LA JOLLA PHARMACEUTICAL CO
Form 10-Q
November 12, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2014
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 1-36282

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

California	33-0361285
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4660 La Jolla Village Drive, Suite 1070 San Diego, CA	92122
(Address of principal executive offices)	(Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x
As of November 7, 2014, La Jolla Pharmaceutical Company had 15,225,980 shares of common stock, $0.0001 par value per share, outstanding.

LA JOLLA PHARMACEUTICAL COMPANY
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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

LA JOLLA PHARMACEUTICAL COMPANY
Condensed Balance Sheets
(in thousands, except share and per-share amounts)

	September 30, 2014 (Unaudited)	December 31, 2013
ASSETS:		
Current assets:		
Cash and cash equivalents	$54,131	$8,629
Restricted cash	37	37
Prepaid expenses and other current assets	153	43
Total current assets	54,321	8,709
Equipment and furnishings, net	114	38
Total assets	$54,435	$8,747
LIABILITIES AND SHAREHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$683	$834
Accrued expenses	900	187
Accrued payroll and related expenses	32	73
Total current liabilities	1,615	1,094
Shareholders’ equity:		
Common Stock, $0.0001 par value; 100,000,000 and 12,000,000,000 shares authorized, and 15,225,980 and 4,404,407 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	4	4
Series C-1[2] Convertible Preferred Stock, $0.0001 par value; 11,000 shares authorized, 3,917 and 7,016 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	3,917	7,016
Series F Convertible Preferred Stock, $0.0001 par value; 10,000 shares authorized, 2,798 and 3,250 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	2,798	3,250
Additional paid-in capital	525,866	462,684
Accumulated deficit	(479,765)	(465,301)
Total shareholders’ equity	52,820	7,653
Total liabilities and shareholders' equity	$54,435	$8,747

See accompanying notes to the condensed financial statements.

LA JOLLA PHARMACEUTICAL COMPANY
Unaudited Condensed Statements of Operations and Comprehensive Loss
(in thousands, except per-share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Expenses:				
Research and development	$2,625	$948	$6,218	$2,303
General and administrative	2,436	3,225	8,259	9,238
Total expenses	5,061	4,173	14,477	11,541
Loss from operations	(5,061)	(4,173)	(14,477)	(11,541)
Other income:				
Other income, net	9	1	13	3
Net loss and comprehensive loss	(5,052)	(4,172)	(14,464)	(11,538)
Convertible preferred stock dividends earned	—	(337)	—	(801)
Net loss attributable to common shareholders	$(5,052)	$(4,509)	$(14,464)	$(12,339)
Basic and diluted net loss per share	$(0.37)	$(5.45)	$(1.58)	$(21.35)
Shares used in computing basic and diluted net loss per share	13,646	827	9,131	578

See accompanying notes to the condensed financial statements.

LA JOLLA PHARMACEUTICAL COMPANY
Unaudited Condensed Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2014	2013
Operating activities:		
Net loss	$(14,464)	$(11,538)
Adjustments to reconcile net loss to net cash used for operating activities:		
Share-based compensation expense	6,595	8,568
Depreciation expense	10	3
Changes in operating assets and liabilities:		
Restricted cash	—	(37)
Prepaid expenses and other current assets	(110)	(22)
Accounts payable and accrued expenses	562	322
Accrued payroll and related expenses	(68)	39
Net cash used for operating activities	(7,475)	(2,665)
Investing activities:		
Purchase of equipment and furnishings	(86)	(40)
Net cash used for investing activities	(86)	(40)
Financing activities:		
Net proceeds from the issuance of common stock	53,063	6,750
Proceeds from the issuance of Series F Convertible Preferred Stock	—	3,250
Net cash provided by financing activities	53,063	10,000
Net increase in cash and cash equivalents:	45,502	7,295
Cash and cash equivalents at beginning of period	8,629	3,405
Cash and cash equivalents at end of period	$54,131	$10,700
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activity:		
Conversion of Series C-1[2] and D-1[2] Convertible Preferred Stock into common stock	$3,099	$58
Exchange of Series C-2[2] Convertible Preferred Stock for Series C-1[2] Convertible Preferred Stock	$—	$557
Redemption of Series D-1[2] Convertible Preferred Stock and Series C-2[2] Convertible Preferred Stock Warrants	$—	$4,568
Conversion of Series F Convertible Preferred Stock into common stock	$452	$—
Dividends paid in shares of Series C-1[2] and C-2[2] Convertible Preferred Stock	$—	$801

See accompanying notes to the condensed financial statements.

LA JOLLA PHARMACEUTICAL COMPANY

Notes to Condensed Financial Statements
(Unaudited)

September 30, 2014

1. Basis of Presentation and Description of Business

La Jolla Pharmaceutical Company (the "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.

Basis of Presentation

The accompanying unaudited condensed financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8 of the Securities and Exchange Commission ("SEC") Regulation S-X. Accordingly, they should be read in conjunction with the audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2013, included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2014. The unaudited financial statements contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the condensed balance sheet of the Company at September 30, 2014, the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2014, and the condensed statement of cash flows for the nine months ended September 30, 2014. All intercompany accounts and transactions have been eliminated. It should be understood that accounting measurements at interim dates inherently involve greater reliance on estimates than at year end. The results of operations for the three and nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the full year or any future interim periods.

Corporate Structure

The Company was incorporated in 1989 as a Delaware corporation. In June 2012, the Company reincorporated in the State of California. All common and preferred shares of the Delaware corporation were exchanged for common and preferred shares of the Company.

Use of Estimates

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed financial statements and disclosures made in the accompanying notes to the unaudited condensed financial statements. Actual results could differ materially from those estimates.

Reverse Stock Split

Effective January 14, 2014, the Company effected a 1-for-50 reverse split (the "2014 Reverse Stock Split") of its outstanding common stock (See Note 2). All common stock share and per-share information in the accompanying unaudited condensed financial statements have been restated to reflect retrospective application of the 2014 Reverse Stock Split for all periods presented, except for par value per share and the number of authorized shares, which were

not affected. All stock options and the shares of common stock underlying outstanding convertible preferred stock were appropriately adjusted to give effect to the 2014 Reverse Stock Split.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted-average number of common shares outstanding during the periods presented. Basic earnings per share ("EPS") is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net loss by the weighted-average number of common shares and common stock equivalents outstanding for the period. These common stock equivalents are included in the calculation of diluted EPS only if their effect is dilutive. There is no difference between basic and diluted net loss per share for the three and nine months ended September 30, 2014. There were potentially dilutive securities of 8.1 million shares and 13.1 million shares as of September 30, 2014 and September 30, 2013, respectively. These potentially dilutive securities relate to outstanding convertible preferred stock and stock options, and have been excluded from the calculation of diluted net loss per share because the inclusion of such securities would be antidilutive.

Restricted Cash

Restricted cash consists of $37,000 in the form of a certificate of deposit on hand with the Company’s financial institutions as collateral for its San Diego office space.

Equipment and Furnishings

Equipment and furnishings is stated at cost and has been depreciated using the straight-line method over the estimated useful lives of the assets, which range from two to seven years. Depreciation expense of $10,000 and $3,000 was recognized for the nine months ended September 30, 2014 and 2013, respectively.

Comprehensive Loss

The Company’s net loss is equal to its comprehensive loss for all periods presented.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2013-11, Income Taxes (Topic 740). This update improves the reporting for unrecognized tax benefits when a net operating loss carry-forward, a similar tax loss or a tax credit carry-forward exists. The update is expected to reduce diversity in practice by providing guidance on the presentation of unrecognized tax benefits and will better reflect the manner in which an entity would settle at the reporting date any additional income taxes that would result from the disallowance of a tax position when net operating loss carry-forwards, similar tax losses or tax credit carry-forwards exist. The update is effective prospectively for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2013, which for the Company was January 1, 2014. The adoption of this update did not have a material impact on the Company's financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). This update outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. This new guidance is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016, which for the Company is January 1, 2017; early adoption is not permitted. Entities have the option of using either a full retrospective or a modified approach to adopting the guidance. The Company does not

anticipate that the adoption of this update will have a material impact on its financial statements.

In June 2014, the FASB issued ASU No. 2014-12, Compensation - Stock Compensation (Topic 781): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period. This update requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. This update is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2015, which for the Company is January 1, 2016; early adoption is permitted. Entities may apply the amendments in this update either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The Company does not anticipate that the adoption of this update will have a material impact on its financial statements.

Management is evaluating the significance of the recent accounting pronouncement ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, and has not yet concluded whether the pronouncement will have a significant effect on the Company's future financial statements.

2. Shareholders’ Equity

Common Stock

Amendments to Articles of Incorporation

On August 27, 2014 at the Company's annual meeting of shareholders (the "2014 Annual Meeting"), the shareholders approved an amendment to the Company's articles of incorporation to reduce the number of authorized common shares available for issuance to 100,000,000 shares from 12,000,000,000 shares.

2014 Common Stock Offering

In July 2014, the Company entered into an underwriting agreement, in which the Company agreed to issue and sell an aggregate of 4,800,000 shares of its common stock. The shares were sold at a public offering price of $10.50 per share, with gross proceeds of approximately $56.6 million. Under the terms of the underwriting agreement, the Company granted the underwriters an option for 30 days to purchase up to an additional 720,000 shares of the Company's common stock. On July 23, 2014, the underwriters partially exercised their option to purchase an additional 595,000 shares of the Company's common stock. This transaction closed on July 28, 2014, and the Company received total net proceeds of approximately $53.1 million, net of approximately $3.5 million in underwriting commissions, discounts and other issuance costs.

2014 Reverse Stock Split

The Board of Directors of the Company enacted a reverse split of the Company's outstanding common stock, which became effective on January 14, 2014. The 2014 Reverse Stock Split was approved by the shareholders on June 5, 2013. As a result of the 2014 Reverse Stock Split, every 50 shares of the Company’s issued and outstanding common stock were automatically combined into one share of the Company’s common stock. No fractional shares were issued in connection with the 2014 Reverse Stock Split. Shareholders who were entitled to fractional shares instead became entitled to receive a cash payment in lieu of receiving fractional shares (after taking into account and aggregating all

shares of the Company's common stock then held by such shareholder) equal to the fractional share interest. The 2014 Reverse Stock Split affected all of the holders of the Company's common stock uniformly. Shares of the Company's common stock underlying outstanding options were proportionately reduced, and the exercise prices of outstanding options were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of the Company's common stock underlying outstanding convertible preferred stock were proportionately reduced, and the conversion rates were proportionately decreased in accordance with the terms of the agreements governing such securities.

Preferred Stock

As of September 30, 2014, the Company is authorized to issue 8,000,000 shares of preferred stock, with a par value of $0.0001 per share, in one or more series, of which 11,000 are designated Series C-1[2] Convertible Preferred Stock and 10,000 are designated Series F Convertible Preferred Stock. During the nine months ended September 30, 2014, the Company issued 5,341,670 shares of common stock upon the conversion of Series C-1[2] Convertible Preferred Stock and 129,105 shares of common stock upon the conversion of Series F Convertible Preferred Stock. The Series C-1[2] Convertible Preferred Stock is convertible into common stock at a rate 1,724 shares of common stock for each share of Series C-1[2] Convertible Preferred Stock, and the Series F Convertible Preferred Stock is convertible into common stock at a rate of 286 shares of common stock for each share of Series F Convertible Preferred Stock. As of September 30, 2014, 3,917 shares of Series C-1[2] Convertible Preferred Stock and 2,798 shares of Series F Convertible Preferred Stock were issued and outstanding. As such, as of September 30, 2014, the issued and outstanding Series C-1[2] Convertible Preferred Stock and Series F Convertible Preferred Stock were convertible into 6,752,908 and 800,228 shares of common stock, respectively.

Share-Based Compensation

2013 Equity Incentive Plan

In September 2013, the Company adopted an equity compensation plan entitled the 2013 Equity Incentive Plan (the "2013 Equity Plan"). The 2013 Equity Plan is an omnibus equity compensation plan that permits the issuance of various types of equity-based compensation awards, including options, stock awards, stock appreciation rights and restricted stock units, as well as cash awards, to employees, directors and eligible consultants of the Company. The 2013 Equity Plan has a ten-year term and permits the issuance of incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended. The administrator under the plan has broad discretion to establish the terms of awards, including the size, term, exercise price (if applicable) and applicable vesting conditions. Generally, grants to employees vest over four years, with 25% vesting on the one-year anniversary, and the remainder vesting either quarterly or monthly thereafter; grants to non-employee directors vest over three years, with 33% vesting on the one-year anniversary, and the remainder vesting either quarterly or monthly thereafter.

The 2013 Equity Plan previously allowed for automatic annual increases to the number of shares of common stock authorized for issuance under the plan on the first day of each year, with such increases based on 10% of the outstanding shares of the Company's common stock as of the last day of the previous year end. On January 1, 2014, the total shares available for grant under the 2013 Equity Plan increased to 440,441. At the 2014 Annual Meeting, the shareholders approved and adopted an amendment to the 2013 Equity Plan to increase the number of shares of common stock authorized for issuance up to a total of 1,100,000 shares and eliminated the automatic annual increase on the first day of each year.

As of September 30, 2014, there were 576,304 shares available for future grants under the 2013 Equity Plan.

Share-Based Compensation Expense

The following table summarizes all share-based compensation expense related to stock options, restricted stock and restricted stock units by expense category (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development:				
Stock options	$98	$250	$142	$897
Restricted stock	147	7	652	51
Research and development share-based compensation expense	245	257	794	948
General and administrative:				
Stock options	286	1,892	575	6,854
Restricted stock	1,212	593	5,226	714
Restricted stock units	—	—	—	52
General and administrative share-based compensation expense	1,498	2,485	5,801	7,620
Total share-based compensation expense included in expenses	$1,743	$2,742	$6,595	$8,568

Stock Options

During the three and nine months ended September 30, 2014, stock options representing the right to acquire a total of up to 137,000 shares and 466,900 shares of common stock were granted, respectively. The Company uses the Black-Scholes valuation model to calculate the fair value of its stock options. Share-based compensation expense is recognized over the vesting period using the straight-line method. The fair values of the stock options were estimated at the respective grant dates using the following weighted-average assumptions:

	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014
Dividend yield	—	—
Volatility	190.2%	188.1%
Risk-free interest rate	2.08%	2.15%
Expected life of options (years)	6.59	6.73

The grant date, weighted-average fair value per share of the stock options granted during the three and nine months ended September 30, 2014 was $8.38 and $9.49, respectively.

As of September 30, 2014, there was $4.0 million in unrecognized share-based compensation expense attributable to stock options to be recognized over the next 40 months. If there are any modifications or cancellations of underlying unvested stock options, we may be required to accelerate, increase or cancel the remaining unearned share-based compensation expense. Future share-based compensation expense and unearned share-based compensation will increase, to the extent that we grant additional stock options.

A summary of the Company's stock option activity and related data for the nine months ended September 30, 2014 is as follows:

	Outstanding Stock Options		
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Balance at December 31, 2013	54,000	$ 6.00	9.63
Granted	466,900	$ 9.70	
Balance at September 30, 2014	520,900	$ 9.32	9.53

Restricted Stock

On January 25, 2014, the Company granted 2,976 shares of restricted stock to a consultant. The restricted stock vested immediately and was issued under the 2013 Equity Plan.

On March 31, 2014, restricted stock awards representing 39,811 shares of common stock were canceled upon forfeiture. The remaining unrecognized share-based compensation expense for the canceled restricted stock awards was expensed during the three months ended March 31, 2014. An additional 7,318 restricted stock awards were canceled upon forfeiture during the three months ended September 30, 2014.

The remaining unrecognized share-based compensation expense for research and development attributable to restricted stock to be recognized over the next 16 months is $1.9 million. The remaining unrecognized share-based compensation expense for general and administrative attributable to restricted stock to be recognized over the next 27 months is $8.5 million.

3. Income Taxes

Deferred income tax assets and liabilities are recognized for temporary differences between financial statements and income tax carrying values, using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding the Company's ability to generate future taxable income and consequently realize such deferred income tax assets, a full valuation allowance has been established. The Company continues to maintain a full valuation allowance against its deferred tax assets as of September 30, 2014.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant tax authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There have been no material changes in the Company's unrecognized tax benefits since December 31, 2013, and as such, disclosures included in the Company's 2013 Annual Report on Form 10-K continue to be relevant for the period ended September 30, 2014.

4. Commitments and Contingencies

On March 21, 2014, the Company entered into a lease amendment with La Jolla Centre I LLC, to lease additional office space in the building known as La Jolla Centre I, located at 4660 La Jolla Village Drive, San Diego, California, covering approximately 1,795 square feet. The premises are being used by the Company for office space. The Company now leases a total of 3,713 square feet of office space. The lease term is through March 2018, and the Company’s total lease payments through the end of the lease are approximately $0.5 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In this document, "we," "our," "us," "La Jolla" and the "Company" refer to La Jolla Pharmaceutical Company.

Forward-Looking Statements

The forward-looking statements in this report involve significant risks, assumptions and uncertainties, and a number of factors, both foreseen and unforeseen, which could cause actual results to differ materially from our current expectations. Forward-looking statements include those that express a plan, belief, expectation, estimation, anticipation, intent, contingency, future development or similar expression. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Forward-looking statements include, but are not limited to, statements regarding our expectations around timing of commencement and completion of future clinical trials, the ability to successfully develop drug candidates, our ability to obtain orphan drug status or other regulatory approvals, and the expected duration over which our cash balances will fund our operations. The outcome of the events described in these forward-looking statements are subject to the risks, uncertainties and other factors described in "Management's Discussion and Analysis of Financial Condition and Results of Operations," in the "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2013, and in other reports and registration statements that we file with the Securities and Exchange Commission from time to time. We expressly disclaim any intent to update forward-looking statements.

Program Overview

La Jolla 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. Our drug development efforts are focused on four product candidates: LJPC-501, GCS-100, LJPC-1010 and LJPC-401, which are described below.

LJPC-501

LJPC-501 is our proprietary formulation of angiotensin II. Angiotensin II, the major bioactive product 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 and is poorly responsive to current treatments. LJPC-501 has been shown to raise blood pressure in a randomized, placebo-controlled clinical trial in CRH, as well as animal models of hypotension. In October 2014, we presented positive data from a preclinical study of LJPC-501 in the treatment of CRH. In June 2014, we had a meeting with the U.S. Food and Drug Administration, or FDA, in which agreement was reached that blood pressure can be the primary endpoint for approval in CRH. As a result of this meeting, we plan to initiate a registration Phase 3 clinical trial of LJPC-501 in CRH in the first quarter of 2015. We believe CRH to be an orphan indication, and, therefore, in July 2014, we submitted an Orphan Drug Designation application to the FDA for LJPC-501 in the treatment of CRH.

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 conducting a Phase 1/2 clinical trial of LJPC-501 in HRS, and, in August 2014, we enrolled our first patient in this trial. The Phase 1/2 clinical trial is currently enrolling patients.

GCS-100

GCS-100, our first-in-class galectin-3 inhibitor, is a complex polysaccharide derived from pectin that binds to, and blocks the activity of, the pro-fibrotic mediator galectin-3, a type of galectin. Over-expression of galectin-3 has been implicated in a number of human diseases characterized by progressive tissue fibrosis, such as chronic kidney disease, or CKD. We are developing GCS-100 for the treatment of CKD. As described in more detail below, we have recently completed a multicenter, randomized, placebo-controlled, Phase 2 clinical trial in advanced CKD patients in which treatment with GCS-100 resulted in a statistically significant improvement in kidney function compared to placebo. We plan to initiate a large, multicenter, randomized, placebo-controlled, Phase 2b clinical trial of GCS-100 in CKD in the first quarter of 2015. GCS-100 and LJPC-1010, our pectin-based drugs, are covered by an intellectual property portfolio that includes several issued and pending patents.

We announced positive top-line results from our Phase 2 clinical trial in CKD in March 2014. We are presenting additional results of this Phase 2 trial in November 2014 at the American Society of Nephrology's (ASN) Annual Kidney Week. The trial met its predefined primary efficacy endpoint of a statistically significant improvement in kidney function. Specifically, a dose of 1.5 mg/m^2 led to a statistically significant (p=0.045) increase in eGFR compared to placebo between baseline and end of treatment. This improvement, on a placebo-corrected basis, was maintained at 5 weeks following the completion of dosing (p=0.07). At the 30 mg/m^2 dose, there was no statistically significant difference. The lack of consistent response in the 30 mg/m^2 group may be due to off-target drug effects, as this dose is 1,400-fold in excess, on a molar basis, versus known circulating galectin-3 levels. Off-target effects may include antagonizing other galectins like galectin-9, which has opposing biological effects to galectin-3.

GCS-100's effect on eGFR in this Phase 2 trial was more pronounced (p=0.029) in the prospectively defined subset of patients with diabetic etiology. Analysis of this subset was predefined based on the observation that galectin-3 is elevated in diabetes patients and that galectin-3 levels correlate with proteinuria (a marker of kidney health) in these patients.

Of the 121 patients enrolled in this Phase 2 trial, 117 completed treatment, including all 41 patients treated at the 1.5 mg/m^2 dose. There were no serious adverse events, or SAEs, in the 1.5 mg/m^2 dose group compared to two in the placebo group and two in the 30 mg/m^2 group. All SAEs were deemed by the investigators as not drug-related.

LJPC-1010

LJPC-1010, our second-generation galectin-3 inhibitor, is a more potent and purified derivative of GCS-100 that can be delivered orally. We are developing LJPC-1010 for the treatment of nonalcoholic steatohepatitis, or NASH, and other diseases characterized by tissue fibrosis. NASH is the more serious form of nonalcoholic fatty liver disease, or NAFLD, which can lead to liver failure. In July 2014, we announced positive preclinical data of LJPC-1010 in NASH. We plan to file an Investigational New Drug Application, or IND, with the FDA and initiate a Phase 1 clinical trial of LJPC-1010 in the first quarter of 2015.

LJPC-401

LJPC-401 is our novel formulation of hepcidin, which is a naturally occurring peptide hormone that controls and regulates iron metabolism. By suppressing iron release, hepcidin prevents iron accumulation in tissues, such as the heart, where it can cause significant damage and even result in death. We are developing LJPC-401 for the treatment of iron overload. We are currently in the preclinical development stage with LJPC-401 and expect to file an IND and commence a Phase 1 clinical trial of LJPC-401 in iron overload in 2015. We licensed intellectual property covering the composition of hepcidin from INSERM in February 2014.

Results of Operations Overview

As a result of the significant expansion of our product pipeline over the past 12 months, we have significantly expanded our preclinical and clinical study activity. As a result, our research and development expenditures have increased in the nine months ended September 30, 2014 versus the same period in the prior year and are expected to continue to increase during the fourth quarter of 2014 and throughout 2015, due to planned increases in personnel and the initiation of additional clinical trials for all four of our development programs. Details of these trends and results are presented below.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed financial statements, which have been prepared in accordance with GAAP. The preparation of these unaudited condensed financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

There have been no material changes to the critical accounting policies as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013, which was filed on March 31, 2014.

Recent Accounting Pronouncements

See Note 1 to the unaudited condensed financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations for the Three and Nine Months Ended September 30, 2014 and 2013

The following summarizes the results of our operations for the three and nine months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development expense	$(2,625)	$(948)	$(6,218)	$(2,303)
General and administrative expense	(2,436)	(3,225)	(8,259)	(9,238)
Other income, net	9	1	13	3
Preferred stock dividends	—	(337)	—	(801)
Net loss attributable to common shareholders	$(5,052)	$(4,509)	$(14,464)	$(12,339)

Research and Development Expense

The following summarizes our research and development expense for the three and nine months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Clinical development costs	$1,836	$471	$3,969	$863
Personnel and related costs	419	110	854	317
Share-based compensation expense	245	258	794	947
Technology in-licensing costs	40	—	218	—
Other research and development costs	85	109	383	176
Research and development	$2,625	$948	$6,218	$2,303

For the three and nine months ended September 30, 2014, research and development expense increased to $2.6 million and $6.2 million, respectively, from $0.9 million and $2.3 million, respectively, for the same periods in 2013. The increase was primarily due to increased clinical development costs associated with the extension of the Phase 2 clinical trial of GCS-100 in CKD, the preparation of the Phase 1/2 clinical trial of LJPC-501 in HRS and pre-clinical costs associated with LJPC-1010 and LJPC-401. Additionally, an increase in personnel and related costs, which were mainly due to additional headcount to support the increased development activities noted above, also led to the increase in research and development expense. Lastly, the intellectual property in-licensing costs primarily related to LJPC-401, and an increase in other research and development costs, also led to the increase in research and development expense during the nine months ended September 30, 2014. We anticipate research and development expense to increase during the fourth quarter of 2014 and throughout 2015, due to planned increases in personnel and the initiation of additional clinical trials.

General and Administrative Expense

For the three and nine months ended September 30, 2014, general and administrative expense decreased to $2.4 million and $8.3 million, respectively, from $3.2 million and $9.2 million, respectively, for the same periods in 2013. The decrease was primarily due to a reduction in share-based compensation expense of $1.0 million and $1.8 million for the three and nine months ended September 30, 2014, respectively, as compared to the same periods in 2013. This decrease was partially offset by increased personnel and related costs due to additional headcount and increased facility costs. We anticipate general and administrative expense to increase during the fourth quarter of 2014 and throughout 2015, due to planned increases in personnel and additional facility costs to accommodate our operations in light of the additional programs that we have acquired or developed.

Preferred Stock Dividends

There were no preferred stock dividends paid in the three and nine months ended September 30, 2014, compared to $337,000 and $801,000, respectively, for the same periods in 2013. Until September 24, 2013, dividends payable-in-kind at a rate of 15% per year accrued on our outstanding Series C-1[2] Preferred Stock and Series C-2[2] Preferred Stock. As part of a waiver agreement with the holders of such preferred stock, after September 24, 2013, such preferred stock was no longer entitled to earn the aforementioned dividends.

Liquidity and Capital Resources

Since January 2012, when the Company was effectively restarted with new assets and a new management team, through September 30, 2014, we have incurred a cumulative net loss of approximately $40.1 million. From inception in 1989 through September 30, 2014, we have incurred a cumulative net loss of approximately $479.8 million and have financed our operations through public and private offerings of securities, revenues from collaborative agreements, equipment financings and interest income on invested cash balances. From inception through September 30, 2014, we have raised approximately $481.1 million in net proceeds from the sales of equity securities.

As of September 30, 2014, we had approximately $54.1 million of cash, as compared to approximately $8.6 million of cash at December 31, 2013. Cash used in operating activities for the nine months ended September 30, 2014 was $7.5 million, compared to $2.7 million for the same period in 2013. At September 30, 2014, we had positive working capital of approximately $52.7 million, as compared to positive working capital of approximately $7.6 million at December 31, 2013. The increase in our cash and working capital was primarily due to the receipt of net cash proceeds of approximately $53.1 million from our common stock offering completed in July 2014, offset by operating expenses for the nine months ended September 30, 2014.

We expect to use our cash and working capital to fund planned increases in research and development expenses related to ongoing and future clinical trials, including the initiation of a Phase 3 clinical trial of LJPC-501 in CRH in the first quarter of 2015, a large, multicenter, randomized, placebo-controlled, Phase 2b clinical trial of GCS-100 in CKD in the first quarter of 2015, a Phase 1 clinical trial of LJPC-1010 in the first quarter of 2015 and a Phase 1 clinical trial of LJPC-401 in iron overload in 2015.

Based on our cash and working capital as of September 30, 2014, we believe that we have sufficient capital to fund our operations through 2016. However, 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 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.

Cash Flows for the Nine Months Ended September 30, 2014 and 2013

Operating Activities

Cash used in operating activities for the nine months ended September 30, 2014 was $7.5 million, compared to $2.7 million for the same period in 2013. The increase relates primarily to the increase in both research and development expense and general and administrative expense, which are discussed above.

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2014 was $86,000, compared to $40,000 for the same period in 2013.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2014 was $53.1 million, compared to $10.0 million for the same period in 2013.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, expenses, results of operations, liquidity, capital expenditures or capital resources.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not hold any marketable securities at September 30, 2014.

ITEM 4. CONTROLS AND PROCEDURES

Our management, including our President and Chief Executive Officer ("CEO"), who also serves as our principal accounting officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (“Exchange Act”), means controls and procedures that are designed to ensure that information required to be disclosed in report filings and submissions under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information disclosed in filings is accumulated and communicated to the company’s management, including its CEO, as well as senior financial and accounting executives, as appropriate to allow timely decisions regarding said disclosures. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2014, our CEO, along with our senior financial and accounting executives, concluded that as of such date the Company’s disclosure controls and procedures were effective at a reasonable level of assurance.

No change in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That being said, no evaluation of controls can provide absolute assurance that all control issues, fraudulence, or misstatements due to error have been detected. We believe that our disclosure controls and procedures and internal control over financial reporting have been and continue to be effective, and will continue to examine and refine where need be our disclosure controls and procedures and internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we may face various claims brought by third parties. Any of these claims could subject us to costly litigation. However, as of the date of this report, management believes the outcome of currently identified potential claims and lawsuits will not have a material adverse effect on our financial condition or results of operations.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing our Company. Additional risks not presently known to us or that we currently consider immaterial may also adversely affect our business. We have attempted to identify below the major factors that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors.

If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose all or part of your investment.

I. 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 September 30, 2014, we had no revenue sources, an accumulated deficit of $479.8 million and available cash and cash equivalents of approximately $54.1 million. On July 28, 2014, we closed an underwritten public offering of our common stock in which we received net proceeds of approximately $53.1 million. We believe that our current cash resources are sufficient to fund operations through 2016. However, 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;
- identifying, assessing, acquiring and/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, GCS-100, LJPC-1010 and LJPC-401 are based on unproven technologies and therapeutic approaches that have not been widely tested or used. To date, no products that use the LJPC-501, GCS-100, LJPC-1010 or LJPC-401 technology 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 LJPC-501, GCS-100, LJPC-1010 and LJPC-401 may be viewed as a test of our entire approach to developing therapies for patients suffering from life-threatening diseases. If LJPC-501, GCS-100, LJPC-1010 or LJPC-401 do not work as intended, or if the data from our future clinical trials indicate that LJPC-501, GCS-100, LJPC-1010 or LJPC-401 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. For example, the safety or efficacy results generated to date in clinical trials for GCS-100 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 practice, 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 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 its 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. In addition, we will need to successfully preserve our trade secrets and operate without infringing on the rights of others.

We depend on patents and other unpatented intellectual property to prevent others from improperly benefiting from products or technologies that we may have developed or acquired. Our patents and patent applications cover various technologies and drug candidates. 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, that may delay the review and issuance of any patents. 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 patents that have been issued or may be the subject of 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. However, there can be no assurance that patents will be issued from any of these applications, or that the scope of any issued patents will protect our technology.

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 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. In addition, we may have to incur significant expense and management time in defending or enforcing our patents.

We do not have complete patent protection for our product candidates. Therefore, it is possible that a competitor could develop the same or similar technology. If we cannot obtain and maintain effective patent rights for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

We could incur substantial costs and devote substantial management time in defending suits that others might bring against us for infringement of intellectual property rights or in prosecuting suits that we might bring against others to protect our intellectual property rights.

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 proprietary know-how, 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 or 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 or maintain orphan drug exclusivity for LJPC-501, 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 the development of LJPC-501 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, or COMP, 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. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Because the extent and scope of patent protection for our drug candidates (including LJPC-501) may in some cases be limited, orphan drug designation is especially important for our products for which orphan drug designation may be available. For eligible drugs, we plan to rely on the exclusivity period under the Orphan Drug Act to maintain a competitive position. If we do not obtain orphan drug exclusivity for our drug products and biologic 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 will be reduced.

Even though we have applied for orphan drug designation for LJPC-501 in the United States, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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, and selling 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.

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 invention 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
- 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.

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 competing products more quickly than we are able to, and to market any competing product more quickly or effectively so as to make 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 currently carry product liability insurance in the amount of $3.0 million in the aggregate. We believe our product liability insurance coverage is sufficient in light of our current 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.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, 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 New Drug Application, or NDA, Biologics License Application, or BLA, or marketing 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 IV 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 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 they are, 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.

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, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the 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 that require pharmaceutical companies 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.

II. RISK FACTORS RELATED SPECIFICALLY TO OUR STOCK

We currently have approximately 15.2 million shares of common stock outstanding and currently may be required to issue up to a total of approximately 8.1 million additional shares of common stock upon conversion of existing convertible preferred stock and upon exercise of outstanding stock option grants. Such an issuance would be significantly dilutive to our existing common shareholders. You will experience further dilution if we issue additional equity securities in future fund raising transactions.

As of September 30, 2014, there were 3,917 shares of Series C-1[2] Convertible Preferred Stock and 2,798 shares of Series F Convertible Preferred Stock issued and outstanding. In light of the conversion rate of our preferred stock (1,724 shares of common stock are issuable upon the conversion of one share of Series C-1[2] Convertible Preferred Stock, and 286 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 shareholders and provide the preferred investors with a sizeable interest in the Company.

Assuming the conversion of all preferred stock into common stock at the current conversion rates, and the exercise of all outstanding options, we would have approximately 23.3 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 shareholder, which such cap maybe amended or waived by each such holder with no less than 61-days' notice to the Company. With approximately 15.2 million shares of common stock issued and outstanding as of the date of this report, the issuance of this number of shares of common stock underlying the convertible preferred stock and outstanding stock options would represent approximately 35% dilution to our existing shareholders.

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 shareholders 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 shareholders;
- 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

		Incorporated by Reference Herein	
Exhibit Number	Description	Form	Date
3.1	Certificate of Amendment of Articles of Incorporation of La Jolla Pharmaceutical Company dated September 25, 2014	Form 8A12B/A	October 17, 2014
3.2	Amended and Restated Bylaws of La Jolla Pharmaceutical Company dated August 27, 2014	Form 8A12B/A	October 17, 2014
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith	
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith	
101.INS	XBRL Instance Document	Filed herewith	
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith	
101.DEF		Filed herewith	

	XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

La Jolla Pharmaceutical Company

Date: November 12, 2014

/s/ George F. Tidmarsh
George F. Tidmarsh, M.D., Ph.D.
President, Chief Executive Officer and Secretary
(As Principal Executive, Financial and Accounting Officer)