LA JOLLA PHARMACEUTICAL CO

FORM 8-K
(Current report filing)

Filed 12/29/17 for the Period Ending 12/22/17

Address 4550 TOWNE CENTRE COURT
          SAN DIEGO, CA, 92121
Telephone 858-207-4264
CIK 0000920465
Symbol LJPC
SIC Code 2836 - Biological Products, (No Diagnostic Substances)
Industry Biotechnology & Medical Research
Sector Healthcare
Fiscal Year 12/31
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): December 22, 2017

LA JOLLA PHARMACEUTICAL COMPANY
(Exact name of registrant as specified in its charter)

California

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)

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

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))

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 8.01 OTHER EVENTS.

On December 22, 2017, La Jolla Pharmaceutical Company made available on its website a copy of an investor presentation regarding the U.S. Food and Drug Administration (FDA) approval of Giapreza™ (angiotensin II). A copy of this presentation is filed herewith as Exhibit 99.1.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits. The following exhibits are furnished with this report on Form 8-K:

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>99.1</td>
<td>Investor Presentation dated December 2017</td>
</tr>
</tbody>
</table>
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

/s/ Dennis M. Mulroy
Dennis M. Mulroy
Chief Financial Officer
These slides contain forward-looking statements as that term is defined in 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 www.sec.gov. These risks include, but are not limited to, risks relating to: the timing for commercial launch of GIAPREZA (angiotensin II); the degree of physician or pharmacy and therapeutics committee adoption of GIAPREZA and La Jolla’s success in commercializing GIAPREZA; the timing and availability of GIAPREZA in the market; the anticipated treatment of future clinical data by the FDA, the EMA or other regulatory authorities, including whether such data will be sufficient for approval of GIAPREZA in the EMA and for approval of other product candidates by either the FDA or EMA; risks relating to the scope of the GIAPREZA product label; potential market sizes, including for septic or other distributive shock; potential indications for which La Jolla’s products and product candidates may be developed; the anticipated timing for regulatory actions; the timing, costs, conduct and outcome of clinical studies; the impact of pharmaceutical industry regulation and healthcare legislation in the United States; and the success of future development activities. La Jolla expressly disclaims any intent to update any forward-looking statements to reflect the outcome of subsequent events.
GIAPREZA™ Now Approved

GIAPREZA (angiotensin II) Injection for Intravenous Infusion is indicated to increase blood pressure in adults with septic or other distributive shock.

“We appreciate FDA’s rapid review and approval of GIAPREZA and are especially grateful to the patients, families and dedicated critical care teams who made the development of GIAPREZA possible,” said George F. Tidmarsh, M.D., Ph.D., President and Chief Executive Officer of La Jolla. “We look forward to bringing this new treatment option to the many critically ill patients suffering from septic or other distributive shock.”

GIAPREZA is classified as a new chemical entity exclusivity (NCE) with 5 years of market exclusivity.
La Jolla is dedicated to improving the lives of patients suffering from life-threatening diseases by discovering and developing innovative therapies.
Shock: Deadly, Costly and Prevalent

- A well-characterized syndrome
  - Occurs when the organs and tissue of the body do not receive an adequate flow of blood (oxygen) due to a lack of blood pressure (hypotension)

- Deadly
  - Mortality rate exceeds that of most acute conditions requiring hospitalization
  - Can kill old and young alike within hours

- Costly
  - Estimated costs are 2-3 times greater compared to other conditions

- Prevalent
  - Affects one-third of patients in the intensive care unit

Mortality Rates Compared

- ≥50% mortality in patients with shock in the ICU
- 30-day mortality rate
- 14% Shock
- 12% AMI
- 16% CHF
- 16% Pneumonia

Abbreviations: AMI=acute myocardial infarction; CHF=congestive heart failure.

Distributive Shock is the Most Common Type of Shock in the Inpatient Setting

Prevalence

- Cardiogenic: 16%
- Hypovolemic: 16%
- Obstructive: 2%
- Distributive: 66%
  (94% is Septic Shock)

Types of Shock

- Distributive Shock (Vasodilation)
- Hypovolemic Shock (Loss of plasma or intravascular volume)
- Cardiogenic Shock (Ventricular failure)
- Obstructive Shock (Pericardial tamponade)

Hypotension, or Abnormally Low Blood Pressure, is an Important Hemodynamic Marker for a Vasodilatory or Distributive Shock

Distributive Shock is Costly

Source: CMS FY14 Inpatient Public Use File (IPUF)

$87,282

$42,243

$31,453

$30,702

Severe Distributive Shock
AMI
CHF
Pneumonia

An average day in the ICU costs between $4,500 to $6,000

Mechanical ventilation adds ~$1,500

Hospitals are implementing multiple quality initiatives to improve patient care and maximize CMS reimbursements

Abbreviations: AMI=acute myocardial infarction; CHF=congestive heart failure.
GIAPREZA™
(angiotensin II)
Injection for Intravenous Infusion

THERAPIES AND MECHANISMS

GIAPREZA™
(angiotensin II)
Injection for Intravenous Infusion

- RENIN ANGIOTENSIN-ALDOSTERONE
- CATECHOLAMINES¹: SYMPATHETIC NERVOUS
- VASOPRESSIN: ARGININE-VASOPRESSIN

¹ Catecholamines include: norepinephrine, epinephrine, dopamine, phenylephrine, ephedrine
GIAPREZA: A Novel Vasopressor For Patients with Distributive Shock

A Unique Mechanism of Action - First and only synthetic human angiotensin II

Robust Response - 70% Patients achieved and maintained target MAP primary endpoint at hour 3

Rapid Response - Median response time to reach target MAP was 5 minutes

Mortality trend – Mortality through Day 28 was 46% on GIAPREZA and 54% on placebo (hazard ratio 0.78; 95% confidence interval 0.57 – 1.07)

Sustained Response – Maintained throughout the treatment period

Safety – Percent of patients with AEs were similar between the two treatment arms

- There is a potential for venous and arterial thromboembolic events (AEs 12.9% v 5.1%, DVT SAEs 1.8% v 0%)
- May be prevented by use of concurrent venous thromboembolism prophylaxis

Abbreviations: MAP=Mean Arterial Pressure; AEs=Adverse Events; SAEs=Serious Adverse Events; DVT=Deep Vein Thrombosis
Distributive Shock is Prevalent


2. SHU Integrated Pack Units from Aug 2017 – Jul 2017 3.01M, Filtered for hospitals, applying an estimated 10% stocking adjustment, inpatient percentage and average vials/patient based on Premier data inpatient Vasostrict patients projected to national numbers.
Preparing For Commercialization in 2018

Commercial
- Market Research
- Healthcare Professional Marketing
- Multi-Channel Marketing
- Professional Education
- Commercial Insights & Operations
- Market Access

Field Sales
- National and Regional Sales Leadership*
- Critical Care Nurse Educators*
- Hospital Critical Care Field Representative*
- Market Access Team*
- Sales Training
- Field Trade

*136 Customer Facing FTEs

Medical Affairs
- Medical Science Liaisons*
- Medical Communications
- HEOR Team
- Medical Education
# Financial Position

## Condensed Balance Sheet Data

<table>
<thead>
<tr>
<th></th>
<th>As of September 30, 2017 (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cash</strong></td>
<td>$120.8</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>$10.3</td>
</tr>
<tr>
<td><strong>Total shareholders’ equity</strong></td>
<td>$119.8</td>
</tr>
</tbody>
</table>

**Cash resources expected to fund Company into second half of 2018**

## Fully Diluted, As-Converted Shares Outstanding

<table>
<thead>
<tr>
<th></th>
<th>34,017,102</th>
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</table>

1 Includes common stock, preferred stock (as-converted), and outstanding equity awards as of September 30, 2017
Thank You