LA JOLLA PHARMACEUTICAL CO
Form 8-K
May 13, 2015

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): May 7, 2015

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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.)

10182 Telesis Court, 6th Floor, San Diego, California 92121
(Address of Principal Executive Offices) (Zip Code)
Registrant's telephone number, including area code: (858) 207-4264

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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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01 OTHER EVENTS.

On May 7, 2015, La Jolla Pharmaceutical Company (the "Company" or "La Jolla") issued a press release announcing a reprioritization of its product development programs. As a result of this reprioritization of its product development programs, La Jolla will discontinue development of its polysaccharide-based galectin-3 inhibitors, GCS-100 and LJPC-1010. The reprioritization will allow La Jolla to reallocate resources to its other development candidates, including its lead product candidate LJPC-501, La Jolla's proprietary formulation of angiotensin II that is currently the subject of a Phase 3 registration clinical trial in patients suffering from catecholamine-resistant hypotension, LJPC-401, La Jolla's novel formulation of hepcidin for the potential treatment of conditions characterized by iron overload, and LJPC-30Sa and LJPC-30Sb, La Jolla's recently announced next-generation gentamicin derivative product candidates for the potential treatment of serious bacterial infections and rare genetic disorders.

The portfolio reprioritization is the result of both the addition of the next-generation gentamicin derivative program and a recent interaction with the U.S. Food and Drug Administration (the "FDA") regarding La Jolla's galectin-3 inhibitor program. In this interaction, the FDA indicated that the Company would be required to conduct additional chemical characterization of GCS-100 prior to further clinical development. GCS-100 and LJPC-1010 are complex polysaccharide mixtures that cannot be readily chemically characterized using conventional analytical methods, and the Company believes that the timeframe and ultimate success of developing analytical methods that would satisfy the FDA's requirements are highly uncertain. There were no issues raised by the FDA related to patient safety or preclinical toxicology.

The Company will continue to treat and follow patients already enrolled in its Phase 2b study in diabetic patients with advanced chronic kidney disease, but will stop enrolling new patients. The Company will not proceed with a Phase 1 study of LJPC-1010 as previously planned. La Jolla will instead explore out-licensing opportunities for these product candidates.

On May 7, 2015, the Company also issued a press release announcing that it has entered into an exclusive option agreement to acquire the Indiana University Research and Technology Center's ("IURTC") intellectual property rights covering next-generation gentamicin derivatives. Gentamicin has become one of the most commonly prescribed hospital antibiotics, despite causing kidney toxicity. Gentamicin consists of a mixture of distinct but closely related chemical entities that may contribute differentially to the product's toxicity profile. IURTC's technology covers the use of next-generation, parenteral gentamicin derivatives as antimicrobial agents with the potential for reduced toxicity.

La Jolla also entered into a second option agreement with IURTC and the University of Alabama at Birmingham ("UAB") for the use of these next-generation compounds for the treatment of certain rare genetic diseases, such as cystic fibrosis and Duchenne muscular dystrophy. Gentamicin's ability to induce a lack of fidelity in gene transcription, intrinsic to its antimicrobial mechanism of action, can be leveraged in the correction of certain human genetic mutations that lead to rare genetic disorders. In spite of favorable short-term clinical proof-of-efficacy data in cystic fibrosis, development of gentamicin as a chronic treatment for these genetic diseases has been limited by its toxicity profile.

La Jolla has initially selected two lead development candidates from the technology, LJPC-30Sa and LJPC-30Sb, which are purified components of the currently marketed gentamicin product. LJPC-30Sa and LJPC-30Sb retain the biologic activity of gentamicin, yet appear to lack the traditional kidney toxicity associated with it. La Jolla plans to pursue a dual development strategy in serious bacterial infections and rare genetic disorders characterized by stop codon mutations, such as cystic fibrosis and Duchenne muscular dystrophy. Following a pre-Investigational New Drug application ("IND") meeting with the FDA, La Jolla has received guidance that it may proceed with its proposed Phase 1 clinical trial following the submission of an IND.

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: May 13, 2015

/s/ George F. Tidmarsh
George F. Tidmarsh, M.D., Ph.D.
President, Chief Executive Officer and Secretary