Corvus Pharmaceuticals, Inc.
Form 10-Q
August 04, 2016
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended June 30, 2016

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Corvus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-37719**	**46-4670809**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

863 Mitten Road, Suite 102
Burlingame, CA 94010
(Address of principal executive offices, including Zip Code)

Registrant s telephone number, including area code: **(650) 900-4520**

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 o No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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 the definitions 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 x (Do not check if a smaller reporting company)	Smaller reporting company o

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 August 4, 2016, 20,909,474 shares of the registrant s common stock, $0.0001 par value per share, were outstanding.

Table of Contents

CORVUS PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2016

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

CORVUS PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(in thousands, except share and per share data)

(unaudited)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 4,343	$ 4,105
Marketable securities	147,809	90,281
Prepaid and other current assets	1,343	1,277
Total current assets	153,495	95,663
Property and equipment, net	2,807	1,845
Deferred offering costs		951
Other assets	619	
Total assets	$ 156,921	$ 98,459
Liabilities, Convertible Preferred Stock, and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,320	$ 1,575
Accrued and other liabilities	2,287	1,495
Total current liabilities	3,607	3,070
Other liabilities	1,346	710
Total liabilities	4,953	3,780
Commitments and contingencies *(Note 13)*		
Convertible preferred stock: $0.0001 par value; 0 and 14,274,741 shares authorized at June 30, 2016 and December 31, 2015, respectively; 0 and 14,274,741 issued and outstanding at June 30, 2016 and December 31, 2015, respectively (liquidation preference of $0 and $108,500 at June 30, 2016 and December 31, 2015, respectively)		125,780
Stockholders equity (deficit) :		
Preferred stock: $0.0001 par value; 10,000,000 and 0 shares authorized at June 30, 2016 and December 31, 2015, respectively; no shares issued and outstanding at June 30, 2016 and December 31, 2015		
Common stock: $0.0001 par value; 290,000,000 and 20,000,000 shares authorized at June 30, 2016 and December 31, 2015, respectively; 20,909,474 and 1,431,615 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	2	

Additional paid-in capital		198,376		440
Accumulated other comprehensive income (loss)		78		(45)
Accumulated deficit		(46,488)		(31,496)
Total stockholders equity (deficit)		151,968		(31,101)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$	156,921	$	98,459

The accompanying notes are an integral part of these financial statements.

Table of Contents

CORVUS PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 7,119	$ 2,005	$ 12,517	$ 3,928
General and administrative	1,706	327	2,734	618
Total operating expenses	8,825	2,332	15,251	4,546
Loss from operations	(8,825)	(2,332)	(15,251)	(4,546)
Change in fair value of convertible preferred stock liability		(17,900)		(17,600)
Interest income	180		259	1
Net loss	$ (8,645)	$ (20,232)	$ (14,992)	$ (22,145)
Net loss per share, basic and diluted	$ (0.43)	$ (58.42)	$ (1.42)	$ (68.80)
Shares used to compute net loss per share, basic and diluted	19,959,459	346,339	10,568,562	321,868
Other comprehensive income (loss):				
Unrealized gain on marketable securities	49		123	
Total other comprehensive income (loss)	49		123	
Comprehensive loss	$ (8,596)	$ (20,232)	$ (14,869)	$ (22,145)

The accompanying notes are an integral part of these financial statements.

Table of Contents

CORVUS PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands, except share and per share data)

(unaudited)

	Six Months Ended June 30,	
	2016	**2015**
Cash flows from operating activities		
Net loss	$ (14,992)	$ (22,145)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	250	36
Amortization/accretion related to marketable securities	310	5
Stock-based compensation	1,517	20
Change in fair value of convertible preferred stock liability		17,600
Changes in operating assets and liabilities:		
Prepaid and other current assets	84	(203)
Other assets	(619)	(20)
Accounts payable	129	300
Accrued and other liabilities	920	356
Other long-term liabilities	636	13
Net cash used in operating activities	(11,765)	(4,038)
Cash flows from investing activities		
Purchases of marketable securities	(152,790)	(25,722)
Maturities of marketable securities	94,925	
Purchase of property and equipment	(1,487)	(877)
Net cash used in investing activities	(59,352)	(26,599)
Cash flows from financing activities		
Proceeds from issuance of common stock in IPO, net of issuance costs	71,355	
Proceeds from issuance of convertible preferred stock, net of issuance costs		20,730
Proceeds from exercise of common stock options		42
Net cash provided by financing activities	71,355	20,772
Net (decrease) increase in cash and cash equivalents	238	(9,865)
Cash and cash equivalents at beginning of the period	4,105	12,517
Cash and cash equivalents at end of the period	$ 4,343	$ 2,652
Supplemental disclosures of cash flow information		
Purchases of property and equipment incurred but not paid	$ 11	$ 9

The accompanying notes are an integral part of these financial statements.

Table of Contents

CORVUS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (unaudited)

1. Organization

Corvus Pharmaceuticals, Inc. (Corvus or the Company) was incorporated in Delaware on January 27, 2014 and commenced operations in November 2014. Corvus is a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology therapies that are designed to harness the immune system to attack cancer cells. The Company s primary activities have been establishing its facilities, recruiting personnel, conducting research and development of its product candidates, including conducting a clinical trial, and raising capital. The Company s operations are located in Burlingame, California.

Initial Public Offering

On March 22, 2016, the Company s registration statement on Form S-1 (File No. 333-208850) relating to its initial public offering (IPO) of its common stock was declared effective by the Securities and Exchange Commission (SEC) and the shares of its common stock began trading on the NASDAQ Global Market on March 23, 2016. The public offering price of the shares sold in the IPO was $15.00 per share. The IPO closed on March 29, 2016, pursuant to which the Company sold 4,700,000 shares of its common stock. On April 26, 2016, the Company sold an additional 502,618 shares of its common stock to the underwriters upon partial exercise of their over-allotment option, at the initial offering price of $15.00 per share. The Company received aggregate net proceeds of approximately $70.6 million, after underwriting discounts, commissions and offering expenses. Immediately prior to the consummation of the IPO, all outstanding shares of convertible preferred stock were converted into common stock.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP). The Company s functional and reporting currency is the U.S. dollar.

Unaudited Interim Financial Information

The accompanying interim condensed financial statements and related disclosures are unaudited, have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the results of operations for the periods presented.

The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. The condensed results of operations for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period. The accompanying condensed financial statements should be read in conjunction with the audited financial statements and the related notes for the year ended December 31, 2015 included in the Company s Prospectus dated March 22, 2016 filed pursuant to Rule 424(b)(4) with the SEC.

Use of Estimates

The preparation of the Company s financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from such estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

Substantially all of the Company s cash and cash equivalents are deposited in accounts with two financial institutions that management believes are of high credit quality. Such deposits may, at times, exceed federally insured limits. The Company maintains its cash with an accredited financial institution and accordingly, such funds are subject to minimal credit risk. The Company s marketable securities are direct obligations of the United States government. The Company has not experienced any losses on its deposits of cash, cash equivalents or marketable securities.

Since inception, the Company has incurred recurring net losses and negative cash flows from operations. At June 30, 2016, the Company had an accumulated deficit of $46.5 million and does not expect to experience positive cash flows from operations in the near future. The Company has financed its operations to date primarily through private placements of convertible preferred stock and proceeds from its IPO. As of June 30, 2016, the Company had cash, cash equivalents and marketable securities of $152.2 million.

Table of Contents

The Company is subject to a number of risks similar to other early stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, its reliance on third parties to conduct its clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company s product candidates, its right to develop and commercialize its product candidates pursuant to the terms and conditions of the licenses granted to the Company, and protection of proprietary technology. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate product revenue or achieve profitability.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment, that of the development of and commercialization of novel immuno-oncology therapies that are designed to harness the immune system to attack cancer cells.

Cash and Cash Equivalents and Marketable Securities

The Company considers all highly liquid investment securities with remaining maturities at the date of purchase of three months or less to be cash equivalents.

Investments with remaining maturities, at the date of purchase, greater than three months, but less than one year are considered short-term. The Company determines the appropriate classification of marketable securities at the time of purchase and evaluates such designation as of each balance sheet date. To date, all marketable securities have been classified as available-for-sale and are carried at fair value with unrealized gains and losses, if any, included as a component of accumulated other comprehensive income (loss) in stockholders equity (deficit). Interest and realized gains and losses are included in interest income. Realized gains and losses are recognized based on the specific identification method.

Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The carrying amount of the Company s financial instruments, including cash equivalents, accounts payable and accrued liabilities, approximate fair value due to their short-term maturities.

Deferred Offering Costs

Deferred offering costs consist primarily of direct incremental costs related to the Company s initial public offering of its common stock. Upon completion of the initial public offering in March 2016, these amounts were offset against the proceeds of the offering.

Property and Equipment, Net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets:

Laboratory equipment	5 years
Computer equipment and purchased software	3 years
Leasehold improvements	Shorter of asset s useful life or remaining term of lease

Maintenance and repairs that do not extend the life or improve the asset are expensed when incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations.

Table of Contents

Impairment of Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment, to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management s estimate of the asset s ability to generate positive income from operations and positive cash flow in future periods as well as the strategic significance of the assets to the Company s business objectives. Should impairment exist, the impairment loss to be recognized is measured by the amount by which the carrying amount of the asset exceeds the projected discounted future net cash flows arising from the asset. All long-lived assets are maintained in the United States of America.

Convertible Preferred Stock Liability

The Company determined that the Company s obligation to issue additional shares of the Company s convertible preferred stock represented a freestanding financial instrument, which was accounted for as a liability. The freestanding convertible preferred stock liability was initially recorded at fair value, with fair value changes recognized in the statements of operations and comprehensive loss. The Company estimated the fair value of this liability using an option-pricing model that included assumptions for future financings, expected volatility, expected life and risk-free interest rate. At the time of the exercise of the option (June 2015), the remaining value of the convertible preferred stock liability was reclassified to convertible preferred stock with no further remeasurement required.

Research and Development Expense

The Company records research and development expenses as incurred. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made. Research and development expenses consist of costs incurred by the Company for the discovery and development of the Company s product candidates and include:

- employee-related expenses, including salaries, benefits, travel and non-cash stock-based compensation expense;

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, contract manufacturing organizations, academic and non-profit institutions and consultants;

- costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use;

- license fees; and

- other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

Clinical Trial Accruals

Costs for preclinical studies and clinical trial activities are recognized based on an evaluation of the vendors progress towards completion of specific tasks, using data such as clinical site activations, patient enrollment or information provided to the Company by its vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services are performed. The Company determines accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion, or the services completed. The Company s estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time.

Stock-Based Compensation

The Company maintains incentive plans under which incentive stock options and nonqualified stock options may be granted to employees and non-employee service providers.

The Company accounts for stock-based employee compensation arrangements in accordance with the provisions of ASC 718, *Compensation Stock Compensation*. For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair values. The value of the award is recognized as an expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. Forfeitures are accounted for when they occur.

Table of Contents

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model. The expense for options granted to non-employees is periodically re-measured as the underlying options vest. The awards generally vest over the time period the Company expects to receive service from the non-employee.

Income Taxes

The Company accounts for income taxes under the asset and liability method. The Company estimates actual current tax exposure together with assessing temporary differences resulting from differences in accounting for reporting purposes and tax purposes for certain items, such as accruals and allowances not currently deductible for tax purposes. These temporary differences result in deferred tax assets and liabilities, which are included in the Company s balance sheets. In general, deferred tax assets represent future tax benefits to be received when certain expenses previously recognized in the Company s statements of operations and comprehensive loss become deductible expenses, under applicable income tax laws or when net operating loss or credit carryforwards are utilized. Accordingly, realization of the Company s deferred tax assets is dependent on future taxable income against which these deductions, losses and credits can be utilized.

The Company must assess the likelihood that the Company s deferred tax assets will be recovered from future taxable income and a valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered. The Company applies judgment in the determination of the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Based on the available evidence, the Company is unable, at this time, to support the determination that it is more likely than not that its deferred tax assets will be utilized in the future. Accordingly, the Company recorded a full valuation allowance for all periods presented. The Company intends to maintain valuation allowances until sufficient evidence exists to support its reversal. The Company recognizes any material interest and penalties related to unrecognized tax benefits in income tax expense.

The Company recognizes benefits of uncertain tax positions if it is more likely than not such positions will be sustained upon examination based solely on their technical merits as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company is required to file income tax returns in the U.S. federal jurisdiction. The Company currently is not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders equity (deficit) that result from transactions and economic events other than those with stockholders. The Company s only element of other comprehensive loss in any period presented was unrealized gains on available for sale marketable securities.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted average

number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock subject to repurchase, and stock options are considered to be potentially dilutive securities. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers,* which required an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU No. 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective January 1, 2018 for public companies. Early application is permitted as of January 1, 2017. The standard permits the use of either the retrospective or cumulative effect transition method. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies the implementation guidance on principal versus agent considerations in ASU No. 2014-09. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing,* which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, which relates to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of January 1, 2018. The Company does not believe adopting this guidance will have a material impact on its financial statements as the Company is not yet generating revenues.

Table of Contents

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties About an Entity s Ability to Continue as a Going Concern*. This standard update provides guidance around management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. The new guidance is effective for all annual and interim periods ending after December 15, 2016. The Company does not believe that adopting ASU 2014-15 will have a material impact on its financial statements.

In November 2015, the FASB issued ASU No 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. This standard amends the accounting for income taxes and requires all deferred tax assets and liabilities to be classified as non-current on the balance sheet. The new standard is effective for reporting periods beginning after December 15, 2016, with early adoption permitted. The standard may be adopted either prospectively or retrospectively. We are currently evaluating the impact of ASU 2015-17.

In February 2016, the FASB issued *ASU No. 2016-02, Leases (Topic 842)* that replaces existing lease guidance. The new standard requires lessees to record right-of-use assets and corresponding lease liabilities on the balance sheet. The new guidance will continue to classify leases as either finance or operating, with classification affecting the pattern of expense recognition in the statement of income. The standard is effective for the Company beginning June 1, 2019, with early application permitted. The new standard is required to be applied with a modified retrospective approach to each prior reporting period presented with various optional practical expedients. The Company is currently assessing the impact of this guidance on its financial statements.

In March 2016, the FASB issued *ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.* The updated guidance changes how companies account for certain aspects of share-based payment awards to employees, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The update to the standard is effective for the Company beginning June 1, 2017, with early application permitted. The Company has adopted the provisions of this standard early, the impact of which on its financial statements was not significant.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The new standard changes the impairment model for most financial assets and certain other instruments. Under the new standard, entities holding financial assets and net investment in leases that are not accounted for at fair value through net income to be presented at the net amount expected to be collected. An allowance for credit losses will be a valuation account that will be deducted from the amortized cost basis of the financial asset to present the net carrying value at the amount expected to be collected on the financial asset. The new standard will be effective for us on January 1, 2020. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

Table of Contents

3. Net Loss per Share

The following table shows the calculation of net loss per share (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Numerator:				
Net loss - basic and diluted	$ (8,645)	$ (20,232)	$ (14,992)	$ (22,145)
Denominator:				
Weighted average common shares outstanding	20,771,392	1,196,615	11,414,296	1,158,193
Less: weighted average common shares subject to repurchase	(811,933)	(850,276)	(845,734)	(836,325)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	19,959,459	346,339	10,568,562	321,868
Net loss per share, basic and diluted	$ (0.43)	$ (58.42)	$ (1.42)	$ (68.80)

The amounts in the table below were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect:

	Three and Six Months Ended June 30,	
	2016	2015
Convertible preferred stock		8,921,429
Common stock subject to repurchase	770,550	820,440
Outstanding options	2,034,386	168,636
Total shares of common stock equivalents	2,804,936	9,910,505

4. Fair Value Measurements

Financial assets and liabilities are measured and recorded at fair value. The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 Quoted prices in active markets for identical assets or liabilities

Level 2 Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly

Level 3 Unobservable inputs that reflect the Company s own assumptions about the assumptions market participants would use in pricing the asset or liability

There have been no transfers of assets and liabilities between levels of hierarchy.

Table of Contents

The following tables present information as of June 30, 2016 and December 31, 2015 about the Company s assets that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy the Company utilized to determine such fair values (in thousands):

	June 30, 2016			
	Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
Assets				
Cash equivalents	$ 2,676	$	$	$ 2,676
Marketable securities	147,809			147,809
	$ 150,485	$	$	$ 150,485

	December 31, 2015			
	Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
Assets				
Cash equivalents	$ 3,245	$	$	$ 3,245
Marketable securities	90,281			90,281
	$ 93,526	$	$	$ 93,526

The Company s marketable securities are invested in direct obligations of the United States government for all periods.

As of June 30, 2016, marketable securities had a maximum remaining maturity of seven months and consisted of U.S. Treasury securities.

The following table presents the issuances, changes in fair value, exercise and reclassification of the Company s Level 3 financial instrument which is measured at fair value on a recurring basis (in thousands):

	Convertible Preferred Stock Call Option Liability
Balance as of December 31, 2014	$ 2,600
Change in fair value of convertible preferred stock liability through March 31, 2015	(300)
Balance as of March 31, 2015	2,300
Change in fair value of convertible preferred stock liability through date of Series A second tranche issuance	17,900
Recognition of fair value upon issuance of second tranche Series A convertible preferred stock	(20,200)
Balance as of June 30, 2015	$

As of June 30, 2016 and December 31, 2015, the fair value of available for sale marketable securities by type of security were as follows (in thousands):

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 147,731	$ 80	$ (2)	$ 147,809

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 90,326	$	$ (45)	$ 90,281

Table of Contents

5. License and Collaboration Agreements

Scripps Licensing Agreement

In December 2014, the Company entered into a license agreement with The Scripps Research Institute (Scripps), pursuant to which it was granted a non-exclusive, world-wide license for all fields of use under Scripps rights in certain know-how and technology related to a mouse hybridoma clone expressing an anti-human CD73 antibody, and to progeny, mutants or unmodified derivatives of such hybridoma and any antibodies expressed by such hybridoma. Scripps also granted the Company the right to grant sublicenses in conjunction with other proprietary rights the Company holds, or to others collaborating with or performing services for the Company. Under this license agreement, Scripps has agreed not to grant any additional commercial licenses with respect to such materials, other than march-in rights granted to the U.S. government.

Upon execution of the agreement, the Company made a one-time cash payment to Scripps of $10,000 in 2015 and is also obligated to pay a minimum annual fee to Scripps of $25,000. The one-time cash payment was recorded as research and development expense as technological feasibility of the asset had not been established and there was no alternative future use. The first minimum annual fee payment is due on the first anniversary of effective date of the agreement and will be due on each subsequent anniversary of the effective date for the term of the agreement. The Company is also required to make performance-based cash payments upon successful completion of clinical and sales milestones. The aggregate potential milestone payments are $2.6 million. The Company is also required to pay royalties on net sales of licensed products sold by it, its affiliates and its sublicensees at a rate in the low-single digits. In addition, should the Company sublicense the rights licensed under the agreement, it has agreed to pay a percentage of sublicense revenue received at specified rates that start at double digit percentages and decrease to single digit percentages based on the elapsed time from the effective date of the agreement and the time of entry into such sublicense. To date, no milestone payments have been made.

The Company s license agreement with Scripps will terminate upon expiration of its obligation to pay royalties to Scripps under the license agreement. The Company s license agreement with Scripps is terminable by the consent of the parties, at will by the Company upon providing 90 days written notice to Scripps, or by Scripps for certain material breaches, or if the Company undergoes a bankruptcy event. In addition, Scripps may terminate the license on a product-by-product basis, or the entire agreement, if the Company fails to meet specified diligence obligations related to the development and commercialization of licensed products. Scripps may also terminate the agreement after the third anniversary of the effective date of the agreement if it reasonably believes, based on reports the Company provides to Scripps, that the Company has not used commercially reasonable efforts as required under the agreement, subject to a specified notice and cure period.

Vernalis Licensing Agreement

In February 2015, the Company entered into a license agreement with Vernalis (R&D) Limited (Vernalis), which was subsequently amended as of November 5, 2015, and, pursuant to which the Company was granted an exclusive, worldwide license under certain patent rights and know-how, including a limited right to grant sublicenses, for all fields of use to develop, manufacture and commercialize products containing certain adenosine receptor antagonists, including CPI-444. Pursuant to this agreement, a one-time cash payment to Vernalis in the amount of $1.0 million, which was recorded as research and development expense as technological feasibility of the asset had not been established and there was no alternative future use. The Company is also required to make cash milestone payments to Vernalis upon the successful completion of clinical and regulatory milestones for licensed products depending on the indications for which such licensed products are developed and upon achievement of certain sales milestones. The aggregate potential milestone payments exceed $200 million for all indications. To date, no milestone payments have been made.

The Company has also agreed to pay Vernalis tiered incremental royalties based on the annual net sales of licensed products containing CPI-444 on a product-by-product and country-by-country basis, subject to certain offsets and reductions. The tiered royalty rates for products containing CPI-444 range from the mid-single digits up to the low-double digits on a country-by-country net sales basis. The royalties on other licensed products that do not include CPI-444 also increase with the amount of net sales on a product-by-product and country-by-country basis and range from the low-single digits up to the mid-single digits on a country-by-country net sales basis. The Company is also obligated to pay to Vernalis certain sales milestones as indicated above when worldwide net sales reach specified levels over an agreed upon time period.

Table of Contents

The agreement will expire on a product-by-product and country-by-country basis upon the expiration of the Company s payment obligations to Vernalis in respect of a particular product and country. Both parties have the right to terminate the agreement for an uncured material breach by the other party. The Company may also terminate the agreement at its convenience by providing 90 days written notice, provided that the Company has not received notice of its own default under the agreement at the time the Company exercises such termination right. Vernalis may also terminate the agreement if the Company challenges a licensed patent or undergoes a bankruptcy event.

Genentech Collaboration Agreement

In October 2015, the Company entered into a clinical trial collaboration agreement with Genentech to evaluate the safety, tolerability and preliminary efficacy of CPI-444 combined with Genentech s investigational cancer immunotherapy, TECENTRIQTM(atezolizumab), a fully humanized monoclonal antibody targeting protein programmed cell death ligand 1(PD-L1), in a variety of solid tumors in a Phase 1/1b clinical trial. Pursuant to this agreement, the Company will be responsible for the conduct and cost of the relevant studies, under the supervision of a joint development committee made up of representatives of the Company and representatives of Genentech. Genentech will supply TECENTRIQTM. As part of the agreement, the Company granted Genentech certain rights of first negotiation to participate in future clinical trials that the Company may conduct evaluating the administration of CPI-444 in combination with an anti-PD-1 or anti-PD-L1 antibody. If the Company and Genentech do not reach agreement on the terms of any such participation by Genentech within a specified time period, the Company retains the right to collaborate with third parties in such activities. The Company also granted Genentech certain rights of first negotiation should it decide to license development and commercialization rights to CPI-444. Should the Company and Genentech not reach agreement on the terms of such a license within a specified time period, it retains the right to enter into a license with another third party.

The Company and Genentech each have the right to terminate the agreement for material breach by the other party. In addition, the agreement may be terminated by either party due to safety considerations, if directed by a regulatory authority or if development of CPI-444 or TECENTRIQTM is discontinued.

Further, the agreement will expire after a set period of time following the provision by the Company of the final clinical study report to Genentech.

Table of Contents

6. Balance Sheet Components (in thousands):

	June 30, 2016	December 31, 2015
Prepaid and Other Current Assets		
Prepaid insurance	$ 306	$ 15
Prepaid research and development manufacturing expenses	208	722
Tenant improvement allowance receivable		347
Other	829	193
	$ 1,343	$ 1,277
Property and Equipment, net		
Leasehold improvements	$ 1,688	$ 74
Laboratory equipment	1,471	829
Computer equipment and purchased software	33	18
Construction in progress		1,059
	3,192	1,980
Less: accumulated depreciation and amortization	(385)	(135)
	$ 2,807	$ 1,845
Accrued and Other Liabilities		
Accrued clinical trial related	$ 597	$ 376
Accrued manufacturing expense	537	12
Personnel related	360	305
Deferred rent	305	223
Accrued legal and accounting	163	314
Accrued contruction in progress costs		101
Other accrued expenses	325	164
	$ 2,287	$ 1,495
Other Liabilities		
Deferred rent	$ 1,294	$ 642
Shares subject to vesting	52	68
	$ 1,346	$ 710

7. Convertible Preferred Stock

Under the amended and restated certificate of incorporation in effect as of June 30, 2016, the Company is authorized to issue two classes of stock: preferred stock and common stock.

Immediately prior to the consummation of the IPO on March 29, 2016, all outstanding shares of Series A and B convertible preferred stock were converted into 14,274,741 shares of common stock on a one-for-one basis.

Convertible preferred stock as of December 31, 2015 consisted of the following (in thousands, except share data):

	Shares	Net

	Shares Authorized	Issued & Outstanding	Carrying Value	Liquidation Value
Series A	8,921,429	8,921,429	$ 50,941	$ 33,500
Series B	5,353,312	5,353,312	74,839	75,000
Total	14,274,741	14,274,741	$ 125,780	$ 108,500

Table of Contents

8. Convertible Preferred Stock Liability

On November 26, 2014, the Company executed the Series A Convertible Preferred Stock Purchase Agreement for the issuance of up to 8,921,438 shares of Series A convertible preferred stock and issued 3,395,468 shares for net proceeds of $12.6 million in connection with the first closing of the first tranche. In January 2015, in connection with the second closing of the first tranche, the Company issued 1,065,246 shares of Series A convertible preferred stock for net proceeds of $4.0 million and in June 2015, in connection with the closing of the second tranche, an additional 4,460,715 shares of Series A convertible preferred stock were issued for net proceeds of $16.7 million.

The Series A Convertible Preferred Stock Purchase Agreement provided that, upon the earliest to occur of any of three defined triggers, each investor of the first tranche agreed to purchase its pro-rata portion of the shares to be issued in the second tranche and the Company agreed to sell and issue said shares of Series A convertible preferred stock on the same terms as the first tranche.

A convertible preferred stock liability was recorded for the Company s obligation to sell the second tranche of the Series A convertible preferred stock to the first tranche stockholders at a fixed price of $3.755 per share upon the satisfaction of certain conditions. A liability was initially recorded in connection with the first tranche of the Series A convertible preferred stock financing at its initial estimated fair value of $2.6 million, with gains and losses arising from changes in fair value recognized in the statements of operations at each period while such instrument was classified as a liability. A gain of $0.3 million was recorded for the change in estimated fair value of the Series A convertible preferred stock liability for the period from January 1, 2015 through March 31, 2015. A $17.9 million charge was recorded for the change in estimated fair value of the Series A convertible preferred stock liability for the period from April 1, 2015 to the closing of the second tranche in June 2015. Upon the closing of the second tranche in June 2015, the liability terminated and the balance of the liability of $20.2 million was reclassified to convertible preferred stock.

The preferred stock liability related to Series A convertible preferred stock was valued at issuance and at December 31, 2014 and March 31, 2015 using a backsolve option-pricing method based on the consideration paid for the Series A convertible preferred stock and the convertible preferred stock liability using an assumed term of 1.0 years and 0.75 years, an interest rate of 0.13% and 0.20% and a volatility of 85% and 85%, respectively.

Immediately prior to its exercise on June 10, 2015, the convertible preferred stock liability s fair value was estimated based on its intrinsic value, with the fair value of the Series A convertible preferred stock estimated as of June 10, 2015 and compared to the exercise price of the Series A convertible preferred stock liability.

To estimate the fair value of the Series A convertible preferred stock as of June 10, 2015, the enterprise value of the Company was estimated based on potential IPO and sale estimates. The enterprise value was then allocated to the various classes of securities using an option pricing model that assumed a term of two years to a liquidity event, an interest rate of 0.75% and a volatility of 75% based on market conditions and expectations as of the June valuation date.

9. Common Stock

As of June 30, 2016, the amended and restated certificate of incorporation authorizes the Company to issue 290 million shares of common stock and 10 million shares of preferred stock.

Each share of common stock is entitled to one vote. Common stockholders are entitled to dividends if and when declared by the board of directors. As of June 30, 2016, no dividends on common stock had been declared.

The Company has reserved shares of common stock for issuance as follows:

	June 30, 2016	December 31, 2015
Convertible preferred stock		14,274,741
Shares available for future option grants	2,804,750	2,559,499
Outstanding options	2,034,386	784,136
Unvested restricted common stock (founders and early exercise of stock options)	770,550	924,535
Shares reserved for employee stock purchase plan	200,000	
Total	5,809,686	18,542,911

Table of Contents

10. Stock Option Plans

In February 2014, the Company adopted the 2014 Equity Incentive Plan (the 2014 Plan), which was subsequently amended in November 2014, July 2015 and September 2015, under which it granted incentive stock options (ISOs) or non-qualified stock options (NSOs). Terms of stock agreements, including vesting requirements, are determined by the board of directors or a committee authorized by the board of directors, subject to the provisions of the 2014 Plan. In general, awards granted by the Company vest over four years and have maximum exercise term of 10 years. The 2014 Plan provides that grants must be at an exercise price of 100% of fair market value of the Company s common stock as determined by the board of directors on the date of the grant.

In connection with the consummation of the IPO in March 2016, the 2016 Equity Incentive Award Plan (the 2016 Plan), became effective. Under the 2016 Plan. incentive stock options, non-statutory stock options, stock purchase rights and other stock-based awards may be granted. Terms of stock agreements, including vesting requirements, are determined by the board of directors or a committee authorized by the board of directors, subject to the provisions of the 2016 Plan. In general, awards granted by the Company vest over four years and have maximum exercise term of 10 years. The 2016 Plan provides that grants must be at an exercise price of 100% of fair market value of the Company s common stock as determined by the board of directors on the date of the grant. In conjunction with adopting the 2016 Plan, the 2014 Plan was terminated and no further awards will be granted under the 2014 Plan. Options outstanding under the 2014 Plan as of the effective date of the 2016 Plan that are forfeited or lapse unexercised may be re-issued under the 2016 Plan, up to a maximum of 1,136,229 shares.

Activity under the Company s stock option plans is set forth below:

		Options Outstanding	
	Shares Available for Grant	Number of Options	Weighted-Average Exercise Price
Balance at December 31, 2015	2,559,499	784,136	$ 4.09
Additional shares authorized	1,496,001		
Options granted	(1,322,250)	1,322,250	14.63
Options exercised		(500)	0.28
Options forfeited	71,500	(71,500)	4.62
Balance at June 30, 2016	2,804,750	2,034,386	$ 10.92

11. Stock-Based Compensation

The Company s results of operations include expenses relating to employee and non-employee stock-based awards as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$ 486	$ 17	$ 787	$ 20

General and administrative	589		730	
Total	$ 1,075	$ 17	$ 1,517	$ 20

12. Income Taxes

The Company did not record a provision or benefit for income taxes during the three or six months ended June 30, 2016 or 2015. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

Table of Contents

13. Commitments and Contingencies

Facility Lease

In January 2015, the Company signed an operating lease, effective February 1, 2015, for 8,138 square feet of office and laboratory space located in Burlingame, California with a one-year term. In March 2015, the Company signed the first amendment to the lease, effective April 15, 2015, whereby the original premises were expanded by an additional 3,163 square feet and the lease term was extended through January 2017. In August 2015, the Company signed the second amendment to the lease whereby the size of the existing premises was increased by adding 10,834 square feet and the term of the lease was extended through January 2021. The landlord agreed to provide $1.6 million to fund qualifying tenant improvements, defined as building design, permits and construction costs. Tenant improvements associated with the tenant improvement allowance were $1.6 million. The lease agreement includes an annual rent escalation clause, a right to extend the term at the then current market rate for three years and a right of first refusal on certain space. The Company records rent expense on a straight-line basis over the effective term of the lease, including any free rent periods and incentives. The lease requires the Company to pay additional amounts for operating and maintenance expenses. In June 2016, the Company amended its existsing facility lease to add a net of 4,523 square feet. After completing approximately $250,000 of improvements, the Company plans to occupy the space in November 2016. Rent expense related to the facilities lease for the three and six months ended June 30, 2016 was approximately $127,000 and $256,000, respectively. Rent expense for the three and six months ended June 30, 2015 was approximately $74,000 and $120,000, respectively. As of June 30, 2016, future minimum lease payments under the facility lease were as follows (in thousands):

		Operating Leases
2016 *	$	428
2017		992
2018		1,022
2019		1,052
2020		1,085
Thereafter		90
Total	$	4,669

*Remainder of the year

Pursuant to the Company s license agreements with each of Vernalis and Scripps, it has obligations to make future milestone and royalty payments to these parties, respectively. However, because these amounts are contingent, they have not been included on the Company s balance sheet.

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the

termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. There have been no claims to date and the Company has a directors and officers insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Legal Proceedings

The Company is not a party to any material legal proceedings.

14. 401(k) Plan

In April 2015, the Company adopted a 401(k) retirement and savings plan (the 401(k) Plan) covering all employees. The 401(k) Plan allows employees to make pre- and post-tax contributions up to the maximum allowable amount set by the IRS. The Company does not make matching contributions to the 401(k) plan on behalf of participants.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and related notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and notes for the year ended December 31, 2015, included in our prospectus dated March 22, 2016 filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424 (b)(4) under the Securities Act of 1933, as amended (the Prospectus)

This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled Risk Factors. Except as may be required by law, we assume no obligation to update these forward-looking statements or the reasons that results could differ from these forward-looking statements.

Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology therapies that are designed to harness the immune system to attack cancer cells. Since we began operations in November 2014, we have built a pipeline of four immuno-oncology programs, three of which focus on the adenosine-cancer axis to modulate an immune response. Our lead product candidate, CPI-444, is an oral, small molecule antagonist of the A2A receptor for adenosine, an immune checkpoint. In January 2016, we began enrolling patients in a large expansion cohort trial for CPI-444. This Phase 1/1b clinical trial is designed to examine safety, tolerability, biomarkers and preliminary efficacy of CPI-444 in several solid tumor types, both as a single agent and in combination with Genentech, Inc. s investigational cancer immunotherapy TECENTRIQTM (atezolizumab), a fully humanized monoclonal antibody targeting protein programmed cell death ligend 1 (PD-L1). We have also chosen a lead development candidate for our second program, an anti-CD73 monoclonal antibody that inhibits the production of adenosine, and plan to select development candidates for our other two programs in 2016. We believe the breadth and status of our pipeline demonstrates our management team s expertise in understanding and developing immuno-oncology assets as well as in identifying product candidates that can be in-licensed and further developed internally to treat many types of cancer. We hold worldwide rights to all of our product candidates.

To date, substantially all of our efforts have been focused on the research, development and advancement of CPI-444, and we have not generated any revenue from product sales and, as a result, we have incurred significant losses. We expect to continue to incur significant research and development and general and administrative expenses related to our operations. Our net loss for the six months ended June 30, 2016 and 2015, was $15.0 million and $22.1 million, respectively. The net loss for the six months ended June 30, 2015 included a $17.6 million non-cash charge associated with the change in fair value of a convertible preferred stock liability. As of June 30, 2016, we had an accumulated deficit of $46.5 million.. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for and begin to commercialize CPI-444, and as we develop other product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Since our inception and through June 30, 2016, we have funded our operations primarily through the sale and issuance of stock. In November 2014, January 2015 and June 2015, we received aggregate net proceeds of $33.3 million from the sale of our Series A convertible preferred stock. In September 2015, we received net proceeds of $74.8 million from the sale of our Series B convertible preferred stock. On March 22, 2016, our registration statement on Form S-1 (File No. 333-208850) relating to its initial public offering (IPO) of our common stock was declared effective by the SEC. Shares of our common stock began trading on the NASDAQ Global Market on March 23, 2016. The IPO closed on March 29, 2016, pursuant to which we sold 4,700,000 shares of our common stock at a public offering price of $15.00 per share. On April 2016, we sold an additional 502,618 shares of our common stock to the underwriters upon partial exercise of their over-allotment option, at the initial offering price of $15.00 per share. We received aggregate net proceeds of approximately $70.6 million, after underwriting discounts, commissions and offering expenses. Immediately prior to the consummation of the IPO, all of our outstanding shares of convertible preferred stock were converted into 14.3 million shares of our common stock.

As of June 30, 2016, we had capital resources consisting of cash, cash equivalents and marketable securities of approximately $152.2 million. We do not expect our existing capital resources to be sufficient to enable us to fund the completion of our clinical trials and remaining development program of CPI-444 through commercialization. In addition, our operating plan may change as a result of many factors, including those described in the section of this report entitled Risk Factors and others currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. Such financing would result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. If we raise additional capital through strategic collaboration agreements, we may have to relinquish valuable rights to our product candidates, including possible future revenue streams. In addition, additional funding may not be available to us on acceptable terms or at all and any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

Critical Accounting Policies

Our critical accounting policies are described in Note 2 to our financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. There have been no material changes to our critical accounting policies during the six months ended June 30, 2016.

Table of Contents

Financial Overview

Revenue

To date, we have not generated any revenues. We do not expect to receive any revenues from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into revenue-generating collaboration agreements with third parties.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred to conduct research, such as the discovery and development of our product candidates, as well as the in-licensing of CPI-444. We record research and development expenses as incurred. Research and development expenses consist of costs incurred for the discovery and development of our product candidates and include:

- employee-related expenses, including salaries, benefits, travel and non-cash stock-based compensation expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, preclinical testing organizations, contract manufacturing organizations, academic and non-profit institutions and consultants;
- costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use;
- license fees; and
- other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

We plan to increase our research and development expenses substantially as we continue the development of our product candidates. Our current planned research and development activities include the following:

- enrollment and completion of our Phase 1/1b clinical trial of CPI-444;

- process development and manufacturing of drug supply for CPI-444;

- process development and manufacturing of drug supply for our anti-CD73 antibody to support IND-enabling studies; and

- preclinical studies under our other programs in order to select development product candidates in 2016.

In addition to our product candidates that are in clinical development, we believe it is important to continue substantial investment in potential new product candidates to build the value of our product candidate pipeline and our business.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties related to timing and cost to completion. The duration, costs and timing of clinical trials and development of product candidates will depend on a variety of factors, including many of which are beyond our control. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming, and the successful development of our product candidates is uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in the section s titled Risk Factors Risks Related to the Discovery and Development of Our Product Candidates. As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses include personnel costs, expenses for outside professional services and allocated expenses. Personnel costs consist of salaries, benefits and stock-based compensation. Outside professional services consist of legal, accounting and audit services and other consulting fees. Allocated expenses consist of rent expense related to our office and research and development facility.

Table of Contents

We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase our administrative headcount significantly to operate as a public company and as we advance our product candidates through clinical development, which will also increase our general and administrative expenses.

Change in Fair Value of Convertible Preferred Stock Liability

Our Series A convertible preferred stock financing included two tranches of investment. The first tranche included two separate closings in November 2014 and January 2015, and the second tranche occurred in June 2015 following the occurrence of a defined triggering event under the financing transaction documents.

The change in the fair value of the convertible preferred stock liability is associated with the investors right to purchase the second tranche of Series A convertible preferred stock at the same price per share as the first tranche. Changes in the fair value were recorded each period based on the estimated fair value of the convertible preferred stock liability until the option is exercised or expires. The option was deemed exercised upon the closing of the second tranche in June 2015, at which time the $20.2 million fair value of the convertible preferred stock liability was reclassified from a liability to convertible preferred stock.

Results of Operations

***Comparison of the periods below as indicated (in thousands)*:**

	Three Months Ended June 30,			Six Months Ended June 30,		
	2016	2015	Change	2016	2015	Change
Operating expenses:						
Research and development	$ 7,119	$ 2,005	$ 5,114	$ 12,517	$ 3,928	$ 8,589
General and administrative	1,706	327	1,379	2,734	618	2,116
Total operating expenses	8,825	2,332	6,493	15,251	4,546	10,705
Loss from operations	(8,825)	(2,332)	(6,493)	$ (15,251)	$ (4,546)	(10,705)
Change in fair value of convertible preferred stock liability		(17,900)	17,900		(17,600)	17,600
Interest income	180		180	259	1	258
Net loss	$ (8,645)	$ (20,232)	$ 11,587	$ (14,992)	$ (22,145)	$ 7,153

Research and Development Expense

Research and development expenses for the three and six months ended June 30, 2016 and 2015 consisted of the following costs by program (specific program costs consist solely of external costs):

(In thousands)	Three Months Ended June 30, 2016	2015	Change	Six Months Ended June 30, 2016	2015	Change
CPI - 444	$ 2,578	$ 445	$ 2,133	$ 4,914	$ 1,476	$ 3,438
Anti - CD73	812	114	698	945	146	799
Other programs	547	186	361	885	289	596
Unallocated employee and overhead costs	3,182	1,260	1,922	5,773	2,017	3,756
Total	$ 7,119	$ 2,005	$ 5,114	$ 12,517	$ 3,928	$ 8,589

Table of Contents

For the three months ended June 30, 2016, the increase in CPI-444 costs of $2.1 million as compared to the three months ended June 30, 2015, primarily consisted of an increase of $1.1 million in clinical trial costs related to our Phase 1/1b clinical trial and an increase of $0.8 million of drug manufacturing costs to support our clinical trial. For the six months ended June 30, 2016, the increase in CPI-444 costs of $3.4 million as compared to the six months ended June 30, 2015, primarily consisted of an increase of $2.4 million in clinical trial costs related to our Phase 1/1b clinical trial and an increase of $1.6 million in drug manufacturing costs to support our clinical trial, which increases were partially offset by a $1.0 million license payment to Vernalis in 2015.

For the three months ended June 30, 2016, the increase in anti-CD73 costs of $0.7 million as compared to the three months ended June 30, 2015, primarily consisted of $0.6 million in drug manufacturing costs. For the six months ended June 30, 2016, the increase in anti-CD73 costs of $0.8 million as compared to the six months ended June 30, 2015, primarily consisted of an increase of $0.6 million in drug manufacturing costs.

For the three months ended June 30, 2016, the increase in other program costs of $0.4 million as compared to the three months ended June 30, 2015, primarily consisted of an increase in outside chemical synthesis and testing of preclinical compounds. For the six months ended June 30, 2016, the increase in other program costs of $0.6 million as compared to the six months ended June 30, 2015, primarily consisted of an increase in outside chemical synthesis and testing of preclinical compounds.

For the three months ended June 30, 2016, the increase in unallocated costs of $1.9 million as compared to the three months ended June 30, 2015, primarily consisted of an increase of $1.4 million in personnel and related costs associated with an increase in headcount (including an increase in stock compensation expense of $0.4 million) and an increase of $0.2 million in facility and related overhead costs associated with an increase in the amount and cost or our leased space and an increase in depreciation expense. For the six months ended June 30, 2016, the increase in unallocated costs of $3.8 million as compared to the six months ended June 30, 2015, primarily consisted of an increase of $2.8 million in personnel and related costs (including an increase in stock compensation expense of $0.4 million), an increase of $0.4 million in facility and related overhead costs and a $0.4 million increase in laboratory supplies and materials.

General and Administrative Expense

For the three months ended June 30, 2016, the increase in general and administrative expenses of $1.4 million as compared to the three months ended June 30, 2015, primarily consisted of an increase of $0.9 million in personnel and related costs associated with an increase in headcount (including an increase in stock compensation expense of $0.6 million) and an increase of $0.3 million in costs associated with being a public company. For the six months ended June 30, 2016, the increase in general and administrative expenses of $2.1 million as compared to the six months ended June 30, 2015, primarily consisted of an increase of $1.2 million in personnel and related costs associated with an increase in headcount (including an increase in stock compensation expense of $0.7 million) and an increase of $0.6 million in costs associated with being a public company.

Change in Fair Value of Convertible Preferred Stock Liability

In connection with the issuance of shares of our Series A convertible preferred stock in November 2014, we granted a second tranche option to the Series A investors to purchase 4,460,715 shares of our Series A convertible preferred stock upon the achievement of certain milestones. At initial recognition, we recorded the option as a liability on our balance sheet at its estimated fair value of $2.6 million. The fair value of the

convertible preferred stock liability at December 31, 2014 was $2.6 million, resulting in no gain or loss on remeasurement for the period from January 27, 2014 (inception) to December 31, 2014. The fair value of the convertible preferred stock liability at March 31, 2015 was $2.3 million, resulting in a $0.3 million gain on remeasurement for the period from January 1, 2015 to March 31, 2015. In June 2015, we achieved the relevant milestones, and the investors exercised their right to purchase 4,460,715 shares of Series A convertible preferred stock for net proceeds of $16.7 million. Immediately prior to the closing of this tranche, we remeasured the convertible preferred stock liability to its then fair value and recorded a loss from remeasurement of $17.9 million in our statement of operations to bring the convertible preferred stock liability to its then fair value of $20.2 million, which was reclassified to convertible preferred stock upon the closing of the second tranche.

Liquidity and Capital Expenditures

As of June 30, 2016, we had cash, cash equivalents and marketable securities of $152.2 million. Since our inception and through June 30, 2016, we have financed our operations primarily through private placements of convertible preferred stock and the sale of common stock in our IPO.

Table of Contents

We believe our current cash and cash equivalents will be sufficient to fund our planned expenditures and meet our obligations through at least the next twelve months. The amounts and timing of our actual expenditures depend on numerous factors, including:

- the initiation, progress, timing, costs and results of clinical trials for CPI-444;
- the timing, progress, costs and results of preclinical and clinical development activities for our other product candidates;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the costs involved in prosecuting, maintaining and enforcing patent and other intellectual property rights;
- the cost and timing of regulatory approvals;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company; and
- other factors described in the section of this report entitled Risk Factors.

We expect to increase our spending in connection with the development and commercialization of our product candidates. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financings. We may also enter into additional collaboration arrangements or selectively partner for clinical development and commercialization. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the governing documents would likely include operating and financing covenants that would restrict our operations. In addition, sufficient additional funding may not be available on acceptable terms, or at all. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned programs. Any of these actions could have a material effect on our business financial condition and results of operations.

Cash Flows

The following table summarizes our cash flows for the quarterly periods indicated (in thousands):

	Six Months Ended June 30,	
	2016	2015
Net cash provided by (used in):		
Operating activities	$ (11,765)	$ (4,038)
Investing activities	(59,352)	(26,599)
Financing activities	71,355	20,772
Net increase (decrease) in cash and cash equivalents	$ 238	$ (9,865)

Cash Flows used in Operating Activities

Cash used in operating activities during the six months ended June 30, 2016 was $11.8 million, which primarily consisted of a net loss of $15.0 million, adjusted by non-cash charges of $2.1 million and a net change of $1.1 million in our net operating assets. The non-cash charges were primarily associated with stock-based compensation expense of $1.5 million. The change in our net operating assets and liabilities was primarily attributable to an increase in other long-term liabilities of $0.6 million, primarily due to an increase in deferred rent.

Cash used in operating activities during the six months ended June 30, 2015 was $4.0 million, which consisted primarily of a net loss of $22.1 million, partially offset by a $17.6 million increase in our convertible preferred stock liability.

Cash Flows used in Investing Activities

Cash used in investing activities during the six months ended June 30, 2016 was $59.4 million, which consisted of purchases of marketable securities of $152.8 million and purchases of property and equipment of $1.5 million, which were partially offset by proceeds from maturities of marketable securities of $94.9 million.

Cash used in investing activities during the six months ended June 30, 2015 was $26.6 million, which consisted of purchases of marketable securities of $25.7 million and $0.9 million of purchases of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities during the six months ended June 30, 2016 was $71.4 million, consisting of net proceeds from our IPO.

Table of Contents

Cash provided by financing activities during the six months ended June 30, 2015 was $20.8 million, primarily consisting of net proceeds from the issuance of convertible preferred stock.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Contractual Obligations

We lease our facilities under a non-cancelable operating lease that expires in 2021.

As of June 30, 2016, future minimum lease payments under the facility lease were as follows (in thousands):

		Operating Leases
2016 *	$	428
2017		992
2018		1,022
2019		1,052
2020		1,085
Thereafter		90
Total	$	4,669

*Remainder of the year

Pursuant to our license agreements with each of Vernalis and Scripps, we have obligations to make future milestone and royalty payments to these parties. However, because these amounts are contingent, they have not been included on our balance sheet.

Table of Contents

JOBS Act Accounting Election

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We also intend to rely on other exemptions provided by the JOBS Act, including, without limitation, providing an auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents and marketable securities of $152.2 million as of June 30, 2016 and cash, cash equivalents and marketable securities of $94.4 million as of December 31, 2015, which consisted of bank deposits, money market investments and U.S. Treasury securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% increase in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

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 (the Exchange Act) refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

As required by Rule 13a-15(b) under the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2016, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that

our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

(b) Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

Item 1 Legal Proceedings

We are not currently a party to any material litigation or legal proceedings.

Item 1A Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in the Prospectus and this Quarterly Report on Form 10-Q, including our financial statements and related notes included elsewhere in this prospectus and Management s Discussion and Analysis of Financial Condition and Results of Operations, before making an investment decision. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

We are a clinical stage biopharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused primarily on developing our lead product candidate, CPI-444, which is currently our only product candidate that has undergone clinical development, and researching additional product candidates. We have incurred significant operating losses since we were founded in January 2014 and have not yet generated any revenue from sales. If our products are not approved, we may never generate any revenue. We incurred a net loss of $0.2 million for the period from January 27, 2014 (inception) to December 31, 2014 and $31.3 million for the year ended December 31, 2015, and $22.1 million and $15.0 million for the six months ended June 30, 2015 and 2016, respectively. We had an accumulated deficit of $31.5 million and $46.5 million as of December 31, 2015 and June 30, 2016, respectively. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for and begin to commercialize CPI-444, and as we develop other product candidates. Even if we achieve profitability in the future, we may not be able to sustain it in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and results of operations.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

Since commencing our operations in 2014, substantially all of our efforts have been focused on the research and development of CPI-444. We believe that we will continue to expend substantial resources for the foreseeable future as we continue clinical development of, seek regulatory approval for and prepare for the commercialization of CPI-444, as well as develop other product candidates. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, obtaining regulatory approvals, manufacturing and supply, sales and marketing and general operations. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we may not be able to accurately estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of CPI-444 or any other product candidates.

In March 2016, we completed our initial public offering, or IPO, of our common stock pursuant to which we received proceeds of approximately $63.7 million, net of underwriting discounts and commission, and offering expenses. In April 2016, the underwriters exercised their option to purchase an additional 502,618 shares of our common stock, pursuant to which we received additional proceeds of approximately $7.0 million, net of underwriting discounts and commission, and offering expenses. As of June 30, 2016, we had capital resources consisting of cash, cash equivalents and marketable securities of $152.2 million. We do not expect our existing capital resources to be sufficient to enable us to fund the completion of our clinical trials and remaining development program of CPI-444 through commercialization. In addition, our operating plan may change as a result of many factors, including those described below as well as others currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. Such financing would result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. If we raise additional capital through strategic collaboration agreements, we may have to relinquish valuable rights to our product candidates, including possible future revenue streams. In addition, additional funding may not be available to us on acceptable terms, or at all, and any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

Table of Contents

The amount and timing of any expenditures needed to implement our development and commercialization programs will depend on numerous factors, including, but not limited to:

- the type, number, scope, progress, expansions, results of and timing of our planned preclinical studies and clinical trials of CPI-444 and any of our other product candidates which we are pursuing or may choose to pursue in the future;

- the need for, and the progress, costs and results of, any additional clinical trials of CPI-444 or any of our other product candidates we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require;

- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;

- the costs and timing of obtaining or maintaining manufacturing for CPI-444 and our other product candidates, including commercial manufacturing if any product candidate is approved;

- the costs and timing of establishing sales and marketing capabilities and enhanced internal controls over financial reporting;

- our ability to achieve sufficient market acceptance, coverage and reimbursement from third-party payors and adequate market share for our product candidates;

- the terms and timing of establishing collaborations, license agreements and other partnerships;

- costs associated with any new product candidates that we may develop, in-license or acquire;

- the effect of competing technological and market developments;

- our ability to attract, hire and retain qualified personnel;

- our ability to establish and maintain partnering arrangements for development; and

- the costs associated with being a public company.

Several of these factors are outside of our control and if we are unable to obtain funding on a timely basis, we will be unable to complete the clinical trials for CPI-444 and our other product candidates, and we may be required to significantly curtail some or all of our activities.

Risks Related to the Discovery and Development of Our Product Candidates

Our business currently depends substantially on the success of CPI-444, which will require significant clinical testing before we can seek regulatory approval and potentially launch commercial sales, and which may not be successful in clinical trials, receive regulatory approval or be successfully commercialized, even if approved. If we are unable to obtain regulatory approval for, or successfully commercialize, CPI-444, our business will be materially harmed.

Our product candidates are in the early stage of development and will require additional preclinical studies, substantial clinical development and testing, manufacturing bridging studies and process validation and regulatory approval prior to commercialization. To date, we have only one product candidate that has been the focus of advanced development efforts: CPI-444. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of CPI-444. However, we need to raise sufficient funds for, and successfully enroll and complete, our planned clinical trials of CPI-444. We cannot be certain that CPI-444 will be successful in clinical trials, and CPI-444 may not receive regulatory approval even if it is successful in clinical trials. Even if we do receive regulatory approval necessary for the commercialization of CPI-444, we do not expect that such commercialization will occur for at least the next several years. In particular, the future regulatory and commercial success of CPI-444 is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for CPI-444;

- we may not be able to demonstrate evidence of efficacy and safety for CPI-444 to the satisfaction of regulatory authorities;

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval;

- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to CPI-444;

- we do not know the degree to which CPI-444 will be accepted as a therapy, even if approved; and

- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Table of Contents

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a New Drug Application (NDA) or Biologics License Application (BLA) to the FDA or comparable marketing applications to foreign regulatory authorities, and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market CPI-444, any such approval may be subject to limitations on the indicated uses for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure our stockholders that CPI-444 will be successfully developed or commercialized. If we or any of our potential future collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize CPI-444, we may not be able to generate sufficient revenue to continue our business.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Any product candidate we or any of our potential future collaborators advance into clinical trials, including CPI-444, may not have favorable results in later clinical trials, if any, or receive regulatory approval.

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 preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical 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 trials.

Furthermore, our future trials will need to demonstrate sufficient safety and efficacy for approval by regulatory authorities in larger patient populations. Prior to licensing our lead product candidate, CPI-444, it exhibited encouraging safety data in clinical studies performed by third parties. However, previous studies with CPI-444 had only been conducted in healthy volunteers and patients with attention deficit and hyperactivity disorder (ADHD). Only recently, in our Phase 1/1b clinical trial, which we initiated in January 2016, has CPI-444 been administered to cancer patients and limited information is available concerning safety and efficacy from clinical results obtained to date. It is possible that patients enrolled in our Phase 1/1b clinical trial for CPI-444, could respond in unexpected ways. For instance, older patients with cancer may behave differently and experience more toxicity with CPI-444 than the subjects in the prior clinical studies. In addition, we expect that the dosing regimen and duration of treatment in any clinical trial will vary from those utilized in the studies previously performed by third parties. Furthermore, a portion of our Phase 1/1b clinical trial includes the administration of CPI-444 in combination with Genentech s investigational cancer immunotherapy, TECENTRIQTM (atezolizumab), which could exacerbate immune system related adverse events, cause increased toxicity or otherwise lead to unexpected adverse events. As a result, there can be no assurance that the results of clinical studies of CPI-444 conducted by third parties will be indicative of results of our Phase 1/1b clinical trial.

For the foregoing reasons, we cannot be certain that our planned clinical trial or any other future clinical trials will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical trials in the United States for our product candidates, we must submit the results of preclinical testing to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an investigational new drug (IND) application. In addition, we may rely in part on preclinical, clinical and quality data generated by clinical research organizations (CROs) and other third parties for regulatory submissions for our product candidates. If these third parties do not make timely regulatory submissions for our product candidates, it will delay our plans for our clinical trials. If those third parties do not make this data available to us, we will likely have to develop all necessary preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development. Delays in the completion of our planned clinical trials for CPI-444 or other product candidates could significantly affect our product development costs.

Table of Contents

We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed or placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing CPI-444 or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing CPI-444, any of our other product candidates or any of their components being ordered by the FDA or other regulatory authorities to temporarily or permanently shut down due to violations of good manufacturing practice (cGMP) regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- any failure or delay in reaching an agreement with CROs and clinical trial sites;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or regulatory requirements or other third parties not performing data collection or analysis in a timely or accurate manner;

- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications;

- one or more Institutional Review Boards (IRBs) refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or

- patients failing to complete a trial or return for post-treatment follow-up.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. See also the risk factor below titled If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Table of Contents

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. For example, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of CPI-444 or other product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

CPI-444 and our other product candidates are subject to extensive regulation, compliance with which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our or any of our potential future collaborators clinical trials;

- we or any of our potential future collaborators may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;

- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;

- we or any of our potential future collaborators may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;

- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;

- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any of our potential future collaborators contract for clinical and commercial supplies; or

- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

Table of Contents

If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. Potential subjects for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for our studies. We also may encounter difficulties in identifying and enrolling subjects with a stage of disease appropriate for our planned clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or other foreign regulatory agencies. In addition, the process of finding and diagnosing subjects may prove costly.

In January 2016, we initiated a Phase 1/1b clinical trial for CPI-444 in which we administer CPI-444 as a single agent and in combination with TECENTRIQ . In this ongoing trial, we plan to enroll patients with many different types of cancer, and it may be difficult to enroll such a diverse group of patients. In addition, there will be ten different treatment cohorts in the clinical trial and it may not be possible to fully enroll all the cohorts or any expansions thereof. Furthermore, if patients are unwilling to participate in our studies for any reason, including the existence of competitive clinical trials for similar patient populations or the availability of approved therapies, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll a sufficient number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We believe we have appropriately accounted for the above factors in our trials when determining expected clinical trial timelines, but we cannot assure our stockholders that our assumptions are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

The occurrence of serious complications or side effects in connection with use of our product candidates, either in clinical trials or post-approval, could lead to discontinuation of our clinical development programs, refusal of regulatory authorities to approve our product candidates or, post-approval, revocation of marketing authorizations or refusal to approve new indications, which could severely harm our business, prospects, operating results and financial condition.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. For example, in clinical studies of CPI-444 performed by third parties prior to our licensing it from Vernalis, patients exhibited mild transient hypertension as well as minor gastrointestinal disorders due to gastric irritation.

Further, we expect that the dosing regimen and duration of treatment in any clinical trial will vary from those utilized in the studies previously performed by third parties. It is possible that as we test our product candidates in larger, longer and more extensive clinical programs with different dosing regimens, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. For example, although no cardiac adverse events have been observed in the clinical trials for CPI-444 to date, CPI-444 is known to bind to the A1 adenosine receptor. This receptor is expressed in the heart, and although CPI-444 binds to the A1 receptor at

a low affinity, it is possible that sufficient binding of the drug to the A1 receptor could occur, leading to adverse effects on the heart such as irregular heart rate or rapid heart rate.

Many times side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. To date, CPI-444 has only been studied in healthy volunteers and patients with ADHD, and it is possible that older patients with cancer may behave differently and experience more toxicity with CPI-444. Although not seen to date with CPI-444, other immune-oncology drugs have been found occasionally to induce immune related toxicities such as colitis, hepatitis, pneumonitis and various endocrine diseases. Such side effects could also be exacerbated when CPI-444 is administered in combination with TECENTRIQ . Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Table of Contents

In addition, 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:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of