LA JOLLA PHARMACEUTICAL CO
Form 424B2
September 09, 2015
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The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus do not constitute an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED SEPTEMBER 9, 2015

PROSPECTUS SUPPLEMENT

(To Prospectus dated July 11, 2014)

Shares

Common Stock

We are offering shares of our common stock, $0.0001 par value per share. Our common stock is currently listed on The NASDAQ Capital Market under the symbol LJPC. On September 8, 2015, the last reported sale price of our common stock was $43.90 per share.

Investing in our common stock involves a high degree of risk. Please read Risk Factors beginning on page S-5 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public Offering Price	$	$

Underwriting Discounts and Commissions [(1)]	$	$
Proceeds to La Jolla Pharmaceutical Company, Before Expenses	$	$

(1) We refer you to Underwriting beginning on page S-20 for additional information regarding underwriter compensation.

Delivery of the shares of common stock is expected to be made on or about , 2015. We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $ and the total proceeds to us, before expenses, will be $.

Book-Running Manager

Jefferies

Prospectus Supplement dated , 2015.

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You should rely only on the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of the accompanying prospectus entitled Where You Can Find More Information and Incorporation of Certain Information by Reference.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus each form a part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. This prospectus supplement provides you with specific information about this offering. The accompanying prospectus, including the documents incorporated by reference therein, provides more general information, some of which may not apply to this offering. Generally, when we refer only to the prospectus, we are referring to both parts combined. This prospectus supplement may add, update or change information contained in the accompanying prospectus and the documents incorporated by reference therein. To the extent that any statement we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference herein or therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference herein and therein.

In this prospectus supplement, La Jolla, the Company, we, us, and our and similar terms refer to La Jolla Pharmaceutical Company. References to our common stock refer to the common stock of La Jolla Pharmaceutical Company.

All references in this prospectus supplement to our financial statements include, unless the context indicates otherwise, the related notes.

The industry and market data and other statistical information contained in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference are based on management s own estimates, independent publications, government publications, reports by market research firms or other published independent sources, and, in each case, are believed by management to be reasonable estimates. Although we believe these sources are reliable, we have not independently verified the information.

CAUTIONARY STATEMENT ABOUT FORWARD-LOOKING INFORMATION

This prospectus supplement, the accompanying prospectus, and the documents incorporated by reference therein contain forward-looking statements within the meaning of the federal securities laws. You can identify forward-looking statements by the use of the words believe, expect, anticipate, intend, estimate, project, wil may, plan, intend, assume and other expressions (including their use in the negative) that predict or indicate future events and trends, including our future financial performance, and that do not relate to historical matters.

Such statements include, but are not limited to, statements about: our ability to successfully develop LJPC-501, LJPC-401, LJPC 30s and our other product candidates (collectively our product candidates); the future success of our clinical trials with our product candidates; the timing for the commencement and completion of clinical trials; and our ability to obtain orphan status, break-through status, other regulatory designations or additional patent protection with respect to any of our product candidates. Forward-looking statements are neither historical facts nor assurances of future performance.

These statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others:

- the risk that our clinical trials with our product candidates may not be successful in evaluating their safety and tolerability or providing preliminary evidence of efficacy;

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- the successful and timely completion of clinical trials;
- our plans and timing with respect to seeking regulatory approvals and uncertainties regarding the regulatory process;
- the availability of funds and resources to pursue our research and development projects, including our clinical trials with our product candidates;
- general economic conditions;
- uncertainties associated with obtaining and enforcing patents;
- the potential commercialization of any of our drug candidates that receive regulatory approval;
- our estimates for future performance; and
- our estimates regarding our capital requirements and our needs for, and ability to obtain, additional financing.

In addition, the factors described under the section captioned Risk Factors in this prospectus, as may be updated from time to time by our future filings under the Securities Exchange Act of 1934, and elsewhere in the documents incorporated by reference in this prospectus, may result in these differences. You should carefully review all of these factors.

We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements. The forward-looking statements were based on information, plans and estimates at the date of this prospectus supplement, the accompanying prospectus or the documents incorporated by reference therein, as applicable, and we assume no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

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PROSPECTUS SUMMARY

The following summary of our business highlights certain of the information contained elsewhere in or incorporated by reference into this prospectus supplement and the accompanying prospectus. Because this is only a summary, however, it does not contain all of the information that may be important to you. You should carefully read this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference, which are described under Where You Can Find More Information and Information Incorporated By Reference in the accompanying prospectus. You should also carefully consider the matters discussed in the section in this prospectus supplement titled Risk Factors and in the accompanying prospectus and in other periodic reports incorporated herein by reference.

Our 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. We have several product candidates in development. LJPC-501 is our proprietary formulation of angiotensin II for the potential treatment of catecholamine-resistant hypotension. LJPC-401 is our novel formulation of hepcidin for the potential treatment of conditions characterized by iron overload, such as hereditary hemochromatosis and beta thalassemia. LJPC-30Sa and LJPC-30Sb are our next-generation gentamicin derivatives for the potential treatment of serious bacterial infections and rare genetic disorders, such as cystic fibrosis and Duchenne muscular dystrophy.

Our common stock is currently listed on The NASDAQ Capital Market under the symbol LJPC.

Program Overview

LJPC-501

Catecholamine-Resistant Hypotension

LJPC-501, our lead product candidate, is our proprietary formulation of angiotensin II. Angiotensin II, the major bioactive component of the renin-angiotensin system, serves as one of the body s central regulators of blood pressure. We are developing LJPC-501 for the treatment of catecholamine-resistant hypotension, or CRH, which is an acute, life-threatening condition in which blood pressure drops to dangerously low levels in patients who respond poorly to current treatments. Angiotensin II has been shown to raise blood pressure in a randomized, placebo-controlled clinical trial in CRH, which was recently published in the journal Critical Care, as well as in animal models of hypotension. Preclinical pharmacology studies that we have conducted have demonstrated that catecholamine resistance may be in part a result of reduced endogenous production of angiotensin II. In October 2014, we presented positive data from a preclinical study of LJPC-501 for the treatment of CRH.

We initiated a Phase 3 clinical trial with LJPC-501 for the treatment of CRH, called the ATHOS (Angiotensin II for the Treatment of High-Output Shock) 3 trial, in March 2015. In February 2015, we reached agreement with the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment, or SPA, for this multicenter, randomized, double-blind, placebo-controlled, Phase 3 clinical trial. In accordance with the SPA, the primary efficacy endpoint for the ATHOS 3 registration trial is increase in blood pressure at three hours. The ATHOS 3 trial is designed to enroll approximately 315 patients. Patients are to be randomized in a 1:1 fashion to receive either: (i) LJPC-501 plus standard-of-care vasopressors; or (ii) placebo plus standard-of-care vasopressors. Randomized patients are to receive their assigned treatment via continuous IV infusion for up to seven days. The primary efficacy endpoint in the study is

to compare the change in mean arterial pressure in patients with CRH who receive an IV infusion of LJPC-501 plus standard-of-care vasopressors to those that receive placebo plus standard-of-care vasopressors. Secondary endpoints include comparison of changes in Cardiovascular Sequential Organ Failure Assessment scores, and the safety and tolerability of LJPC-501 in patients with CRH. Results from ATHOS 3 are expected by the end of 2016.

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Hepatorenal Syndrome

We are also developing LJPC-501 for hepatorenal syndrome, or HRS. HRS is a life-threatening form of progressive renal failure in patients with liver cirrhosis or fulminant liver failure. In these patients, the diseased liver secretes vasodilator substances (e.g., nitric oxide and prostaglandins) into the bloodstream that cause under-filling of blood vessels. This low blood pressure state causes a reduction in blood flow to the kidneys. As a means to restore systemic blood pressure, the kidneys induce both sodium and water retention, which contribute to ascites, a major complication associated with HRS. Studies have shown that LJPC-501 may improve renal function in patients with conditions similar to HRS. We are currently enrolling patients in a Phase 1/2 clinical trial of LJPC-501 in HRS.

LJPC-401

LJPC-401 is our novel formulation of hepcidin. Hepcidin is a naturally occurring regulator of iron absorption and distribution. By regulating the absorption and distribution of iron, hepcidin prevents excessive iron accumulation in tissues, such as the liver and heart, where it can cause significant damage and even result in death.

We are developing LJPC-401 for the treatment of conditions characterized by iron overload, such as hereditary hemochromatosis and beta thalassemia. Hereditary hemochromatosis, or HH, is a disease characterized by a deficiency in hepcidin that results in excessive iron accumulation. HH is the most common genetic disease in Caucasians and causes liver cirrhosis, liver cancer, heart disease and/or failure, dementia and diabetes.

LJPC-401 has been shown to be effective in reducing serum iron in preclinical testing. We filed an Investigational New Drug Application, or IND, with the FDA and expect to release preliminary results from a Phase 1 study by the end of 2015.

LJPC-30Sa and LJPC-30Sb

LJPC-30Sa and LJPC-30Sb are our next-generation gentamicin derivatives. Despite kidney toxicity, gentamicin has become one of the most commonly prescribed hospital antibiotics due to its broad spectrum of antimicrobial efficacy. Gentamicin consists primarily of a mixture of four distinct but closely related chemical entities that may contribute differentially to the product s toxicity profile.

LJPC-30Sa and LJPC-30Sb are purified components of the currently marketed gentamicin product that retain the biologic activity of gentamicin, yet appear to lack the traditional kidney toxicity associated with it. We are developing LJPC-30Sa and LJPC-30Sb not only for the potential treatment of serious bacterial infections but also for the potential treatment of rare genetic disorders, such as cystic fibrosis and Duchenne muscular dystrophy.

We believe that gentamicin s ability to induce a lack of fidelity in gene transcription, intrinsic to its antimicrobial mechanism of action, can also be leveraged in the correction of certain human genetic mutations that lead to rare genetic disorders, such as cystic fibrosis and Duchenne muscular dystrophy. 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.

Following a pre-IND meeting with the FDA, we have received guidance that we may proceed with a proposed Phase 1 clinical trial following the submission of an IND.

Patents and Proprietary Technologies

We own two U.S. patent applications and two international applications covering methods of use for LJPC-501. Our license with the George Washington University provides rights in two U.S. applications and an international application directed to methods of using LJPC-501. These applications, if issued as patents, will have expiration dates from 2029 to 2035.

Our license from Inserm in France provides rights in a portfolio of patents and applications covering methods of use of LJPC-401. This portfolio includes one issued U.S. patent, two pending U.S. applications, issued

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patents in Canada, China, Europe, and Japan, and pending applications in Europe, China, and Japan. The issued U.S. patent will expire in May 2022.

We have licensed rights in one U.S. provisional patent application and one issued U.S. patent and one pending U.S. non-provisional patent application from Indiana University Research and Technology Corporation. The licensed rights cover methods of using LJPC-30Sa and LJPC-30Sb. The issued patent and any patents issuing from the pending U.S. non-provisional patent application will expire in 2027, if not extended, and any patents that may issue based on the provisional application are expected to expire no earlier than 2036.

In addition to the above, we plan to file additional patent applications that, if issued, would provide further protection for LJPC-501, LJPC-401 and LJPC-30S.

Recent Developments

In May 2015, we announced a reprioritization of our product development programs that resulted in the discontinuation of the development of our polysaccharide-based galectin-3 inhibitors, GCS-100 and LJPC-1010. This reprioritization has allowed us to reallocate resources to our other development candidates that are more in line with our strategic focus.

Corporate Information

Our executive offices are located at 10182 Telesis Court, 6th Floor, San Diego, California 92121 and our telephone number is (858) 207-4264. Additional information regarding our company, including our audited financial statements and descriptions of our business, is contained in the documents incorporated by reference in this prospectus. See Where You Can Find More Information on page 9 of the accompanying prospectus and Incorporation of Certain Information by Reference beginning on page 10 of the accompanying prospectus.

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THE OFFERING

Common Stock we are Offering	shares
Common Stock to be Outstanding after this Offering	shares
Option to Purchase Additional Shares	We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to additional shares.
Use of Proceeds	We intend to use the net proceeds of this offering for general corporate purposes, funding our ongoing and future clinical trials and for general and administrative expenses, and for potential future acquisitions and other strategic purposes. See Use of Proceeds on page S-18 of this prospectus supplement.
Risk Factors	See Risk Factors beginning on page S-5 of this prospectus supplement for a discussion of factors you should read and consider carefully before investing in our common stock.
NASDAQ Capital Market symbol	LJPC

If the underwriters option to purchase additional shares is exercised in full, we will issue and sell an additional shares of our common stock and will have shares outstanding after the offering.

The number of shares of common stock shown above to be outstanding after this offering is based on the 15,250,840 shares outstanding as of June 30, 2015 and excludes:

- 1,278,435 shares of our common stock subject to options outstanding as of June 30, 2015 having a weighted average exercise price of $14.76 per share;
- 171,089 shares of our common stock that have been reserved for issuance in connection with future grants under the La Jolla 2013 Equity Incentive as of June 30, 2015;
- 6,754,128 shares of our common stock that have been reserved for issuance upon the conversion of 3,917 shares of our Series C-1[2] Convertible Preferred Stock (the Series C-1[2] Preferred Stock) issued and outstanding as of June 30, 2015; and

- 782,032 shares of our common stock that have been reserved for issuance upon the conversion of 2,737 shares of our Series F Convertible Preferred Stock (the Series F Preferred Stock) issued and outstanding as of June 30, 2015.

During the six months ended June 30, 2015, a total of 60.762 shares of Series F Preferred Stock were converted into a total of 17,360 shares of common stock.

Except as otherwise noted, all information in this prospectus supplement assumes no exercise of the underwriters option to purchase additional shares.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below and discussed under the section captioned Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2014, which is incorporated by reference in the accompanying prospectus in its entirety, together with other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

This prospectus supplement, the accompanying prospectus and the incorporated documents also contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks mentioned below. Forward-looking statements included in this prospectus supplement are based on information available to us on the date hereof, and all forward-looking statements in documents incorporated by reference are based on information available to us as of the date of such documents. We disclaim any intent to update any forward-looking statements.

RISK FACTORS RELATING TO THE COMPANY AND THE INDUSTRY IN WHICH WE OPERATE

We have only limited assets and will need to raise additional capital before we can expect to become profitable.

As of June 30, 2015, we had no revenue sources, an accumulated deficit of $506.2 million and available cash and cash equivalents of approximately $36.0 million. To fund future operations to the point where we are able to generate positive cash flow from the sales or out-licensing of our drug candidates, we will need to raise significant additional capital. The amount and timing of future funding requirements will depend on many factors, including the timing and results of our ongoing development efforts, the potential expansion of our current development programs, potential new development programs and related general and administrative support, as well as the overall condition of capital markets, including capital markets for development-stage biopharmaceutical companies. We anticipate that we will seek to fund our operations through public and private equity and debt financings or other sources, such as potential collaboration agreements. We cannot assure you that anticipated additional financing will be available to us on favorable terms, or at all. Although we have previously been successful in obtaining financing through equity securities offerings, there can be no assurance that we will be able to do so in the future. If we are unable to raise additional capital to fund our clinical development and other business activities, we could be forced to abandon one or more programs and curtail or cease our operations.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and nonclinical and clinical development of our product candidates;

- obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;

- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;

- obtaining market acceptance of our product candidates as viable treatment options;

- addressing any competing technological and market developments;

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- identifying, assessing, acquiring or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

The technology underlying our compounds is uncertain and unproven.

The development efforts for LJPC-501, LJPC-401 and LJPC-30s are based on unproven technologies and therapeutic approaches that have not been widely tested or used. To date, no products that use the technology underlying these drug candidates have been approved or commercialized. Application of our technology to treat life-threatening diseases is in early stages. Preclinical studies and future clinical trials of these product candidates may be viewed as a test of our entire approach to developing therapies for patients suffering from life-threatening diseases. If our product candidates do not work as intended, or if the data from our future clinical trials indicate that our product candidates are not safe and effective, the applicability of our technology for successfully treating life-threatening diseases will be highly uncertain. As a result, there is a significant risk that our therapeutic approaches will not prove to be successful, and there can be no guarantee that our drug technologies will result in any commercially successful products.

Results from any future clinical trials we may undertake may not be sufficient to obtain regulatory approvals to market our drug candidates in the United States or other countries on a timely basis, if at all.

Drug candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. In order to sell any product that is under development, we must first receive regulatory approval. To obtain regulatory approval, we must conduct clinical trials and toxicology studies that demonstrate that our drug candidates are safe and effective. The process of obtaining FDA and foreign regulatory approvals is costly, time-consuming, uncertain and subject to unanticipated delays.

The FDA and foreign regulatory authorities have substantial discretion in the approval process and may not agree that we have demonstrated that our drug candidates are safe and effective. If our drug candidates are ultimately not found

to be safe and effective, we would be unable to obtain regulatory approval to manufacture, market and sell them. We can provide no assurances that the FDA or foreign regulatory authorities will approve our drug candidates or, if approved, what the scope of the approved indication might be.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials.

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For example, the safety or efficacy results generated to date in our clinical trials do not ensure that later clinical trials will demonstrate similar results. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy, despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain regulatory approval to market our drug candidates.

Future clinical trials that we may undertake may be delayed or halted.

Any clinical trials of our drug candidates that we may conduct in the future may be delayed or halted for various reasons, including:

- we do not have sufficient financial resources;
- supplies of drug product are not sufficient to treat the patients in the studies;
- patients do not enroll in the studies at the rate we expect;
- the product candidates are not effective;
- patients experience negative side effects or other safety concerns are raised during treatment;
- the trials are not conducted in accordance with applicable clinical practices;
- there is political unrest at foreign clinical sites; or
- there are natural disasters at any of our clinical sites.

If any future trials are delayed or halted, we may incur significant additional expenses, and our potential approval of our drug candidates may be delayed, which could have a severe negative effect on our business.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have agreements with third-party contract research organizations, or CROs, to monitor and manage data for our preclinical and clinical programs. We rely heavily on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our

studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fails to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP regulations, and will require a large number of test subjects. Our or our CROs failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated

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and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, we may incur significant additional expenses, and our potential approval of our drug candidates may be delayed, which could have a severe negative effect on our business.

If the third-party manufacturers upon which we rely fail to produce our drug candidates that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the trials, regulatory submissions, required approvals or commercialization of our drug candidates.

We do not manufacture our drug candidates nor do we plan to develop any capacity to do so. We contract with third-party manufacturers to manufacture all of our drug candidates. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, which include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The third-party manufacturers we contract with may not perform as agreed or may terminate their agreements with us.

In addition to product approval, any facilities in which our drug candidates are manufactured or tested for their ability to meet required specifications must be inspected by and approved by the FDA and/or the EMA before a commercial product can be manufactured. Failure of such a facility to be approved could delay the approval of one or more of our drug candidates.

Any of these factors could cause us to delay or suspend any future clinical trials, regulatory submissions, required approvals or commercialization of one or more of our drug candidates, entail higher costs and result in our being unable to effectively commercialize products.

Our success in developing and marketing our drug candidates depends significantly on our ability to obtain patent protection and operate without infringing on the rights of others.

We depend on patents and other intellectual property to prevent others from improperly benefiting from products or technologies that we developed or acquired. Our patents and patent applications cover various technologies and drug candidates. The patent position of biotechnology firms like ours is highly uncertain and involves complex legal and factual questions, and no consistent policy has emerged regarding the breadth of claims covered in biotechnology patents or the protection afforded by these patents. Additionally, recent U.S. Supreme Court and Federal Circuit opinions further limit the scope of patentable inventions in the life sciences space and have added increased uncertainty around the validity of certain issued patents and the successful prosecution of certain pending patent applications. We intend to continue to file patent applications as we believe is appropriate to obtain patents covering both our products and processes. There can be no assurance, however, that any additional patents will be issued, that the scope of any patent that has issued or may issue will be sufficient to protect our technology, or that any current or future issued patent will be held not invalid if subsequently challenged. There is a substantial backlog of biotechnology patent applications at the United States Patent and Trademark Office, or USPTO, which may delay the review and issuance of any patents.

Others, including our competitors, could have patents or patent applications pending that relate to compounds or processes that overlap or compete with our intellectual property or which may affect our freedom to operate.

There can be no assurance that third-party patents will not ultimately be found to impact the advancement of our drug candidates. For example, we are aware that the USPTO has issued a patent to a third party with claims that may cover

one of our product candidates. While we intend to challenge the issuance and validity of this patent, we may not be successful. If the USPTO or any foreign counterpart issues or has issued any other patents containing competitive or conflicting claims, and if these claims are valid, the protection provided by our existing patents or any future patents that may be issued could be significantly reduced, and our ability to prevent competitors from developing products or technologies identical or similar to ours could be negatively affected. In addition, there can be no guarantee that we would be able to obtain licenses to these patents on commercially reasonable terms, if at all, or that we would be able to develop or obtain alternative technology. Our failure to obtain a license to a

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technology or process that may be required to develop or commercialize one or more of our drug candidates may have a material adverse effect on our business.

We do not have complete patent protection for our product candidates as the active pharmaceutical ingredients in our product candidates are known compounds that are not themselves covered by composition of matter patents, and thus may only be protected by formulation or method-of-use patents (to the extent that such patents are granted and are enforceable) and/or regulatory exclusivity (to the extent available). Therefore, it is possible that a competitor could develop the same or similar technology if we fail to obtain protection of this type. We may have to incur significant expense and management time in defending or enforcing our patents. If we cannot obtain and maintain effective patent rights and/or regulatory exclusivity for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first-to-file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If our product candidates infringe the rights of others, we could be subject to expensive litigation or be required to obtain licenses from others to develop or market them.

Our competitors or others may have patent rights that they choose to assert against us or our licensees, suppliers, customers or potential collaborators. Moreover, we may not know about patents or patent applications that our products would infringe. For example, because patent applications do not publish for at least 18 months, if at all, and can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates would infringe. In addition, if third parties file patent applications or obtain patents claiming technology also claimed by us or our licensors in issued patents or pending applications, we may have to participate in interference proceedings in the USPTO to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our foreign patent applications.

If a third party claims that we infringe its proprietary rights, any of the following may occur:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit;
- we may become liable for substantial damages for past infringement if a court decides that our technology infringes a competitor s patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms, if at all, or which may require us to pay substantial royalties or grant cross licenses to our patents; and

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- we may have to redesign our product candidates or technology so that they do not infringe patent rights of others, which may not be possible or commercially feasible.

If any of these events occurs, our business and prospects will suffer and the market price of our common stock will likely decline substantially.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when patents relating to our product candidates are controlled by our licensors. If any of our future licensing partners fail to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be materially adversely affected and we may not be able to prevent competitors from making, using, selling and importing competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to us assuming control over patent prosecution.

In addition to patent protection, we will need to successfully preserve our trade secrets. If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

If we fail to obtain orphan or other regulatory exclusivity for our product candidates, we may face greater commercial competition and our revenue will be reduced.

Regulatory authorities in some jurisdictions, including the United States and the European Union, or EU, may designate drugs for relatively small patient populations as orphan drugs. Our business strategy for certain of our drug candidates includes seeking orphan drug designation. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no

reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA s Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. If orphan drug status is granted, we may be eligible for a period of commercial exclusivity, which would afford us additional protection from generic competition, beyond that protection that may be afforded by patents. Even if a particular disease has a small

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patient population that we believe may be eligible for orphan status, it is possible that the FDA and/or EMA may not grant orphan status. If we do not obtain orphan drug exclusivity for our drug products and biologic products, particularly for any products that do not have broad patent protection, our competitors may then sell the same drug to treat the same condition sooner than if we had obtained orphan drug exclusivity and our revenue could be reduced.

Because a number of companies compete with us, many of which have greater resources than we do, and because we face rapid changes in technology in our industry, we cannot be certain that our products will be accepted in the marketplace or capture market share.

Competition from domestic and foreign biotechnology companies, large pharmaceutical companies and other institutions is intense and is expected to increase. A number of companies and institutions are pursuing the development of pharmaceuticals in our targeted areas. Many of these companies are very large, and have financial, technical, sales and distribution and other resources substantially greater than ours. The greater resources of these competitors could enable them to develop or market competing products more quickly or effectively, making it extremely difficult for us to develop a share of the market for our products. These competitors also include companies that are conducting clinical trials and preclinical studies in the field of cancer therapeutics. Our competitors may develop or obtain regulatory approval for products more rapidly than we do. Also, the biotechnology and pharmaceutical industries are subject to rapid changes in technology. Our competitors may develop and market technologies and products that are more effective or less costly than those we are developing or that would render our technology and proposed products obsolete or noncompetitive.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of undesirable side effects. In such an event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications.

The drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study, or result in potential product liability claims. We carry product liability insurance in the amount of $10.0 million in the aggregate. We believe our product liability insurance coverage is sufficient in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management s attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;

- regulatory authorities may require additional warnings on the label;

- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;

- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

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Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate and could significantly harm our business, results of operations, and prospects.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, biologic license application, or BLA, or market authorization application, or MAA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product s approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA, or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval were obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;

- impose civil or criminal penalties;

- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory

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sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected.

We may not be successful in our efforts to identify, license, discover, develop, or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business also depends upon our ability to identify, license, discover, develop or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

If the market opportunities for our product candidates are smaller than we believe, our revenue may be adversely affected, and our business may suffer.

Our estimates of the potential market opportunity for each of our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of our potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

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The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product s approved labeling;
- the clinical indications for which approval is granted;
- relative convenience and ease of administration;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in nonclinical and clinical trials, market acceptance of the product will not be fully known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

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- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, or Health Care Reform Laws, require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Laws, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Laws provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We rely on certain key employees, and the loss of their service could negatively impact our future success.

We have only a small number of employees, and we rely in particular on the services of certain key employees, including George F. Tidmarsh, M.D. Ph.D., who serves as our President and Chief Executive Officer. The loss of the services of Dr. Tidmarsh or other key employees could negatively affect our ability to execute on our business plan and development activities and could cause a decline in our stock price.

RISK FACTORS RELATED SPECIFICALLY TO OUR STOCK

We currently have approximately 15.3 million shares of common stock outstanding and currently may be required to issue up to a total of approximately 8.2 million additional shares of common stock upon conversion of existing convertible preferred stock and upon exercise of outstanding stock option grants and warrants. Such an issuance would be significantly dilutive to our existing common stockholders. You will experience further dilution if we issue additional equity securities in future fundraising transactions.

As of June 30, 2015, there were approximately 3,917 shares of Series C-1[2] Convertible Preferred Stock and approximately 2,737 shares of Series F Convertible Preferred Stock issued and outstanding. In light of the conversion rate of our preferred stock (approximately 1,724 shares of common stock are issuable upon the conversion of one share of Series C-1[2] Convertible Preferred Stock, and approximately 285 shares of common stock are issuable upon the conversion of one share of Series F Convertible Preferred Stock), the presence of such a large number of convertible preferred shares may dilute the ownership of our existing stockholders and provide the preferred investors with a sizeable interest in the Company.

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Assuming the conversion of all preferred stock into common stock at the current conversion rates, and the exercise of all outstanding options and warrants, we would have approximately 24.1 million shares of common stock issued and outstanding following any such conversion and exercise, although the issuance of the common stock upon the conversion of our preferred stock is limited by a 9.999% beneficial ownership cap for each preferred stockholder, which cap may be amended or waived by each such holder with no less than 61 days notice to the Company. With approximately 15.3 million shares of common stock issued and outstanding as of June 30, 2015, the issuance of this number of shares of common stock underlying the convertible preferred stock and outstanding stock options and warrants would represent approximately 37% dilution to our existing stockholders.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders or result in downward pressure on the price of our common stock.

The price of our common stock has been, and will be, volatile and may decline.

Our stock has historically experienced significant price and volume volatility and could continue to be volatile. Market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The following factors, among others, can have a significant effect on the market price of our securities:

- significant conversions of preferred stock into common stock and sales of those shares of common stock;
- results from our preclinical studies and clinical trials;
- limited financial resources;
- announcements regarding financings, mergers or other strategic transactions;
- future sales of significant amounts of our capital stock by us or our stockholders;
- developments in patent or other proprietary rights;
- developments concerning potential agreements with collaborators; and
- general market conditions and comments by securities analysts.

The realization of any of the risks described in these Risk Factors could have a negative effect on the market price of our common stock. In addition, class action litigation is sometimes instituted against companies whose securities have

experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management s attention and resources, which could hurt our business, operating results and financial condition.

Because we do not expect to pay dividends on our common stock in the foreseeable future, you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends on our common stock in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares, and you may not realize a return on your investment in our common stock.

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RISK FACTORS RELATING TO THIS OFFERING

We will have discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

We intend to use the net proceeds of this offering for general corporate purposes, funding our ongoing and future clinical trials and for general and administrative expenses, and for potential future acquisitions and other strategic purposes. We will retain discretion as to the application of the net proceeds and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which we choose to allocate and spend the net proceeds. Moreover, we may use the net proceeds for corporate purposes that may not increase our profitability or our market value. See Use of Proceeds on page S-18 for a description of our management s intended use of the proceeds from this offering.

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of $ per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $ per share in the net tangible book value of the common stock. See Dilution on page S-19 for a more detailed discussion of the dilution you will incur in this offering.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of common stock that we are offering will be approximately $, or approximately $ if the underwriters exercise in full their option to purchase up to additional shares of common stock, based on the public offering price of $ per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from the sale of the shares of common stock offered hereby primarily for general corporate purposes, which include, but are not limited to, funding our ongoing and future clinical trials relating to LJPC-501, LJPC-401 and LJPC-30s and for general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products and technologies. As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. Accordingly, our management will have broad discretion in the application of these proceeds.

Pending the use of the net proceeds, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

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DILUTION

Our net tangible book value as of June 30, 2015 was approximately $38.7 million, or $2.54 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of June 30, 2015. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of shares of our common stock in this offering at the public offering price of $ per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2015 would have been approximately $, or $ per share. This represents an immediate increase in net tangible book value of $ per share to existing stockholders and immediate dilution in net tangible book value of $ per share to new investors purchasing our common stock in this offering. The following table illustrates this dilution on a per share basis:

Public offering price per share		$
Net tangible book value per share as of June 30, 2015	$ 2.54	
Increase per share attributable to new investors	$	
As adjusted net tangible book value per share as of June 30, 2015 after this offering		$
Dilution per share to new investors purchasing our common stock in this offering		$

If the underwriters exercise in full their option to purchase additional shares of common stock at the public offering price of $ per share, the as adjusted net tangible book value after this offering would be $ per share, representing an increase in net tangible book value of $ per share to existing stockholders and immediate dilution in net tangible book value of $ per share to new investors purchasing our common stock in this offering. Furthermore, if the underwriters option to purchase additional shares is exercised in full, we will issue and sell an additional shares of our common stock and will have shares outstanding after the offering.

The above discussion and table are based on the 15,250,840 shares outstanding as of June 30, 2015 and exclude:

- 1,278,435 shares of our common stock subject to options outstanding as of June 30, 2015 having a weighted average exercise price of $14.76 per share;

- 171,089 shares of our common stock that have been reserved for issuance in connection with future grants under the La Jolla 2013 Equity Incentive as of June 30, 2015;

- 6,754,128 shares of our common stock that have been reserved for issuance upon the conversion of 3,917 shares of our Series C-1[2] Preferred Stock issued and outstanding as of June 30, 2015; and

- 782,032 shares of our common stock that have been reserved for issuance upon the conversion of 2,737 shares of our Series F Preferred Stock issued and outstanding as of June 30, 2015.

To the extent that such options or shares of convertible preferred stock outstanding as of June 30, 2015 have been or may be exercised or converted, respectively, or other shares issued, investors purchasing our common stock in this offering may experience further dilution. During the six months ended June 30, 2015, 60.762 shares of Series F Preferred Stock were converted into a total of 17,360 shares of common stock.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2015, between us and Jefferies LLC, as the representative of the underwriters named below and the book-running manager of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of our common stock. After the offering, the public offering price and concession to dealers may be reduced by the representative. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus supplement.

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The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with the shares. Such amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate that the total offering expenses payable by us, excluding underwriting discounts and commissions, will be approximately $. We have agreed to reimburse the underwriters a maximum of $ for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

Listing

Our common stock is listed on The NASDAQ Capital Market under the trading symbol LJPC .

Stamp Taxes

If you purchase shares of common stock offered in this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter s initial purchase commitment as indicated in the table above.

No Sales of Similar Securities

We and our officers and directors have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open put equivalent position within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended, or

- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or

- publicly announce an intention to do any of the foregoing,

for a period of 90 days after the date of this prospectus supplement without the prior written consent of Jefferies LLC.

These restrictions terminate after the close of trading of the shares of our common stock on and including the 90th day after the date of this prospectus supplement.

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Jefferies LLC may, in its sole discretion and at any time or from time to time before the termination of the 90-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, and certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either covered short sales or naked short sales.

Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

Naked short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker s bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the

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prospectus in electronic format, the information on the underwriters websites and any information contained in any other website maintained by any of the underwriters is not part of this prospectus supplement or the accompanying prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Disclaimers About Non-U.S. Jurisdictions

Australia

This prospectus supplement and the accompanying prospectus are not a disclosure document for the purposes of Australia s Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus supplement and the accompanying prospectus in Australia:

You confirm and warrant that you are either:

- a sophisticated investor under section 708(8)(a) or (b) of the Corporations Act;

- a sophisticated investor under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant s certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;

- a person associated with the Company under Section 708(12) of the Corporations Act; or

- a professional investor within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus supplement and the accompanying prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus supplement and the accompanying prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

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Canada

The shares of our common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares of our common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), an offer to the public of any common shares which are the subject of the offering contemplated by this prospectus supplement and the accompanying prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of common shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an offer common shares to the public in relation to the common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common shares to be offered so as to enable an investor to decide to

purchase or subscribe to the common shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (SFO) and any rules made under that Ordinance; or in other circumstances which do not result in the document being a prospectus as defined in the Companies Ordinance (Cap. 32) of Hong Kong (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or

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advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors as defined in the SFO and any rules made under that Ordinance.

This prospectus supplement and the accompanying prospectus have not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus supplement and the accompanying prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the initial purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus supplement and the accompanying prospectus have not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus supplement and the accompanying prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

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Switzerland

The common shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a of the CO or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus supplement and the accompanying prospectus nor any other offering or marketing relating to the common shares or this offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to this offering, the Company or the common shares has been or will be filed with or approved by any Swiss regulatory authority.

United Kingdom

This prospectus supplement and the accompanying prospectus are only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order) and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a relevant person).

This prospectus supplement and the accompanying prospectus and their contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

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LEGAL MATTERS

Gibson, Dunn & Crutcher LLP of San Francisco, California will issue an opinion with respect to the validity of the issuance of the securities being offered hereby. Latham & Watkins LLP of San Diego, California is counsel to the underwriters in connection with this offering.

EXPERTS

The financial statements and the effectiveness of internal control over financial reporting incorporated in this Prospectus Supplement by reference to the Annual Report on Form 10-K for the year ended December 31, 2014, have been audited by Squar Milner LLP (formerly Squar, Milner, Peterson, Miranda & Williamson, LLP), an independent registered public accounting firm, as stated in their reports incorporated by reference herein, and have been so incorporated in reliance upon such reports and upon the authority of such firm as experts in accounting and auditing.

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PROSPECTUS

$150,000,000

La Jolla Pharmaceutical Company

Common Stock

Preferred Stock

Warrants

This prospectus will allow us to issue, from time to time in one or more offerings,

shares of our common stock,

shares of our preferred stock, and

warrants.

The common stock, preferred stock and warrants may be offered and sold separately or together in one or more series of issuances, for an aggregate dollar amount not to exceed $150,000,000. We will provide specific terms of the securities in supplements to this prospectus.

In this prospectus, we refer to the common stock, preferred stock and the warrants collectively as the securities.

This prospectus provides a general description of the securities we may offer. We may sell the securities to or through underwriters, directly to investors or through agents, or through a combination of these methods. Each time we sell securities we will provide a prospectus supplement that will contain specific information about the terms of that sale, including the names of any underwriters or agents, and may add, update or change the information contained in this prospectus. You should read this prospectus and any prospectus supplement, and the information incorporated by reference herein and therein, carefully before you invest in our securities. This prospectus may not be used to consummate a sale of securities unless accompanied by a prospectus supplement for those securities.

Our common stock is listed on the Nasdaq Capital Market under the symbol LJPC. On June 26, 2014, the last reported sale price of our common stock on the Nasdaq Capital Market was $8.66.

Investing in our securities involves a high degree of risk. You should carefully consider the Risk Factors beginning on page 3 before you invest in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to

the contrary is a criminal offense.

The date of this prospectus is July 11, 2014

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a shelf registration process. Under this shelf registration process, we may offer from time to time any combination of the securities described in this prospectus for a total dollar amount not to exceed $150,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading Where You Can Find More Information.

We have not authorized any dealer, salesperson or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and any accompanying prospectus supplement. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or any accompanying prospectus supplement as if we had authorized it. This prospectus and any accompanying prospectus supplement do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor does this prospectus and any accompanying prospectus supplement constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus and any accompanying prospectus supplement is correct on any date after their respective dates, even though this prospectus or any prospectus supplement is delivered or securities are sold on a later date.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as intends, believes, anticipates, indicates, plans, intends, expects, suggests, may, should, potential, designed to, will and similar references. Su include, but are not limited to, statements about: our ability to successfully develop GCS-100, LJPC-401, LJPC-501 and our other product candidates; the future success of our clinical trials with GCS-100, LJPC-401 and LJPC-501; the timing for the commencement and completion of clinical trials; and our ability to implement cost-saving measures. Forward-looking statements are neither historical facts nor assurances of future performance. These statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others: the risk that our clinical trials with GCS-100, LJPC-401 and LJPC-501 may not be successful in evaluating the safety and tolerability of GCS-100, LJPC-401 and LJPC-501 or providing preliminary evidence of efficacy; the successful and timely completion of clinical trials; uncertainties regarding the regulatory process; the availability of funds and resources to pursue our research and development projects, including our clinical trials with GCS-100, LJPC-401 and LJPC-501; general economic conditions; and those identified in this Prospectus under the heading Risk Factors and in other filings the Company periodically makes with the Securities and Exchange Commission. Forward-looking statements contained in this Prospectus speak as of the date hereof and the Company does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this Prospectus.

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ABOUT THE COMPANY

La Jolla Pharmaceutical Company is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapeutics intended to significantly improve outcomes in patients with life-threatening diseases. Our drug development efforts are focused on three product candidates: GCS-100, LJPC-501 and LJPC-401. GCS-100 targets the protein galectin-3, which, when overproduced by the human body, has been associated with chronic organ failure and cancer. In 2013, we conducted a Phase 1 trial and a randomized, placebo-controlled Phase 2 clinical trial with GCS-100 for the treatment of chronic kidney disease, or CKD. In March 2014, we announced positive top-line results from the Phase 2 trial of GCS-100 in CKD. LJPC-501 is a peptide agonist of the renin-angiotensin system, which is designed to help restore kidney function in patients with hepatorenal syndrome, or HRS. The Food and Drug Administration, or FDA, accepted our Investigational New Drug Application, or IND, for LJPC-501 for the treatment of HRS and we plan to initiate a Phase 1 clinical trial in 2014. In February 2014, we announced the licensing of technology related to hepcidin (LJPC-401), which will be evaluated for the treatment of iron disorders. We also plan to continue to evaluate other opportunities for potential product candidates for the treatment of unmet medical needs.

Our common stock is listed on the NASDAQ Capital Market under the symbol LJPC .

Our executive offices are located at 4660 La Jolla Village Drive, Suite 1070, San Diego, California, 92122 and our telephone number is (858) 207-4264. Additional information regarding our company, including our audited financial statements and descriptions of our business, is contained in the documents incorporated by reference in this prospectus. See Where You Can Find More Information on page 9 and Incorporation of Certain Information by Reference on page 10.

RISK FACTORS

We are a development-stage company and we have not yet generated significant revenues. Before making an investment decision, you should carefully consider the risks described in the sections entitled Risk Factors in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on form 10-Q, as filed with the SEC, which are incorporated herein by reference in their entirety, as well as any amendment or updates to our risk factors reflected in subsequent filings with the SEC, including the applicable prospectus supplement. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment. This prospectus and the incorporated documents also contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks mentioned elsewhere in this prospectus.

USE OF PROCEEDS

Unless we provide otherwise in a supplement to this prospectus, we intend to use the net proceeds from the sale of our securities and from the exercise of the warrants issued pursuant hereto, if any, for general corporate purposes, which may include one or more of the following:

- working capital;

research and clinical development activities;

potential future acquisitions of companies and/or technologies; and

capital expenditures.

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Our management will have broad discretion in the allocation of the net proceeds of any offering. Pending such uses, we intend to invest the net proceeds in short-term, investment grade, interest-bearing securities.

SECURITIES WE MAY OFFER

We may offer shares of our common stock, preferred stock and/or warrants to purchase common stock or preferred stock with a total value of up to $150,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

Common Stock

The following summary of the terms of our common stock is subject to and qualified in its entirety by reference to our charter and by-laws, copies of which are on file with the SEC as exhibits to previous SEC filings. Please refer to Where You Can Find More Information below for directions on obtaining these documents.

We may issue shares of our common stock from time to time. Holders of our common stock are entitled to one vote per share on all matters that require shareholder approval. There are no cumulative voting rights while our common stock is listed on a national securities exchange, such as NASDAQ. Our common stock does not carry any redemption rights or any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock.

Our common stock is listed on the NASDAQ Capital Market under the symbol LJPC . The transfer agent and registrar for the common stock is American Stock Transfer & Trust Company, LLC.

Preferred Stock

We may issue shares of our preferred stock from time to time, in one or more series. Under our certificate of incorporation, our board of directors has the authority, without further action by shareholders, to designate up to 8,000,000 shares of preferred stock $0.0001 par value in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including but not limited to dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of the common stock.

If we issue preferred stock, we will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under this prospectus and applicable prospectus supplements in the certificate of designations relating to that series. If we issue preferred stock, we will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designations that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the prospectus supplement related to any series of preferred stock we may offer, as well as the complete certificate of designations that contains the terms of the applicable series of preferred stock.

As of March 31, 2014, a total of 8,459 shares of preferred stock were issued and outstanding.

Warrants

We may issue warrants for the purchase of common stock and/or preferred stock in one or more series, from time to time. We may issue warrants independently or together with common stock and/or preferred stock, and the warrants may be attached to or separate from those securities.

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If we issue warrants, they will be evidenced by warrant agreements or warrant certificates issued under one or more warrant agreements, which are contracts between us and an agent for the holders of the warrants. We urge you to read the prospectus supplement related to any series of warrants we may offer, as well as the complete warrant agreement and warrant certificate that contain the terms of the warrants. If we issue warrants, forms of warrant agreements and warrant certificates relating to warrants for the purchase of common stock, preferred stock and debt securities will be incorporated by reference into the registration statement of which this prospectus is a part from reports we would subsequently file with the SEC.

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PLAN OF DISTRIBUTION

We may sell our securities from time to time in any manner permitted by the Securities Act, including any one or more of the following ways:

directly to investors;

to investors through agents;

to dealers; and/or

through one or more underwriters or dealers.

Any underwritten offering may be on a best efforts or a firm commitment basis. We may also make direct sales through subscription rights distributed to our shareholders on a pro rata basis, which may or may not be transferable. In any distribution of subscription rights to shareholders, if all of the underlying securities are not subscribed for, we may then sell the unsubscribed securities directly to third parties or may engage the services of one or more underwriters, dealers or agents, including standby underwriters, to sell the unsubscribed securities to third parties. Under agreements into which we may enter, underwriters, dealers and agents who participate in the distribution of the securities may be entitled to indemnification by us against some liabilities, including liabilities under the Securities Act, or contribution from us for payments which the underwriters, dealers or agents may be required to make. Underwriters, dealers and agents may engage in transactions with us or perform services for us from time to time in the ordinary course of business.

The distribution of the securities may be effected from time to time in one or more transactions:

at a fixed price or prices, which may be changed;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices; or

at negotiated prices.

Any of the prices may represent a discount from prevailing market prices.

We will seek authorization for listing and trading on the NASDAQ Capital Market for the shares of common stock sold pursuant to the registration statement of which this prospectus is a part and may seek to have any warrants we sell pursuant to this prospectus listed for trading on the NASDAQ Capital Market or another exchange. In any sale of the securities, underwriters or agents may receive compensation from us or from purchasers of the securities, for whom

they may act as agents, in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities may be deemed to be underwriters under the Securities Act of 1933, and any discounts or commissions they receive from us and any profit on the resale of securities they realize may be deemed to be underwriting discounts and commissions under the Securities Act.

Each time we sell securities, we will describe the method of distribution of the securities in the prospectus supplement relating to such transaction. The applicable prospectus supplement will, where applicable:

identify any such underwriter or agent;

describe any compensation in the form of discounts, concessions, commissions or otherwise received from us by each such underwriter or agent and in the aggregate to all underwriters and agents;

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identify the amounts underwritten or to be sold through the agent; and

identify the nature of the underwriter s or agent s obligation to take the securities.

If underwriters are utilized in the sale of the securities, the securities may be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at fixed public offering prices or at varying prices determined by the underwriters at the time of the sale. We may offer the securities to the public either through underwriting syndicates represented by managing underwriters or directly by the managing underwriters. If any underwriters are utilized in the sale of the securities, unless otherwise stated in the applicable prospectus supplement, the underwriting agreement will provide that the obligations of the underwriters are subject to specified conditions precedent and that the underwriters with respect to a sale of the securities will be obligated to purchase all of the securities offered if any are purchased.

Until the distribution of the securities is completed, rules of the Securities and Exchange Commission may limit the ability of any underwriters and selling group members to bid for and purchase the securities. As an exception to these rules, underwriters are permitted to engage in some transactions that stabilize the price of the securities, such as over allotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended. Over allotment involves sales in excess of the offering size which create a short position for the underwriter. Stabilizing transactions consist of bids or purchases for the purpose of pegging, fixing or maintaining the price of the securities. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. The underwriters may also impose a penalty bid, under which selling concessions allowed to syndicate members or other broker-dealers for securities sold in the offering for their account may be reclaimed by the syndicate if the securities are repurchased by the syndicate in stabilizing or covering transactions. In general, purchases of a security for the purpose of stabilization or to reduce a short position could cause the price of the security to be higher than it might be in the absence of such purchases. The imposition of a penalty bid might also have an effect on the price of a security to the extent that it were to discourage resales of the security before the distribution is completed.

We do not make any representation or prediction as to the direction or magnitude of any effect that the transactions described above might have on the price of the securities. In addition, we do not make any representation that underwriters will engage in such transactions or that such transactions, once commenced, will not be discontinued without notice.

Underwriters, dealers and agents may engage in transactions with us or perform services for us in the ordinary course of business.

If indicated in the applicable prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by particular institutions to purchase securities from us at the public offering price set forth in such prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in such prospectus supplement. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the applicable prospectus supplement.

To comply with applicable state securities laws, the securities offered by this prospectus will be sold, if necessary, in such jurisdictions only through registered or licensed brokers or dealers. In addition, securities may not be sold in some states unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

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EXPERTS

The consolidated financial statements of La Jolla Pharmaceutical Company as of December 31, 2013 and 2012 and for each of the two years in the period ended December 31, 2013 incorporated in this Prospectus by reference have been so included in reliance on the report of Squar, Milner, Peterson, Miranda & Williamson, LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

LEGAL MATTERS

Certain legal matters, including the validity of the securities offered pursuant to this registration statement, will be passed upon for us by Gibson, Dunn & Crutcher, LLP, San Francisco, California.

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WHERE YOU CAN FIND MORE INFORMATION

We must comply with the informational requirements of the Securities Exchange Act of 1934, as amended, and we are required to file reports and proxy statements and other information with the Securities and Exchange Commission. You may read and copy these reports, proxy statements and other information at the Public Reference Room maintained by the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies at the prescribed rates from the Public Reference Section of the Securities and Exchange Commission at its principal office in Washington, D.C. You may call the Securities and Exchange Commission at 1-800-SEC-0330 for further information about the public reference room. The Securities and Exchange Commission also maintains a website that contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the Securities and Exchange Commission. You may access the Securities and Exchange Commission s web site at http://www.sec.gov.

Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete, and in each instance we refer you to the copy of the contract or document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference.

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INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The Securities and Exchange Commission allows us to incorporate by reference in this prospectus the information that we file with them. Incorporation by reference means that we can disclose important information to you by referring you to other documents that are legally considered to be part of this prospectus. Later information that we file with the Securities and Exchange Commission will automatically update and supersede the information in this prospectus, any supplement and the documents listed below. We incorporate by reference the specific documents listed below and any future filings made with the Securities and Exchange Commission under Section 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934, as amended, including those filed after the date of the initial registration statement and prior to the effectiveness of the registration statement, until all of the shares of common stock, preferred stock and warrant shares covered by this prospectus are sold:

- The Company s annual report on Form 10-K for the fiscal year ended December 31, 2013;
- The Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014;
- The Company s Current Reports on Form 8-K filed on January 15, 2014, March 4, 2014, March 11, 2014, and April 9, 2014; and
- The description of the Company s Common Stock contained in its registration statement on Form 8-A (Registration No. 001-36282), filed on January 28, 2014, including any amendments or reports filed for the purpose of updating such description.

We will furnish without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, a copy of any document incorporated by reference. Requests should be addressed to Corporate Secretary, 4660 La Jolla Village Drive, Suite 1070, San Diego, CA or via telephone at (858) 207-4264.

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with different information. You should not assume that the information contained in this prospectus or the accompanying prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying prospectus supplement is delivered or securities are sold on a later date.

Nothing in this prospectus shall be deemed to incorporate information furnished but not filed with the SEC pursuant to Item 2.02 or 7.01 of Form 8-K.

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Shares

Common Stock

PROSPECTUS SUPPLEMENT

Book-Running Manager

Jefferies

, 2015