BELLICUM PHARMACEUTICALS, INC
Form 424B4
December 18, 2014
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Filed pursuant to Rule 424(b)(4)
Registration Nos. 333-200328 and 333-201031

PROSPECTUS

7,350,000 Shares

Common Stock

Bellicum Pharmaceuticals, Inc. is offering 7,350,000 shares of its common stock. This is our initial public offering and no public market currently exists for our shares. The initial public offering price of our common stock is $19.00 per share.

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol BLCM.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves risks. See Risk Factors beginning on page 12.

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

	PER SHARE	TOTAL
Public Offering Price	$ 19.00	$ 139,650,000
Underwriting Discounts and Commissions (1)	$ 1.33	$ 9,775,500
Proceeds to Bellicum Pharmaceuticals, Inc. (before expenses)	$ 17.67	$ 129,874,500

(1) We have agreed to reimburse the underwriters for certain expenses. See Underwriting.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing up to approximately $50.0 million of shares of our common stock in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these entities may determine to purchase more or fewer shares than they have indicated or not to purchase any shares in this offering.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 1,102,500 shares of common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $11,241,825, and the total proceeds to us, before expenses will be $149,355,675.

The underwriters expect to deliver the shares of common stock to purchasers on or about December 23, 2014.

Joint Book-Running Managers

Jefferies **Citigroup** **Piper Jaffray**

Co-Manager

Trout Capital

Prospectus dated December 17, 2014

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Neither we nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where or to any person to whom the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.

Through and including January 11, 2015 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

We have obtained registered trademarks for Bellicum®, CaspaCIDe® and DeCIDE® based on an intent to use in the United States. We are currently prosecuting registrations for the GoCAR-T and GOCART marks. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially Risk Factors beginning on page 12 and our financial statements and the related notes, before deciding to buy shares of our common stock.

Unless the context requires otherwise, references in this prospectus to we, us and our refer to Bellicum Pharmaceuticals, Inc.

Overview

We are a clinical stage biopharmaceutical company focused on discovering and developing novel cellular immunotherapies for various forms of cancer, including both hematological cancers and solid tumors, as well as orphan inherited blood disorders. Cellular immunotherapy has the potential to transform medicine by harnessing immune cells, principally T cells, to attack and eliminate harmful diseased cells in the body. Unlike traditional small molecule and biologic therapies which are predictably metabolized and eliminated from the body, cellular immunotherapies are unpredictable and uncontrollable. We are using our proprietary Chemical Induction of Dimerization, or CID, technology platform to engineer and then control components of the immune system in real time. By incorporating our CID platform, our product candidates may offer better safety and efficacy outcomes than are seen with current cellular immunotherapies.

Our lead clinical product candidate, BPX-501, is an adjunct T-cell therapy administered after allogeneic hematopoietic stem cell transplantation, or HSCT, and is currently being evaluated in multiple Phase 1/2 clinical trials. Our next clinical product candidate, BPX-201, is a dendritic cell cancer vaccine in a Phase 1 clinical trial for the treatment of metastatic castrate-resistant prostate cancer, or mCRPC, targeting the prostate-specific membrane antigen, or PSMA. Dendritic cells are specialized cells that are key regulators of the immune system that process and present antigens on the cell surface to T cells in order to activate the T cells. We are also focused on developing next-generation chimeric antigen receptor, or CAR, T-cell therapies and T-cell receptor, or TCR, therapies and are planning to advance several product candidates into human clinical trials, including: (1) BPX-401, a CAR-T product candidate for hematological cancers that express the CD19 antigen, (2) BPX-601, a CAR-T product candidate for solid tumors overexpressing the prostate stem cell antigen, or PSCA, and (3) BPX-701, a TCR product candidate for solid tumors expressing the preferentially-expressed antigen in melanoma, or PRAME.

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Our product candidate pipeline is set forth below:

Our Proprietary CID Technology Platform

We are developing next-generation product candidates in some of the most important areas of cellular immunotherapy, including HSCT, CAR T cell therapy, and dendritic cell vaccines. HSCT, also known as bone marrow transplantation, has for decades been curative for many patients with hematological cancers or orphan inherited blood disorders. However, application of HSCT is limited by graft-versus-host-disease, or GvHD, a condition in which the transplanted immune cells recognize the host cells as foreign and attack them. Since the transplanted cells can persist indefinitely, GvHD does not resolve by itself and is a major cause of transplant-related morbidity and mortality. CAR T cell therapy is an innovative approach in which a patient s T cells are genetically modified to carry CARs, which redirect the T cells against cancer cells. While high objective response rates have been reported in some hematological malignancies, serious and sometimes fatal toxicities have arisen in patients treated with CAR T cell therapies. These toxicities include instances in which the CAR T cells have caused high levels of cytokines due to over-activation, referred to as cytokine release syndrome , frequent transient neurologic toxicities and cases in which they have attacked healthy organs instead of the targeted tumor, leading to death. In solid tumors, where the behavior of CAR T cells is particularly unpredictable and results have been inconsistent, researchers are developing enhanced CAR T cell approaches called armored CARs that raise even greater safety concerns. Lastly, despite the integral role that dendritic cells play in the immune system, they are difficult to activate appropriately and as a result their use has delivered only modest therapeutic benefit.

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Our proprietary CID technology is designed to address these challenges. Events inside a cell are controlled by cascades of specialized signaling proteins. CID consists of molecular switches, modified forms of these signaling proteins, which are triggered inside the patient by infusion of a small molecule, rimiducid (AP1903), instead of by natural upstream signals. We include these molecular switches in the appropriate immune cells and deliver the cells to the patient in the manner of conventional cellular immunotherapy. We have developed two such switches: a safety switch designed to initiate programmed cell death, or apoptosis, of the immunotherapy cells, and an activation switch designed to stimulate activation and in some cases proliferation of the immunotherapy cells. Each of our technologies incorporates one of these switches, for enhanced, real-time control of safety and efficacy:

- ***CaspaCIDe*** is our safety switch, incorporated into our HSCT and TCR product candidates, where it is inactive unless the patient experiences a serious side effect. In that event, rimiducid is administered to fully or partially eliminate the cells, with the goal of terminating or attenuating the therapy and resolving the serious side effect.

- ***CIDeCAR*** consists of CAR T cells modified to include our CaspaCIDe safety switch and in which the CAR incorporates the signaling domains of two proteins, MyD88 and CD40. Together, these form our proprietary dual co-stimulatory domain, MC, which is designed to activate T cells in the presence of cancer cells more potently than co-stimulatory molecules CD28 and 4-1BB, which are used in current CAR T cell therapy. Incorporation of CaspaCIDe in a CIDeCAR product candidate is intended to allow the enhanced potency of MC co-stimulation to be deployed safely in patients.

- ***GoCAR-T*** consists of CAR T cells that are modified to include the proprietary dual co-stimulatory domain, MC. In contrast to CIDeCAR, MC is structured in GoCAR-T as a molecular switch, separate from the chimeric antigen receptor, which itself contains no co-stimulatory domains. GoCAR-T is designed to allow control of the activation and proliferation of the CAR T cells through the scheduled administration of a course of rimiducid infusions that may continue until the desired patient outcome is achieved. In the event of emergence of side effects, the level of activation of the GoCAR-T cells is designed to be attenuated by reducing the rimiducid administration schedule.

- ***DeCIDe*** consists of dendritic cells that are modified to include the same MC switch used in GoCAR-T. Upon exposure to rimiducid, dendritic cells containing DeCIDe become highly activated in a process that is less susceptible to being turned off by the immune system s natural inhibitory processes. By administering rimiducid after the patient has been vaccinated and the dendritic cells have had time to migrate to the draining lymph nodes, our DeCIDe product candidates are designed to be activated in a potent and long-lasting manner.

By incorporating our novel switch technologies, we are developing product candidates with the potential to elicit positive clinical outcomes and ultimately change the treatment paradigm in various areas of cellular immunotherapy. Our clinical product candidates, each of which is a combination product of genetically modified immune cells and rimiducid, are described below.

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BPX-501. We are developing a CaspaCIDe product candidate, BPX-501, as an adjunct T-cell therapy administered after allogeneic HSCT, using donor stem cells. In a typical allogeneic HSCT procedure, a patient receives a full complement of immune cells including both donor stem cells and donor T cells. T cells in the transplant often cause serious and potentially fatal side effects, such as GvHD. BPX-501 is designed to decrease the risk of including T cells with the transplant by enabling the elimination of donor T cells through the triggering of the CaspaCIDe safety switch upon emergence of GvHD. In a 10-patient Phase 1 clinical trial with CaspaCIDe modified T cells, conducted by an academic collaborator, four patients developed GvHD after donor T-cell infusion. A single dose of rimiducid rapidly eliminated over 90% of the modified T cells and resolved GvHD in all four patients without recurrence of GvHD. These findings have been replicated in preliminary data from three patients in a second clinical trial of CaspaCIDe-modified T cells. BPX-501 is currently being evaluated in multiple Phase 1/2 clinical trials in the United States and Europe, with the first top-line data expected in the second half of 2015.

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- ***BPX-201.*** We are developing a DeCIDe product candidate, BPX-201, as a dendritic cell cancer vaccine made from the patient s own white blood cells, designed to treat mCRPC. It targets the prostate specific membrane antigen, or PSMA, and uses our DeCIDe activation switch technology. BPX-201 is currently being evaluated in an 18-patient Phase 1 clinical trial for mCRPC. We are evaluating opportunities for BPX-201 in combination with other cancer immunotherapies, such as checkpoint inhibitors, which are antibodies designed to block certain inhibitory receptors on the surface of T cells, and thus potentiate the T cells ability to promote an immune response against cancer. We believe that the increased numbers of PSMA-specific T cells migrating to deposits of prostate cancer in the body that BPX-201 is designed to generate may serve as a substrate for checkpoint inhibitors, resulting in a synergistic, more potent anti-cancer immune response.

In addition, our preclinical product candidates are designed to overcome the current limitations of CAR-T and TCR therapies and include the following:

- ***BPX-401.*** We are developing a CIDeCAR product candidate, BPX-401, as a next-generation CAR T cell therapy for hematological cancers that express the CD19 antigen. CD19 is an antigen expressed in many hematological cancers, including acute lymphocytic leukemia, or ALL, chronic lymphocytic leukemia, or CLL, and certain non-Hodgkin s lymphomas. We believe that, while the activity of CAR T cell therapy has been demonstrated in early-stage clinical trials by third party researchers in these indications, safety issues, such as cytokine release syndrome, a systemic inflammatory response that is produced by elevated levels of cytokines that are associated with T-cell activation and proliferation, remain a major concern, which may be addressed by BPX-401.

- ***BPX-601.*** We are developing a GoCAR-T product candidate, BPX-601, for solid tumors overexpressing PSCA, such as some prostate, pancreatic, bladder, esophageal and gastric cancers. We have obtained positive proof-of-principle data in an animal pancreatic tumor model, which we believe validate BPX-601 s activity and rimiducid s ability to modulate therapeutic effect.

- ***BPX-701.*** We are developing a CaspaCIDe TCR product candidate, BPX-701, in collaboration with Leiden University Medical Center, initially for the treatment of PRAME-expressing melanoma, sarcomas and neuroblastoma. Based on *in vitro* studies, BPX-701 has demonstrated strong affinity to panels of cancer cells presenting PRAME peptides and low affinity to non-tumor cells. In other *in vitro* studies, rimiducid administration has shown the ability to eliminate BPX-701 cells.

We expect to file investigational new drug applications, or INDs, for BPX-701 in the second half of 2015 and for BPX-401 and BPX-601 in 2016. Our IND-enabling activities for each of these preclinical product candidates include manufacturing key components and developing a robust process to produce cell products that comply with regulations of the U.S. Food and Drug Administration, or FDA, and other regulatory agencies. We have developed an efficient and scalable process to manufacture genetically modified T cells of high quality and purity. This process is being implemented by our third-party contract manufacturers to produce BPX-501 for our clinical trials. We expect to leverage our resources, capabilities and expertise for the manufacture of our CAR-T and TCR product candidates.

Strategy

Our goal is to become a leading innovator in the field of cellular immunotherapy by maximizing the inherent potential of this therapeutic modality and developing medicines with a differentiated combination of safety and efficacy. The key elements of our strategy to achieve this goal are as follows:

- ***Pursue a broad development strategy that will maximize the market potential of BPX-501.*** We believe that BPX-501 will enable physicians to maximize the benefits of adjunct T-cell therapy for allogeneic HSCT, such as immune system recovery, prevention or treatment of relapse of underlying disease and improvement in stem cell engraftment, while mitigating safety issues associated with the therapy. Based on these attributes, BPX-501 may serve an integral role in the treatment paradigm for allogeneic HSCT in various diseases and increase the overall patient eligibility for the procedure. In

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order to make BPX-501 accessible to a broad group of patients and maximize the market potential of this product candidate, we are conducting multiple Phase 1/2 clinical trials that include U.S. and European protocols, adult and pediatric patients and different indications and usage of BPX-501. We expect to report data from these clinical trials and discuss registration trial design at an end-of-Phase 2 meeting with the FDA and European regulatory authorities in the first half of 2016.

- ***Focus on developing proprietary CAR-T and TCR product candidates with an improved safety and efficacy profile.*** We intend to build a robust clinical pipeline of our own novel CAR-T and TCR product candidates, which incorporate our proprietary switch technologies, CIDeCAR, GoCAR-T and CaspaCIDe, and focus on indications in which current CAR-T and TCR therapies have significant shortcomings. To this end, we are developing BPX-401 for hematological cancers expressing the CD19 antigen, BPX-601 for solid tumors overexpressing PSCA and BPX-701 for solid tumors expressing PRAME. We believe that these product candidates may address serious safety concerns associated with conventional CAR-T and TCR therapies and achieve higher overall potency and efficacy, thereby widening the therapeutic window compared to other CAR-T and TCR product candidates. We intend to dedicate significant resources in the near term to advance BPX-401, BPX-601 and BPX-701 as well as our other product candidates toward human proof-of-concept data.

- ***Selectively pursue partnerships and collaborations.*** Although our priority is to develop internal product candidates, we may pursue opportunistic partnerships and collaborations for our technologies, including CaspaCIDe and DeCIDe. In indications outside of our interest or expertise, we may structure transactions in which our molecular switches are incorporated into our partners CAR-T or TCR product candidates. We intend to build on our existing strong relationships with premier cancer research centers around the world to identify new opportunities and position our company at the forefront of innovations in the field of cellular immunotherapy.

- ***Continue to innovate around our proprietary CID platform.*** We believe that our CID platform can be further leveraged to discover other novel technologies and therapeutic applications to capitalize on additional market opportunities. We intend to evaluate BPX-201 and other product candidates based on our DeCIDe technology in combination with other cancer immunotherapy such as checkpoint inhibitors. We are also developing new switches and two-switch systems to provide greater control over cellular immunotherapy.

- ***Continue to strengthen our intellectual property profile.*** We believe that having a comprehensive patent estate that provides strong barriers to entry is critical to the success of our business. As such, our management team has made a concerted effort to develop and secure our intellectual property since inception. We currently own or have exclusive licenses to 74 issued patents and 45 pending patent applications. These patents and patent applications include composition and/or method of use claims in the United States, Europe and other jurisdictions. We intend to continue to strengthen our patent estate by developing and filing for patents on various aspects of our technologies and product candidates as well as through in-licensing activities with research institutions and other biopharmaceutical companies.

- ***Become a fully integrated cellular immunotherapy company.*** Developing product candidates for cellular immunotherapy is complex and requires significant in-house capabilities in various areas of drug

development. Over the years we have built a solid foundation from which to fulfill the highly demanding clinical and regulatory requirements of genetically modified cellular immunotherapy, with expertise in research and discovery, clinical trial management, data analysis, manufacturing, quality assurance and regulatory affairs. We intend to use a portion of the net proceeds from this offering to continue hiring staff with necessary expertise and investing in infrastructure to support the growth of our clinical development activities and to enable us to become the leading cellular immunotherapy company.

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Recent Developments

To enable further development of our proprietary technology and product candidates, we completed a private placement of $55 million of Series C convertible preferred stock in August 2014. Investors in the transaction included, among others, Baker Brothers, RA Capital Management, LLC, Perceptive Advisors, LLC, Jennison Associates LLC (on behalf of certain clients), Sabby Capital, LLC, Ridgeback Capital Management, venBio Select, Redmile Group, LLC and AJU IB Investment, as well as our then current investors, including AVG Ventures and Remeditex Ventures.

Certain aspects of our platform technology are licensed from ARIAD Pharmaceuticals, Inc., or ARIAD. In October 2014, we amended our license agreement with ARIAD, pursuant to which we agreed to pay ARIAD $50 million in three tranched payments, including an initial payment of $15 million in connection with the execution of the amendment. In exchange, ARIAD gave us a fully paid-up license to its cell-signaling technology and agreed to return of all of the 677,463 shares of our common stock currently held by ARIAD at the time of the second tranche payment. The scope of the license and the field of use were also expanded as part of the amendment. The amended agreement gives us a worldwide exclusive license to ARIAD s cell-signaling technology for broad use in human cell therapies for all diseases on a royalty- and milestone-free basis. See Business Our License Agreements.

Risks Associated With Our Business

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable.
- We have concentrated our therapeutic product research and development efforts on our CID platform, a novel therapeutic approach, and our future success depends on the successful development of this therapeutic approach.
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.
- We may not be successful in our efforts to use and expand our CID platform to build a pipeline of product candidates and develop marketable products.
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The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates. Further, the FDA may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

- Due to the novel nature of our technology and the potential for our product candidates to offer therapeutic benefit in a single administration, we face uncertainty related to pricing and reimbursement for these product candidates. Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

- We have identified a material weakness in our internal control over financial reporting. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

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Corporate Information

We were incorporated in Delaware in July 2004. Our principal executive offices are located at 2130 W. Holcombe Blvd., Ste. 800, Houston, Texas and our telephone number is (832) 384-1100. Our corporate website address is www.bellicum.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenue exceed $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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THE OFFERING

Common stock offered by us	7,350,000 shares
Common stock to be outstanding after this offering	25,849,571 shares
Option to purchase additional shares	We have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,102,500 additional shares of common stock.
Use of proceeds	We estimate that we will receive net proceeds of approximately $127.1 million (or approximately $146.5 million if the underwriters option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for the following purposes: (1) $21.0 million to fund our ongoing and planned Phase 1/2 clinical trials of BPX-501, (2) $30.0 million to fund pre-clinical and Phase 1/2 clinical trial of BPX-401, BPX-601 and BPX-701 as well as preclinical development of our other CART and TCR programs, (3) $4.0 million to fund our ongoing Phase 1/2 clinical trial and our planned Phase 1/2 clinical trial of BPX-201 in combination with checkpoint inhibitors, (4) $11.0 million to fund the construction of tenant improvements and the purchase of capital equipment at our Houston facility, and (5) the remainder to fund other working capital purposes, including general operating expenses. See Use of Proceeds.
Risk factors	You should read the Risk Factors section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.
NASDAQ Global Market symbol	BLCM

The number of shares of our common stock to be outstanding after this offering is based on 2,124,386 shares of common stock outstanding as of September 30, 2014, and assumes:

- the issuance by us of 7,350,000 shares of our common stock in this offering;

- the conversion of all of our convertible preferred stock outstanding into an aggregate of 12,224,819 shares of common stock upon the closing of this offering;

- the net exercise of outstanding warrants to purchase common stock for an aggregate of 114,468 shares of common stock;

- that all of the holders of Series B convertible preferred stock will elect to have their accrued dividends converted into common stock at the time of conversion of their shares of Series B convertible preferred stock into shares of common stock in connection with this offering, which will result in the issuance by us of 177,349 shares of common stock;

- the issuance by us of 6,559,598 shares of Series C convertible preferred stock issuable upon the exercise of warrants issued by us in August 2014, pursuant to that certain Series C Preferred Stock and Warrant Purchase Agreement, or the Series C Purchase Agreement and the conversion of these shares of Series C convertible preferred stock into an aggregate of 3,858,549 shares of common stock;

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and excludes:

- 1,602,339 shares of common stock issuable upon the exercise of outstanding stock options as of September 30, 2014, at a weighted-average exercise price of $2.33 per share;

- 2,956,909 shares of our common stock reserved for future issuance under our 2014 equity incentive plan, or the 2014 Plan, which will become effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, which number includes the 258,823 shares subject to stock options and a stock award that will be granted upon the effective date of the 2014 Plan and includes the 1,382,481 shares of common stock reserved for issuance under our 2011 stock option plan, as amended, or the 2011 Plan as of September 30, 2014, reduced by the 1,031,454 shares of common stock issuable upon the exercise of the stock options granted under the 2011 Plan subsequent to September 30, 2014, which aggregate of 351,027 shares will be added to the shares reserved under the 2014 Plan when the 2014 Plan becomes effective;

- 550,000 shares of common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, or the ESPP, which will become effective upon the execution and delivery of the underwriting agreement for this offering; and

- 355,392 shares of common stock issuable upon the exercise of outstanding warrants as of September 30, 2014, at an exercise price of $0.0017 per share.

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to:

- a 1-for-1.7 reverse stock split of our common stock effected on December 5, 2014;

- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the closing of this offering; and

- no exercise by the underwriters of their option to purchase up to an additional 1,102,500 shares of our common stock.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing up to approximately $50.0 million of shares of our common stock in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these entities may determine to purchase more or fewer shares than they have indicated or not to purchase any shares in this offering.

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SUMMARY FINANCIAL DATA

The following summary financial data should be read together with our financial statements and related notes, Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. The summary financial data in this section are not intended to replace our financial statements and the related notes. We derived the summary statement of operations data for the years ended December 31, 2012 and 2013 from our audited financial statements and related notes appearing elsewhere in this prospectus. We derived the summary statement of operations data for the nine months ended September 30, 2013 and 2014 and the summary balance sheet data as of September 30, 2014, from our unaudited financial statements and related notes appearing elsewhere in this prospectus. The unaudited financial data, in management s opinion, have been prepared on the same basis as the audited financial statements and related notes included elsewhere in this prospectus, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the information for the periods presented. Our historical results are not necessarily indicative of the results that may be expected in the future, and results from our interim period may not necessarily be indicative of the results of the entire year.

(in thousands, except share and per share data)	YEAR ENDED DECEMBER 31,		NINE MONTHS ENDED SEPTEMBER 30,	
	2012	2013	2013 (unaudited)	2014 (unaudited)
Statement of Operations Data:				
Grant revenue	$ 1,470	$ 1,941	$ 1,122	$ 1,766
Operating expenses:				
Research and development	5,796	7,050	4,564	7,078
General and administrative	1,943	2,813	1,997	3,135
Total operating expenses	7,739	9,863	6,561	10,213
Loss from operations	(6,269)	(7,922)	(5,439)	(8,447)
Other income (expense):				
Interest income	7	4	2	15
Interest expense	(1)	(51)	(38)	(38)
Change in value of warrant liability				(1,197)
Total other income (expense)	6	(47)	(36)	(1,220)
Net loss	$ (6,263)	$ (7,969)	$ (5,475)	$ (9,667)
Preferred stock dividends	(757)	(1,094)	(695)	(1,432)

Net loss available to common stockholders	$ (7,020)	$ (9,063)	$ (6,170)	$ (11,099)
Net loss per share, basic and diluted[1]	$ (4.26)	$ (5.25)	$ (3.58)	$ (5.45)
Weighted-average shares outstanding, basic and diluted	1,648,198	1,725,992	1,725,992	2,036,025
Pro forma net loss (unaudited)		$ (7,969)		$ (9,667)
Pro forma net loss per share, basic and diluted (unaudited)[2]		$ (1.32)		$ (0.98)
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)[2]		6,051,619		9,827,767

(1) See Note 2 to our financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per common share and the number of shares used in the computation of the per share amounts.

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(2) The calculations for the unaudited pro forma net loss per common share, basic and diluted, assume (1) the conversion of all our outstanding shares of convertible preferred stock as of September 30, 2014, into an aggregate of 12,224,819 shares of our common stock, (2) the net exercise of outstanding warrants to purchase common stock (which will expire upon the closing of this offering if not exercised) into 114,468 shares of our common stock, (3) the issuance of 6,559,598 shares of Series C convertible preferred stock upon the exercise of warrants, and the conversion of such shares into 3,858,549 shares of common stock in connection with the closing of this offering. The calculations exclude the impact of the issuance by us of an aggregate of 177,349 shares of our common stock as payment of the accrued dividend payable to the holders of Series B convertible preferred stock in connection with this offering.

	AS OF SEPTEMBER 30, 2014		
(in thousands)	**ACTUAL (unaudited)**	**PRO FORMA (1)(2)**	**PRO FORMA AS ADJUSTED (3)**
Balance Sheet Data:			
Cash and cash equivalents	$ 61,932	$ 86,287	$ 213,469
Working capital	49,849	65,269	192,369
Total assets	66,331	90,686	217,786
Convertible preferred stock	90,753		
Accumulated deficit	(38,646)	(83,559)	(83,559)
Total stockholders (deficit) equity	(38,794)	51,913	179,013

(1) Pro forma amounts reflect (1) the conversion of all our outstanding shares of our convertible preferred stock as of September 30, 2014 into an aggregate of 12,224,819 shares of our common stock in connection with the closing of this offering, and (2) the net exercise of outstanding warrants to purchase shares of our common stock (which will expire upon the closing of this offering if not exercised) into 114,468 shares of our common stock, (3) the issuance by us of 177,349 shares of common stock, as payment of the accrued dividend on the outstanding shares of Series B convertible preferred stock payable to the holders of Series B convertible preferred stock in connection with this offering, (4) the issuance of 6,559,598 shares of Series C convertible preferred stock upon the exercise of warrants, and the conversion of such shares into 3,858,549 shares of common stock in connection with the closing of this offering.

(2) Pro forma amounts reflect the October 2014 amendment to our license agreement with Ariad, pursuant to which we agreed to pay $50.0 million in exchange for expanded use of the license and the termination of all obligations to make milestone and royalty payments to Ariad in the future. We have reflected (1) a decrease in cash for the initial payment of $15.0 million in October 2014, (2) a liability of $35.0 million to recognize the promissory note for the remaining balance, (3) a $5.1 million reduction in equity to reflect the estimated fair value, as of October 2014, of the common stock to be returned to us in connection with the second payment to Ariad and (4) a $44.9 million charge to research and development expense. The final accounting treatment is still under review and may

ultimately result in different accounting treatment, including discounting the liability or less research and development expense.

(3) Pro forma as adjusted amounts reflect the pro forma conversion adjustments described in footnotes (1) and (2) above, as well as the sale of 7,350,000 shares of our common stock in this offering at the initial public offering price of $19.00 per share after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Business and Industry

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical stage biopharmaceutical company with a limited operating history. We are not profitable and have incurred losses in each period since our inception in 2004. To date, we have financed our operations primarily through private placements of convertible debt and preferred stock. For the years ended December 31, 2012 and 2013, we reported a net loss of $6.3 million and $8.0 million, respectively. For the nine months ended September 30, 2013 and 2014, we reported a net loss of $5.5 million and $9.7 million, respectively. As of September 30, 2014, we had an accumulated deficit of $38.6 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders equity and working capital.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable.

We have devoted substantially all of our financial resources and efforts to developing our proprietary CID technology platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We are still in the early stages of developing our product candidates, and we have not completed development of any products. Our ability to generate revenue and achieve profitability depends in large part on our ability, alone or with partners, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of products for the foreseeable future. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing clinical trials through all phases of clinical development of our current product candidates, as well as the product candidates that are being developed by our partners and licensees;

- seeking and obtaining marketing approvals for product candidates that successfully complete clinical trials;
- launching and commercializing product candidates for which we obtain marketing approval, with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- identifying and developing new product candidates;
- progressing our pre-clinical programs into human clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- developing new molecular switches based on our proprietary CID technology platform;
- maintaining, protecting, expanding and enforcing our intellectual property; and
- attracting, hiring and retaining qualified personnel.

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Because of the numerous risks and uncertainties associated with biologic product development, we are unable to predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. In addition, our expenses could increase beyond expectations if we are required by the FDA, or foreign regulatory agencies, to perform studies and clinical trials in addition to those that we currently anticipate, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates. If one or more of the product candidates that we independently develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing such product candidates. Even if we or our partners are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations, which may not be available to us on favorable terms, if at all. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have concentrated our therapeutic product research and development efforts on our CID platform, and our future success depends on the successful development of this therapeutic approach.

Our proprietary CID technology platform is novel and there are no approved products or product candidates in late-stage clinical trials based on this technology. Additionally, the safety and efficacy profile of rimiducid has not been subject to large scale clinical testing. If rimiducid is found to have a poor safety profile in clinical trials, or if our technology is not effective, we may be required to redesign all of our product candidates, which would require significant time and expense. In addition, our CID platform technology may not be applicable or effective in the development of additional cellular immunotherapies beyond our current programs which would adversely affect our business and prospects.

CAR T cell therapies are novel and present significant challenges.

CAR-T and TCR product candidates represent a relatively new field of cellular immunotherapy and there are no FDA-approved products in this area. Advancing this novel and personalized therapy creates significant challenges for us, including:

- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of T-cell therapies for cancer;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a consistent and reliable process, while limiting contamination risks, for engineering and manufacturing T cells *ex vivo* and infusing the engineered T cells into the patient;
- educating medical personnel regarding the potential safety benefits, as well as the challenges, of incorporating our product candidates into their treatment regimens; and

- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

Our inability to successfully develop CAR-T and TCR cell therapies or develop processes related to the manufacture, sales and marketing of these therapies would adversely affect our business, results of operations and prospects. We believe that we have appropriately accounted for the above factors while pursuing the development and commercialization of our product candidates, but we cannot entirely eliminate the risks associated with novel technology.

Failure to successfully develop and obtain approval of our lead product candidate BPX-501 or our other clinical product candidates could adversely affect our future success.

Our business and future success depends, in part, on our ability to obtain regulatory approval of and then successfully commercialize our lead product candidate, BPX-501 and our other clinical product candidates. BPX-501 is in the early stages of development. All of our product candidates, including BPX-501, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because BPX-501 is our most advanced product candidate,

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and because many of our other product candidates are based on similar technology, if BPX-501 encounters safety or efficacy problems, developmental delays or regulatory issues or other problems, our development plans and business for our other product candidates would be significantly harmed. In addition, our product candidates that incorporate the CID safety switch combine genetically modified T cells that are used to enhance the patients immune system and a small molecule that leads to the death of these modified T cells if they cause safety issues.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. 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. We expect there may be greater variability in results for cellular immunotherapy products processed and administered on a patient-by-patient basis, like all of our CID technology-based development and product candidates, than for off-the-shelf products, like many drugs. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile 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 unacceptable safety issues, notwithstanding promising results in earlier clinical trials. Most product candidates that commence clinical trials are never approved as products.

We have not completed any clinical studies of our current product candidates. Success in early clinical studies may not be indicative of results obtained in later studies.

Many of our current product candidates have not initiated evaluation in human clinical studies, and we may experience unexpected results in the future. Differences in cell processing, time of administration and patient conditioning, among other factors, may result in our experiencing different results in our clinical trials from those reported in trials by our collaborators, and may mean that we experience different results in our clinical trials. In addition, data from preclinical studies and investigator-led Phase 1 or Phase 1/2 clinical trials of BPX-501 therapy should not be relied upon as evidence that later or later-scale clinical trials will succeed. We have designed our planned Phase 1/2 single-arm multicenter clinical trial of BPX-501 primarily to assess safety and efficacy in a small number of adult patients with malignant disease. In addition, we are initiating additional Phase 1 and Phase 1/2 clinical trials of BPX-501 and there are a number of investigator-led clinical trials of BPX-501 ongoing and planned.

Similarly, results from preclinical studies, such as *in vitro* and *in vivo* studies, of BPX-401, BPX-601, BPX-701 and our other preclinical programs may not be indicative of the results of clinical trials of these product candidates. Furthermore, we may not be able to commence human clinical trials on any of our preclinical product candidates on the time frames we expect. Our failure to meet these expected targets would likely have an adverse effect on our stock price.

Even if the clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

We may not be successful in our efforts to use and expand our CID platform to build a pipeline of product candidates and develop marketable products.

We believe that our CID platform, which serves as the foundation of our CaspaCIDe, CIDeCAR, GoCAR-T and DeCIDe technologies, can be further leveraged to discover other novel technologies, therapeutic applications and market opportunities. For example, we are currently conducting research in applying our platform TCR therapies for solid tumors, where immune toxicities associated with treatment are even more severe than CAR-T therapies. We are also developing new molecular switches and two-switch systems to provide greater control over cellular immunotherapy.

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We are at a very early stage of development and our platform has not yet, and may never lead to, approved or marketable products. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including for reasons related to their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our technological approach, we may not be able to obtain product or partnership revenues in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

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

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct our preclinical and clinical trials under agreements with us. Negotiations of budgets and contracts with study sites may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices, or cGMPs, regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

Additionally, we are conducting multiple clinical trials in Europe and may plan additional testing of our technology and product candidates in other foreign jurisdictions. We currently have limited staffing and capabilities in foreign countries, and may not be able to effectively resolve potential disputes with our independent investigators and collaborators.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial s primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion.

In particular, some of our clinical trials will look to enroll patients with characteristics which are found in a very small population, such as patients with CD19-expressing cancers, such as ALL, CLL and non-Hodgkin s lymphomas, and patients with orphan inherited blood disorders. Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than enroll patients in any of our future clinical trials. Patients may also be unwilling to participate in our clinical trials because of negative publicity from adverse events in the biotechnology or gene therapy industries.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Any adverse developments that occur during any clinical trials conducted by academic investigators, our collaborators or other entities conducting clinical trials under independent INDs may affect our ability to obtain regulatory approval or commercialize our product candidates.

BPX-501 and certain of our other CaspaCIDe product candidates are being used by third parties in clinical trials for which we are collaborating or in clinical trials which are completely independent of our development program. We have little to no control over the conduct of such clinical trials. If serious adverse events occur during these or any other clinical trials using our product candidates, the FDA and other regulatory authorities may delay, limit or deny approval of our product candidate or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for BPX-501 or any other CaspaCIDe product candidate and a new and serious safety issue is identified in connection with clinical trials conducted by third parties, the FDA and other regulatory authorities may withdraw their approval of the product or otherwise restrict our ability to market and sell our product. In addition, treating physicians may be less willing to administer our product due to concerns over such adverse events, which would limit our ability to commercialize our product.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of clinical trials by us, the FDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product

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candidates will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

In other clinical trials involving CAR T cells, the most prominent acute toxicities included symptoms thought to be associated with the release of cytokines, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, such as confusion, cranial nerve dysfunction and speech impairment. Adverse events by worst grade and attributed to CAR T cells were severe and life threatening in some patients. The life threatening events were related to kidney dysfunction and toxicities of the central nervous system. Severe and life threatening toxicities occurred mostly in the first two weeks after cell infusion and generally resolved within three weeks. In the past, several patients have also died in clinical trials by others involving CAR T cells.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technology and engineered on a patient-by-patient basis, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from therapies such as our current and future product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products. In addition, our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. The costs of our clinical trials may increase if the FDA does not agree with our clinical development plans or requires us to conduct additional clinical trials to demonstrate the safety and efficacy of our product candidates.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Specifically, genetically engineering T cells faces significant competition in both the CAR and TCR technology space from multiple companies, including Adaptimmune Limited, bluebird bio, Inc., Celgene Corporation, Cellectis SA, GlaxoSmithKline plc, Intrexon Corporation, Juno Therapeutics, Inc., Kite Pharma, Inc., Novartis AG and Pfizer Inc.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see Business Competition.

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We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer, our Chief Operating Officer, our Chief Medical Officer and Chief Technology Officer, and our Chief Scientific Officer. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled scientific and medical personnel.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2014, we had 30 employees, all of whom were full-time. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees, including a Chief Financial Officer;

- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and

- improving our operational, financial and management controls, reporting systems and procedures.

There are a small number of individuals with experience in cell therapy and the competition for such individuals is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management, and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely

basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

In addition to expanding our organization, we expect to increase the size of our facility and build out our development and manufacturing capabilities, which will require significant capital expenditures. If these capital

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expenditures are higher than expected, it may adversely affect our financial condition and capital resources. In addition, if the increase in the size of our facility is delayed, it may limit our ability to rapidly expand the size of our organization in order to meet our corporate goals.

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates, including our planned clinical development and preclinical studies of our product candidates and other programs. If approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of September 30, 2014, we had cash and cash equivalents of approximately $61.9 million. We estimate that our net proceeds from this offering will be approximately $127.1 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to fund (1) our ongoing and planned Phase 1/2 clinical trials of BPX-501; (2) pre-clinical studies for BPX-401, BPX-601 and BPX-701 and fund the Phase 1/2 clinical trial of BPX-401, partially fund the planned Phase 1/2 clinical trial of BPX-601 and fund the Phase 1/2 clinical trial of BPX-701 as well as preclinical development of our other CAR T and TCR programs; (3) our planned Phase 1/2 clinical trials of BPX-201 in combination with checkpoint inhibitors; (4) the construction of tenant improvements and the purchase of capital equipment at our Houston facility, to accommodate our anticipated personnel needs for the next three years and to support our planned in-house new product discovery and development, as well as process development and manufacturing for U.S. clinical trials of planned product candidates or certain critical components thereof; and (5) other working capital purposes, including general operating expenses. We believe that such proceeds together with our existing cash and cash equivalents will be sufficient to fund our operations through at least 2016. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

Additional funding may not be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness

would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

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We need to oversee manufacturing of a complex supply chain of cellular therapy product candidates, viral vectors and small molecule drugs.

Because of the complex nature of our products, we need to oversee manufacture of multiple components that require a diverse knowledge base and appropriate manufacturing personnel. The supply chain for these components is separate and distinct, and no single manufacturer can supply more than one component of each of our products. Additionally, it is likely that the cell therapy products will need to be made within an appropriate geographic location for the area in which the products will be utilized, so one cell therapy manufacturing facility may not be able to supply diverse geographic areas. Any lack of capabilities to store, freeze, thaw and infuse our cell therapies would adversely affect our business and prospects.

We expect to rely on third parties to manufacture a substantial portion of our clinical cell therapy product candidates, viral vectors and small molecule supplies in the United States and Europe.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility, and must currently rely on outside vendors to manufacture supplies and process our product candidates, which is and will need to be done on a patient-by-patient basis. We have not yet caused our product candidates to be manufactured or processed on a commercial scale. We may not be able to scale patient-by-patient manufacturing and processing to satisfy clinical or commercial demands for any of our product candidates. In addition, our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or an equivalent foreign regulatory agency must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.

- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, or corresponding agencies in other geographic locations, to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.

- Our third-party manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We expect to create our own manufacturing facility for supply of U.S. clinical and/or commercial cell therapy product candidate requirements, but there is no guarantee we will be able to do so.

Our intent to create internal manufacturing infrastructure will rely upon finding personnel with an appropriate background and training to staff and operate the facility on a daily basis. Should we be unable to find such individuals, we may need to rely on external contractors longer than anticipated, and train additional personnel to fill the needed roles. There are a small number of individuals with experience in cell therapy and the competition for such individuals is high.

Specifically, the establishment of a cell-therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals who have successful previous experience in cleanroom designs. Cell therapy facilities, like other biological agent manufacturing facilities, require appropriate commissioning and validation activities to

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demonstrate that they operate as designed. Additionally, each manufacturing process must be validated through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. While we have developed our own manufacturing processes using an in-house process development team to maximize our understanding of our process, there is timing risk associated with in-house product manufacture.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Gene-modified cell therapy manufacture requires many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. Some suppliers typically support biomedical researchers or blood-based hospital businesses and may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have commercial supply arrangements with many of these suppliers, and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

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- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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 manufacture our drug substance and our drug product, and because we collaborate with various organizations and academic institutions on the advancement of our technology platform, we must, at times, 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, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees 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, such as trade secrets. Despite these contractual provisions, 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 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.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications 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 for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product

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candidate, we may relinquish valuable rights to that product candidate through strategic 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, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. We are particularly susceptible to this risk because we are pursing clinical and preclinical development program in each of our CaspaCIDe, DeCIDe, CIDeCAR and GoCAR-T technologies. Resources spent on one of these programs could result in fewer resources to further develop the other programs.

We have limited information available regarding the ultimate cost of our products, and cannot estimate what the cost of our products will be upon commercialization, should that occur.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product. Because of the patient-specific nature of our manufacturing process, it is not amenable to traditional scale up to manufacture larger lots as is performed for traditional drugs and biological agents.

We and our contractors utilize hazardous materials in our business operations, and any claims relating to improper handling, storage, or disposal of these materials could harm our business.

Our activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials, and similar laws in other geographic regions. Although we believe that our manufacturers procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Our internal computer systems, or those used by our clinical investigators, contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, 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. 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. 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.

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

Our operations, and those of our clinical investigators, contractors and consultants, could be subject to power shortages, telecommunications failures, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient by patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the federal Physician Payment Sunshine Act, created under the Health Reform Law, and its implementing regulations, which requires manufacturers of drugs, devices, biologicals 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 United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

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- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Effective upon the completion of this offering, we will adopt a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. 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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical 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, negligence, strict liability or 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 commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;

- costs to defend the related litigation;
- a diversion of management s time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop, alone or with corporate collaborators. We currently carry $10.0 million of product liability insurance covering our clinical trials. Although we maintain such insurance, our insurance policies may 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

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able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our most recent private placements and other transactions that have occurred over the past three years, we may have experienced, and, upon completion of this offering, may experience, an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2013, we had U.S. net operating loss carryforwards of approximately $26.9 million, which begin to expire in 2024, and U.S. research and development credits of $0.8 million, which could be limited if we experience an ownership change.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a Biologics License Application, or BLA, to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate s safety, purity and potency for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of T cell therapies for cancer. In addition, the cell and gene therapy office of the FDA has limited experience with combination products that include a small molecule component. Approval of our product candidates, including BPX-501, will require this FDA office to consult with another division of the FDA, which may result in further challenges in obtaining regulatory approval, including in developing final product labeling. The regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete our planned clinical trials;
- reaching agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- obtaining approval at each clinical trial site by an independent institutional review board, or IRB;

- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol, failing to follow GCPs, or dropping out of a clinical trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted, the Data Monitoring Committee for such clinical trial, or by the FDA or other regulatory authorities 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 clinical 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 product candidate, changes in governmental

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regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

The FDA may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

Our ongoing and planned Phase 1 and Phase 1/2 clinical trials of BPX-501 are designed to show enhanced immune system recovery in patients following an allogeneic (donor cells as opposed to the patient s own cells) HSCT. Following the completion of those clinical trials, and if the results are satisfactory, we plan to meet with the FDA in an end of phase two meeting to discuss our clinical trial design that could serve as the registration trial for our BLA for BPX-501 in that indication. We, or our institutional collaborators, are conducting and planning additional Phase 1 and Phase 1/2 clinical trials of BPX-501 in clinical trials designed to evaluate BPX-501 as a treatment for patients with recurrent disease (relapse) after an allogeneic HSCT. Following the completion of those clinical trials, and if the results are satisfactory, we plan to meet with the FDA in another end of phase two meeting to discuss whether our planned clinical trial design could serve as the registration trial for our BLA for BPX-501 in that indication. However, the general approach for FDA approval of a new biologic or drug is dispositive data from two adequate and well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that a single Phase 3 clinical trial strategy is warranted given the limited alternatives for patients for which BPX-501 therapy is potentially beneficial, but the FDA may ultimately require more than one Phase 3 clinical trial and may limit clinical trial designs allowed to serve as a registration trial.

Our clinical trials results may not support approval. In addition, BPX-501 and our other product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;