

Corvus Pharmaceuticals, Inc.  
Form 10-K  
March 10, 2017

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[INDEX TO CONSOLIDATED FINANCIAL STATEMENTS](#)

[Table of Contents](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

---

**FORM 10-K**

---

(Mark One)

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

**For the Fiscal Year Ended December 31, 2016**

**OR**

**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**  
(State or other jurisdiction  
of incorporation)

**001-37719**  
(Commission  
File Number)

**46-4670809**  
(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**

---

Securities registered pursuant to Section 12(b) of the Act:

Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

Title of each class  
Common Stock, \$0.0001 par value

Name of each exchange on which registered  
The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the issuer (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  No

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  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Small reporting company   
(Do not check if a smaller reporting company)

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

As of June 30, 2016, the aggregate market value of the 8,314,653 shares of Common Stock held by non-affiliates of the registrant was approximately \$118.6 million, computed by reference to the closing price as reported on The NASDAQ Stock Market. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding common stock of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes. As of March 10, 2017, 20,933,387 shares of the registrant's common stock were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement to be filed for its 2017 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Table of Contents

**CORVUS PHARMACEUTICALS, INC.**

**ANNUAL REPORT ON FORM 10-K**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	
<b><u>ITEM 1.</u></b> <u>Business</u>	<u>1</u>
<b><u>ITEM 1A.</u></b> <u>Risk Factors</u>	<u>36</u>
<b><u>ITEM 1B.</u></b> <u>Unresolved Staff Comments</u>	<u>77</u>
<b><u>ITEM 2.</u></b> <u>Properties</u>	<u>77</u>
<b><u>ITEM 3.</u></b> <u>Legal Proceedings</u>	<u>77</u>
<b><u>ITEM 4.</u></b> <u>Mine Safety Disclosures</u>	<u>77</u>
<b><u>PART II</u></b>	
<b><u>ITEM 5.</u></b> <u>Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities</u>	<u>78</u>
<b><u>ITEM 6.</u></b> <u>Selected Financial Data</u>	<u>81</u>
<b><u>ITEM 7.</u></b> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>82</u>
<b><u>ITEM 7A.</u></b> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>92</u>
<b><u>ITEM 8.</u></b> <u>Financial Statements and Supplementary Data</u>	<u>93</u>
<b><u>ITEM 9.</u></b> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>120</u>
<b><u>ITEM 9A.</u></b> <u>Controls and Procedures</u>	<u>120</u>
<b><u>ITEM 9B.</u></b> <u>Other Information</u>	<u>120</u>
<b><u>PART III</u></b>	
<b><u>ITEM 10.</u></b> <u>Directors, Executive Officers of the Registrant and Corporate Governance Matters</u>	<u>121</u>
<b><u>ITEM 11.</u></b> <u>Executive Compensation</u>	<u>121</u>
<b><u>ITEM 12.</u></b> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>121</u>
<b><u>ITEM 13.</u></b> <u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>121</u>
<b><u>ITEM 14.</u></b> <u>Principal Accounting Fees and Services</u>	<u>121</u>
<b><u>PART IV</u></b>	
<b><u>ITEM 15.</u></b> <u>Exhibits and Financial Statement Schedules</u>	<u>121</u>
<b><u>ITEM 16.</u></b> <u>Form 10-K Summary</u>	<u>121</u>
<u>Signatures</u>	<u>122</u>

Table of Contents

**Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "potential" or "continue" or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

the anticipated timing, costs and conduct of our planned preclinical studies and clinical trials for CPI-444 and other product candidates in our development programs;

our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;

the timing or likelihood of regulatory filings and approvals for CPI-444 and our other product candidates;

our ability to commercialize CPI-444, if approved, and our other product candidates;

our expectations regarding the clinical effectiveness of our product candidates;

our commercialization, marketing and manufacturing capabilities and strategy;

the pricing and reimbursement of our product candidates, if approved;

the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including projected terms of patent protection;

the potential benefits of strategic collaborations and our ability to enter into strategic arrangements;

developments and projections relating to our competitors and our industry, including competing therapies;

our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and

our financial performance.

Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors and discussed elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

### Table of Contents

industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Except where the context otherwise requires, in this Annual Report on Form 10-K, "we," "us," "our" and the "Company" refer to Corvus Pharmaceuticals, Inc.

### **Trademarks**

This Annual Report on Form 10-K includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Annual Report on Form 10-K are the property of their respective owners.

Table of Contents

**Part I**

**Item 1. Business**

**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. 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 early 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.

Immuno-oncology therapies that stimulate or enhance immune responses to tumors are a new and emerging approach with several potential benefits over existing therapies. First, the immune system exhibits immunologic diversity and selectivity, which enables it to respond selectively to a large number of potential targets. Second, once triggered, the immune response can be amplified, offering the potential to enhance the efficacy of treatment. Third, once activated, the immune system possesses immunologic memory, potentially providing for a durable and long-lasting response. Some of the most successful types of immuno-oncology therapies are immune checkpoint inhibitors. Immune checkpoints are signaling molecules produced by or expressed on immune cells that act to shut down or block an immune response. In a healthy person, these checkpoints function to limit an immune response to ensure that the immune system does not overreact, which could lead to excessive inflammation and tissue damage, as occurs in patients with autoimmune diseases or allergies. Tumor cells have evolved to activate these checkpoints to shield the tumor from immune response attacks, but studies have shown that immune checkpoint inhibitors can counter these tumor-protective measures and unleash the immune system's cancer-destroying properties.

The FDA has approved agents that target specific immune checkpoints, including antibodies against the cytotoxic T-lymphocyte-associated antigen-4 ("CTLA-4"), programmed death 1 ("PD-1") receptors, and programmed death receptor-ligand 1 ("PD-L1"). These antibodies represent the first immune checkpoint inhibitors to demonstrate effectiveness in the clinic, and preclinical data suggest

Table of Contents

that there are many other immune checkpoints or targets that may be modulated to promote the activation of a patient's anti-tumor immune system.

Since we began operations in November 2014, we have built a pipeline of four immuno-oncology programs. Three of our programs are aimed at disabling cancer's ability to subvert immune attack by inhibiting adenosine in the tumor microenvironment or by blocking its production by tumors. Adenosine activates an immune checkpoint, the adenosine A2A receptor, that is used by the body to limit inflammation and immune responses. Adenosine accomplishes this by interacting with the A2A and A2B receptors expressed on several cells of the immune system; including T-cells, natural killer ("NK") cells, macrophages, dendritic cells and myeloid derived suppressor cells, as well as other cells. We are developing small molecules that selectively inhibit the binding of adenosine to either A2A receptors or to A2B receptors. We also are developing injectable monoclonal antibodies that block the production of adenosine by tumors by inhibiting the cell surface enzyme CD73. Our fourth program is aimed at developing product candidates that regulate T-cell activation and differentiation by inhibiting interleukin-2 inducible kinase ("ITK"). Several of our product candidates are orally administered small molecules, which may provide for easier administration and facilitate their use in combination with other anti-cancer agents. Our oral product candidates are designed to be rapidly eliminated from the body, which, in turn, could reduce the potential for excessive toxicity when used in combination with other antibody-based checkpoint inhibitors.

Our immuno-oncology product candidate pipeline includes the following:

***CPI-444 Adenosine A2A Receptor Antagonist.*** In February 2015, we in-licensed patent rights and know-how related to CPI-444 and related molecules from Vernalis (R&D) Limited ("Vernalis"), where it was under development for treatment of Parkinson's disease and other neurologic diseases. Vernalis and its corporate partner conducted two Phase 1 clinical trials in healthy volunteers and one Phase 1b clinical trial in patients with attention deficit and hyperactivity disorder (ADHD), with an aggregate of approximately 75 healthy volunteers and patients dosed. These trials provided early indications of a favorable safety profile and assessed pharmacokinetics, oral bioavailability and receptor occupancy for CPI-444. We conducted further testing in *in vitro* and *in vivo* models to evaluate CPI-444's immune-enhancing and anti-tumor properties. In these studies, orally administered CPI-444 inhibited tumor growth in multiple mouse models of cancer as a single agent, in combination with anti-PD-1 agents and in combination with anti-PD-L1 agents.

In October 2015, we filed an investigational new drug ("IND") application for CPI-444 for treatment of several solid tumor types. In January 2016, we began enrolling patients in a large expansion cohort clinical trial for CPI-444. This Phase 1/1b clinical trial is designed to examine safety, tolerability, biomarkers and preliminary efficacy of CPI-444, both as a single agent and in combination with Tecentriq (atezolizumab), and includes patients with different types of solid tumors enrolled in disease-specific cohorts.

In November 2016, we completed enrollment of the first step of the Phase 1/1b clinical trial, which was designed to determine the optimal dose for use in the disease-specific expansion cohort component of the trial. We also reported results of initial safety, tolerability, biomarkers and preliminary efficacy. In December 2016, we initiated the second step of the Phase 1 /1b clinical trial with our optimal dose of CPI-444 as both a single agent therapy and in combination with Tecentriq (atezolizumab). This portion of the trial is now enrolling patients in ten disease specific cohorts; five of the cohorts receive CPI-444 as a single agent and five receive CPI-444 in combination with Tecentriq (atezolizumab). The cohorts include patients with non-small cell lung cancer, malignant melanoma, renal cell cancer, triple-negative breast cancer and others (bladder cancer, prostate cancer and colorectal cancer with high mutation rates).

The issued U.S. patents that we in-licensed from Vernalis are directed to the composition of matter of CPI-444 and its method of use for treating disorders treatable by purine receptor blocking.

Table of Contents

The composition of matter patent covering CPI-444 is expected to expire in the United States in July 2029, excluding any patent term extension that may be available. We hold an exclusive, worldwide license under these patent rights and related 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.

***Anti-CD73 Adenosine Production Inhibitor.*** In December 2014, we in-licensed from The Scripps Research Institute ("Scripps") a mouse hybridoma clone expressing an anti-human CD73 antibody, from which we have developed our lead product candidate, CPX-006, a humanized anti-CD73 monoclonal antibody. We have further modified CPX-006 to improve binding to CD73 and maximize its inhibition of catalytic activity. CD73 is often found on lymphocytes, tumors and other tissues and is believed to play an important role in tumor immune suppression by catalyzing the production of extracellular adenosine. In preclinical *in vitro* studies, our humanized monoclonal anti-CD73 antibody has been shown to inhibit the catalytic activity of CD73, resulting in the blocking of extracellular adenosine production by tumor cells, which we believe could stimulate or enhance immune response to tumors. In 2016, we initiated IND-enabling studies for CPX-006 for potential clinical trials in patients with advanced cancer and, subject to the completion of such studies and the submission and acceptance by the FDA of an IND, we plan to begin a Phase 1 clinical trial in early 2018. We hold a non-exclusive, world-wide license for all fields of use under Scripps' rights in a hybridoma clone expressing an anti-CD73 antibody, and to progeny, mutants or unmodified derivatives of such hybridoma and any antibodies expressed by such hybridoma. In 2016, we filed a patent application covering the composition of matter of CPX-006.

***Adenosine A2B Receptor Antagonist.*** We have in-licensed several selective and potent adenosine A2B receptor antagonists from Vernalis. In addition, we are synthesizing and have identified other A2B receptor antagonists from our internal research program. Adenosine A2B receptors have recently been found to play an important role in the immune response to tumors. Similar to adenosine A2A receptors, adenosine binds to adenosine A2B receptors, which leads to immunosuppression. We intend to further develop our A2B agents to improve potency, selectivity, pharmacokinetic behavior and immune enhancing properties. We expect to conduct preclinical studies similar to those we have conducted for CPI-444 in order to select a development candidate in 2017. Upon selection, we intend to conduct further IND-enabling studies and potential Phase 1 clinical trials. We hold an exclusive, worldwide license under certain Vernalis patent rights and know-how, including a limited right to grant sublicenses, for all fields of use to develop, manufacture and commercialize products containing such compounds that have been developed using the intellectual property rights that we in-license from Vernalis.

***ITK Inhibitor.*** We are currently developing a series of selective, covalent inhibitors of ITK and are evaluating them in preclinical studies for potency, safety and efficacy. ITK, an enzyme that functions in T-cell signaling and differentiation, is expressed predominantly in T-cells, which are lymphocytes that play a vital role in immune responses. One of the key survival mechanisms of tumors is believed to be the reprogramming of T-cells to create an inflammatory environment that inhibits anti-tumor immune response and favors tumor growth. We believe highly selective inhibitors of this enzyme will facilitate induction of T-cell anti-tumor immunity and also may be useful in the treatment of T-cell lymphomas. In 2016, we selected a lead development candidate for this program and initiated IND-enabling studies. Subject to the completion of such studies and the submission and acceptance by the FDA of an IND, we plan to advance the candidate into Phase 1 clinical trials in cancer patients in 2018. We have filed patent applications covering composition of matter and uses of our ITK inhibitors and hold exclusive worldwide rights for all indications.

Table of Contents

**Our Company Origins and Team**

Since we began operations in November 2014, our focus has been on improving and expanding upon the recent success achieved with immune checkpoint inhibitors and on developing agents to new targets in the evolving immuno-oncology field. Our founders and management team consist of industry veterans who have played significant roles in the discovery and development of successful oncology and immunology antibodies and drugs, including rituximab and ibrutinib. Our co-founders include our Chief Executive Officer, Richard A. Miller, M.D., our Chief Financial Officer, Leiv Lea, and our Executive Vice President, Discovery Research, Joseph Buggy, Ph.D. Dr. Miller previously co-founded IDEC (which merged to form Biogen IDEC, now Biogen), where he led research efforts on lymphoma, culminating in the development of rituximab. Dr. Miller, an oncologist, also co-founded and was the initial CEO of Pharmacyclics, Inc. where he and colleagues in-licensed ibrutinib and, together with Dr. Buggy, led its development. Our Chief Financial Officer, Leiv Lea, has previously led finance teams for emerging biotechnology companies, including Pharmacyclics. Mr. Lea has extensive commercial and operating experience in addition to having completed a number of financial and strategic transactions. In 2016, Jason Coloma, Ph.D., was hired as our Senior Vice President and Chief Business Officer. Dr. Coloma previously led oncology business development efforts for Roche. In addition, we have recruited industry veterans and experts to join our management team, and established collaborations with leading biotechnology companies, including Genentech, and collaborative relationships with research institutions, including The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. With our management team's expertise in developing both small molecule and antibody-based oncology treatments, we believe we are well positioned to identify and develop novel therapeutic agents that have diverse but complementary mechanisms of action, allowing for their potential integration into immuno-oncology treatment regimens for a broad variety of cancers.

**Our Strategy**

Our goal is to become a leader in the field of immuno-oncology treatments for multiple cancer indications. Specific elements of our strategy are:

***Leverage our expertise in immunology and oncology to identify, develop and commercialize new product candidates.*** We have established development expertise and capabilities in synthetic chemistry, molecular biology, immunology and clinical oncology, which we believe will help us advance product candidates in the immuno-oncology field. We plan to become a leader in the development and commercialization of product candidates targeting adenosine in what is known as the adenosine-cancer axis, a key mechanism used by tumors to evade immune attack. Three of our product programs, each of which was in-licensed, are focused on the development of product candidates targeting this axis, including an A2A receptor antagonist, an anti-CD73 antibody and an A2B receptor antagonist. We intend to seek opportunities to in-license additional product candidates with a focus on the potential to address unmet needs within our areas of expertise.

***Utilize efficient clinical trial designs to enable us to identify the most promising clinical indications.*** Our Phase 1/1b clinical trial is designed to evaluate multiple variables, such as single agent and combination therapy, impact of prior therapy with immune-oncology agents and the role of various biomarkers, which may allow us to determine tumor types that are most responsive to treatment with CPI-444 alone or in combination. This approach has the potential to shorten development time by quickly identifying the most promising clinical indications, which would then be evaluated in subsequent definitive pivotal trials. For instance, In January 2017, the protocol-predefined criteria for expansion in our Phase 1/1b clinical trial for CPI-444 was reached for the cohort of patients with renal cell carcinoma treated with single-agent CPI-444. Accordingly, the size of that cohort has been increased from 14 to 26 patients. We intend to use similar clinical trial designs for our other product candidates in the future.

Table of Contents

***Advance product candidates for use alone or in combination with other oncology treatments.*** We intend to focus on product candidates with single agent activity, which are also designed to be combined synergistically with other cancer therapies. We believe that many immuno-oncology therapeutic regimens will likely be built on a backbone of anti-PD-1/PD-L1 blockade, and our initial Phase 1/1b clinical trial includes the administration of CPI-444 in combination with Tecentriq (atezolizumab). Our product candidates are designed to target the patient's immune system rather than a specific type of malignant cell, and, if approved, could be suitable as a single agent as well as in combination with current and future immunotherapy agents as well as traditional cancer treatments, including chemotherapy, biologic therapy, targeted therapy and radiation therapy.

***Identify biomarkers to select patients and monitor treatment with our product candidates.*** Predicting optimal drug responses in patients requires the identification and validation of predictive biomarkers. We believe that developing the ability to identify patient subsets most likely to respond to our product candidates will increase the clinical benefit to patients and improve the probability of success of our clinical trials. Our Phase 1/1b clinical trial of CPI-444 includes the examination of numerous biomarkers to identify those that may correlate with clinical efficacy and increase our likelihood of success.

***Pursue collaborative relationships, partnerships and in-licensing opportunities to help advance and expand our product candidate portfolio.*** In addition to developing product candidates through preclinical and clinical stages of development, we plan to identify and pursue strategic collaborative relationships, partnerships and in-licensing opportunities, which could enhance the development of our programs and product candidates. As evidenced by our collaboration with Genentech for CPI-444, we intend to build upon our relationships with leading biotechnology companies and research institutions to identify new opportunities to position us at the forefront of immuno-oncology.

## **Cancer Treatment and Immuno-oncology**

Cancer is the second leading cause of mortality in the United States, accounting for nearly one in every four deaths. Approximately 40% of Americans will develop some form of cancer, and, according to the American Cancer Society, there were 1.7 million new cases of cancer and 595,000 deaths due to cancer in the United States in 2016. Cancer treatment has traditionally included chemotherapy, biologic therapy, radiation, surgery or a combination of these approaches. Treatment with targeted agents is becoming more widely used. These agents often react with specifically mutated proteins in cancer. Many different mutations are now known to occur frequently in cancer and, in many cases, are responsible for driving tumor progression.

Immuno-oncology is a new and emerging approach to treating cancer that is based on stimulating or enhancing an immune response to the tumor. This approach is based on the findings that the mutations occurring in cancer cells may be immunogenic and capable of eliciting an immune response against the tumor. Immuno-oncology therapies offer several potential advantages over existing cancer therapies due to the intrinsic features of the immune system. For instance, the immune system exhibits immunologic diversity and selectivity, which enables it to respond to a large number of potential targets. In addition, once triggered, the immune response can be amplified, offering the potential to enhance the efficacy of treatment. Furthermore, once activated, the immune system possesses immunologic memory, potentially providing for a durable and long-lasting response. Finally, because immunotherapy mechanisms are indifferent to tissue origin and are instead focused on immunogenic mutations, which are often expressed across tumor types, immunotherapy may be widely applicable to many types of cancer and not limited to a particular tumor type. This allows for these agents to be potentially active in a multitude of cancer histologies. However, while the modulation of the immune system to eradicate cancer has been a long-standing goal in cancer therapy, historically it has not been

Table of Contents

possible to consistently produce clinically meaningful anti-tumor immune responses despite the immunogenicity of tumors.

Recently, the reasons for the previous failures of immunologic approaches to cancer treatment have become better understood. Tumors evolve sophisticated survival mechanisms, allowing them to avoid immune-mediated destruction as occurs with pathogens, such as bacteria or viruses. These mechanisms include the activation of immune checkpoints on cells of the immune system, which act to block immune responses, and the reprogramming of T-cells to create an inflammatory environment that inhibits immune response and favors tumor growth. Immune checkpoints are signaling molecules produced by or expressed on immune cells that shut down or block an immune response. In a healthy person, these checkpoints function to limit an immune response to ensure that the immune system does not overreact, which could lead to excessive inflammation and tissue damage, as occurs in patients with autoimmune diseases or allergies. Tumors have evolved to activate these checkpoints to shield them from immune response attacks. However, studies have shown that these mechanisms can be countered using immune checkpoint inhibitors, which can unleash the immune system's cancer-destroying properties. The new found understanding of immune checkpoints has led to a revolution in cancer treatment and the growing field of immuno-oncology. Specific immune checkpoint inhibitors, including antibodies against CTLA-4, PD-1 receptor or its ligand PD-L1 have produced impressive results in the clinic in a range of cancers, leading to FDA approvals for ipilimumab (anti-CTLA-4), nivolumab (anti-PD-1), pembrolizumab (anti-PD-1) and atezolizumab (anti-PD-L1).

Despite their recent success, current checkpoint inhibitors suffer from several limitations. Only a minority of patients treated with checkpoint inhibitors exhibit robust anti-tumor responses, and most responses are partial and temporary. Many patients initially respond, but then relapse due to the emergence of resistant pathways, which may occur due to tumor cell expression of other checkpoints. Some patients experience unusual toxicities related to an over-exuberant immune response against normal tissues leading to pneumonitis, hepatitis, colitis and other autoimmune related disorders. These limitations have motivated a search for other immune checkpoint targets and the use of combinations of various checkpoint inhibitors in an attempt to improve efficacy, reduce resistance and limit or reduce toxicity. To date, the use of combinations of immune checkpoint inhibitors has been limited by excessive and serious autoimmune toxicities.

The recent success of checkpoint inhibitors has stimulated increased interest in utilizing various immunotherapy approaches to treating cancer, including vaccines, cellular therapies and other immunomodulatory agents. These approaches include modulating the function of various immune cells. For example, ibrutinib, an FDA approved BTK inhibitor, is currently being evaluated as an immunomodulatory agent in solid tumors because it is believed to also affect the differentiation of T-cells.

**Product Pipeline**

We are developing novel checkpoint inhibitors and immuno-oncology therapies that we believe may overcome some of the limitations of current immuno-oncology therapies. Three of our programs are aimed at disabling cancer's ability to subvert immune attack by inhibiting adenosine in the tumor microenvironment or by blocking its production by tumors. Our fourth program is aimed at developing product candidates that regulate T-cell activation and differentiation by inhibiting ITK, an enzyme important in T cell differentiation and function. We intend to commercialize any approved product candidates primarily in the United States and Europe for any oncology indications our product candidates are approved for. We expect cancer patients or their healthcare providers to be our primary customers for any approved product candidates and expect that our commercial sales of such product candidates will depend on the availability of adequate coverage and reimbursement from government health administration authorities, private health insurers and other third-party payors.

Table of Contents

The following chart summarizes key information regarding our current product candidate pipeline and expected milestones:

**Adenosine Inhibitors**

*Adenosine-Cancer Axis and Anti-tumor Immune Response*

Adenosine activates an immune checkpoint, the adenosine A2A receptor, that is used by the body to limit inflammation and immune responses. It is produced during acute, inflammatory processes in two steps. The first step is the catalytic conversion of adenosine triphosphate ("ATP") to adenosine monophosphate ("AMP") by the enzyme CD39. The second and rate-limiting step is the conversion of AMP to adenosine by CD73, an enzyme expressed on the surface of several types of immune cells, tumor cells and cells of certain other tissues. Under normal circumstances, the level of adenosine is increased to protect a person from over-injury in response to such stimuli as inflammation, infection or ischemia. However, as a self-protective maneuver, many tumor types actively sustain increased levels of extracellular adenosine by production through CD73 or by direct secretion of adenosine. These increased levels of adenosine interact with the A2A and A2B receptors expressed on several cells of the immune system, including T-cells, NK cells, macrophages, dendritic cells and myeloid derived suppressor cells, as well as other cells, which has the effect of dampening the immune response to the tumor, a system known as the adenosine-cancer axis.

Table of Contents

The following figure provides an overview of adenosine production by tumors and its effects on the immune system:

**Adenosine-Cancer Axis**  
**Immunosuppressive Effects of Adenosine Mediated through Multiple Pathways**

The immune system is composed of several cellular components that mediate a variety of functions in response to tumor cells and foreign pathogens. For instance, macrophages and dendritic cells function primarily to process foreign antigens and tumor antigens. These cells then present such antigens to other cells, such as T-cells. The presentation of these antigens to T-cells stimulates cytotoxic T-cells (also known as killer T-cells) to destroy the tumor cells or foreign pathogens. Other cells, such as NK cells, are capable of destroying tumor cells without the need for antigen presentation from macrophages or dendritic cells. In addition, certain immune cells, such as myeloid derived suppressor cells and T regulatory cells, function to suppress or dampen immune responses. The various cellular components of the immune system work in a coordinated manner to recognize and destroy pathogens and tumor cells, and then return the tissue to its normal state.

Adenosine hinders the immune response to tumors by both blocking the activation and effectiveness of immune cells capable of destroying tumor cells, and by increasing the number of immune cells that act to suppress immune cells from responding to the tumor. For instance, adenosine reduces T-cell and NK cell production of cytokines, such as interleukin-2 ("IL-2") and gamma interferon ("IFN $\gamma$ "), which results in the blockade or reduction in the ability of such cells to destroy tumor cells. Adenosine also leads to activation and proliferation of T regulatory cells, which function to suppress or dampen immune responses. In addition, adenosine causes dendritic cells to both decrease the rate at which they present antigens to T-cells, thereby inhibiting the ability of T-cells to destroy tumor cells, and decrease their production of co-stimulatory cytokines, which also has the effect of suppressing or dampening the immune response. Macrophages exposed to adenosine will similarly decrease their function, which results in the suppression of immune activity. Finally, adenosine stimulates and increases the number of myeloid derived suppressor cells in the tumor microenvironment, which suppresses immune responses to the tumor. As tumor cells evolve and form cancerous growths, they utilize these processes to evade immune attack and promote their survival. Many of the effects of adenosine on the immune system are mediated through binding to A2A

Table of Contents

receptors present on several immune cells. Much less is known about A2B receptors, but they have recently been found on certain immune cells, such as macrophages and myeloid derived suppressor cells, and adenosine binding to A2B receptors also appears to play a role in tumor induced immune suppression.

Cancer cells also appear to directly utilize adenosine to promote their own growth. Many solid tumors upregulate CD73 for increased adenosine production. In some cases, it appears adenosine can stimulate growth in tumors by increasing a tumor's blood supply.

A significant body of data indicates that targeting the adenosine-cancer axis through the A2A receptor can promote anti-tumor immune responses leading to tumor regression. Consistent with studies of the inhibition of the A2A receptor, A2A receptor gene knockout mice, which completely lack expression of the A2A receptor, exhibit improved anti-tumor immunity. In addition, several preclinical tumor model studies have shown that treatment with A2A receptor inhibitors leads to tumor regression that is enhanced when administered in combination with various other checkpoint inhibitors, such as anti-PD-1 therapies and anti-CTLA-4 therapies.

***Lead Product Candidate: CPI-444, an A2A selective, orally administered antagonist of the adenosine A2A receptor***

*Overview*

Our lead product candidate, CPI-444, is a selective oral adenosine A2A receptor antagonist that we licensed from Vernalis in February 2015. This molecule was under development for treatment of Parkinson's and other neurologic diseases. Studies conducted by Vernalis and its corporate partner, Biogen IDEC, showed that A2A receptor antagonists were relatively safe and well-tolerated. Three human clinical trials involving approximately 75 healthy volunteers and patients with ADHD were conducted previously with CPI-444 by Vernalis and Biogen IDEC, of whom 43 received single doses and 54 received once-daily or twice-daily doses for up to 14 days. One of these, a randomized, Phase 1b, double-blind, cross-over, placebo controlled trial in 28 patients with ADHD, was conducted in the United States from 2013 to 2014 under an IND. At the time, little was known about the A2A receptor and the potential effects of adenosine on the immune system, and these studies did not attempt to measure effects of treatment on immune cells or on immune function.

Since licensing CPI-444, we have conducted extensive laboratory studies *in vitro* and *in vivo* in animal models to evaluate CPI-444's immune-enhancing and anti-tumor properties. In these studies, orally administered CPI-444 inhibited tumor growth in multiple mouse models of cancer as a single agent, in combination with anti-PD-1, in combination with anti-PD-L1, in combination with other immune-oncology agents and in combination with certain chemotherapy drugs. We also have shown *in vitro* that CPI-444 binds potently and selectively to human activated T-cells and blocks adenosine mediated immunosuppression by restoring T-cell function. In addition, we have shown that there is anti-tumor activity in mice for a significant time following oral administration, which appears to be mediated through a long-lasting memory immune response. Furthermore, we have shown in animal models that the treatment is well tolerated. Our IND in oncology was filed in October 2015, and we began enrolling patients in a Phase 1/1b clinical trial in January 2016.

*Human Safety and Pharmacokinetic Data for CPI-444*

Prior to licensing CPI-444 from Vernalis, Vernalis and its corporate partner conducted two Phase 1 clinical trials in healthy volunteers and one Phase 1b trial in patients with ADHD, with oral doses ranging from 30 mg/day to 300 mg/day. Two studies were completed in healthy human male volunteers, the first of which was a single ascending dose or multiple dose study with 41 healthy volunteers. Of these 41 subjects, 21 were dosed in both the single ascending dose and multiple dose portions of the study. The second study was a receptor occupancy study performed in six human subjects using PET

Table of Contents

imaging to determine receptor occupancy. The third study was a randomized, double blind, placebo controlled, cross-over Phase 1b trial in 28 patients with ADHD, which evaluated doses up to 200 mg/ day. The results of these studies were as follows:

*Safety and tolerability:* In studies involving healthy volunteers, there was no pattern in the incidence, severity, or relationship of adverse events to CPI-444 dose level. The main toxicity exhibited was gastro-intestinal disorders (abdominal pain, nausea) due to gastric irritation; however, these findings were also observed in the placebo group. No differences in gastric endoscopy were seen between treatment and placebo groups. No dose limiting toxicities were observed and no subject experienced a serious adverse event considered by the investigator to be related to CPI-444. There were no treatment-associated changes seen for any routine laboratory safety tests. A minimal and transient increase in blood pressure that may have been dose-related was observed on day one, but was not detected by day 14 of continuous daily dosing. No clinically significant cardiac abnormalities on telemetry or electrocardiogram recordings were observed. There were no clinically significant changes from baseline in physical examination findings and there were no treatment-emergent clinically significant findings. Based on these studies, we believe that administration of CPI-444 was not associated with any clear evidence of toxicity.

*Human pharmacokinetics:* CPI-444 was absorbed promptly following oral administration (lag time of less than 0.5 hours) with maximum plasma concentrations ("C<sub>max</sub>") observed within four hours of dosing ("t<sub>max</sub>"). The plasma half-life ("t<sub>1/2</sub>") of CPI-444 was determined to be approximately 10 hours after 14 days of dosing. Preliminary data indicate that the effect of food on bioavailability of CPI-444 is negligible, indicating that the drug can be given to fasting or fed patients.

*Receptor occupancy in human brain:* In a receptor occupancy study conducted by Vernalis during its development of CPI-444 for Parkinson's disease, CPI-444 was shown to bind to brain A2A receptor in a dose-dependent manner following oral administration. CPI-444 appeared to display a direct relationship between plasma concentration and brain A2A receptor occupancy, with 50% of the receptor occupied at a concentration of 320 ng/mL. Approximately 15% of drug crosses the blood brain barrier in studies conducted in non-human primates. Trough level plasma concentrations greater than 960 ng/mL of CPI-444 are, therefore, calculated to lead to greater than 90% A2A receptor occupancy in peripheral tissues. These studies indicate that at the lowest plasma levels of CPI-444 achieved following 100 mg given twice per day, there would be an expected 90% or higher occupancy of the peripheral A2A receptors.

#### Human Pharmacokinetics of CPI-444

	200 mg Once Daily Oral		100 mg Twice Daily Oral	
	Day 1	Day 14	Day 1	Day 14
C <sub>max</sub> (µg/mL)	4.29	5.59	3.54	4.06
T <sub>max</sub> (h)	1.78	3.0	3.00	2.00
C <sub>min</sub> (µg/mL)	Not applicable	0.22	Not applicable	1.12
t <sub>1/2</sub> (h)	Not calculated	10.2	3.00	10.6

#### CPI-444 Clinical Development Plan

In January 2016, we began enrolling patients in a Phase 1/1b, open-label, expansion cohort design clinical trial for patients with selected advanced, incurable cancers. The trial is examining oral CPI-444 administered as both a single agent and in combination with Tecentriq (atezolizumab). Under our clinical trial collaboration agreement with Genentech, we are responsible for the design, conduct and cost of the relevant studies, which are under the review of a joint development committee made up of

Table of Contents

our representatives and representatives of Genentech. Genentech supplies Tecentriq (atezolizumab). Pre-treatment and on-treatment tissue, blood and serum samples are collected and tested for a wide range of biomarkers including the characteristics of immune cell infiltrates and expression of numerous genes in tumor tissue samples.

We are currently conducting the trial in approximately 36 sites in the United States, Australia and Canada. Patients with non-small cell lung cancer, malignant melanoma, renal cell cancer, triple-negative breast cancer, bladder cancer, prostate cancer or colorectal cancer with high mutation rates are eligible for participation. Studies by others, utilizing anti-CTLA-4 therapies, anti-PD-1 therapies and anti-PD-L1 therapies have shown that these tumors are more likely to possess immunogenic proteins that are capable of eliciting anti-tumor immune responses. As a result, we believe that selecting patients with these types of tumors will enhance our chances of identifying patients responsive to CPI-444 therapy.

The primary objectives of our clinical trial for CPI-444, as a single agent and in combination with Tecentriq (atezolizumab), are to:

evaluate the safety and tolerability of CPI-444 in cancer patients;

determine optimum dosage based on safety, pharmacokinetic and pharmacodynamic data;

assess primary efficacy endpoints: overall response rate, duration of clinical benefit defined as complete response, partial response and stable disease (stable disease defined as no disease progression for at least 3 months).

assess secondary efficacy endpoints: include progression free survival, duration of response, and overall survival; and

assess the potential role of various biomarkers to predict or monitor response to therapy.

We are conducting the clinical trial of CPI-444 in two steps:

**Step 1 Dose Selection:** We initiated the first step of the clinical trial in January 2016. During this step, we determined the appropriate dosing based on safety, pharmacokinetic and biomarker studies. We randomized patients into one of four cohorts, with up to twelve patients per cohort. In three of the cohorts, we tested single agent CPI-444 at three different doses and schedules as follows: 100 mg twice per day for 14 days, 200 mg once per day for 14 days and 100 mg twice per day for 28 days. Treatment cycles are 28 days and patients continue on therapy until disease progression and/or toxicity. In the fourth cohort, we evaluated 100 mg twice per day for 14 days and then for 28 days in combination with a fixed dose of Tecentriq (atezolizumab). In each case, patients continued the therapy until there was evidence of disease progression and/or toxicity. We completed the first step of the clinical trial in November 2016, after enrolling 48 patients, 47 of whom received study treatment and one of whom withdrew from the study prior to receiving any therapy. The optimum dose of CPI-444 selected for step 2 was based on safety and pharmacodynamics.

**Step 2 Dose Expansion:** We initiated this portion of the clinical trial in November 2016. During this step, we plan to further evaluate the selected dose and schedule of CPI-444 as a single agent and in combination with Tecentriq (atezolizumab) in disease-specific expansion cohorts. This phase of the study has ten cohorts, with five cohorts receiving single agent CPI-444 at a dose of 100mg twice per day for 28 days and five cohorts receiving the combination of CPI-444 at a dose of 100 mg twice per day for 28 days and Tecentriq (atezolizumab). Patients are placed into disease-specific cohorts based on type of cancer and prior exposure to an anti-PD-1 or anti-PD-L1 antibody. We expect that each cohort will initially enroll up to 14 patients, with cohorts to be expanded if evidence of anti-tumor activity is shown. If a response (defined as partial or complete tumor response or disease stabilization for three months or more) in one or

Table of Contents

more patients out of 14 patients in a cohort is observed, then we intend to expand that cohort by twelve additional patients to a total of 26 patients. If no response is seen in the initial 14 patients, then we expect to cease enrollment in that cohort. If a response in five or more patients out of 26 patients in the expanded cohort is observed, then we intend to expand that cohort again by an additional 22 patients, for a total of 48 patients. We believe this design will enhance our ability to detect tumor responses in a range of tumor types.

The goal of the clinical trial is to determine optimal dosing and to identify the tumors that are most responsive to treatment with CPI-444 alone or in combination, which we expect to form the basis for subsequent potential pivotal trials either with CPI-444 alone or in combination. The endpoints for the trial are safety, tolerability and efficacy for CPI-444 administered as both a single agent and in combination with Tecentriq (atezolizumab). Numerous biomarker and immunologic analyses undertaken during the clinical trial may provide additional exploratory endpoints. Evaluation of responses will be made according to the Response Evaluation Criteria in Solid Tumors ("RECIST") criteria. RECIST is a set of published rules that define when tumors in cancer patients improve (respond), stay the same (stabilize), or worsen (progress) during treatments. The criteria were published in February 2000 by an international collaboration including the European Organization for Research and Treatment of Cancer, National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group.

The following is a schematic of the overall study design of our Phase 1/1b clinical trial showing three CPI-444 single agent dose selection cohorts and one combination CPI-444 and Tecentriq (atezolizumab) cohort followed by disease-specific expansion cohorts that will receive single agent CPI-444 or CPI-444 combined with Tecentriq (atezolizumab). The disease cohorts include non-small cell lung cancer ("NSCLC"), malignant melanoma ("MEL"), renal cell cancer ("RCC"), triple-negative

Table of Contents

breast cancer ("TNBC") and one additional cohort ("Other"), which includes bladder cancer, prostate cancer and colorectal cancer with high mutation rates.

**Phase 1/1b Clinical Trial Protocol**

*CPI-444 Preliminary Clinical Trial Results*

In November 2016, we completed enrollment in the first step, the dose selection phase, of the Phase 1/1b clinical trial. Of 47 patients enrolled and receiving study treatment, all patients had failed all approved therapies for their disease, with a median of four prior treatment regimens and a range of one to five treatment regimens. All of the patients had an Eastern Cooperative Oncology Group ("ECOG") performance status of 0 or 1, meaning that the patients were fully active, able to carry on all pre-disease performance without restriction (ECOG status of 0) or somewhat restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work (ECOG status of 1). The majority of patients were resistant or refractory to prior therapies with an anti-PD-1/PD-L1 agent.

As of November 2016, the results from the first step of the Phase 1/1b clinical trial for CPI-444 were as follows:

Of the 32 patients who reached the first efficacy assessment at two months, 12 had stable disease and 20 had shown disease progression. Fourteen patients did not reach their two-month assessment. Six of the patients with disease progression remained on treatment based on investigator judgment that there was clinical benefit.

Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

Of the 12 patients with stable disease, several showed ongoing tumor regression (1-20% reduction of the volume of tumor lesions) by computerized tomography ("CT") scan, but had

Table of Contents

not yet reached the criteria for partial response (greater than 30% percent reduction in tumor size compared to baseline CT scan per RECIST criteria). Seven of the 12 patients with stable disease received CPI-444 as a single agent.

Of the 10 patients with NSCLC, seven received single agent CPI-444. Five of seven evaluable patients had stable disease at two or more months (three of whom received single agent therapy). Nine patients remained on treatment and one patient discontinued treatment.

Of the five patients with renal cancer, four received single agent CPI-444. Four patients remained on treatment and three of four evaluable patients had stable disease.

Two of four evaluable patients with bladder cancer showed stable disease at first assessment, both of whom received single agent CPI-444.

Of the ten patients with TNBC, one of seven evaluable patients showed stable disease. Eight patients remained on treatment.

One of five evaluable patients with melanoma had stable disease with regression of cutaneous tumor lesions. The patient who exhibited stable disease received single agent CPI-444.

One of two evaluable patients with prostate cancer treated with combination therapy had stable disease and showed a decrease in prostate-specific antigen ("PSA") at 29 weeks. The patient who exhibited stable disease gained weight and required significantly less narcotics for pain management.

As of January 2017, 33 patients had reached their initial three month efficacy assessment. Among such patients, there were no complete responses, two partial responses and 12 patients with stable disease. Of the partial responses, one was observed in a patient with renal cell cancer and one was observed in a patient with malignant melanoma; both of these patients received single agent CPI-444 and had been refractory to prior therapy with [an anti-PD-1 antibody]. Tumor regression has been observed in liver, lung and lymph node sites of disease.

On January 10, 2017, we announced that the protocol-predefined criteria for expansion was reached for the cohort of patients with renal cell carcinoma treated with single-agent CPI-444. Accordingly, the size of that cohort has been increased from 14 to 26 patients. Of the initial four patients with renal cell cancer treated with single agent CPI-444 (in either the dose-selection or disease-specific cohorts), one patient, who was refractory to prior treatment with [an anti-PD-1 antibody], achieved a partial response (as noted above), two patients had stable disease, and one patient showed tumor progression. A fifth patient (in the dose-selection cohort), who was refractory to prior treatment with an anti-PD-1 antibody, received CPI-444 in combination with Tecentriq (atezolizumab), and had stable disease. In the renal cell cancer patient where a partial response was achieved, tumor regression of metastases in the left and right lobe of the patient's liver was seen in the CT scan taken after three months of treatment. A biopsy of the regressing liver lesion performed at three months was compared to a pre-treatment specimen and showed absence of detectable tumor cells and dense infiltration with lymphocytes, consistent with a robust anti-tumor immune response.

We believe these preliminary data indicate that CPI-444 has single agent activity in multiple tumor histologies and in patients refractory to prior therapies with anti-PD-1/PDL-L antibodies.

*CPI-444 Clinical Safety Data*

CPI-444 has been well tolerated to date, with grade three or higher serious adverse events seen only in patients treated with CPI-444 and Tecentriq (atezolizumab) in combination. In particular, one patient in the combination cohort of the first step of the clinical trial experienced Grade 3 autoimmune hemolytic anemia and a different patient in the combination cohort of the second step of the clinical trial experienced Grade 4 aseptic meningoencephalitis thought to be an immune related toxicity. Both

Table of Contents

of these patient's adverse events resolved upon discontinuation of therapy. Other observed toxicities were mild and are commonly seen in patients with advanced cancers, such as nausea (15%), fatigue (21%), constipation (21%) and vomiting (18%).

*CPI-444 Dose Selection and Biomarkers*

As part of our pharmacodynamic analysis, we evaluated occupancy of the A2A receptor by CPI-444, and its ability to block adenosine receptor mediated signaling. Whole blood was collected on day 1 pre-treatment and on day 14 at pre-dose and post-dose at 1.5 hr, 3 hr, 5.5 hr and 8 hr. Blood was activated with an adenosine analog ("NECA") and subsequently tested for intracellular phospho-CREB ("pCREB") signaling in lymphocytes by flow cytometry.

Seven of seven patients receiving CPI-444 100 mg twice daily had sustained, complete blockade of peripheral blood lymphocyte A2A receptors. Further, plasma levels of CPI-444 of 2 mcg/ml resulted in complete saturation of A2A receptors in peripheral blood lymphocytes. These results were in line with our expectation that such plasma concentrations of CPI-444 would lead to greater than 90% A2A receptor occupancy in peripheral tissues, thereby blocking adenosine receptor mediated signaling. In addition, treatment-related increases in cytotoxic T-lymphocytes that were both PD-1-positive and CD8-positive (double positive) provided evidence of immune activation of peripheral blood lymphocytes. Previous research from others has shown that PD-1, CD8 double positive T-cells are associated with anti-tumor immune responses. In 14 patients tested to date, increases in PD-1, CD8 double positive T-cells were observed in seven of seven patients receiving single agent CPI-444 100 mg twice daily, in one of three patients receiving single agent CPI-444 200 mg once daily, and in three of four patients receiving CPI-444 50 mg twice daily combined with Tecentriq (atezolizumab). Based on these and other data, we selected an oral dose of 100 mg twice daily for 28 days for both the single agent and combination arms of the second part (Step Two) of the trial.

***Product Candidate: A monoclonal anti-CD73 antibody for cancer***

*Overview*

In December 2014, we in-licensed from Scripps a mouse anti-human CD73 antibody, CPX-006. We have genetically engineered CPX-006 to be humanized by replacing the immunoglobulin ("Ig") heavy and light chain constant regions, and by replacing the murine variable framework regions with human heavy and light chain Ig frameworks. In addition, we have further engineered CPX-006 to enhance binding to CD73 and to block its catalytic activity, which we expect will inhibit conversion of AMP to adenosine by tumor cells.

*The Role of CD73 in Cancer*

CD73 is an enzyme expressed on lymphocytes and tumor cells that regulates immune responses by producing immunosuppressive adenosine. The catalytic production of adenosine by CD73 may play an important role in tumor immune suppression by increasing the concentration of adenosine in the tumor microenvironment. CD73 is overexpressed in many cancers, and high levels of CD73 have been shown to be associated with poor prognosis. CD73 expression on tumor cells as well as on the host immune cells has been shown to promote tumor immune suppression and metastasis in mice. Other studies in mice have shown that the targeted blockade of CD73 with antibodies can enhance the therapeutic activity of anti-PD-1 and anti-CTLA-4 checkpoint blockade. We believe CD73 and the adenosine-cancer axis may play a role in acquired resistance to anti-PD-1 and anti-PD-L1 therapies.

*Preclinical Proof of Concept*

In preclinical studies using tumor cells that express the CD73 enzyme, the addition of various concentrations of CPX-006 to such cells in culture substantially inhibited the catalytic activity of the

Table of Contents

enzyme to background levels of the assay. This was studied by measuring the conversion of AMP to adenosine. These studies demonstrated that at concentrations of 10 µg/ml, CPX-006 was capable of substantially inhibiting the production of adenosine, which indicates that CPX-006 binds to a critical site in the CD73 enzyme necessary for its function. By blocking the cellular production of adenosine, we believe CPX-006 could lead to enhancement of the anti-tumor immune response by lowering the amount of adenosine in the tumor environment. Other preclinical studies we conducted have shown that CPX-006 binds to a variety of different types of cancer cell lines *in vitro*, including those derived from human breast cancer, lung cancer, lymphoma, leukemias and sarcomas.

*Anti-CD73 Development Plan*

We are conducting IND-enabling studies for the development of CPX-006 in potential clinical trials in patients with advanced cancer and plan to complete these studies in late 2017. In particular, we intend to conduct additional preclinical studies in non-human primates to determine optimum dose and schedule. Subject to the completion of our IND-enabling studies and the submission and acceptance by the FDA of an IND, we plan to initiate a Phase 1 clinical trial for CPX-006 in early 2018.

***Product Candidate: An antagonist of the adenosine A2B receptor***

We have in-licensed several selective and potent adenosine A2B receptor antagonists from Vernalis. In addition, we are synthesizing and have identified other A2B receptor antagonists from our internal research program. Adenosine A2B receptors have recently been found to play an important role in the immune response to tumors. Similar to adenosine A2A receptors, adenosine binds to adenosine A2B receptors, which leads to immunosuppression. However, adenosine A2B receptor expression is found on different immune cells, and its function in tumor induced immune suppression is not yet well understood. We intend to further develop our A2B agents to improve potency, selectivity, pharmacokinetic behavior and immune enhancing properties. We expect to conduct studies similar to those we have conducted for CPI-444 in order to select a development candidate in 2017. Upon selection, we intend to conduct further IND-enabling studies and potential Phase 1 clinical trials.

**ITK Inhibitor**

***ITK and Anti-tumor Immune Response***

ITK is an enzyme expressed predominantly in T-cells where it plays a key role in T-cell signaling. T-cell signaling involving ITK is required in the development of T-cells within the thymus, where ITK regulates the production of various T-cell subsets and functions. The ITK cell signaling pathway is similar to the signaling that occurs in B-cells, which is mediated by a homologous enzyme known as BTK, the target of ibrutinib, an approved treatment for patients with B-cell lymphomas and leukemias. We believe that inhibiting ITK in malignant T-cells may be of therapeutic benefit in patients with T-cell leukemias and lymphomas, analogous to the effects of ibrutinib on B-cell lymphomas and leukemias. In malignant T-cells, ITK was found to be over-expressed specifically in certain T-cell lymphomas, including peripheral T-cell lymphoma ("PTCL"), angioimmunoblastic T-cell lymphoma ("AITL") and in a subgroup of T-lymphoblastic leukemia and lymphoma ("T-ALL").

In ITK genetic knockout mice, which completely lack expression of ITK, T-cells exhibit defects in T helper cell differentiation and cytokine secretion but retain the ability to differentiate into cytotoxic T-cells that secrete IL-2 and IFN $\gamma$ , which are the cells responsible for tumor rejection. We believe that skewing T helper cell differentiation to favor cytotoxic T-cells may be beneficial in treating cancer. T-cells also express a redundant enzyme called resting lymphocyte kinase ("RLK"). RLK can signal in place of ITK in killer T-cells. It is believed that blocking ITK selectively, without affecting RLK, results in production of anti-tumor cytotoxic T-cells necessary for tumor rejection, as occurs in ITK genetic knockout mice.

Table of Contents

***Product Candidate: An ITK kinase inhibitor***

We have identified ITK as a product candidate target because it plays a key role in T-cell receptor signaling and in the differentiation of T-cells responsible for tumor immunity. Small molecule inhibitors of ITK, such as ibrutinib, have been shown to shift the balance in signaling to enhance anti-tumor immune responses in combination with a checkpoint inhibitor. While this observation provides important target validation, ibrutinib is primarily a BTK inhibitor and lacks the necessary potency and selectivity for ITK, which is believed to limit the clinical use of ibrutinib as an ITK inhibitor in this setting. As a result, we believe an inhibitor specifically targeting ITK could enhance anti-tumor immune response.

We are currently developing selective small molecule covalent inhibitors of ITK by targeting the cysteine amino acid residue at position 442 in the ITK protein. Covalent targeting of ITK is expected to provide a selective and prolonged duration of activity without the need for high systemic exposures and thereby improve the therapeutic window. This approach was previously used by our co-founders to generate ibrutinib. We have synthesized several ITK inhibitors that are selective for ITK and do not react appreciably with RLK. It is anticipated that this selectivity will mimic the immune properties seen in ITK knockout mice and skew the immune response toward a more favorable anti-tumor immune response. In 2016, we selected a lead development candidate under this program and are currently conducting IND-enabling studies. Subject to the completion of such studies and the submission and acceptance by the FDA of an IND, we plan to advance the candidate into clinical trials in patients with cancers, including patients with T-cell lymphoma and other cancers, such as solid tumors, in 2018.

**Manufacturing**

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize. We are able to internally produce small quantities of our product candidates required for relatively short preclinical animal studies. We believe that this allows us to accelerate the drug development process by not having to rely on third parties for all of our research and development needs. However, we currently rely, and expect to continue to rely, on a number of contract manufacturers to produce sufficient quantities of our product candidates for use in more lengthy preclinical development and clinical trials and in relation to any future commercialization of our product candidates. Additional contract manufacturers are used to fill, label, package and distribute investigational drug products. This strategy allows us to maintain a more efficient infrastructure, avoid depending on our own manufacturing facility and equipment while simultaneously enabling us to focus our expertise on developing our products. Although we believe we have multiple potential sources for the manufacturing of our product candidates, we currently rely on single manufacturers for different components of CPI-444 and our anti-CD73 antibody.

**Competition**

The pharmaceutical and biotechnology industries are characterized by intense competition and rely heavily on the ability to move quickly, adapt to changing medical and market needs, and to develop and maintain strong intellectual property positions. We believe that the development experience of our scientific and management team, as well as the strength and promise of our product candidates, provide us with a competitive advantage; nevertheless, we face potential competition from myriad sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions.

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

Table of Contents

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, Palobiofarma SL has submitted an IND to begin a Phase 1 dose finding clinical trial with an adenosine A2A antagonist in lung cancer patients. Novartis has announced an exclusive licensing agreement with Palobiofarma. AstraZeneca plc has licensed a preclinical A2A antagonist for use in cancer therapy from Heptares, Inc. Merck KgaA has entered into a pre-clinical collaboration with Domain Therapeutics Inc. to develop programs targeting the adenosine pathway. 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 and MedImmune LLC have recently announced the initiation of a Phase 1 study with an anti-CD73 antibody. Bristol-Myers Squibb also announced the development of an anti-CD73 antibody. 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.

**Intellectual Property**

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from our collaborators or other third parties. We do not yet own any issued patents relating to our product candidates. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States covering our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of immuno-oncology. We also plan to rely on data exclusivity, market exclusivity, and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets; to obtain and maintain licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

We have in-licensed patents and patent applications directed to certain of our product candidates and related uses thereof. We also possess and in-license substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology. As of December 31, 2016, our owned and licensed patent portfolio consisted of eight licensed U.S. issued patents, two licensed U.S. pending patent applications and six owned U.S. provisional patent applications directed to CPI-444 or certain of our proprietary technology, inventions, improvements or other potential product candidates. In addition, our licensed patent portfolio included 16 licensed patents issued in jurisdictions outside of the United States and five licensed patent applications pending in jurisdictions outside of the United States that are foreign counterparts to one or more of the foregoing U.S. patents and patent applications. The patents and patent applications outside of the United States in our portfolio are held primarily in Europe, Canada, Japan, Australia and China.

Table of Contents

With respect to the immuno-oncology product candidates and processes we intend to develop and commercialize in the normal course of business, we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued United States patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. The issued United States patents we license from Vernalis directed to the composition of matter of CPI-444 and its method of use for treating disorders treatable by purine receptor blocking are expected to expire between January 2022 and July 2029, excluding any patent term extension that may be available. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of immuno-oncology has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and enforce the patent rights that we license, and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even the issued patents that we license do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and the issued patents that we in-license and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents that we own or exclusively in-license. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire

Table of Contents

or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

**Licenses and Collaborations**

***Vernalis Licensing Agreement***

In February 2015, we entered into a license agreement with Vernalis, pursuant to which we were 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. The issued U.S. patents that we in-licensed from Vernalis pursuant to this agreement are directed to the composition of matter of CPI-444 and its method of use for treating disorders treatable by purine receptor blocking. These patents are expected to expire in the United States between January 2022 and July 2029, excluding any patent term extension that may be available. Vernalis has the first right to prosecute and maintain the licensed patent rights worldwide, subject to our right with respect to certain of the licensed patents to continue prosecution and maintenance if Vernalis elects not to do so. We also have the right to prosecute and maintain any patent rights that we may own that cover the licensed compounds that do not fall within the licensed patent rights. Pursuant to this agreement, we are required to use commercially reasonable efforts to conduct certain activities to obtain marketing authorizations for licensed products and to conduct certain preclinical and clinical studies for CPI-444. We also must use commercially reasonable efforts to conduct certain preclinical and clinical studies to support the use of CPI-444 as an immunotherapeutic agent for cancer studies, and to meet certain specified development, regulatory and commercial milestones within specified time periods.

Pursuant to this agreement, we made a one-time cash payment to Vernalis in the amount of \$1.0 million upon entering into the agreement. We are 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. On February 13, 2017, we made a milestone payment of \$3 million to Vernalis following the expansion of a cohort of patients with renal cell cancer treated with single-agent CPI-444 in our Phase 1/1b clinical trial. The aggregate potential milestone payments are approximately \$220 million for all indications.

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

***Scripps Licensing Agreement***

In December 2014, we entered into a license agreement with Scripps, pursuant to which we were granted a non-exclusive, world-wide license for all fields of use under Scripps' rights in certain

Table of Contents

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 us the right to grant sublicenses in conjunction with other proprietary rights we hold, or to others collaborating with or performing services for us. Under this license agreement, Scripps has agreed not to grant any additional commercial licenses with respect to such materials, other than march-in rights granted to the U.S. government.

Upon execution of the agreement, we made a one-time cash payment to Scripps of \$10,000 and are also obligated to pay a minimum annual fee to Scripps of \$25,000. 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. We are 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. We are also required to pay royalties on net sales of licensed products sold by us, our affiliates and our sublicensees at a rate in the low-single digits. In addition, should we sublicense the rights licensed under the agreement, we have 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.

Our license agreement with Scripps will terminate upon expiration of our obligation to pay royalties to Scripps under the license agreement. The license agreement is terminable by the consent of the parties, at will by us or upon providing 90 days written notice to Scripps, or by Scripps for certain material breaches by us, or if we undergo a bankruptcy event. In addition, Scripps may terminate our license on a product-by-product basis, or the entire agreement, if we fail 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 we provide to Scripps, that we have not used commercially reasonable efforts as required under the agreement, subject to a specified notice and cure period.

***Genentech Collaboration Agreement***

In October 2015, we 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 PD-L1, in a variety of solid tumors in our Phase 1/1b clinical trial. Pursuant to this agreement, we will be responsible for the conduct and cost of the relevant studies, under the supervision of a joint development committee made up of our representatives and representatives of Genentech. Genentech will supply Tecentriq (atezolizumab). As part of the agreement, we granted Genentech certain rights of first negotiation to participate in future clinical trials that we may conduct evaluating the administration of CPI-444 in combination with an anti-PD-1 or anti-PD-L1 antibody. If we do not reach agreement on the terms of any such participation by Genentech within a specified time period, we retain the right to collaborate with third parties in such activities. We also granted Genentech certain rights of first negotiation should we decide to license development and commercialization rights to CPI-444. Should we not reach agreement on the terms of such a license within a specified time period, we retain the right to enter into a license with another third party.

We 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 (atezolizumab) is discontinued. Further, the agreement will expire after a set period of time following the provision by us of the final clinical study report to Genentech.

Table of Contents

**Regulation**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the NDA process and a new biologic must be approved by the FDA through the BLA process before it may be legally marketed in the United States.

*United States Drug Development Process*

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act ("FDCA"), and in the case of biologics, also under the Public Health Service Act ("PHSA"), and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests, animal studies and formulation studies in accordance with GLP regulations and other applicable regulations;

submission to the FDA of an IND, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice ("GCP") regulations to establish the safety and efficacy of the proposed drug for its intended use;

submission to the FDA of an NDA or BLA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practices (cGMP) requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and

FDA review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety

Table of Contents

concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board ("IRB") at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

**Phase 1:** The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. Sponsors sometimes designate their Phase 1 trials as Phase 1a or Phase 1b. Phase 1b trials are typically aimed at confirming dosing, pharmacokinetics and safety in larger number of patients. Some Phase 1b studies evaluate biomarkers or surrogate markers that may be associated with efficacy in patients with specific types of diseases.

**Phase 2:** This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and appropriate dosage.

**Phase 3:** Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug or biologic, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of

Table of Contents

development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug or biologic.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion.

Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

***United States Review and Approval Process***

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and

Table of Contents

purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured.

After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA or BLA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

The Food and Drug Administration Safety and Innovation Act ("FDASIA") made permanent the Pediatric Research Equity Act ("PREA"), which requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug or biologic product available in the United States for this type of disease or condition will be recovered from sales

Table of Contents

of the product. Orphan designation must be requested before submitting an NDA or BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug or biologic also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug or biologic as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

Although we have not sought or obtained orphan designation for any of our product candidates, we may pursue such designation in the future if we determine that our proposed indications meet the qualifying criteria for such designation.

***Expedited Development and Review Programs***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

Any product submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original BLAs and new molecular entity NDAs under its standard review goals.

In addition, a product may be eligible for accelerated approval. Drug and biologic products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is

Table of Contents

reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

FDASIA established a new category of drugs and biologics referred to as "breakthrough therapies" that may be eligible to receive Breakthrough Therapy Designation. A sponsor may seek FDA designation of a drug or biologic candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will expedite the development and review of such drug. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and the FDA will either grant or deny the request.

***Post-approval requirements***

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug and biologics manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations.

Any drug products manufactured or distributed by us or our partners pursuant to FDA approvals will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug and biologics manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or

Table of Contents

manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

***Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some of the U.S. patents that we may be granted in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the 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, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application, less any time the applicant did not act with due diligence. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for patents that may be issued to us, depending on the expected length of clinical trials and other factors involved in the filing of the relevant marketing application.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application ("ANDA") or a NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is a type of marketing exclusivity available in the United States. Pediatric exclusivity under the Best Pharmaceuticals for Children Act ("BPCA") provides for an additional six months of marketing exclusivity if a sponsor conducts clinical trials in children in response to a written

Table of Contents

request from the FDA. If such written request does not include clinical trials in neonates, the FDA is required to include its rationale for not requesting those clinical trials. The FDA may request studies on approved or unapproved indications in separate written requests. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

***Biosimilars and Exclusivity***

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. To date, only four biosimilars have been licensed under the BPCIA, although numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being addressed by the FDA.

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 their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the twelve-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

***Government Regulation Outside of the United States***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of our product candidates.

Table of Contents

Whether or not we obtain FDA approval for a product candidates, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product candidates in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. In the European Union, for example, a clinical trial authorization ("CTA") must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed.

The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the

Table of Contents

product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, marketing authorization may be granted to a similar product for the same indication at any time if:

the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;

the applicant consents to a second orphan medicinal product application; or

the applicant cannot supply enough orphan medicinal product.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***Other Healthcare Laws***

In addition to FDA restrictions on marketing of pharmaceutical and biological products, other U.S. federal and state healthcare regulatory laws restrict business practices in the pharmaceutical industry, which include, but are not limited to, state and federal anti-kickback, false claims, data privacy and security and physician payment transparency laws. These laws may affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with physicians, customers and third-party payors including discount practices, customer support, education and training programs, physician consulting and other service arrangements. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. These laws are broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. Such laws include:

The federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. 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 False Claims Act;

The federal false claims and civil monetary penalties laws, including the False Claims Act, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government;

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully

Table of Contents

obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;

The Physician Payments Sunshine Act, which imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates; and

Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

***Coverage and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any product candidates for which we receive regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations.

The process for determining whether a third-party payor will provide coverage for a pharmaceutical or biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a pharmaceutical or biological product does not imply that an adequate reimbursement

Table of Contents

rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, coverage and reimbursement for new products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time consuming process.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of pharmaceutical or biological products have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, biological products, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

*Healthcare Reform*

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Affordable Care Act was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced 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; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs, and created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. President Trump has also recently issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the burdensome provisions of the Affordable Care Act to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several

Table of Contents

Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. 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.

In addition, the Budget Control Act of 2011 and the Bipartisan Budget Act of 2015 led to 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. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

**Research and Development Expenses**

Our research and development expenses were \$29.4 million, \$11.4 million and \$0 for the years ended December 31, 2016, 2015, and 2014, respectively. Please see "Management's Discussion and Analysis of Financial Condition and Results of Operations-Research and Development Expenses" for additional detail regarding our research and development activities.

**Environment**

Our third-party manufacturers are subject to inspections by the FDA for compliance with cGMP and other U.S. regulatory requirements, including U.S. federal, state and local regulations regarding environmental protection and hazardous and controlled substance controls, among others. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We have incurred, and may continue to incur, significant expenditures to ensure we are in compliance with these laws and regulations. We would be subject to significant penalties for failure to comply with these laws and regulations.

**Employees**

As of December 31, 2016, we had 44 total employees, all of whom were full-time and 35 of whom were primarily engaged in research and development activities.

**Facilities**

We currently lease a total of approximately 28,633 square feet of office and research and development facilities in Burlingame, California. Our lease expires in 2021. We regularly explore alternatives which would provide us with additional space to accommodate our anticipated growth.

**Legal Proceedings**

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

**Corporate Information**

We were incorporated in Delaware on January 27, 2014 and began operations in November 2014. Our principal executive offices are located at 863 Mitten Road, Suite 102, Burlingame, California 94010, and our telephone number is (650) 900-4520. Our website address is

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

### Table of Contents

<http://corvuspharma.com>. The information on our website is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the SEC.

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 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 Securities Exchange Act of 1934, as amended (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. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company,

We may present only two years of audited consolidated financial statements, plus unaudited condensed consolidated financial statements for any interim period, and related management's discussion and analysis of financial condition and results of operations;

We may avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley);

We may provide less extensive disclosure about our executive compensation arrangements; and

We may not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We have chosen to opt out of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition periods for complying with new or revised accounting standards is irrevocable.

### **Financial Information about Segments**

We view our operations and manage our business as one reportable segment. See Note 2 to our audited consolidated financial statements included in this Annual Report on Form 10-K. Additional information required by this item is incorporated herein by reference to Part II, Item 6, "Selected Financial Data."

### **Available Information**

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at <http://corvuspharma.com>, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov). The information on or accessible through the SEC and our website is not incorporated into, and is not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Table of Contents

**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 our Annual Report on Form 10-K, including our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K 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 \$0.2 million for the period from January 27, 2014 (inception) to December 31, 2014. We had an accumulated deficit of \$67.9 million as of December 31, 2016. 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

Table of Contents

of approximately \$7.0 million, net of underwriting discounts and commission, and offering expenses. As of December 31, 2016, we had capital resources consisting of cash, cash equivalents and marketable securities of \$134.9 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.

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.

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

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.

Table of Contents

**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;

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.

Table of Contents

***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.

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

Before we can initiate clinical trials in the United States for our product candidates, we must submit the results of preclinical testing to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an investigational new drug ("IND") application. In addition, we may rely in part on preclinical, clinical and quality data generated by clinical research organizations ("CROs") and other third parties for regulatory submissions for our product candidates. If these third parties do not make timely regulatory submissions for our product candidates, it will delay our plans for our clinical trials. If those third parties do not make this data available to us, we will likely have to develop all necessary

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

### Table of Contents

preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development. Delays in the completion of our planned clinical trials for CPI-444 or other product candidates could significantly affect our product development costs.

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.

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

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

Table of Contents

trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

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;

Table of Contents

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.

***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 plan 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 will be ten different treatment cohorts in the clinical trial and it may not be possible to fully enroll all the cohorts or any expansions thereof. Furthermore, if patients are unwilling to participate in our studies for any reason, including the existence of competitive clinical trials for similar patient populations or the availability of approved therapies, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll a sufficient number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We believe we have appropriately accounted for the above factors in our trials when determining expected clinical trial timelines, but we cannot assure our stockholders that our assumptions are correct

Table of Contents

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 meningoenzephalitis thought to be an immune related toxicity. These toxicities resolved in both patients upon discontinuing therapy. Other observed toxicities observed during the first step of our Phase 1/1b clinical trial were mild and are commonly seen in patients with advanced cancers, such as nausea, fatigue, constipation and vomiting. 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.

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;

Table of Contents

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 36 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.

**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

Table of Contents

CPI-444 and 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,

Table of Contents

and we may not be able to negotiate alternative arrangements on commercially reasonable terms, or at all.

***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 our anti-CD73 antibody.

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.

Table of Contents

***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.

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 preclinical or early-stage clinical 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

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

### Table of Contents

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.

***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

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

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.

Table of Contents

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.

Table of Contents

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 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, 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;

Table of Contents

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.

***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

Table of Contents

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.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. President Trump has also recently issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the burdensome provisions of the Affordable Care Act to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

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.

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.

***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

Table of Contents

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

Table of Contents

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.

***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. However, we and Genentech each have the right to terminate the 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 our strategic collaboration 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 agreement 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

Table of Contents

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.

***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, Palobiofarma SL has initiated a Phase 1 dose finding clinical trial with an adenosine A2A antagonist in lung cancer patients. Novartis has announced an exclusive licensing

Table of Contents

agreement with Palobiofarma. AstraZeneca plc has recently licensed a preclinical A2A antagonist for use in cancer therapy from Heptares, Inc. 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 and MedImmune LLC have recently announced the initiation of a Phase 1 study with an anti-CD73 antibody. Bristol-Myers Squibb also announced the development of an anti-CD73 antibody. 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.

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

Table of Contents

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.

Table of Contents

**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;

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



Table of Contents

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.

***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;

Table of Contents

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.

***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.

Table of Contents

***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.

***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.***

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

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.

Table of Contents

***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 our anti-CD73 antibody 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

Table of Contents

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.

**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

Table of Contents

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.

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.

Table of Contents

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.

***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

Table of Contents

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.

Table of Contents

*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.

Table of Contents

***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.

***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

Table of Contents

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.

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.



Table of Contents

***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 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

Table of Contents

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.



Table of Contents

**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;

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

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;

Table of Contents

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.***

Following the completion of our IPO, 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.

Table of Contents

***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 requirements of Section 404 of Sarbanes-Oxley, reduced disclosure obligations regarding executive compensation in this 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 \$1.0 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

Table of Contents

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;

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 66<sup>2</sup>/<sub>3</sub>% 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 66<sup>2</sup>/<sub>3</sub>% 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;



Table of Contents

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 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.

Table of Contents

**Item 1B. *Unresolved Staff Comments***

None

**Item 2. *Properties***

We currently lease approximately 28,633 square feet of office and research and development facilities in Burlingame, California. Our lease expires in 2021. We frequently explore alternatives that would provide us with additional space to accommodate our anticipated growth.

**Item 3. *Legal Proceedings***

We are not currently a party to any material litigation or legal proceedings; however, we may from time to time be involved in various legal proceedings incident to the ordinary course of our business.

**Item 4. *Mine Safety Disclosures***

Not applicable.

Table of Contents**Part II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities****Market Information for Common Stock**

Our common stock has been listed on The NASDAQ Global Market under the symbol "CRVS" since March 23, 2016. Prior to that there was no public trading market for our common stock. The following table sets forth for the indicated periods the high and low sales prices per share for our common stock on the NASDAQ stock market.

<b>Year ended December 31, 2016</b>	<b>High</b>	<b>Low</b>
First Quarter (beginning March 23, 2016)	\$ 15.39	\$ 13.75
Second Quarter	\$ 15.90	\$ 9.63
Third Quarter	\$ 17.77	\$ 12.04
Fourth Quarter	\$ 17.33	\$ 13.01

 **Holders of Record**

As of March 10, 2017, there were approximately 24 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Dividend Policy**

We currently intend to retain future earnings, if any, for use in operation of our business and to fund future growth. We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

**Stock Performance Graph**

The following graph shows the total stockholder's return on an investment of \$100 in cash at market close on March 23, 2016 (the first day of trading of our common stock), through December 31, 2016 for (i) our common stock, (ii) the NASDAQ Composite Index and (iii) the NASDAQ Biotechnology Index.

Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends, however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder return. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our

Table of Contents

filings under the Securities Act of 1933, as amended (the "Securities Act"), whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

<b>\$100 investment in stock or index</b>	<b>March 23, 2016</b>	<b>June 30, 2016</b>	<b>September 30, 2016</b>	<b>December 30, 2016</b>
Corvus (CRVS)	\$ 100.00	\$ 100.07	\$ 115.44	\$ 100.35
NASDAQ Composite Index (IXIC)	\$ 100.00	\$ 101.55	\$ 111.39	\$ 112.88
NASDAQ Biotech Index (^NBI)	\$ 100.00	\$ 101.37	\$ 113.93	\$ 104.36

**Securities Authorized for Issuance Under Equity Compensation Plans**

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

**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.

**Recent Sales of Unregistered Equity Securities**

From January 1, 2016 through December 31, 2016, we sold and issued the following unregistered securities:

1. Prior to filing our registration statement on Form S-8 in March 2016, we granted stock options and stock awards to employees, directors and consultants under our 2014 Equity Incentive Plan, as amended, covering an aggregate of 1,025,250 shares of common stock, at a weighted-average average exercise price of \$15.00 per share. Of these, options covering an aggregate of 0 shares were cancelled without being exercised.

Table of Contents

2. Prior to filing our registration statement on Form S-8 in March 2016, we sold an aggregate of 500 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of \$140.00 upon the exercise of stock options.
3. In March 2016, upon the closing of our IPO, all 14,274,741 shares of our then-outstanding convertible preferred stock automatically converted into 14,274,741 shares of common stock.

**Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

### Table of Contents

#### Item 6. Selected Financial Data

You should read the following selected financial data together with the information under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included in Part II, Item 8 of this Annual Report on Form 10-K. The statement of operations data for each of the years ended December 31, 2016, 2015 and 2014 and the balance sheet data as of December 31, 2016 and 2015 are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected balance sheet data as of December 31, 2014 are derived from our consolidated audited financial statements which are not included in this Annual Report on Form 10-K. Our historical results of any prior periods are not necessary indicative of results to be expected in any future period.

<b>Consolidated Statements of Operations and Comprehensive Loss Data:</b>	<b>Year Ended December 31, 2016</b>	<b>Year Ended December 31, 2015</b>	<b>Period from January 27, 2014 (inception) to December 31, 2014</b>
(In thousands, except per share amounts)			
<b>Operating expenses:</b>			
Research and development	\$ 29,356	\$ 11,352	\$ 38
General and administrative	7,620	2,418	123
Total operating expenses	36,976	13,770	161
Loss from operations	(36,976)	(13,770)	(161)
Change in fair value of convertible preferred stock liability		(17,600)	
Interest income and other expense, net	601	35	
Net loss	\$ (36,375)	\$ (31,335)	\$ (161)
Net loss per share, basic and diluted	\$ (2.36)	\$ (83.86)	\$ (0.95)
Shares used to compute net loss per share, basic and diluted	15,422,041	373,643	170,278
<b>Other comprehensive income (loss):</b>			
Unrealized gain (loss) on marketable securities	6	(45)	
Total other comprehensive income (loss)	6	(45)	
Comprehensive loss	\$ (36,369)	\$ (31,380)	\$ (161)

<b>Consolidated Balance Sheet Data:</b>	<b>As of December 31,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
(In thousands)			
Cash, cash equivalents and marketable securities	\$ 134,896	\$ 94,386	\$ 12,517
Working capital	130,089	92,593	9,855
Total assets	140,150	98,459	12,529

Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

Convertible preferred stock			125,780		10,011
Total stockholders' equity (deficit)	\$	132,801	\$	(31,101)	\$ (159)

---

81

Table of Contents

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual report on Form 10-K. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of this Annual Report on Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-K.*

**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. 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 early 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, substantially all of our efforts have been focused on the research, development and advancement of CPI-444, and we have not generated any revenue from product sales and, as a result, we have incurred significant losses. We expect to continue to incur significant research and development and general and administrative expenses related to our operations. Our net loss for the years ended December 31, 2016 and 2015 was \$36.4 million and \$31.3 million, respectively. As of December 31, 2016, we had an accumulated deficit of \$67.9 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.

Table of Contents

Since our inception and through December 31, 2016, we have funded our operations primarily through the sale and issuance of stock. In November 2014, January 2015 and June 2015, we received aggregate net proceeds of \$33.3 million from the sale of our Series A convertible preferred stock. In September 2015, we received net proceeds of \$74.8 million from the sale of our Series B convertible preferred stock. On March 22, 2016, our registration statement on Form S-1 (File No. 333-208850) relating to 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 December 31, 2016, we had capital resources consisting of cash, cash equivalents and marketable securities of approximately \$134.9 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.

**Components of Results of Operations**

*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;

Table of Contents

license fees; and

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

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

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

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

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

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 1, 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.

Table of Contents**Results of Operations**

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

	Year ended December 31, 2016	Year ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014	Change 2015 to 2016	Change 2014 to 2015
Operating expenses:					
Research and development	\$ 29,356	\$ 11,352	\$ 38	\$ 18,004	\$ 11,314
General and administrative	7,620	2,418	123	5,202	2,295
Total operating expenses	36,976	13,770	161	23,206	13,609
Loss from operations	(36,976)	(13,770)	(161)	(23,206)	(13,609)
Change in fair value of convertible preferred stock liability		(17,600)		17,600	(17,600)
Interest income and other expense, net	601	35		566	35
Net loss	\$ (36,375)	\$ (31,335)	\$ (161)	\$ (5,040)	\$ (31,174)

*Research and Development Expenses*

Research and development for the years ended December 31, 2016, 2015 and 2014, consisted of the following costs by program (specific program costs consist solely of external costs):

	Year ended December 31, 2016	Year ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014	Change 2015 to 2016	Change 2014 to 2015
CPI-444	\$ 12,150	\$ 4,092	\$	\$ 8,058	\$ 4,092
CPX-006	2,823	315		2,508	315
ITK Inhibitor	1,655	539		1,116	539
Other Programs	591	181		410	181
Unallocated employee and overhead costs	12,137	6,225	38	5,912	6,187
	\$ 29,356	\$ 11,352	\$ 38	\$ 18,004	\$ 11,314

For the year ended December 31, 2016, the increase in CPI-444 costs of \$8.1 million as compared to the year ended December 31, 2015, primarily consisted of an increase of \$6.5 million in clinical trial costs related to our Phase 1/1b clinical trial that started in 2016, an increase of \$1.1 million in drug manufacturing costs to support our clinical trial, and an increase of \$1.1 million of biology research activities which increases were partially offset by a \$1.0 million license payment to Vernalis in 2015.

For the year ended December 31, 2016, the increase in CPX-006 costs of \$2.5 million as compared to the year ended December 31, 2015, primarily consisted of an increase of \$2.2 million in drug manufacturing costs.

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

For the year ended December 31, 2016, the increase in ITK costs of \$1.1 million as compared to the year ended December 31, 2015, primarily consisted of an increase of \$0.5 million in manufacturing costs and \$0.6 million in outside biology and pre-clinical costs.

For the year ended December 31, 2016, the increase in other program costs of \$0.4 million as compared to the year ended December 31, 2015, primarily consisted of an increase in outside chemical synthesis and testing of research compounds.

Table of Contents

For the year ended December 31, 2016, the increase in unallocated costs of \$5.9 million as compared to the year ended December 31, 2015, primarily consisted of an increase of \$4.5 million in personnel and related costs due to an increase in headcount (including an increase in stock compensation expense of \$1.4 million), an increase of \$0.9 million in facility and related overhead costs and an increase of \$0.4 million in laboratory supplies and materials.

For the year ended December 31, 2015, CPI-444 costs of \$4.1 million primarily consisted of a \$1.0 million license payment to Vernalis, \$1.7 million in drug purchases and \$0.7 million in clinical trial expenses. CPX-006 costs of \$0.3 million primarily consisted of outside development costs. ITK costs of \$0.5 million primarily consisted of the outside synthesis and testing of chemical compounds. Other program costs of \$0.2 million primarily consisted of outside biology and pre-clinical costs.

For the year ended December 31, 2015, unallocated costs of \$6.2 million primarily consisted of personnel related costs of \$3.3 million, lab materials and expensed equipment costs of \$1.5 million and facility and related overhead costs of \$0.8 million.

*General and Administrative Expenses*

For the year ended December 31, 2016, the increase in general and administrative expenses of \$5.2 million as compared to the year ended December 31, 2015, primarily consisted of an increase of \$3.1 million in personnel and related costs associated with an increase in headcount (including an increase in stock compensation expense of \$2.0 million), an increase of \$0.9 million in costs associated with being a public company, an increase of \$0.6 million in patent and related costs and an increase of \$0.2 million in facility related expenses.

General and administrative expense increased \$2.3 million during the year ended December 31, 2015 compared to the period from January 27, 2014 (inception) through December 31, 2014. The increase was primarily attributable to an increase of \$0.9 million in personnel-related expenses due to an increase in headcount and an increase of \$0.9 million in professional services expenses and an increase of \$0.2 million in facility related expenses

*Change in Fair Value of Convertible Preferred Stock Liability*

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

The fair value of the convertible preferred stock liability at December 31, 2014 was \$2.6 million, resulting in no gain or loss on remeasurement for the period from January 27, 2014 (inception) to December 31, 2014. In June 2015, we achieved the relevant milestones, and the investors exercised their right to purchase 4,460,715 shares of Series A convertible preferred stock for net proceeds of \$16.7 million. Immediately prior to the closing of this tranche, we remeasured the convertible preferred stock liability to its then fair value and recorded a loss from remeasurement of \$17.6 million in our statement of operations to bring the convertible preferred stock liability to its then fair value of \$20.2 million, which was reclassified to convertible preferred stock upon the closing of the second tranche.

**Liquidity and Capital Resources**

*Sources of Liquidity*

As of December 31, 2016, we had cash, cash equivalents and short-term investments of \$134.9 million and an accumulated deficit of \$67.9 million, compared to cash and cash equivalents of \$94.4 million and an accumulated deficit of \$31.5 million as of December 31, 2015. We have financed

Table of Contents

our operations primarily through sales of our common stock in conjunction with the IPO and convertible preferred stock.

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 consummated IPO, all outstanding shares of the convertible preferred stock and convertible preferred stock 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. 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.

Table of Contents**Summary of Statement of Cash Flows**

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

	Year ended December 31, 2016	Year ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014	Change 2015 to 2016	Change 2014 to 2015
Net cash provided by (used in)					
Operating activities	\$ (27,857)	\$ (11,328)	\$ (96)	\$ (16,529)	\$ (11,232)
Investing activities	(42,556)	(92,032)		49,476	(92,032)
Financing activities	71,358	94,948	12,613	(23,590)	82,335
Net increase (decrease) in cash and cash equivalents	\$ 945	\$ (8,412)	\$ 12,517	\$ 9,357	\$ (20,929)

*Cash Flows from Operating Activities*

Cash used in operating activities during the year ended December 31, 2016 was \$27.9 million, which primarily consisted of a net loss of \$36.4 million, adjusted by non-cash charges of \$5.1 million and a net change of \$3.4 million in our net operating assets. The non-cash charges were primarily associated with stock-based compensation expense of \$3.8 million. The change in our net operating assets and liabilities was primarily attributable to an increase in accounts payable and accrued and other liabilities of \$3.4 million, which was primarily due to the timing of payments to vendors.

Cash used in operating activities during the year ended December 31, 2015 was \$11.3 million, which consisted of a net loss of \$31.3 million, adjusted by non-cash charges of \$18.2 million and a net change of \$1.8 million in our net operating assets. The non-cash charges are primarily associated with remeasurement of our convertible preferred stock liability to fair value of \$17.6 million. The change in our net operating assets and liabilities was primarily due to an increase of \$1.3 million of prepaid and other current assets, including prepaid drug purchases of \$0.7 million and receivables from our landlord of \$0.3 million in connection with improvements to our facility, offset by increases in short-term liabilities of \$2.5 million and increased long-term liabilities of \$0.6 million, primarily in connection with deferred rent.

During the period from January 27, 2014 (inception) to December 31, 2014, cash used in operating activities was \$0.1 million, which consisted of a net loss of \$0.2 million, offset by an increase in accounts payable and accrued liabilities of \$0.1 million.

*Cash Flows used in Investing Activities*

Cash used in investing activities during the year ended December 31, 2016 was \$42.6 million, which consisted of purchases of marketable securities of \$258.3 million and purchases of property and equipment of \$2.2 million, which were partially offset by proceeds from maturities and sales of marketable securities of \$217.9 million.

Cash used in investing activities during the year ended December 31, 2015 was \$92.0 million, which consisted of \$1.7 million of capital expenditures to purchase property and equipment and \$104.4 million of purchases of short-term marketable securities, offset by \$14.1 million in proceeds from the maturity of marketable securities.

Table of Contents

*Cash Flows from Financing Activities*

Cash provided by financing activities during the year ended December 31, 2016 was \$71.4 million, consisting of the net proceeds from our IPO.

Cash provided by financing activities during the year ended December 31, 2015 was \$94.9 million, primarily consisting of net proceeds from the issuances of convertible preferred stock.

During the period from January 27, 2014 (inception) to December 31, 2014, cash provided by financing activities was \$12.6 million, primarily consisting of net proceeds from the issuance of convertible preferred stock.

**Off-Balance Sheet Arrangements**

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

**Contractual Obligations**

We lease our facilities under a non-cancelable operating lease that expires in 2021. As of December 31, 2016, contractual obligations were as follows (in thousands):

	Total	Payments Due by Period			More than 5 Years
		Less than 1 Year	2 - 3 years	4 - 5 Years	
<b>Contractual obligations:</b>					
Operating lease obligations	\$ 4,745	\$ 1,112	\$ 2,321	\$ 1,312	\$
<b>Total contractual obligations</b>	<b>\$ 4,745</b>	<b>\$ 1,112</b>	<b>\$ 2,321</b>	<b>\$ 1,312</b>	<b>\$</b>

In August 2015 we entered into an agreement for a line of credit of \$0.1 million for the purpose of issuing our landlord a letter of credit of \$0.1 million as a security deposit under our facility lease. We pledged money market funds and marketable securities as collateral for the line of credit. Pursuant to our license agreements with each of Vernalis and Scripps, we have obligations to make future milestone and royalty payments to these parties. However, because these amounts are contingent, they have not been included on our balance sheet.

**Critical Accounting Policies**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of these consolidated financial statements requires our management to make judgments and estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these judgments and estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. Our significant accounting policies are more fully described in Note 2 of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

Table of Contents

***Cash and Cash Equivalents and Marketable Securities***

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

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

***Convertible Preferred Stock Liability***

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

***Research and Development Expenses***

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

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

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

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

license fees; and

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

***Clinical Trial Accruals***

Costs for preclinical studies and clinical trial activities are recognized based on an evaluation of the vendors' progress towards completion of specific tasks, using data such as clinical site activations, patient enrollment or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services are performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the

Table of Contents

progress or state of completion, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time.

***Stock-Based Compensation***

We maintain incentive plans under which incentive stock options and nonqualified stock options may be granted to employees and non-employee service providers.

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

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

***Income Taxes***

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

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

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

***Recent Accounting Pronouncements***

See Note 2 in Item 8 "Financial Statements and Supplementary Data."

Table of Contents

**Segment Information**

We have one primary business activity and operate as one reportable segment.

**JOBS Act Accounting Election**

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

**Item 7A. 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 \$134.9 million as of December 31, 2016, which consisted of bank deposits, money market investments and U.S. Treasury securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% increase in interest rates would not have a material effect on the fair market value of our portfolio.

We do not have any foreign currency or other derivative financial instruments.

Table of Contents

**Item 8. Financial Statements and Supplementary Data**

**CORVUS PHARMACEUTICALS, INC.**

**ANNUAL REPORT ON FORM 10-K**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>94</u>
Consolidated Financial Statements	
<u>Consolidated Balance Sheets</u>	<u>95</u>
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	<u>96</u>
<u>Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)</u>	<u>97</u>
<u>Consolidated Statements of Cash Flows</u>	<u>98</u>
<u>Notes to Consolidated Financial Statements</u>	<u>99</u>

Table of Contents

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of Corvus Pharmaceuticals, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' equity (deficit), and of cash flows present fairly, in all material respects, the financial position of Corvus Pharmaceuticals, Inc. and its subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the period from January 27, 2014 (inception) to December 31, 2014 and each of the two years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 10, 2017

Table of Contents**CORVUS PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share data)

	December 31, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 5,050	\$ 4,105
Marketable securities	129,846	90,281
Prepaid and other current assets	1,137	1,277
Total current assets	136,033	95,663
Property and equipment, net	3,248	1,845
Deferred offering costs		951
Other assets	869	
Total assets	\$ 140,150	\$ 98,459
<b>Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,900	\$ 1,575
Accrued and other liabilities	4,044	1,495
Total current liabilities	5,944	3,070
Other liabilities	1,405	710
Total liabilities	7,349	3,780
Commitments and contingencies ( <i>Note 13</i> )		
Convertible preferred stock: \$0.0001 par value; 0 and 14,274,741 shares authorized at December 31, 2016 and December 31, 2015, respectively; 0 and 14,274,741 issued and outstanding at December 31, 2016 and December 31, 2015, respectively		125,780
Stockholders' equity (deficit) :		
Preferred stock: \$0.0001 par value; 10,000,000 and 0 shares authorized at December 31, 2016 and December 31, 2015, respectively; 0 shares issued and outstanding at December 31, 2016 and December 31, 2015		
Common stock: \$0.0001 par value; 290,000,000 and 20,000,000 shares authorized at December 31, 2016 and December 31, 2015, respectively; 20,922,428 and 1,431,615 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	2	
Additional paid-in capital	200,709	440
Accumulated other comprehensive income (loss)	(39)	(45)
Accumulated deficit	(67,871)	(31,496)
Total stockholders' equity (deficit)	132,801	(31,101)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 140,150	\$ 98,459

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

Table of Contents**CORVUS PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

(in thousands, except share and per share data)

	Year Ended December 31, 2016	Year Ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014
Operating expenses:			
Research and development	\$ 29,356	\$ 11,352	\$ 38
General and administrative	7,620	2,418	123
Total operating expenses	36,976	13,770	161
Loss from operations	(36,976)	(13,770)	(161)
Change in fair value of convertible preferred stock liability		(17,600)	
Interest income and other expense, net	601	35	
Net loss	\$ (36,375)	\$ (31,335)	\$ (161)
Net loss per share, basic and diluted	\$ (2.36)	\$ (83.86)	\$ (0.95)
Shares used to compute net loss per share, basic and diluted	15,422,041	373,643	170,278
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities	6	(45)	
Comprehensive loss	\$ (36,369)	\$ (31,380)	\$ (161)

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

Table of Contents**CORVUS PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY  
(DEFICIT)**

(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Accumulated Additional Other Paid-in Comprehensive Income		Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Capital	Deficit	
<b>Balance as January 27, 2014 (inception)</b>		\$		\$	\$	\$	\$
Issuance of common stock to founders, net of repurchase			1,046,749		2		2
Issuance of Series A convertible preferred stock for cash, net of issuance costs of \$139 and convertible preferred stock liability of \$2,600	3,395,468	10,011					
Net loss						(161)	(161)
<b>Balance at December 31, 2014</b>	3,395,468	10,011	1,046,749		2	(161)	(159)
Issuance of Series A convertible preferred stock, net of issuance costs of \$20	5,525,961	20,730					
Reclassification of convertible preferred stock liability		20,200					
Issuance of Series B convertible preferred stock, net of issuance costs of \$161	5,353,312	74,839					
Issuance of common stock for cash upon early exercise of stock options and lapse of restrictions			384,866		10		10
Stock-based compensation expense					428		428
Unrealized loss on marketable securities						(45)	(45)
Net loss						(31,335)	(31,335)
<b>Balance at December 31, 2015</b>	14,274,741	125,780	1,431,615		440	(45)	(31,496)
Conversion of Series A and B convertible preferred stock into common stock	(14,274,741)	(125,780)	14,274,741	1	125,779		125,780
Issuance of common stock upon initial public offering, net of issuance costs of \$7,414			5,202,618	1	70,624		70,625
Common stock issued on exercise of stock options			13,454		4		4
Vesting of restricted stocks issued upon early exercise of stock options					34		34
Stock-based compensation expense					3,828		3,828
Unrealized gain on marketable securities						6	6
Net loss						(36,375)	(36,375)
<b>Balance at December 31, 2016</b>	\$		20,922,428	\$ 2	\$ 200,709	\$ (39)	\$ (67,871)
						\$	\$ 132,801

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

Table of Contents**CORVUS PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands, except share and per share data)

	Year Ended December 31, 2016	Year Ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014
<b>Cash flows from operating activities</b>			
Net loss	\$ (36,375)	\$ (31,335)	\$ (161)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	594	148	
Amortization/accretion related to marketable securities	648	(41)	
Stock-based compensation	3,828	428	
Change in fair value of convertible preferred stock liability		17,600	
Other		40	
Changes in operating assets and liabilities:			
Prepaid and other current assets	290	(1,265)	(12)
Other assets	(869)		
Accounts payable	518	1,240	57
Accrued and other liabilities	2,814	1,218	17
Other long-term liabilities	695	639	3
Net cash used in operating activities	(27,857)	(11,328)	(96)
<b>Cash flows from investing activities</b>			
Purchases of marketable securities	(258,281)	(104,385)	
Sales of marketable securities	4,199		
Maturities of marketable securities	213,725	14,100	
Purchase of property and equipment	(2,199)	(1,747)	
Net cash used in investing activities	(42,556)	(92,032)	
<b>Cash flows from financing activities</b>			
Proceeds from issuance of common stock, net of issuance costs	71,354		2
Proceeds from issuance of convertible preferred stock, net of issuance costs		95,569	12,611
Payment of offering costs		(729)	
Proceeds from exercise of common stock options	4	108	
Net cash provided by financing activities	71,358	94,948	12,613
Net increase in cash and cash equivalents	945	(8,412)	12,517
Cash and cash equivalents at beginning of the period	4,105	12,517	
Cash and cash equivalents at end of the period	\$ 5,050	\$ 4,105	\$ 12,517
<b>Supplemental disclosures of cash flow information</b>			
Convertible preferred stock issuance costs incurred but not paid	\$	\$	\$ 36
Purchases of property and equipment incurred but not paid	84	286	

Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

Convertible preferred stock liability		2,600
Deferred offering costs incurred but not paid	222	

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

Table of Contents

**CORVUS PHARMACEUTICALS, INC.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

**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.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying 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 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. As of December 31, 2016, the Company had an accumulated deficit of \$67.9 million and cash, cash equivalents and marketable securities of \$134.9 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.

*Use of Estimates*

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

*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 stocks.

Table of Contents

**CORVUS PHARMACEUTICALS, INC.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

*Concentrations of Credit Risk and Other Risks and Uncertainties*

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

Since inception, the Company has recurring net losses and negative cash flows from operations. During the year ended December 31, 2016, the Company incurred a net loss of \$36.4 million and used \$27.9 million of cash in operations. At December 31, 2016, the Company had an accumulated deficit of \$67.9 million and does not expect to experience positive cash flows from operations in the near future. The Company has financed operations to date primarily through private placements of convertible preferred stock and proceeds from its IPO. As of December 31, 2016, the Company had cash, cash equivalents and marketable securities of \$134.9 million.

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

*Segments*

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

*Cash and Cash Equivalents and Marketable Securities*

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

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

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of Significant Accounting Policies (Continued)**

included in interest income. Realized gains and losses are recognized based on the specific identification method.

***Fair Value Measurements***

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

***Deferred Offering Costs***

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

***Property and Equipment, Net***

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

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

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

***Impairment of Long-Lived Assets***

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

***Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation

Table of Contents

**CORVUS PHARMACEUTICALS, INC.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

***Convertible Preferred Stock Liability***

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

***Research and Development Expenses***

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

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

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

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

license fees; and

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

***Clinical Trial Accruals***

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

Table of Contents

**CORVUS PHARMACEUTICALS, INC.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

***Stock-Based Compensation***

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

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

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

***Income Taxes***

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

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

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

Table of Contents

**CORVUS PHARMACEUTICALS, INC.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

***Comprehensive Loss***

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

***Net Loss per Share***

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock subject to repurchase, and stock options are considered to be potentially dilutive securities. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

***Recent Accounting Pronouncements***

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

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern. This standard update provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The new guidance is effective for all annual and interim periods ending after December 15, 2016. The Company has adopted ASU 2014-15 as of the year ended December 31, 2016.

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of Significant Accounting Policies (Continued)**

In November 2015, the FASB issued ASU No 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. This standard amends the accounting for income taxes and requires all deferred tax assets and liabilities to be classified as non-current on the balance sheet. The new standard is effective for reporting periods beginning after December 15, 2016, with early adoption permitted. The standard may be adopted either prospectively or retrospectively. The Company has adopted ASU 2015-17 as of the year ended December 31, 2016. There was no impact on the consolidated financial statements.

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

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

**3. Net Loss per Share**

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

	Year Ended December 31, 2016	Year Ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014
<b>Numerator:</b>			
Net loss - basic and diluted	\$ (36,375)	\$ (31,335)	\$ (161)
<b>Denominator:</b>			
Weighted average common shares outstanding	16,188,980	1,269,315	641,046
Less: weighted average common shares subject to repurchase	(766,939)	(895,672)	(470,768)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	15,422,041	373,643	170,278
Net loss per share, basic and diluted	\$ (2.36)	\$ (83.86)	\$ (0.95)



Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Net Loss per Share (Continued)**

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

	Year Ended December 31, 2016	Year Ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014
Convertible preferred stock		14,274,741	3,395,468
Common stock subject to repurchase	611,698	924,535	768,706
Outstanding options	2,350,582	784,136	32,320
Total shares of common stock equivalents	2,962,280	15,983,412	4,196,494

**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.

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

**December 31, 2016**

	Fair Value Measured Using			Total Balance
	(Level 1)	(Level 2)	(Level 3)	
<b>Assets</b>				
Cash equivalents	\$ 2,999	\$	\$	\$ 2,999
Marketable securities	129,846			129,846
	\$ 132,845	\$	\$	\$ 132,845



Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Fair Value Measurements (Continued)**

December 31, 2015

	Fair Value Measured Using			Total Balance
	(Level 1)	(Level 2)	(Level 3)	
<b>Assets</b>				
Cash equivalents	\$ 3,245	\$	\$	\$ 3,245
Marketable securities	90,281			90,281
	\$ 93,526	\$	\$	\$ 93,526

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

As of December 31, 2016, marketable securities had a maximum remaining maturity of nine months and consisted of U.S. Treasury securities.

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

	Convertible Preferred Stock Call Option Liability
<b>Balance as of December 31, 2014</b>	\$ 2,600
Change in fair value of convertible preferred stock liability through date of Series A second tranche issuance	17,600
Recognition of fair value upon issuance of second tranche Series A convertible preferred stock	(20,200)
<b>Balance as of December 31, 2015</b>	\$

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

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

December 31, 2015

Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
U.S. Treasury securities	\$ 90,326	\$	\$ (45)	\$ 90,281

Table of Contents

**CORVUS PHARMACEUTICALS, INC.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. License and Collaboration Agreements**

***Scripps Licensing Agreement***

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

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

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

***Vernalis Licensing Agreement***

In February 2015, the Company entered into a license agreement with Vernalis (R&D) Limited ("Vernalis"), which was subsequently amended as of November 5, 2015, and, pursuant to which the Company was granted an exclusive, worldwide license under certain patent rights and know-how, including a limited right to grant sublicenses, for all fields of use to develop, manufacture and commercialize products containing certain adenosine receptor antagonists, including CPI-444. Pursuant to this agreement, 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

Table of Contents

**CORVUS PHARMACEUTICALS, INC.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. License and Collaboration Agreements (Continued)**

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. On February 13, 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 Agreement***

In October 2015, the Company entered into a clinical trial collaboration agreement with Genentech to evaluate the safety, tolerability and preliminary efficacy of CPI-444 combined with Genentech's investigational cancer immunotherapy, 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 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

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. License and Collaboration Agreements (Continued)**

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.

**6. Balance Sheet Components (in thousands):**

	December 31, 2016	December 31, 2015
<b><i>Prepaid and Other Current Assets</i></b>		
Interest receivable	\$ 365	\$
Prepaid research and development manufacturing expenses		722
Tenant improvement allowance receivable		347
Other	772	208
	\$ 1,137	\$ 1,277

<b><i>Property and Equipment, net</i></b>		
Laboratory equipment	\$ 1,868	\$ 829
Computer equipment and purchased software	58	18
Leasehold improvements	2,051	74
Construction in progress		1,059
	3,977	1,980
Less: accumulated depreciation and amortization	(729)	(135)
	\$ 3,248	\$ 1,845

<b><i>Accrued and Other Liabilities</i></b>		
Accrued clinical trial related	\$ 1,617	\$ 376
Accrued manufacturing expense	955	12
Personnel related	526	305
Deferred rent	378	223
Accrued legal and accounting	255	314
Accrued construction in progress costs		101
Other accrued expenses	313	164
	\$ 4,044	\$ 1,495

<b><i>Other Liabilities</i></b>		
Deferred rent	\$ 1,370	\$ 642
Shares subject to vesting	35	68

\$ 1,405 \$ 710

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Convertible Preferred Stock**

Under the amended and restated certificate of incorporation in effect as of December 31, 2016, the Company is authorized to issue two classes of stock: preferred stock and common stock.

Immediately prior to the consummation of the IPO on March 29, 2016, all outstanding shares of Series A and B convertible preferred stock were converted into 14,274,741 shares of common stock on a one-for-one basis. As such, no convertible preferred stock shares were outstanding as of December 31, 2016.

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

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

**8. Convertible Preferred Stock Liability**

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

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

A convertible preferred stock liability was recorded for the Company's obligation to sell the second tranche of the Series A convertible preferred stock to the first tranche stockholders at a fixed price of \$3.755 per share upon the satisfaction of certain conditions. A liability was initially recorded in connection with the first tranche of the Series A convertible preferred stock financing at its initial estimated fair value of \$2.6 million, with gains and losses arising from changes in fair value recognized in the statements of operations at each period while such instrument was classified as a liability. A \$17.6 million charge was recorded for the change in estimated fair value of the Series A convertible preferred stock liability for the period from January 1, 2015 to the closing of the second tranche in June 2015. Upon the closing of the second tranche in June 2015, the liability terminated and the balance of the liability of \$20.2 million was reclassified to convertible preferred stock.

The preferred stock liability related to Series A convertible preferred stock was valued at issuance and at December 31, 2014 and March 31, 2015 using a black scholes option-pricing method based on the consideration paid for the Series A convertible preferred stock and the convertible preferred stock

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Convertible Preferred Stock Liability (Continued)**

liability using an assumed term of 1.0 years and 0.75 years, an interest rate of 0.13% and 0.20% and a volatility of 85% and 85%, respectively.

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

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

**9. Common Stock**

As of December 31, 2016, the amended and restated certificate of incorporation authorizes the Company to issue 290 million shares of common stock and 10 million shares of preferred stock.

Each share of common stock is entitled to one vote. Common stockholders are entitled to dividends if and when declared by the board of directors. As of December 31, 2016, no dividends on common stock had been declared.

The Company reserved shares of common stock on an as-converted basis, for issuance as follows:

	December 31, 2016	December 31, 2015	December 31, 2014
Convertible preferred stock		14,274,741	8,921,438
Shares available for future option grants	2,475,600	2,559,499	837,547
Outstanding options	2,350,582	784,136	32,320
Unvested restricted common stock (founders and early exercise of stock options)	611,698	924,535	768,706
Shares reserved for employee stock purchase plan	200,000		
Total	5,637,880	18,542,911	10,560,011

**10. Stock Option Plans**

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

In connection with the consummation of the IPO in March 2016, the 2016 Equity Incentive Award Plan (the "2016 Plan"), became effective. Under the 2016 Plan, incentive stock options, non-statutory

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Stock Option Plans (Continued)**

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

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

	Shares Available for Grant	Options Outstanding Number of Options	Weighted- Average Exercise Price
Balance at December 31, 2015	2,559,499	784,136	\$ 4.09
Additional shares authorized	1,496,001		
Options granted	(1,813,400)	1,813,400	15.09
Options exercised		(13,454)	0.28
Options forfeited	233,500	(233,500)	11.35
Balance at December 31, 2016	2,475,600	2,350,582	\$ 11.88

The following table summarizes information about stock options outstanding at December 31, 2016 and 2015:

Exercise Price	Options Outstanding at December 31, 2016			Options Vested at December 31, 2016		
	Number	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price
\$0.28	419,682	8.46	\$ 0.28	159,732	8.44	\$ 0.28
\$4.65	144,500	8.81	\$ 4.65	42,449	8.81	\$ 4.65
\$6.75	5,000	8.87	\$ 6.75	1,438	8.87	\$ 6.75
\$13.34 - 16.37	1,781,400	9.42	\$ 15.21	193,867	9.18	\$ 15.14
	2,350,582	9.21	\$ 11.88	397,486	8.84	\$ 8.02

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Stock Option Plans (Continued)**

Exercise Price	Number	Options Outstanding at December 31, 2015		Options Vested at December 31, 2015		
		Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price
\$0.28 - \$4.65	629,136	9.54	\$ 1.28	9,637	9.06	\$ 0.28
\$6.75 - \$15.79	155,000	10.00	\$ 15.50			
	784,136	9.63	\$ 4.09	9,637	9.06	\$ 0.28

The weighted average grant date fair value of options granted for the year ended December 31, 2016, 2015 and for the period January 27, 2014 (inception) through December 31, 2014, was \$10.78, \$4.37 and \$0.22, respectively.

Options outstanding and exercisable that had vested or were expected to vest at December 31, 2016 were as follows:

	Number of shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Vested	397,486	\$ 8.02	8.84	\$ 2,660
Expected to vest	1,953,096	\$ 12.66	9.27	\$ 4,869

In the table above, aggregate intrinsic value represents the difference between the exercise price of the options to purchase common stock and the estimated fair value of the Company's common stock of \$14.30.

The aggregate intrinsic value of stock options exercised in the year ended December 31, 2016, 2015 and the period January 27, 2014 (inception) through December 31, 2014, was \$216,000, \$714,000 and \$0, respectively.

The total fair value of options that vested in the year ended December 31, 2016, 2015 and the period January 27, 2014 (inception) through December 31, 2014, was \$3,195,000, \$75,000, and \$100, respectively.

Table of Contents

## CORVUS PHARMACEUTICALS, INC.

## NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**11. Stock-Based Compensation**

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

	Year Ended December 31, 2016	Year Ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014
Research and development	\$ 1,685	\$ 292	\$
General and administrative	2,143	136	
<b>Total</b>	<b>\$ 3,828</b>	<b>\$ 428</b>	<b>\$</b>

**Valuation Assumptions**

The Company estimated the fair value of employee stock options using the Black-Scholes valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options were estimated using the following assumptions for the years ended December 31, 2016, 2015 and 2014:

	Year Ended December 31, 2016	Year Ended December 31, 2015	Period from January 27, 2014 (inception) to December 31, 2014
Risk-free interest rate	1.6%	1.7%	1.7%
Expected volatility	84.6%	83.3%	97.0%
Expected term (in years)	6	6.1	6.1
Expected dividend yield	0%	0%	0%

**Risk-free Interest Rate:** The Company based the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

**Volatility:** The Company used an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry using an average of historical volatilities of the Company's industry peers.

**Expected Term:** The Company uses the simplified method prescribed in the ASC 718, Compensation - Stock Compensation, to calculate the expected term of options granted to employees and directors.

**Expected Dividends:** The Company has not paid and does not anticipate paying any dividends in the near future.

At December 31, 2016 and 2015, the unrecognized compensation expense associated with respect to options granted to employees was \$18.5 million and \$4.7 million, respectively, and is expected to be recognized on a straight-line basis over 3.28 and 3.64 years, respectively.

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Stock-Based Compensation (Continued)**

Stock-based compensation expense related to awards to non-employees is recognized based on the then-current fair value at each measurement date over the associated service period of the award, which is generally the vesting term, on a straight line basis. The Company used the Black-Scholes valuation model to assist it in determining the fair value of stock-based awards. Stock-based compensation expense for non-employees was \$142,500 and \$42,848 for the years ended December 31, 2016 and 2015, respectively.

The following assumptions were used in valuation of non-employee stock options:

	Year Ended December 31, 2016	Year Ended December 31, 2015
Risk-free interest rate	1.90% - 1.94%	1.8% - 2.2%
Expected volatility	92.1% - 92.7%	82% - 84.7%
Expected term (in years)	8.1 - 8.6	9.1 - 10.0
Expected dividend yield	0%	0%

**12. Income Taxes**

During the year ended December 31, 2016, 2015 and 2014, the Company recorded no income tax benefits for the net operating losses (NOLs) incurred due to the uncertainty of realizing a benefit from those items.

As of December 31, 2016, the Company had federal NOL carryforwards of approximately \$20.0 million and state NOL carryforwards of approximately \$45.0 million which are available to reduce future taxable income. The NOLs will begin to expire in 2034, if not utilized.

As of December 31, 2016, the Company also had \$1.3 million of federal and \$1.7 million of state research and development tax credit carryforwards available to reduce future income taxes. The federal research and development tax credits will begin to expire 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 provided by the Internal Revenue Code of 1986, as amended ("Code"), and similar state provisions. An annual limitation may result in the expiration of NOLs and credits before utilization. In March and April 2016, the Company issued a total of 5.2 million shares of common stock associated with its IPO. In addition, during the third quarter of 2015, the Company issued a new series of convertible preferred stock. The common and preferred stock issuances may have created an ownership change under these provisions of the Code and similar state provisions. As of December 31, 2016, NOLs and credits are not expected to expire unused in the carryforward period as a result of these recent issuances of convertible preferred shares.

The components of loss before income tax is as follows (in thousands):

	2016	2015	2014
Domestic	\$ (11,375)	\$ (31,335)	\$ (161)
Foreign	(25,000)		
	\$ (36,375)	\$ (31,335)	\$ (161)

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****12. Income Taxes (Continued)**

A reconciliation of the Company's effective tax rate to the U.S. Federal statutory rate is as follows:

	December 31, 2016	December 31, 2015	December 31, 2014
Federal tax benefit at statutory rate	34%	34%	34%
State tax, net of Federal benefit	8	3	6
Loss due to change in fair value of convertible preferred stock liability		(19)	
Foreign rate differential	(23)		
Change in valuation allowance	(19)	(18)	(40)
Effective income tax rate	0%	0%	0%

The effective tax rate is different from the federal statutory tax rate primarily due to a foreign rate differential and a valuation allowance against deferred tax assets as a result of the Company's history of losses.

The principal components of the Company's net deferred tax assets are as follows (in thousands)

	December 31, 2016	December 31, 2015
Net operating loss carryforwards	\$ 9,339	\$ 4,671
Tax credit carryforwards	1,960	445
Capitalized tax assets	241	528
Accruals	230	108
Stock compensation	954	43
Other	67	71
Total deferred tax assets	12,791	5,866
Valuation allowance	(12,791)	(5,866)
Net deferred tax assets	\$	\$

The Company recorded a valuation allowance against its deferred tax assets at December 31, 2016 and 2015 because Company management believed that it was more likely than not that these assets would not be fully realized. The valuation allowance increased by approximately \$ 7.0 million and \$5.8 million for the years ended December 31, 2016 and 2015, respectively. Changes in the valuation allowance for deferred tax assets relate primarily to the increase in the Company's net operating loss carryforward.

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****12. Income Taxes (Continued)**

As of December 31, 2016, the Company had unrecognized tax benefits ("UTBs") of approximately \$0.6 million. All of the deferred tax assets associated with these UTBs are fully offset by a valuation allowance. The following table summarizes the activity related to UTBs:

	December 31, 2016	December 31, 2015	December 31, 2014
Unrecognized tax benefits beginning of the period	\$ 135	\$	\$
Increase related to the prior year	6		
Increase related to the current year	463	135	
Unrecognized tax benefits, end of the period	\$ 604	\$ 135	\$

The Company follows the provisions of ASC 740, Accounting for Income Taxes, and the accounting guidance related to accounting for uncertainty in income taxes. The Company determines its uncertain tax positions based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be sustained upon examination by the relevant income tax authorities. The Company will recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

**13. 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 years ended December 31, 2016 and 2015 was approximately \$584,000 and \$347,000, respectively. As of December 31, 2016, future minimum lease payments under the facility lease were as follows (in thousands):

	Total	Payments Due by Period			More than 5 Years
		Less than 1 Year	2 - 3 years	4 - 5 Years	
<b>Contractual obligations:</b>					
Operating lease obligations	\$ 4,745	\$ 1,112	\$ 2,321	\$ 1,312	\$
Total contractual obligations	\$ 4,745	\$ 1,112	\$ 2,321	\$ 1,312	\$

Table of Contents**CORVUS PHARMACEUTICALS, INC.****NOTE TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. Commitments and Contingencies (Continued)**

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, they have not been included on the Company's balance sheet.

***Indemnifications***

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. There have been no claims to date and the Company has a directors and officers insurance policy that may enable it to recover a portion of any amounts paid for future claims.

***Legal Proceedings***

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

**14. Quarterly Selected Financial Data (unaudited)**

	Quarter Ended			
	December 31, 2016	September 30, 2016	June 30, 2016	March 31, 2016
Operating Expenses	\$ 11,249	\$ 10,476	\$ 8,825	\$ 6,426
Net loss	(11,086)	(10,297)	(8,645)	(6,347)
Net loss per share, basic and diluted	\$ (0.55)	\$ (0.51)	\$ (0.43)	\$ (5.39)

	Quarter Ended			
	December 31, 2015	September 30, 2015	June 30, 2015	March 31, 2015
Operating Expenses	\$ 6,104	\$ 3,120	\$ 2,332	\$ 2,214
Net loss	(6,039)	(3,151)	(20,232)	(1,913)
Net loss per share, basic and diluted	\$ (13.31)	\$ (7.97)	\$ (58.42)	\$ (6.44)

**15. Subsequent Events**

In February 2017, the Company made a \$3.0 million milestone payment to Vernalis pursuant to the license agreement entered into in February 2015.

Table of Contents

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures.**

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.

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 December 31, 2016, the end of the period covered by this Annual Report on Form 10-K. 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.

**Management's Annual Report on Internal Control Over Financial Reporting**

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

**Attestation Report of the Registered Public Accounting Firm**

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

Not applicable.

Table of Contents

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this Item will be set forth in the Company's proxy statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The code of business conduct and ethics is available on our website at <http://corvuspharma.com>. Amendments to, and waivers from, the code of business conduct and ethics that apply to any director, executive officer or persons performing similar functions will be disclosed at the website address provided above and, to the extent required by applicable regulations, on a Current Report on Form 8-K filed with the SEC.

**Item 11. Executive Compensation**

The information required by this Item will be set forth in the Company's proxy statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this Item will be set forth in the Company's proxy statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions and Director Independence**

The information required by this Item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company's fiscal year end and is incorporated herein by reference.

**Item 14. Principal Accountant Fees and Services**

The information required by this Item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company's fiscal year end and is incorporated herein by reference.

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

(1) Financial Statements:

The consolidated financial statements required by Item 15(a) are filed as part of this Annual Report on Form 10-K under Item 8 "Consolidated Financial Statements and Supplementary Data."

(2) Financial Statement Schedules:

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(3) Exhibits.

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

See the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K.

### **Item 16. Form 10-K Summary**

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary.



Table of Contents**POWER OF ATTORNEY**

Each person whose individual signature appears below hereby authorizes and appoints Richard A. Miller, M.D. and Leiv Lea and each of them, with full power of substitution and resubstitution, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agents full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorney-in-fact and agents or his substitute or substitutes may lawfully do or cause to be done by virtue thereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>/s/ RICHARD A. MILLER, M.D.</u>	President, Chief Executive Officer and Director	
Richard A. Miller, M.D.	(Principal Executive Officer)	March 10, 2017
<u>/s/ LEIV LEA</u>	Chief Financial Officer	
Leiv Lea	(Principal Financial and Accounting Officer)	March 10, 2017
<u>/s/ IAN T. CLARK</u>	Director	
Ian T. Clark		March 10, 2017
<u>/s/ TERRY GOULD</u>	Director	
Elisha P. (Terry) Gould III		March 10, 2017
<u>/s/ STEVE E.KROGNES</u>	Director	
Steve E. Krognes		March 10, 2017
<u>/s/ PETER MOLDT, PH.D,</u>	Director	
Peter Moldt, Ph.D		March 10, 2017
<u>/s/ SCOTT W. MORRISON.</u>	Director	
Scott W. Morrison		March 10, 2017
<u>/s/ PETER THOMPSON, M.D.</u>	Director	
Peter Thompson, M.D.		March 10, 2017

Table of Contents**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
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(a)	Office Lease, dated as of January 27, 2015, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC.	S-1	1/4/2016	10.2(a)	
10.1(b)	First Amendment to Office Lease, dated as of March 19, 2015, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC.	S-1	1/4/2016	10.2(b)	
10.1(c)	Second Amendment to Office Lease, dated as of August 20, 2015, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC	S-1	1/4/2016	10.2(c)	
10.1(d)	Third Amendment to Office Lease, dated as of June 27, 2016, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC.	10-Q	8/4/2016	10.1(d)	
10.1(e)	Fourth Amendment to Office Lease, dated as of August 15, 2016, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC.	10-Q	11/3/2016	10.1(e)	
10.2(a)#	2014 Equity Incentive Plan.	S-1	1/4/2016	10.4(a)	
10.2(b)#	Amendment to the 2014 Equity Incentive Plan, dated November 26, 2014.	S-1	1/4/2016	10.4(b)	
10.2(c)#	Amendment to the 2014 Equity Incentive Plan, dated July 24, 2015.	S-1	1/4/2016	10.4(c)	
10.2(d)#	Amendment to the 2014 Equity Incentive Plan, dated September 14, 2015.	S-1	1/4/2016	10.4(d)	

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

### Table of Contents

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.2(e)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan.	S-1	1/4/2016	10.4(e)	
10.2(f)#	Form of Restricted Stock Purchase Right Grant Notice and Restricted Stock Purchase Agreement under the 2014 Equity Incentive Plan.	S-1	1/4/2016	10.4(f)	
10.3(a)#	2016 Equity Incentive Award Plan.	S-8	3/29/2016	99.2(a)	
10.3(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2016 Equity Incentive Award Plan.	S-1	1/4/2016	10.5(b)	
10.3(c)#	Form of Restricted Stock Award Agreement and Restricted Stock Award Grant Notice under the 2016 Equity Incentive Award Plan.	S-1	1/4/2016	10.5(c)	
10.3(d)#	Form of Restricted Stock Unit Award Agreement and Restricted Stock Unit Award Grant Notice under the 2016 Equity Incentive Award Plan.	S-1	1/4/2016	10.5(d)	
10.4#	Form of Indemnification Agreement for directors and officers.	S-1	1/4/2016	10.6	
10.5#	Amended and Restated Employment Agreement, dated as of December 22, 2015, by and between Corvus Pharmaceuticals, Inc. and Richard A. Miller.	S-1	1/4/2016	10.7	
10.6#	Amended and Restated Employment Agreement, dated as of December 22, 2015, by and between Corvus Pharmaceuticals, Inc. and Leiv Lea.	S-1	1/4/2016	10.8	
10.7(a)#	Offer Letter, dated as of November 27, 2014, by and between Corvus Pharmaceuticals, Inc. and William B. Jones.	S-1	1/4/2016	10.9(a)	
10.7(b)#	Change in Control and Severance Agreement, dated December 23, 2015, by and between Corvus Pharmaceuticals, Inc. and William B. Jones.	S-1	1/4/2016	10.9(b)	
10.8(a)#	Offer Letter, dated as of December 28, 2014, by and between Corvus Pharmaceuticals, Inc. and Erik J. Verner.	S-1	1/4/2016	10.10(a)	

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

### Table of Contents

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.8(b)#	Change in Control and Severance Agreement, dated December 23, 2015, by and between Corvus Pharmaceuticals, Inc. and Erik J. Verner.	S-1	1/4/2016	10.10(b)	
10.9#	Corvus Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan.	S-8	3/29/2016	99.3	
10.10#	Non-Employee Director Compensation Program.	S-1	1/4/2016	10.12	
10.11(a)	License Agreement, dated February 25, 2015, by and between Corvus Pharmaceuticals, Inc. and Vernalis (R&D) Limited.	S-1/A	3/10/2016	10.13(a)	
10.11(b)	Amendment to License Agreement dated November 5, 2015, by and between Corvus Pharmaceuticals, Inc. and Vernalis (R&D) Limited.	S-1	1/4/2016	10.13(b)	
10.12	License Agreement, dated December 20, 2014, by and between Corvus Pharmaceuticals, Inc. and The Scripps Research Institute	S-1	1/4/2016	10.14	
10.13	Collaboration Agreement, dated October 5, 2015, by and between Corvus Pharmaceuticals, Inc. and Genentech, Inc	S-1/A	2/8/2016	10.15	
10.14(a)#	Offer Letter, dated as of April 28, 2016 by and between Corvus Pharmaceuticals, Inc. and Jason Coloma.	10-Q	11/3/2016	10.2	
10.14(b)#	Change in Control and Severance Agreement dated May 11, 2016, by and between Corvus Pharmaceuticals, Inc. and Jason Coloma.	10-Q	11/3/2016	10.3	
21.1	List of Subsidiaries				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included on signature page)				X
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X

## Edgar Filing: Corvus Pharmaceuticals, Inc. - Form 10-K

### Table of Contents

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 USC Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				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

Confidential treatment has been granted for a portion of this exhibit

#

Indicates management contract or compensatory plan.

\*\*

The certification attached as Exhibit 32.1 that accompanies this Annual Report on Form 10-K 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 Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.