On August 1, 2019, La Jolla Pharmaceutical Company issued a press release announcing its financial results for the three and six months ended June 30, 2019. 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 August 1, 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.

La Jolla Pharmaceutical Company

Date: August 7, 2019

By: /s/ Dennis Mulroy

Name: Dennis Mulroy

Title Chief Financial Officer

**Exhibit 99.1**

# La Jolla Pharmaceutical Company Announces Financial Results for the Three and Six Months Ended June 30, 2019 and Highlights Recent Corporate Progress

**SAN DIEGO, CA - August 1, 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 six months ended June 30, 2019 and highlighted recent corporate progress.

**Recent Corporate Progress**

***GIAPREZA™ (angiotensin II)***

- **Net Sales:** For the three months ended June 30, 2019, GIAPREZA net sales were $5.7 million, up 258% from the same period in 2018, and up 30% from the three months ended March 31, 2019. For the six months ended June 30, 2019, GIAPREZA net sales were $10.1 million, up 320% from the same period in 2018.

- **Positive CHMP Opinion:** In June 2019, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for La Jolla's Marketing Authorisation Application (MAA) for GIAPREZA for the treatment of refractory hypotension in adults with septic or other distributive shock. The CHMP's positive opinion was sent to the European Commission (EC), which has the authority to approve medicines for the 28 European Union member countries. Approval would also be recognized in Iceland, Norway and Liechtenstein. We expect a final approval decision on the GIAPREZA MAA by the EC in the third quarter of 2019.

***Investigational Products***

- **Breakthrough Therapy Designation and Orphan Drug Designation Received from the FDA for LJPC-0118 (artesunate):** The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation and Orphan Drug designation for LJPC-0118 for the treatment of malaria in April 2019 and July 2019, respectively. 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. We plan to file a New Drug Application (NDA) for LJPC-0118 with the FDA in the fourth quarter of 2019.

- **Positive Results Announced from Pre-Specified Interim Analysis of Phase 2 Study of LJPC-401 in Patients with Hereditary Hemochromatosis:** In June 2019, we announced positive results from the pre-specified interim analysis of our Phase 2 study of LJPC-401 (synthetic human hepcidin) in patients with hereditary hemochromatosis (HH). The interim analysis of efficacy included 26 patients who had reached the end of the 16-week treatment period, and the interim analysis of safety included 60 randomized patients. Treatment with LJPC-401 resulted in a statistically significant reduction in transferrin saturation (TSAT) from baseline to the end of treatment (16 weeks), the primary efficacy endpoint of the study: 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, a key secondary endpoint of the study, also 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). 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.

"We are pleased with the progress made in the first half of 2019, which included the achievement of significant milestones for each of GIAPREZA, LJPC-0118 and LJPC-401," said George Tidmarsh, M.D., Ph.D., La Jolla's President and Chief Executive Officer. "In the second half of 2019, we look forward to continued growth in GIAPREZA net sales, the final approval decision

on the GIAPREZA MAA by the EC, our filing of an NDA for LJPC-0118 with the FDA and top-line results of our Phase 2 study of LJPC-401 in patients with HH."

**Financial Results**

For the three and six months ended June 30, 2019, GIAPREZA net sales were $5.7 million and $10.1 million, respectively, compared to $1.6 million and $2.4 million, respectively, for the same periods in 2018. La Jolla's net loss for the three and six months ended June 30, 2019 was $30.4 million and $62.1 million, or $1.12 per share and $2.29 per share, respectively, compared to $52.8 million and $103.3 million, or $2.02 per share and $4.22 per share, respectively, for the same periods in 2018. La Jolla continues to expect full-year 2019 GIAPREZA net sales of $24 million to $28 million.

As of June 30, 2019, La Jolla had $123.4 million in cash, compared to $172.6 million as of December 31, 2018. Net cash used in operating activities for the three and six months ended June 30, 2019 was $16.5 million and $49.2 million, respectively, compared to $37.5 million and $83.4 million, respectively, for the same periods in 2018. La Jolla has no debt. La Jolla continues to expect that its net cash used in operating activities in 2019 will be $89 million to $94 million.

**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 for the United States.**

**About LJPC-0118**

LJPC-0118 is La Jolla's 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. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation and Orphan Drug designation for LJPC-0118 for the treatment of malaria in April 2019 and July 2019, respectively. La Jolla plans to file a New Drug Application (NDA) for LJPC-0118 with the FDA in the fourth quarter of 2019 for the treatment of severe malaria. 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 (BT), 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 (artesunate) 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. 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 forward-looking statements include, but are not limited 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 Commission 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; the designation status of our product candidates at the time of U.S. Food and Drug Administration (FDA) approval, if approved; the consistency between the full data set, top-line data and interim results from the LJ401-HH01 study; potential indications for which La Jolla's product candidates may be developed; the timing, costs, conduct and outcome of clinical studies; the anticipated timing for regulatory filings and regulatory actions; the anticipated treatment of future clinical data by the FDA, the European Medicines Agency (EMA) and other regulatory authorities, including whether such data will be sufficient for approval; expectations regarding net sales and net cash used in operating activities for the full-year 2019; and the expected duration over which La Jolla's cash balances will fund its operations. Such forward-looking statements involve 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**

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| **Revenue** | | | | |
| Net product sales | $ 5,703 | $ 1,593 | $ 10,098 | $ 2,402 |
| Total revenue | 5,703 | 1,593 | 10,098 | 2,402 |
| **Operating expenses** | | | | |
| Cost of product sales | 551 | 129 | 1,051 | 187 |
| Research and development | 22,043 | 30,867 | 43,287 | 59,296 |
| Selling, general and administrative | 11,323 | 22,164 | 23,643 | 45,180 |
| Total operating expenses | 33,917 | 53,160 | 67,981 | 104,663 |
| Loss from operations | (28,214) | (51,567) | (57,883) | (102,261) |
| **Other (expense) income** | | | | |
| Interest expense | (2,806) | (1,654) | (5,535) | (1,654) |
| Interest income | 604 | 443 | 1,317 | 609 |
| Total other expense, net | (2,202) | (1,211) | (4,218) | (1,045) |
| **Net loss** | **$ (30,416)** | **$ (52,778)** | **$ (62,101)** | **$ (103,306)** |
| **Net loss per share, basic and diluted** | **$ (1.12)** | **$ (2.02)** | **$ (2.29)** | **$ (4.22)** |
| Weighted-average common shares outstanding, basic and diluted | 27,108 | 26,182 | 27,071 | 24,462 |

**LA JOLLA PHARMACEUTICAL COMPANY**

**Condensed Consolidated Balance Sheets**
**(in thousands, except par value and share amounts)**

| | June 30, 2019 | December 31, 2018 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash | $ 123,446 | $ 172,604 |
| Accounts receivable, net | 1,893 | 1,381 |
| Inventory, net | 1,968 | 2,020 |
| Prepaid expenses and other current assets | 5,089 | 5,111 |
| Total current assets | 132,396 | 181,116 |
| Property and equipment, net | 20,430 | 22,267 |
| Right-of-use lease asset | 16,159 | — |
| Restricted cash | 909 | 909 |
| **Total assets** | **$ 169,894** | **$ 204,292** |
| | | |
| **LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,908 | $ 8,572 |
| Accrued expenses | 10,347 | 8,485 |
| Accrued payroll and related expenses | 4,080 | 7,509 |
| Lease liability, current portion | 2,646 | — |
| Deferred rent, current portion | — | 1,370 |
| Total current liabilities | 21,981 | 25,936 |
| Lease liability, less current portion | 27,890 | — |
| Deferred rent, less current portion | — | 13,609 |
| Deferred royalty obligation, net | 124,351 | 124,323 |
| Other noncurrent liabilities | 8,265 | 4,503 |
| **Total liabilities** | **182,487** | **168,371** |
| Shareholders' (deficit) equity: | | |
| Common Stock, $0.0001 par value; 100,000,000 shares authorized, 27,125,215 and 26,259,254 shares issued and outstanding at June 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 June 30, 2019 and December 31, 2018; and liquidation preference of $3,906 at June 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 June 30, 2019 and December 31, 2018, respectively; and liquidation preference of $0 and $2,737 at June 30, 2019 and December 31, 2018, respectively | — | 2,737 |
| Additional paid-in capital | 966,422 | 950,258 |
| Accumulated deficit | (982,924) | (920,983) |
| **Total shareholders' (deficit) equity** | **(12,593)** | **35,921** |
| **Total liabilities and shareholders' (deficit) equity** | **$ 169,894** | **$ 204,292** |

**Company Contacts**

Sandra Vedrick
*Senior Director, Investor Relations & Human Resources*
La Jolla Pharmaceutical Company
Phone: (858) 207-4264 Ext: 1135
Email: svedrick@ljpc.com

*and*

Dennis Mulroy
*Chief Financial Officer*
La Jolla Pharmaceutical Company
Phone: (858) 207-4264 Ext: 1040
Email: dmulroy@ljpc.com