Corvus Pharmaceuticals, Inc.
Form 10-Q
August 03, 2017
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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, 2017

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 x No o

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, smaller reporting company, or any emerging growth company. See the definitions of large accelerated filer, accelerated filer , smaller reporting company and emerging growth 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
Emerging growth company x	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of August 3, 2017, 20,934,514 shares of the registrant s common stock, $0.0001 par value per share, were outstanding.

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CORVUS PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2017

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PART I FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

CORVUS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

(unaudited)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 34,095	$ 5,050
Marketable securities	76,231	129,846
Prepaid and other current assets	1,308	1,137
Total current assets	111,634	136,033
Property and equipment, net	2,984	3,248
Other assets	869	869
Total assets	$ 115,487	$ 140,150
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 4,138	$ 1,900
Accrued and other liabilities	5,380	4,044
Total current liabilities	9,518	5,944
Other liabilities	1,187	1,405
Total liabilities	10,705	7,349
Commitments and contingencies *(Note 11)*		
Stockholders equity:		
Preferred stock: $0.0001 par value; 10,000,000 shares authorized at June 30, 2017 and December 31, 2016; 0 shares issued and outstanding at June 30, 2017 and December 31, 2016		
Common stock: $0.0001 par value; 290,000,000 shares authorized at June 30, 2017 and December 31, 2016; 20,934,514 and and 20,922,428 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	2	2
Additional paid-in capital	203,720	200,709
Accumulated other comprehensive loss	(52)	(39)
Accumulated deficit	(98,888)	(67,871)
Total stockholders equity	104,782	132,801
Total liabilities and stockholders equity	$ 115,487	$ 140,150

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

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CORVUS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED 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,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	$ 12,386	$ 7,119	$ 25,884	$ 12,517
General and administrative	2,788	1,706	5,507	2,734
Total operating expenses	15,174	8,825	31,391	15,251
Loss from operations	(15,174)	(8,825)	(31,391)	(15,251)
Interest income	193	180	374	259
Net loss	$ (14,981)	$ (8,645)	$ (31,017)	$ (14,992)
Net loss per share, basic and diluted	$ (0.73)	$ (0.43)	$ (1.52)	$ (1.42)
Shares used to compute net loss per share, basic and diluted	20,426,849	19,959,459	20,388,820	10,568,562
Other comprehensive income (loss):				
Unrealized (loss) gain on marketable securities	11	49	(13)	123
Comprehensive loss	$ (14,970)	$ (8,596)	$ (31,030)	$ (14,869)

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

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CORVUS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (31,017)	$ (14,992)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	412	250
Amortization (accretion) related to marketable securities	(113)	310
Stock-based compensation	2,989	1,517
Changes in operating assets and liabilities:		
Prepaid and other current assets	(184)	84
Other assets		(619)
Accounts payable	2,322	129
Accrued and other liabilities	1,350	920
Other long-term liabilities	(218)	636
Net cash used in operating activities	(24,459)	(11,765)
Cash flows from investing activities		
Purchases of marketable securities	(47,072)	(152,790)
Maturities of marketable securities	100,800	94,925
Purchase of property and equipment	(232)	(1,487)
Net cash provided by (used in) investing activities	53,496	(59,352)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs		71,355
Proceeds from exercise of common stock options	8	
Net cash provided by financing activities	8	71,355
Net increase in cash and cash equivalents	29,045	238
Cash and cash equivalents at beginning of the period	5,050	4,105
Cash and cash equivalents at end of the period	$ 34,095	$ 4,343
Supplemental disclosures of cash flow information		
Purchases of property and equipment incurred but not paid	$	$ 11

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

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CORVUS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED 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. The Company has four insignificant subsidiaries.

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 condensed consolidated 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. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business. Since its inception, the Company has incurred significant losses and negative cash flows from operations. During the six months ended June 30, 2017, the Company incurred a net loss of $31.0 million and used $24.5 million of cash in operations. As of June 30, 2017, the Company had an accumulated deficit of $98.9 million and cash, cash equivalents and marketable securities of $110.3 million. The Company has financed its operations primarily with the proceeds from the sale of stock. The Company will need to raise additional capital to meet its business objectives. The Company believes that its current cash, cash equivalents and marketable securities will be sufficient to fund its planned expenditures and meet its obligations through at least the next twelve months.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated 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 consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. The condensed consolidated results of operations for the three and six months ended June 30, 2017 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 consolidated financial statements should be read in conjunction with the audited financial statements and the related notes for the year ended December 31, 2016 included in the Company s Annual Report on Form 10-K filed with the SEC on March 10, 2017.

Use of Estimates

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

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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 consist of investments in U.S. Treasury securities, U.S. government agency securities and corporate debt obligations, which can be subject to certain credit risks. However, the Company mitigates the risks by investing in high-grade instruments, limiting its exposure to any one issuer, and monitoring the ongoing creditworthiness of the financial institutions and issuers. The Company has not experienced any losses on its deposits of cash, cash equivalents or marketable securities.

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.

Critical Accounting Policies

The Company s critical accounting policies are described in Note 2 to our consolidated financial statements for the year ended December 31, 2016, included in our Annual Report on Form 10-K. There have been no material changes to the Company s critical accounting policies during the six months ended June 30, 2017.

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 consolidated financial statements as the Company is not yet generating revenues.

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 January 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 consolidated financial statements.

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In May 2017, the FASB issued ASU No 2017-09, Compensation Stock Compensation (Topic 718) Scope of Modification Accounting, to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new standard, modification is required only if the fair value, the vesting conditions, or the classification of an award as equity or liability changes as a result of the change in terms or conditions. ASU 2017-09 will be effective for the Company beginning January 1, 2018 and will be applied prospectively. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

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,	
	2017	2016	2017	2016
Numerator:				
Net loss	$ (14,981)	$ (8,645)	$ (31,017)	$ (14,992)
Denominator:				
Weighted average common shares outstanding	20,934,514	20,771,392	20,931,765	11,414,296
Less: weighted average common shares subject to repurchase	(507,665)	(811,933)	(542,945)	(845,734)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	20,426,849	19,959,459	20,388,820	10,568,562
Net loss per share, basic and diluted	$ (0.73)	$ (0.43)	$ (1.52)	$ (1.42)

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

	June 30,	
	2017	2016
Common stock subject to repurchase	465,451	770,550
Outstanding options	2,441,856	2,034,386
Total shares of common stock equivalents	2,907,307	2,804,936

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.

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The following tables present information as of June 30, 2017 and December 31, 2016 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, 2017			
	Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
Assets				
Cash equivalents	$ 25,305	$ 7,614	$	$ 32,919
Marketable securities	66,638	9,593		76,231
	$ 91,943	$ 17,207	$	$ 109,150

	December 31, 2016			
	Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
Assets				
Cash equivalents	$ 2,999	$	$	$ 2,999
Marketable securities	129,846			129,846
	$ 132,845	$	$	$ 132,845

As of June 30, 2017, marketable securities had a maximum remaining maturity of twelve months.

As of June 30, 2017 and December 31, 2016, the fair value of available for sale marketable securities by type of security were as follows (in thousands):

	June 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 66,685	$	$ (47)	$ 66,638
Government agency securities	8,597		(3)	8,594
Corporate debt obligations	999			999
	$ 76,281	$	$ (50)	$ 76,231

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 129,885	$	$ (39)	$ 129,846

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.

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Upon execution of the agreement, the Company made a one-time cash payment to Scripps of $10.0 thousand in 2015 and is also obligated to pay a minimum annual fee to Scripps of $25.0 thousand. 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, the Company made 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. In February 2017, the Company made a milestone payment of $3.0 million to Vernalis following the expansion of a cohort of patients with renal cell cancer treated with single agent CPI-444 in the Company s Phase 1/1b clinical trial. The aggregate potential milestone payments exceed $200 million for all indications.

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.

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 Agreements

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, Tecentriq (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 Tecentriq. 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

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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 Tecentriq 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.

In May, 2017, the Company signed a second clinical trial collaboration agreement with Genentech. Under the new agreement, CPI-444 administered in combination with Tecentriq (atezolizumab) will be evaluated in a Phase 1b/2 randomized, controlled clinical study as second-line therapy in patients with non-small cell lung cancer who are resistant and/or refractory to prior therapy with an anti PD-(L)1 antibody. It is anticipated that the study will enroll up to 65 patients in the treatment arm. Genentech will be responsible for the conduct of the study and the parties will share the cost of the Phase 1b/2 trial, which is expected to begin enrolling patients in the fourth quarter of 2017. The Company is responsible for supplying CPI-444 and retains global development and commercialization rights to CPI-444. 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 Tecentriq is discontinued.

6. Balance Sheet Components (in thousands)

	June 30, 2017	December 31, 2016
Prepaid and Other Current Assets		
Interest receivable	$ 121	$ 365
Prepaid research and development manufacturing expenses	212	
Other	975	772
	$ 1,308	$ 1,137
Property and Equipment, net		
Laboratory equipment	$ 2,008	$ 1,868
Computer equipment and purchased software	66	58
Leasehold improvements	2,051	2,051
	4,125	3,977
Less: accumulated depreciation and amortization	(1,141)	(729)
	$ 2,984	$ 3,248
Accrued and Other Liabilities		
Accrued clinical trial related	$ 3,145	$ 1,617
Accrued manufacturing expense	838	955
Personnel related	524	526
Deferred rent	394	378
Accrued legal and accounting	134	255
Other accrued expenses	345	313
	$ 5,380	$ 4,044
Other Liabilities		
Deferred rent	$ 1,166	$ 1,370
Shares subject to vesting	21	35

	$	1,187	$ 1,405

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7. Common Stock

As of June 30, 2017, 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, 2017, no dividends on common stock had been declared.

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

	June 30, 2017	December 31, 2016
Shares available for future option grants	3,202,240	2,475,600
Outstanding options	2,441,856	2,350,582
Unvested restricted common stock (founders and early exercise of stock options)	465,451	611,698
Shares reserved for employee stock purchase plan	400,000	200,000
Total	6,509,547	5,637,880

8. 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 a 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 a 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:

	Shares Available for Grant	Options Outstanding		
		Number of Options		Weighted-Average Exercise Price
Balance at December 31, 2016	2,475,600	2,350,582	$	11.88
Additional shares authorized	830,000			
Options granted	(168,900)	168,900		11.62
Options exercised		(12,086)		0.64
Options forfeited	65,540	(65,540)		11.88
Balance at June 30, 2017	3,202,240	2,441,856	$	11.92

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9. 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,	
	2017	2016	2017	2016
Research and development	$ 642	$ 486	$ 1,265	$ 787
General and administrative	879	589	1,724	730
Total	$ 1,521	$ 1,075	$ 2,989	$ 1,517

10. Income Taxes

The Company did not record a provision or benefit for income taxes during the three or six months ended June 30, 2017 or 2016. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

11. Commitments and Contingencies

Facility Lease

In January 2015, the Company signed an initial operating lease, effective February 1, 2015 for 8,138 square feet of office and laboratory space with a one-year term. Between January 2015 and August 2016, the Company entered into a series of lease amendments to increase the amount of leased space to 28,633 square feet and extend the expiration of the lease to February 2021. The lease agreement includes an annual rent escalation clause and a right to extend the term at the then current market rate for three years. Under the lease and subsequent amendments, the landlord provided approximately $1.9 million in free rent and lease incentives. 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. Rent expense related to the facilities lease for the three and six months ended June 30, 2017 was approximately $184,000 and $367,000, respectively. Rent expense for the three and six months ended June 30, 2016 was approximately $127,000 and $256,000, respectively. As of June 30, 2017, future minimum lease payments under the facility lease were as follows (in thousands):

Year Ended December 31:	
2017 *	$ 557
2018	1,143
2019	1,177
2020	1,211
2021	101
Total	$ 4,189

*Remainder of the year

In August 2015 the Company entered into an agreement for a line of credit of $0.1 million for the purpose of issuing its landlord a letter of credit of $0.1 million as a security deposit under its facility lease. The Company pledged money market funds and marketable securities as collateral for the line of credit. 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 and not fixed or determinable, 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

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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.

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 consolidated financial statements and related notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and notes for the year ended December 31, 2016, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 10, 2017.

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, Tecentriq® (atezolizumab), a fully humanized investigational monoclonal antibody targeting PD-L1. In November 2016, we completed enrollment of 48 patients in the first step of the Phase 1/1b clinical trial, which was designed to determine the optimal dose of CPI-444 as both a single agent therapy and in combination with Tecentriq (atezolizumab) for use in the cohort expansion component of the trial. The expansion cohort portion of the trial is now enrolling patients with different types of solid tumors at 36 leading medical centers in the U.S.,

Australia and Canada. To date, we have announced the expansion of three cohorts from fourteen subjects to twenty-six subjects and one cohort from twenty-six subjects to forty-eight subjects.

The other product and development candidates in our pipeline also continue to advance. We have chosen a lead development candidate for our second program, an anti-CD73 monoclonal antibody (CPX-006) that inhibits the production of adenosine. CPX-006 is currently in IND-enabling studies and we plan to initiate a Phase 1 clinical trial in the first half of 2018. In addition, in 2016 we selected a development candidate for our ITK program and are currently conducting IND-enabling studies. We also plan to initiate a Phase 1 clinical trial for this candidate in 2018. We expect to select a development candidate for our other program, a small molecule antagonist of the A2B receptor for adenosine in 2017. 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, the majority 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. During the six months ended June 30, 2017, we incurred a net loss of $31.0 million and used $24.5 million of cash in operations. As of June 30, 2017, we had an accumulated deficit of $98.9 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.

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Since our inception and through June 30, 2017, 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 our 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. In 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, 2017, we had capital resources consisting of cash, cash equivalents and marketable securities of approximately $110.3 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 consolidated financial statements for the year ended December 31, 2016 included in our Annual Report on Form 10-K. There have been no material changes to our critical accounting policies during the six months ended June 30, 2017.

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 and development of our product candidates. We record research and development expenses as incurred. Research and development expenses 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.

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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 CPX-006 antibody to support IND-enabling studies;
- process development and manufacturing of drug supply for our ITK product candidate to support IND-enabling studies; and
- preclinical studies under our other programs in order to select development product candidates

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 Part II, Item 1A Risk Factors. 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.

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.

Results of Operations

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	Change	2017	2016	Change
Operating expenses:						
Research and development	$ 12,386	$ 7,119	$ 5,267	$ 25,884	$ 12,517	$ 13,367
General and administrative	2,788	1,706	1,082	5,507	2,734	2,773
Total operating expenses	15,174	8,825	6,349	31,391	15,251	16,140
Loss from operations	(15,174)	(8,825)	(6,349)	(31,391)	(15,251)	(16,140)
Interest income	193	180	13	374	259	115
Net loss	$ (14,981)	$ (8,645)	$ (6,336)	$ (31,017)	$ (14,992)	$ (16,025)

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Research and Development Expense

Research and development expenses for the three and six months ended June 30, 2017 and 2016 consisted of the following costs by program (specific program costs consist solely of external costs):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	Change	2017	2016	Change
CPI - 444	$ 5,534	$ 2,578	$ 2,956	$ 13,244	$ 4,914	$ 8,330
CPX - 006	2,055	812	1,243	3,948	945	3,003
ITK inhibitor	1,072	320	752	1,428	545	883
Other	344	227	117	359	340	19
Unallocated employee and overhead costs	3,381	3,182	199	6,905	5,773	1,132
Total	$ 12,386	$ 7,119	$ 5,267	$ 25,884	$ 12,517	$ 13,367

For the three months ended June 30, 2017, the increase in CPI-444 costs of $3.0 million as compared to the three months ended June 30, 2016, 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 $0.6 million in contracted research costs. For the six months ended June 30, 2017, the increase in CPI-444 costs of $8.3 million as compared to the six months ended June 30, 2016, primarily consisted of an increase of $4.5 million in clinical trial costs related to our Phase 1/1b clinical trial and an increase of $0.8 million in contracted research costs and a $3.0 million milestone payment to Vernalis.

For the three months ended June 30, 2017, the increase in CPX-006 costs of $1.2 million as compared to the three months ended June 30, 2016, primarily consisted of an increase of $1.2 million in drug manufacturing costs. For the six months ended June 30, 2017, the increase in CPX-006 costs of $3.0 million as compared to the six months ended June 30, 2016, primarily consisted of an increase of $2.9 million in drug manufacturing costs.

For the three months ended June 30, 2017, the increase in ITK program costs of $0.8 million as compared to the three months ended June 30, 2016, primarily consisted of an increase of $0.7 million in drug manufacturing costs. For the six months ended June 30, 2017, the increase in ITK program costs of $0.9 million as compared to the six months ended June 30, 2016, primarily consisted of an increase of $0.7 million in drug manufacturing costs.

For the three months ended June 30, 2017, the increase in unallocated costs of $0.2 million as compared to the three months ended June 30, 2016, primarily consisted of an increase of $0.2 million in stock compensation expense. For the six months ended June 30, 2017, the increase in unallocated costs of $1.1 million as compared to the six months ended June 30, 2016, primarily consisted of an increase of $1.0 million in personnel and related costs (including an increase in stock compensation expense of $0.5 million) associated with an increase in headcount.

General and Administrative Expense

For the three months ended June 30, 2017, the increase in general and administrative expenses of $1.1 million as compared to the three months ended June 30, 2016, primarily consisted of an increase of $0.4 million in personnel and related costs associated with an increase in headcount (including an increase in stock compensation expense of $0.3 million), an increase of $0.3 million in legal and accounting costs, and an increase of $0.3 million in costs associated with being a public company. For the six months ended June 30, 2017, the increase in general and administrative expenses of $2.8 million as compared to the six months ended June 30, 2016, primarily consisted of an increase of $1.3 million in personnel and related costs associated with an increase in headcount (including an increase in stock compensation expense of $1.0 million), an increase of $0.7 million in legal and accounting costs, and an increase of $0.6 million in costs associated with being a public company.

Liquidity and Capital Resources

As of June 30, 2017, we had cash, cash equivalents and marketable securities of $110.3 million, and an accumulated deficit of $98.9 million, compared to cash and cash equivalents and short-term investments of $134.9 million and an accumulated deficit of $67.9 million as of December 31, 2016. We have financed our operations primarily through private placements of convertible preferred stock and the sale of common stock in our IPO.

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In March 2016, we consummated our IPO and sold 4,700,000 shares of our common stock at a price of $15.00 per share, and in April 2016, sold 502,618 shares at a price of $15.00 per share pursuant to the partial exercise of the underwriters option to purchase additional shares of common stock. We received net proceeds of approximately $70.6 million, after deducting underwriting discounts, commissions and estimated offering expenses. Immediately prior to the consummation of our IPO, all outstanding shares of the convertible preferred stock were converted into common stock on a one-for-one basis.

We believe our current cash, cash equivalents and marketable securities will be sufficient to fund our planned expenditures and meet our obligations through at least the next twelve months from issuance of these financial statements. 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 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.

Summary of Statement of Cash Flows

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

	Six Months Ended June 30,	
	2017	**2016**
Net cash provided by (used in)		
Operating activities	$ (24,459)	$ (11,765)
Investing activities	53,496	(59,352)
Financing activities	8	71,355
Net increase (decrease) in csh and cash equivalents	$ 29,045	$ 238

Cash Flows from Operating Activities

Cash used in operating activities during the six months ended June 30, 2017 was $24.5 million, which consisted of a net loss of $31.0 million, adjusted by non-cash charges of $3.3 million, primarily consisting of $3.0 million of stock compensation expense and $0.4 million of depreciation expenses, and an increase of $3.3 million in accounts payable and accrued and other liabilities, primarily associated with our increased research and development 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.

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Cash Flows from Investing Activities

During the six months ended June 30, 2017, cash provided by investing activities was $53.5 million, which consisted of proceeds from maturities of marketable securities of $100.8 million, partially offset by purchases of marketable securities of $47.1 million and purchases of property and equipment of $0.2 million.

During the six months ended June 30, 2016, cash used in investing activities 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, partially offset by proceeds from maturities of marketable securities of $94.9 million.

Cash Flows from Financing Activities

During the six months ended June 30, 2017, cash provided by financing activities was $8.0 thousand, which consisted of the proceeds from the exercise of stock options.

During the six months ended June 30, 2016, cash provided by financing activities was $71.4 million, which primarily consisted of the net proceeds from our IPO.

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

There have been no material changes outside the ordinary course of our business to our contractual obligations during the six months ended June 30, 2017, as compared to those disclosed in our Annual Report on Form 10-K.

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) December 31, 2021, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such fiscal year, or (4) 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 $110.3 million as of June 30, 2017 and cash, cash equivalents and marketable securities of $134.9 million as of December 31, 2016, which consisted of bank deposits, money market investments, U.S. Treasury securities, U.S. government agency securities and corporate debt obligations. 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.

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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, 2017, 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.

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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.

Our business involves a significant risks, some of which are described below. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and Management s Discussion and Analysis of Financial Condition and Results of Operations. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. 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 product candidates are not approved, we may never generate any revenue. We incurred a net loss of $36.4 million and $31.3 million for the years ended December 31, 2016 and 2015, respectively, and $31.0 million and $15.0 million for the six months ended June 30, 2017 and 2016, respectively. We had an accumulated deficit of $98.9 million as of June 30, 2017. 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, including our lead development candidates under our anti-CD73 program, CPX-006, and ITK program. 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 (IPO), of our common stock pursuant to which we received proceeds of approximately $63.6 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, 2017, we had capital resources consisting of cash, cash equivalents and marketable securities of $110.3 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.

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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 clinical trials of CPI-444 and any of our planned preclinical studies and clinical trials of 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;

- 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 (other than CPI-444), 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;

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- 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.

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, while CPI-444 has been well tolerated to date, with two cases of possibly drug-related serious adverse events observed during the trial, 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, the dosing regimen and duration of treatment in our current Phase 1/1b clinical trial is different from those utilized in the studies previously performed by third parties. In addition, our Phase 1/1b clinical trial is conducted in patients with advanced cancers who have failed other approved therapies for their disease, and as such, it may be difficult to establish safety and efficacy in this type of patient population. Furthermore, a portion of our Phase 1/1b clinical trial includes the administration of CPI-444 in combination with Genentech s investigational cancer immunotherapy, Tecentriq (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.

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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 (other than CPI-444), 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 product candidates (other than CPI-444) could significantly affect our product development costs.

While we initiated our Phase 1/1b trial for CPI-444 in January 2016 and completed enrollment in the dose-selection part of the trial in November 2016, we do not know whether any of our other planned trials will begin on time in the future or whether any of our trials will 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.

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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.

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.

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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 (atezolizumab). In this ongoing trial, we have enrolled and plan to continue to enroll patients with many different types of cancer, and while we completed enrollment in the dose-selection part of the trial in November 2016, it may be difficult to enroll such a diverse group of patients in subsequent parts of the trial. For instance, there are ten different treatment cohorts in the clinical trial, three of which have been expanded from fourteen patients to twenty-six patients, and one of which has been expanded from twenty-six patients to forty-eight patients, 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. 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. However, the dosing regimen and duration of treatment in our current Phase 1/1b clinical trial is different 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 and in combination with other immunotherapies, 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, two cases of possibly drug-related serious adverse events have been observed during our Phase 1/1b clinical trial. Both of these patients were treated with the combination of CPI-444 and Tecentriq (atezolizumab) during the dose selection step of the trial. One of these patients developed

Grade 3 autoimmune hemolytic anemia and another patient experienced a Grade 4 aseptic meningoencephalitis thought to be an immune related toxicity. These toxicities resolved in both patients upon discontinuing therapy. Other toxicities observed during our Phase 1/1b clinical trial were mild and are commonly seen in patients with advanced cancers, such as nausea, fatigue, rash, diarrhea, fever, abdominal pain, constipation and decreased appetite. Other immune-oncology drugs also have been found occasionally to induce immune related toxicities such as colitis, hepatitis, pneumonitis, meningitis and various endocrine diseases. Such side effects could also be exacerbated when CPI-444 is administered in combination with Tecentriq (atezolizumab). In addition, 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.

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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. Results of our current clinical trial and any future clinical trials we undertake 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.

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

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

The success of our business depends primarily upon our ability to develop and commercialize CPI-444. Although CPI-444 is currently in clinical development, our research programs may fail to identify other potential product candidates or advance them into clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying other potential product candidates or our other potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. It may also take greater human and financial resources to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through our research programs than we will possess, thereby limiting

our ability to diversify and expand our product candidate portfolio.

We are conducting a clinical trial for CPI-444, and may also in the future, conduct clinical trials of other product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.

We are currently conducting our clinical trial for CPI-444 at 37 leading medical centers in the U.S., Australia and Canada. In the future we may add additional clinical sites outside of the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials for CPI-444 or any other product candidates, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of CPI-444 or any other product candidates.

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Risks Related to Our Reliance on Third Parties

We rely, and expect to continue relying, on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected, or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are dependent on third parties to conduct our Phase 1/1b clinical trial for CPI-444 and expect to continue to be dependent on third parties to conduct any future clinical studies of CPI-444 and preclinical and clinical trials for our other and future product candidates. The timing of the initiation and completion of these trials will therefore be controlled by such third parties and may occur at times substantially different from our estimates. Specifically, we use and rely on medical institutions, clinical investigators, CROs and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Such CROs, investigators and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data, and we will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area (EEA) and comparable foreign regulatory authorities for all of our product candidates in clinical development.

Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated.

If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA or BLA we submit by the FDA. Any such delay or rejection could prevent us from commercializing CPI-444 or our other future product candidates.

We rely on third parties to conduct some or all aspects of our manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our manufacturing, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to these items. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we may not be able to complete, or may be delayed in completing, the preclinical and clinical studies required to support future IND submissions and approval of our product candidates. Furthermore, any of these third parties may terminate its engagement with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities, and we may not be able to negotiate alternative arrangements on commercially reasonable terms, or at all.

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We and our contract manufacturers are subject to significant regulation with respect to manufacturing our products and the contract manufacturers on which we rely may not continue to meet regulatory requirements.

We do not currently have nor do we plan to acquire the infrastructure or internal capability to manufacture our clinical drug supplies for use in the conduct of our trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on several different manufacturers who supply different parts of the CPI-444 molecule and rely on one manufacturer for CPX-006 drug substance.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or BLA on a timely basis and must adhere to the FDA s Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect our manufacturing facilities or those of our third-party contractors involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Such violations could also result in civil and/or criminal penalties, and the FDA may impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, revocation of a pre-existing approval or closing one or more manufacturing facilities.

In addition, if supply from an approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through an NDA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Changing manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective

manner, or at all. In addition, quality issues may arise during scale-up activities. If we or any manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor s independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

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In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will likely expect to be granted rights to publish data arising out of such collaboration. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Commercialization of Our Product Candidates

All of our product candidates are still in early-stage clinical or preclinical development. If we are unable to commercialize our product candidates or if we experience significant delays in obtaining regulatory approval for, or commercializing, any or all of our product candidates, our business will be materially and adversely affected.

All of our product candidates are still in preclinical or early-stage clinical development. In particular, none of our product candidates, other than CPI-444, has ever been tested in a human subject. Our ability to generate product revenue will depend heavily on our ability to successfully develop and commercialize these product candidates. We do not expect that such commercialization of any of our product candidates will occur for at least the next several years, if ever. Our ability to commercialize our product candidates effectively will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials, including the ability to demonstrate safety and efficacy of our product candidates;

- managing the complexity of our clinical trial designs;

- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;

- establishing commercial manufacturing capabilities by making arrangements with third-party manufacturers;

- successfully launching commercial sales of any approved products, whether alone or in collaboration with others;

- acceptance of any approved products by patients, the medical community and third-party payors;

- establishing market share while competing with other therapies;

- a continued acceptable safety profile of any approved products;

- maintaining compliance with post-approval regulation and other requirements; and

- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering our product candidates.

If we experience significant delays or an inability to commercialize our product candidates, our business, financial condition and results of operations will be materially adversely affected.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

We estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones will be based on a variety of assumptions, and the actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

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Any approved products could be subject to restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Following potential approval of any our product candidates, the FDA may impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. Following approval, if any, of CPI-444 or any other product candidate, such candidate will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for CPI-444 or any other product candidate that may receive regulatory approval, if any, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of product or request that we initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy (REMS) as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

In addition, if CPI-444 or any of our other product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

Further, the FDA s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the two-for-one provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the two-for-one provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA s ability to exercise its regulatory authority. If these executive actions impose constraints on FDA s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Even if we receive regulatory approval we still may not be able to successfully commercialize CPI-444 or any other product candidate, and the revenue that we generate from sales, if any, could be limited.

Even if CPI-444 or any of our other product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new formulation by healthcare providers and their patients;
- our ability to obtain and maintain sufficient third-party coverage and reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;

- the willingness of patients to pay out-of-pocket in the absence of third-party coverage and reimbursement;
- the prevalence and severity of any adverse effects;
- pricing and cost-effectiveness;
- the timing of market introduction of our product candidates as well as competitive drugs;
- the effectiveness of our or any of our potential future collaborators sales and marketing strategies; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product candidate and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of CPI-444 or any of our other product candidates may require significant resources and may never be successful.

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Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Successful commercial sales of any approved products will depend on the availability of adequate coverage and reimbursement from government health administration authorities, private health insurers and other third-party payors. Each third-party payor separately decides which products it will cover and establishes the reimbursement level, and there is no guarantee that any of our product candidates that may be approved for marketing by regulatory authorities will receive adequate coverage or reimbursement levels. Obtaining and maintaining coverage approval for a product candidate is time-consuming, costly and may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of coverage and reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or limited, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and biologics. Even if we obtain coverage for a given product, the resulting reimbursement rates may be inadequate and may affect the demand for, or the price of, any product candidate for which we obtain marketing approval.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and biologics and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both governmental and private insurers. The Affordable Care Act, among other things, subjected biological products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program; extended the rebate program to individuals enrolled in Medicaid managed care organizations; established annual fees and taxes on manufacturers of certain prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D; and established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The new Presidential Administration and U.S. Congress has sought and will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These new laws, among other things, included aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that will remain in

effect through 2025 unless additional Congressional action is taken and additional specific reductions in Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers. Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. Additionally, individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the Affordable Care Act, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

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Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While the processes to implement the BPCIA have not yet been fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

Though CPI-444 is a small molecule and will not be regulated as a biological product, we are developing a biological product. We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

We may fail to obtain orphan drug designations from the FDA for our product candidates, and even if we obtain such designations, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

While we have not obtained nor have we sought to obtain orphan designation for any product candidate, we believe many of the potential indications of our product candidates, if approved, could qualify for orphan drug designation. For instance, if CPI-444 is approved for the treatment of certain solid tumors with small patient populations, such as melanoma, renal or triple-negative breast cancer, it is possible that it could qualify for orphan drug designation with respect to such indications. As a result, we may seek to obtain orphan drug designation for our product candidates for any qualifying indications they may be approved for in the future. Even if we obtain such designations, we may not be the first to obtain marketing approval of our product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare

disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

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We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates, including CPI-444. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may not be successful in establishing and maintaining development or other strategic collaborations, which could adversely affect our ability to develop and commercialize product candidates.

In connection with our Phase 1/1b clinical trial for CPI-444, we entered into a clinical trial collaboration agreement with Genentech in October 2015. Pursuant to the agreement, Genentech will provide access to, and supplies of, its cancer immunotherapy, Tecentriq (atezolizumab), to be used in combination with CPI-444 during the clinical trial. The collaboration operates under a joint development committee with equal representation from both companies. In May 2017, we signed a second clinical trial collaboration agreement with Genentech. Under the new agreement, CPI-444 administered in combination with Tecentriq (atezolizumab) will be evaluated in a Phase 1b/2 randomized, controlled clinical study as second-line therapy in patients with non-small cell lung cancer who are resistant and/or refractory to prior therapy with an anti PD-(L)1 antibody. However, we and Genentech each have the right to terminate the respective collaboration agreement due to material breach by either party, for safety considerations, if directed by a regulatory authority or if development of CPI-444 or Tecentriq (atezolizumab) is discontinued. If we fail to maintain these strategic collaborations with Genentech (1) the development of CPI-444 in combination with Tecentriq (atezolizumab) may be terminated or delayed; (2) our cash expenditures related to development of CPI-444 could increase significantly, and we may need to seek additional financing; (3) we may be required to hire additional employees or otherwise develop expertise for which we have not budgeted; (4) we will bear all of the risk related to the development of CPI-444 as a combination therapy; and (5) we will need to seek collaborations with other companies that have anti-PD-1 or anti-PD-L1 antibodies, which will significantly delay our development program.

We may form strategic alliances and collaborative partnerships in the future, and we may not realize the benefits of such alliances.

In addition to our collaboration agreements with Genentech, we may form additional strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, including for the continued development or commercialization of our product candidates. These relationships may result in or include non-recurring and other charges, increased near- and long-term expenditures, the issuance of securities that dilute our existing stockholders or disruptions to our management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because third parties may view the risk of failure in future clinical trials as too significant or the commercial opportunity for our product candidates as too limited. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

Even if we are successful in our efforts to establish strategic alliances or collaborative partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic alliances or collaborative partnerships if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory. In addition, any potential future strategic alliances or collaborative partnerships may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of strategic alliances or collaborative partnerships we enter into in the future, or any delay in entering into collaborative partnership agreements related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

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We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In particular, there is intense and rapidly evolving competition in the immunoregulatory therapeutics field. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we also compete with universities and other research institutions that may be active in oncology research and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, registering subjects for clinical trials and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

All of our product candidates, if approved, will compete with a range of therapeutic treatments that are either in development or currently marketed. We are aware of companies that have advanced adenosine A2A receptor antagonists into early- or late-stage clinical development for non-oncology indications, primarily Parkinson s disease. These companies include Merck & Co., Inc. and Acorda Therapeutics, Inc.(through its acquisition of Biotie Therapies Corp in 2016). In addition, Kyowa Hakko Kirin Pharma, Inc. has approval in Japan for an adenosine A2A receptor antagonist for use in Parkinson s disease and is currently conducting a Phase 3 study in the United States for Parkinson s disease. Within oncology, Merck has initiated a Phase 1 clinical trial with preladenant, an adenosine A2A antagonist in cancer patients with solid tumors. Palobiofarma SL has initiated a Phase 1 dose finding clinical trial with an adenosine A2A antagonist in lung cancer patients. Novartis and AstraZeneca plc have initiated oncology clinical trials with A2A antagonists. In addition, Redoxtherapies, Inc., which was acquired by Juno Therapeutics, is developing an A2A receptor antagonist for cancer. More generally, in the field of immuno-oncology, there are large pharmaceutical companies with approved products or products in late-stage development that target other immune checkpoints, including PD-1, PD-L1 or CTLA-4. These companies include Bristol-Myers Squibb (nivolumab, ipilimumab), Merck (pembrolizumab), Genentech (atezolizumab) and AstraZeneca (durvalumab, tremelimumab). Also, AstraZeneca, MedImmune LLC and Bristol-Myers Squibb have initiated oncology clinical studies with anti-CD73 antibodies. Finally, Janssen Pharmaceuticals, Inc. and AbbVie Inc. are co-marketing Imbruvica (ibrutinib), which is a small molecule inhibitor of the kinase BTK that has also been reported to inhibit ITK.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first-line therapy, usually chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful, second-line therapy may be administered. Second-line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these. Third-line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. In markets with approved therapies, we expect to initially seek approval of our product candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second-line therapy and potentially as a first-line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for second-line or first-line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second-line or first-line therapy.

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Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. In addition, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second-line therapy.

We have no sales, marketing or distribution capabilities, and we may have to invest significant resources to develop these capabilities.

We have no internal sales, marketing or distribution capabilities. If CPI-444 or any of our other product candidates ultimately receives regulatory approval, we may not be able to effectively market and distribute the product candidate. We may have to seek collaborators or invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that CPI-444 or any of our other product candidates will be approved, if at all. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms or at all. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract and build an effective marketing department or sales force;

- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by CPI-444 or any other product candidates that we may develop, in-license or acquire; and

- our direct sales and marketing efforts may not be successful.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Governments may impose price controls, which may adversely affect our future profitability.

We intend to seek approval to market our product candidates in both the United States and in foreign jurisdictions. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials to compare the cost-effectiveness of our product candidates to other available therapies, which is time-consuming and costly. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Risks Related to Our Business Operations

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development and commercialization activities relating to our product candidates, which may change from time to time;

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- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our product candidates;

- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;

- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;

- the level of demand for any approved products, which may vary significantly;

- future accounting pronouncements or changes in our accounting policies; and

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We are dependent on the services of our President and Chief Executive Officer, Richard A. Miller, M.D., and other key executives, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.

We are dependent on the principal members of our management and scientific staff. The loss of service of any of our management could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. If we are not able to retain our management, particularly our President and Chief Executive Officer, Dr. Miller, and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. Although we have executed employment agreements with each member of our current executive management team, including Dr. Miller, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses, particularly in the San Francisco Bay Area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

In addition, we do not currently maintain key person life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We may encounter difficulties in managing our growth and expanding our operations successfully.

We will need to grow our organization substantially to continue development and pursue the potential commercialization of CPI-444 and our other product candidates, as well as function as a public company. As we seek to advance CPI-444 and other product candidates, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

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We are subject to various federal and state healthcare laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial conditions.

Although we do not currently have any products on the market, if we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations. These laws will affect our operations, sales and marketing practices, and our relationships with physicians and other customers and third-party payors. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act);

- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually

to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other transfers of value to such physician owners (manufacturers are required to submit reports to the government by the 90th day of each calendar year); and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our internal operations and business arrangements with third-parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of such laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

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We and any of our potential future collaborators, third-party manufacturers and suppliers will use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our potential future collaborators, third-party manufacturers or suppliers will use biological materials and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of CPI-444 or our other product candidates.

We face an inherent risk of product liability as a result of the clinical testing of CPI-444 and our other product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if CPI-444 or our other product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for CPI-444 or our other product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;

- a diversion of management s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize CPI-444 or our other product candidates; and
- a decline in our stock price.

We have product liability insurance coverage in an amount and on terms and conditions that are customary for similarly situated companies and that are satisfactory to our board of directors. Our inability to retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of CPI-444 or our other product candidates. Although we plan to maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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We and any of our potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we and any of our potential future collaborators are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and any of our potential future collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Our internal computer systems, or those of any of our potential future collaborators, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Our information technology systems could face serious disruptions that could adversely affect our business.

Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause interruptions and delays in our research and development work.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We currently rely on several different manufacturers who supply different parts of the CPI-444 molecule, on one manufacturer for CPX-006 and other third-party manufacturers to produce our other product candidates. Our ability to obtain clinical supplies of CPI-444 or our other product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct involving the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of fines and other sanctions.

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Risks Related to Our Intellectual Property

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by other companies. The patent protection, prosecution and enforcement for some of our product candidates may be dependent on third parties.

We currently are heavily reliant upon licenses of certain patent rights and proprietary technology from third parties that is important or necessary to the development of our technology and products, including technology related to our product candidates. For example, we rely on our license agreement with Vernalis for all of our rights with respect to the intellectual property covering CPI-444 and certain development candidates under our A2B receptor antagonist program. Further, we rely on our license agreement with The Scripps Research Institute for rights related to our lead development candidate for our anti-CD73 program, CPX-006. These and other licenses we may enter into in the future may not provide adequate rights to use such intellectual property and technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to develop and commercialize our technology and products in fields of use and territories for which we are not granted rights pursuant to such licenses.

Licenses to additional third-party technology that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

While we have rights to an issued composition-of-matter patent in the United States and corresponding issued patents in certain foreign territories covering CPI-444, we cannot be certain that the claims in any of our patent applications covering composition-of-matter of our other product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged.

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The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, if issued, or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, inter partes review (IPR) proceedings and post-grant review (PGR) proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. For example, we are aware of an issued patent in Australia that may be relevant to commercialization of CPI-444 in that country. That Australian patent is expected to expire in 2022. Our ability to commercialize CPI-444 in Australia prior to 2022 could be adversely affected if we do not obtain a license under such patent. We are also aware of a corresponding patent application that has been issued in the United States and which is expected to expire in 2023. However, to the extent that any claims of this patent may be interpreted to cover our potential uses of CPI-444, we do not believe that such claims would be valid and enforceable if asserted. We have filed a PGR petition challenging the patentability of certain claims of the patent and the patentee subsequently disclaimed every challenged claim. As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patent applications that, if issued as patents, may be infringed by commercialization of CPI-444 or our other product candidates, and cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing CPI-444 or our other product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis; or

- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent CPI-444 or our other product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market CPI-444 or our other product candidates.

Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing CPI-444 or our other product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

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We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a first to file system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

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We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will depend in part on our ability to acquire, in-license or use these proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We have collaborated with U.S. academic institutions and may in the future collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

We may fail to comply with any of our obligations under existing agreements pursuant to which we license or have otherwise acquired intellectual property rights or technology, which could result in the loss of rights or technology that are material to our business.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. We are party to various agreements that we depend on for rights to use various technologies that are material to our business, including intellectual property rights covering CPI-444 and methods relating to its use and manufacture. In each of these cases, our rights to use the licensed intellectual property are subject to the continuation of and our compliance with the terms of these agreements. Disputes may arise regarding our rights to intellectual property licensed to us from a third party, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- the sublicensing of patent and other rights;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us, alone or with our licensors and collaborators;

- the scope and duration of our payment obligations;

- our rights upon termination of such agreement; and

- the scope and duration of exclusivity obligations of each party to the agreement.

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If disputes over intellectual property and other rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under current or future licensing agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of CPI-444 or other product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, Congress may pass patent reform legislation that is unfavorable to us. The Supreme Court has ruled on several patent cases

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in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

While we have issued patents directed at CPI-444 in the United States and pending patent applications directed at CPI-444 and other product candidates in the United States and other countries, filing, prosecuting and defending patents on CPI-444 and our other product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make adenosine antagonists that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;

- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;

- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- it is possible that our pending patent applications will not lead to issued patents;

- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable; and

- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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Risks Related to Our Common Stock

An active, liquid and orderly market for our common stock may not be maintained.

Prior to our IPO in March 2016, there had been no public market for our common stock. Although our common stock is listed on The NASDAQ Global Market (NASDAQ), an active trading market for our common stock may never be sustained on NASDAQ or any other exchange in the future. The lack of an active market may impair our stockholders ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. If an active market for our common stock is not maintained, it may also be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

The trading price of the shares of our common stock could be highly volatile, and investors in our common stock could incur substantial losses.

Our stock price has been volatile. The stock market in general and the market for stock of pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by those factors discussed in this Risk Factors section and many others, including:

- our ability to enroll subjects in our planned clinical trials;
- results of the clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of CPI-444 and our other product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;

- the success or failure of our efforts to acquire, license or develop additional product candidates;

- innovations or new products developed by us or our competitors;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

- manufacturing, supply or distribution delays or shortages;

- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;

- achievement of expected product sales and profitability;

- variations in our financial results or those of companies that are perceived to be similar to us;

- market conditions in the pharmaceutical sector and issuance of securities analysts reports or recommendations;

- trading volume of our common stock;

- an inability to obtain additional funding;

- sales of our stock by insiders and stockholders;

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- general economic, industry and market conditions other events or factors, many of which are beyond our control;

- additions or departures of key personnel; and

- intellectual property, product liability or other litigation against us.

As a result of this volatility, investors may experience losses on their investment in our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical companies following periods of volatility in the market prices of these companies stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our failure to meet the continued listing requirements of NASDAQ could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of NASDAQ, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders ability to sell or purchase our common stock when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ s listing requirements.

Because a small number of our existing stockholders own a majority of our voting stock, a stockholder s ability to influence corporate matters will be limited.

As of June 30, 2017, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 70% of our outstanding common stock. As a result, such persons, acting together, have the ability to control our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders ability to achieve a return on their investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, certain holders of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

We are an emerging growth company, and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation

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requirements of Section 404 of Sarbanes-Oxley, reduced disclosure obligations regarding executive compensation in our Annual Report on Form 10-K and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until the earlier of (1) December 31, 2021, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such fiscal year, or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. If investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely consolidated financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2017. When we lose our status as an emerging growth company and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure our stockholders that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

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- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- the required approval of at least 662/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;

- the required approval of at least 662/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;

- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror s own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. For a description of our capital stock, see the section titled Description of Capital Stock.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision may limit a stockholder s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find this provision in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Our ability to use net operating loss carryforwards and other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. As of December 31, 2016, we had federal net operating loss (NOL) carryforwards of approximately $20.0 million and state NOL carryforwards of approximately $45.0 million available to offset future taxable income. If not utilized, the federal and state NOL carryforwards will begin to expire in various years beginning in 2034. As of December 31, 2016, we also had $1.3 million of federal and $1.7 million of state research and development tax credit carryforwards

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available to reduce future income taxes. The federal research and development tax credits will begin to expire in 2035, if not utilized. The state research and development tax credits have no expiration date. Utilization of NOL carryforwards and credits may be subject to an annual limitation due to the ownership change provisions under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state provisions. An ownership change is generally defined as a cumulative change in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points. We may have experienced an ownership change prior to December 31, 2016, including in connection with our IPO. Such ownership changes could result in the expiration of our NOL carryforwards and other tax attributes before they can be utilized and, if we are profitable, our future cash flows could be adversely affected due to our increased tax liability.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities.

None

Use of Proceeds from Registered Securities

Shares of our common stock began trading on The NASDAQ Global Market on March 23, 2016. The offer and sale of all the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-208850), which was declared effective by the SEC on March 22, 2016.

There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on March 24, 2016.

Repurchases of Shares or of Company Equity Securities

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

Not applicable

Item 5. Other Information

None

Item 6. Exhibits

The list of exhibits set forth in the accompanying Exhibit Index on the page immediately following the signature page to this Quarterly Report on Form 10-Q is incorporated by reference into this Item 6.

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SIGNATURES

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

CORVUS PHARMACEUTICALS, INC.

Date: August 3, 2017 By: /s/ Richard. A. Miller

Richard A. Miller, M.D.

President, Chief Executive Officer and Director

(Principal Executive Officer)

Date: August 3, 2017 By: : /s/ Leiv Lea

Leiv Lea

Chief Financial Officer

(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation.	8-K	3/29/2016	3.1	
3.2	Amended and Restated Bylaws.	8-K	3/29/2016	3.2	
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1	1/4/2016	4.2	
4.3	Amended and Restated Investors Rights Agreement, dated September 16, 2015, by and among Corvus Pharmaceuticals, Inc. and the investors listed therein.	S-1/A	2/8/2016	4.3	
10.1	Phase 1B/II combination study agreement dated May 1, 2017 by and between Corvus Pharmaceuticals, Inc. and Genentech, Inc.				X
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).				X
31.2	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).				X
32.1*	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any

filing of Corvus Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.