BIO-PATH HOLDINGS INC
Form 10-K
March 15, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016

OR

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

Commission file number 001-36333

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	87-0652870
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401
(Address of principal executive offices)

Registrant's telephone number, including area code: (832) 742-1357

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value $0.001 per share
Securities registered pursuant to Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

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

As of March 1, 2017, there were 95,645,224 of the registrant's common stock issued and outstanding. The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $163.3 million as of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, based on the last sales price of the registrant's common stock as reported on The Nasdaq Capital Market on such date. For purposes of the preceding sentence only, all directors, executive officers and beneficial owners of 10% or more of the shares of the registrant's common stock are assumed to be affiliates.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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Unless the context requires otherwise, references in this Annual Report on Form 10-K to "we," "our," "us," "the Company" and "Bio-Path" refer to Bio-Path Holdings, Inc. and its subsidiary. Bio-Path Holdings, Inc.'s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as "Bio-Path Subsidiary."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements can be identified by words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," "project," "goal," "strategy," "future," "likely," "may," "should," "will" and va words and similar references to future periods, although not all forward-looking statements contain these identifying words. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances, including those discussed in "Item 1A. Risk Factors" of this Annual Report on Form 10-K. As a result, our actual results may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. Please refer to "Item 1A. Risk Factors" of this Annual Report on Form 10-K for a discussion of risks and factors that could cause our actual results and financial condition to differ materially from those expressed or forecasted in this Annual Report on Form 10-K.

Any forward-looking statement made by us in this Annual Report on Form 10-K is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise. However, you should carefully review the risk factors set forth in other reports or documents we file from time to time with the U.S. Securities and Exchange Commission ("SEC").

PART I

ITEM 1. BUSINESS

Overview

We are a clinical and preclinical stage oncology focused antisense drug development company utilizing a novel technology that achieves systemic delivery for target specific protein inhibition for any gene product that is over-expressed in disease. Our drug delivery and antisense technology, called DNAbilize™, is a platform that uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification that is intended to protect the DNA from destruction by the body's enzymes when circulating *in vivo,* incorporated inside of a neutral charged lipid bilayer. We believe this combination allows for high efficiency loading of antisense DNA into non-toxic, cell-membrane-like structures for delivery of the antisense drug substance into cells. *In vivo,* the DNAbilize™ delivered antisense drug substances are systemically distributed throughout the body to allow for reduction or elimination of proteins in blood diseases and solid tumors.

Using DNAbilize™ as a platform for drug development and manufacturing, we currently have two antisense drug candidates in development to treat a total of five different disease indications. Our lead drug candidate, prexigebersen (pronounced prex" i je ber' sen), the unique nonproprietary (generic) drug name for BP1001 designated by the United States Adopted Names Council, targets the protein Grb2 and has entered the efficacy portion of a Phase II clinical trial for acute myeloid leukemia (AML) and is preparing to enter the safety segment of a Phase II clinical trial for blast phase and accelerated phase chronic myelogenous leukemia (CML). Prexigebersen is also in preclinical studies for solid tumors, including breast cancer and ovarian cancer.

Our second drug candidate, Liposomal Bcl2 ("BP1002"), targets the protein Bcl2, which is responsible for driving cell proliferation in up to 60% of all cancers. BP1002 is in preparation for an Investigational New Drug (IND) application.

We currently maintain an exclusive license agreement (the "License Agreement") with The University of Texas, MD Anderson Cancer Center ("MD Anderson"), under which we license from MD Anderson the delivery technology platform, prexigebersen and BP1002. We are developing antisense drug candidates to treat cancer and autoimmune disorders where targeting a single protein may be advantageous and result in reduced adverse effects as compared to small molecule inhibitors with off-target and non-specific effects. We have composition of matter and method of use intellectual property for the manufacture of neutral charged DNA-liposome complexes.

Our pipeline for development of antisense therapeutics is set forth in the table below:

Figure 1. Bio-Path Pipeline for Development of Therapeutics

Ribonucleic acid (RNA) is a biologically significant type of molecule consisting of a chain of nucleotide units. Each nucleotide consists of a nitrogenous base, a ribose sugar and a phosphate. Although similar in some ways to DNA, RNA differs from DNA in a few important structural details. RNA is transcribed from DNA by enzymes called RNA polymerases and is generally further processed by other enzymes. RNA is central to protein synthesis. DNA carries the genetic information of a cell and consists of thousands of genes. Each gene serves as a recipe on how to build a protein molecule. Proteins perform important tasks for the cell functions or serve as building blocks. The flow of information from the genes determines the protein composition and thereby the functions of the cell.

The DNA is situated in the nucleus of the cell, organized into chromosomes. Every cell must contain the genetic information and the DNA is therefore duplicated before a cell divides (replication). When proteins are needed, the corresponding genes are transcribed into RNA (transcription). The RNA is first processed so that non-coding parts are removed (processing) and is then transported out of the nucleus (transport). Outside the nucleus, the proteins are built based upon the code in the RNA (translation).

Our basic drug development concept is to block the expression of proteins that cause disease. RNA is essential in the process of creating proteins. We intend to develop drugs and drug delivery systems that work by delivering short strands of DNA material (antisense DNA) that are inserted into a cell to block the production of proteins associated with disease (Figure 2).

Figure 2.

Antisense DNA therapeutics is the field of designing short DNA sequences that are complementary to an RNA for a protein of interest with the intention of inhibiting the production of the targeted protein. The DNA will find the matching RNA and form a complex. The complexed RNA will not have access to the protein-making machinery, which prevents the cell from translating it into a protein. Thus, protein production is turned off and levels of the targeted protein are reduced in the cell. This gene-specific process of controlling protein expression has led to great interest in using antisense DNA to shut off the production of proteins involved in disease. Antisense therapeutics have been in development for over 20 years; however, there have been many challenges to antisense therapeutics that have prevented or reduced the successful distribution and transfer of DNA into cells. Of all delivery methods in use today, we believe only DNAbilize™ has the potential to overcome the most common challenges associated with antisense therapeutics.

Challenges associated with antisense therapeutics generally fall into two categories: (i) maintaining the stability of the DNA inside of the body as it is transported to the target cell and (ii) achieving efficient delivery and transfer of the DNA into the cell. DNA stability in the blood and lymphatic system is a challenge because of the abundance of enzymes present in human body fluids. Enzymes called nucleases will digest DNA into nonfunctional fragments making them too small to hybridize effectively to the correct RNA and block the protein machinery.

Efforts to overcome the stability challenges led to the development of DNA structural backbone chemistries that block nuclease digestion so that DNA can remain in circulation long enough to reach the target cell. The most popular modification employed is called phosphorothioate in which an oxygen atom in the DNA is replaced with a sulfur atom. This switch alters the DNA’s structure so that enzymes can no longer break down the DNA. However, DNA that contains sulfur has two major drawbacks. First, it has been shown to cause liver toxicity because, as pure DNA that contains sulfur is circulated through the body, it is rapidly cleared by and accumulates in the liver. Second, sulfur also

induces significant toxicity in the form of life threatening bleeding and clotting complications.

While the development and use of phosphorothioate was a step forward in allowing for progress of *in vivo* studies, the amount of antisense drug product that can be delivered is severely limited. Consequently, doses at the level needed for true therapeutic success are not possible. Accordingly, stabilizing the DNA backbone through the use of phosphorothioate has prevented the successful use of antisense therapeutics to treat patients at a therapeutic level without causing significant amounts of toxicity. Alternative approaches have since been developed that reduce the number of sulfur groups in the antisense molecule; however, these methods still contain sulfur, and toxicity will always remain a concern. The P-ethoxy modification used in our DNAbilize™ technology is completely sulfur free.

The second category of challenges to the development of successful antisense therapeutics is achieving efficient delivery and transfer of a DNA molecule across a lipid based cell membrane. Cell membranes have a negative charge on the surface. DNA is also negatively charged. When the pure DNA is delivered to the cell surface, the similar charges repel each other, and uptake of the DNA into the cell is very inefficient. Accordingly, the DNA containing antisense drug products will not be delivered in an amount that will have a therapeutic effect.

Efforts to overcome the efficient delivery and transfer challenges led to the exploration of lipid-based carriers for transfer of DNA containing antisense drug products through the lipid bilayer to mimic the lipid cell membrane. Encapsulating the DNA inside a neutral charged lipid bilayer facilitates the delivery and transfer of DNA into the cell to be fluid and gentle. Research initially focused on cationic lipids because they have an overall positive charge, which would be attracted to the negative charge of the cell membrane. It was thought that this would enhance uptake and delivery of DNA.

Research did, in fact, confirm that cationic liposomes are capable of transferring DNA inside of cells at a higher efficiency than with no delivery liposomes; however, it was found that cationic lipids have major drawbacks in therapeutics. These include absorption of serum proteins while the complexes are circulating in the blood. Absorption of charged serum proteins leads to lipid reorganization, aggregation or disassociation, resulting in poor efficiency of transfer of DNA into cells and non-specific toxicity to cell membranes. DNAbilize™ overcomes this challenge as well by encapsulating the DNA in a neutral lipid-based liposome, which is a lipid membrane without surface charge. The lipid particles can circulate through the blood without interacting with serum proteins, reaching target cells to transfer intact DNA without toxic effects.

We believe the DNAbilize™ technology is a first in class approach that overcomes the challenges associated with both DNA stabilization and lipid-based delivery. We believe that the combination of the protected DNA using P-ethoxy to modify the DNA structure with the neutral lipid membrane is the ideal approach for antisense DNA therapeutics. While many companies have focused research on either the DNA stabilization problem or the lipid delivery problem, we are not aware of any company that has developed improvements in both areas. DNAbilize™ is truly a stand-alone platform because, based on our current research, it allows for high doses of drug products to be delivered throughout the entire body while minimizing toxicity. This allows our research and development efforts to focus on drug targets rather than on indications because the DNAbilize™ system should not be limited in what types of indications it can treat. As such, we believe that DNAbilize™ represents the first ever antisense therapeutic approach that can successfully treat hematological and systemic diseases of the blood and lymph.

Because of our unique ability to address unmet needs in hematological malignancies, our lead drug candidates focus in this area. Our lead drug candidate, prexigebersen, targets the protein Grb2, a bridging protein between activated and mutated cellular kinases and the proteins involved in cell proliferation, and in particular, Ras protein. When mutations occur that activate these kinases, the cell proliferates uncontrollably, via Grb2, and this results in disease. Inhibition of Grb2 interrupts this pathway and shuts off growth signals.

Prexigebersen has entered the efficacy portion of the Phase II clinical trial for AML in combination with frontline therapy low dose Ara C (LDAC) in elderly and induction therapy ineligible patients or patients who have decided to forego intensive induction therapy because of their age or fragile health. We completed the safety segment of Phase II clinical trials (the safety segment of Phase II clinical trials is also referred to as Phase Ib) demonstrating anti-leukemic benefit and no adverse events in two cohorts at two dose levels each with three evaluable patients. Patients in Cohort 7 received a 60 mg/m^2 dose of prexigebersen and patients in Cohort 8 received a 90 mg/m^2 dose of prexigebersen, each in combination with LDAC. Two of three patients in Cohort 7 achieved complete remission, despite having failed at least six other therapies prior to entering the trial. One patient in Cohort 8 achieved complete remission, while the remaining two patients in Cohort 8 achieved partial remission. On November 2, 2016, we announced that the first patient in the efficacy portion of the Phase II trial for AML was dosed. The full trial design includes approximately 54 evaluable patients with an interim analysis to be performed after 19 patients are treated with the combination. In the event the interim results exceed the primary endpoint in the number of patients that meet or exceed statistically determined thresholds, we may seek to convert the trial into a registration trial for accelerated approval. The multi-site trial is being conducted at leading cancer centers, among them are Weill Medical College of Cornell University, Baylor Scott & White Health, The University of Kansas and MD Anderson. In addition, a Phase Ib clinical trial for blast and accelerated phase CML patients is expected to begin in the spring of 2017 in combination with frontline therapy dasatinib.

Our second drug candidate, BP1002, targets the protein Bcl2. Bcl2 is an anti-apoptotic member of the Bcl2 family of proteins that regulate cell death. Amplified expression of Bcl2 protein is associated with numerous cancers due to the defining genetic hallmark of the disease, chromosomal translocation t(14;18). The t(14;18) moves the Bcl2 gene from chromosome 18 into the heavy chain immunoglobin locus on chromosome 14, resulting in uncontrolled high level expression of Bcl2 protein. Overexpression of Bcl2 results in uncontrolled cell growth in affected cells. The IND for BP1002 is being finalized and a Phase I clinical trial for lymphoma is expected to begin in 2017.

Strategy

Our strategy is to develop our lead candidates, prexigebersen and BP1002, for multiple indications where the pathways involving Grb2 or Bcl2, respectively, are utilized to promote cancer growth and proliferation. Using DNAbilize™ technology, we plan to develop therapeutics to a wide range of diseases and disorders independently and in partnership with others. The key elements of our strategy include:

(1) **Develop prexigebersen for treatment of AML and CML in combination with frontline therapies.** The Phase I clinical trial demonstrated an excellent safety profile of prexigebersen in patients with relapsed or refractory AML, CML and Myelodysplastic Syndrome (MDS). Moving forward with AML, the area of highest need, we announced on March 3, 2016 that we completed the Phase Ib trial for combination therapy of prexigebersen with the frontline therapy LDAC. On November 2, 2016, we announced that the first patient in the efficacy portion of the Phase II trial for AML was dosed. Eligible patients include de novo elderly patients ineligible for induction therapy or patients who have decided to forego intensive induction therapy because of their age or fragile health. The Phase Ib clinical trial for blast and accelerated phase CML patients with prexigebersen in combination with dasatinib is expected to begin enrollment in the spring of 2017.

(2) **Develop prexigebersen for treatment of solid tumors.** Preclinical studies are underway to assess the efficacy of prexigebersen in solid tumors. Research using an ovarian cancer model and a breast cancer model are currently in development. Preclinical experiments are being performed in collaboration with leaders in the field of ovarian and breast cancer at MD Anderson. Results from these studies will be used to assess the ability of prexigebersen to work as a monotherapy and in combination therapies for solid tumors.

(3) **Develop BP1002 for lymphoma**. We are finalizing the IND in preparation to start a Phase I trial in lymphoma that will include multiple types of lymphoma, such as Burkitt's lymphoma (BL), diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), mucosa-associated lymphoid tissue (MALT), and mantle cell lymphoma (MCL). It is expected that this will be a single-site, open-label, dose-escalating trial involving between 15-30 patients. The Phase I trial is expected to start enrolling patients in 2017.

(4) **Expand DNAbilize™ to evaluate targets beyond cancer.** We plan to apply the DNAbilize™ delivery technology template to new protein targets that meet scientific, preclinical and commercial criteria and file new patents on these targets. We expect that these efforts will include collaboration with scientific key opinion leaders in the field of study and include developing drug candidates for diseases other than cancer.

(5) **Establish DNAbilize™ as the antisense drug delivery method of choice by forming partnerships with pharmaceutical and academic clinical research labs.** We plan to utilize our business and scientific expertise to identify potential partners and initiate a wide-ranging, proactive licensing program that will include co-development of specific liposomal antisense drug candidates, licensing the delivery template for outside development of one or more liposomal antisense drug candidates or an out-license of a partially developed drug for final development and marketing.

Overview of Drug Candidates and Delivery Technology

The historical perspective of cancer treatments has been the use of drugs that affect the entire body. Advances in the past decade have shifted to treating the tumor tissue itself. One of the main strategies in these developments has been targeted therapy, involving drugs that are targeted to block the expression of specific disease causing proteins while having little or no effect on other healthy tissue. We believe that nucleic acid drug products, specifically antisense, are a promising field of targeted therapy. Development of antisense, however, has been limited by the lack of a suitable method to deliver antisense drugs to the diseased cells with high uptake into the cell without causing toxicity. Our currently licensed DNAbilize™ neutral-lipid based liposome technology is designed to overcome these limitations. Studies conducted at MD Anderson have shown a 10-fold to 30-fold increase in tumor cell uptake with this technology compared to other delivery methods. In addition, to date, no adverse effects attributed to the study drug have been observed in our Phase I clinical trial for leukemia.

Antisense DNA therapeutics of the past have not adequately addressed the issues of toxicity and poor distribution and uptake. Without a lipid carrier, the majority of antisense DNA delivered intravenous is deposited in the liver and does not reach therapeutic levels in other organs in the body. Hence, antisense therapeutics have predominantly focused on diseases of the liver for which delivery of drugs is easy. Below is a table of antisense therapeutics we are aware of that

are currently in clinical trials.

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Table 1. Antisense or Anti-MiR drugs FDA Approved or in Clinical Trials

Nucleic Acid Modification	Drug	Targeted Gene	Clinical Status	Indications
Backbone Modifications				
Phosphorothioate	Vitravene	Cytomegalovirus	Approved	CMV retinitis
P-ethoxy	Prexigebersen	Grb2	Phase II	Leukemia
Sugar Modifications				
Morpholino	Eteplirsen	Dystrophin exon 51	Phase III	Duchenne Myotonic dystrophy
Morpholino	AVI-7100	Influenza virus	Phase I	Influenza
Locked Nucleic Acid	SPC2968	Hypoxia Inducing Factor	Phase II	Hepatocellular carcinoma
Locked Nucleic Acid	Miravirsen	miR-122	Phase II	Hepatitis C
2’-O-methyl	Drisapersen	Dystrophin exon 51	Phase III	Duchenne Myotonic dystrophy
2’- methoxy-O-ethyl	Mipomersen	Apolipoprotein B	Approved	Famial hypercholesterolemia
Lipid System	Natural Components	Potential toxicity		
SNALP	Cholesterol, Phosphatidylcholine	Cationic lipid, PEG		
Lipidoid	Cholesterol	PEG		
LPH	Cholesterol, hyaluronic acid	DOTAP, PEG		
Neutral lipid particle	DOPC lipid	None		

Lipid delivery approaches using cationic lipids, which enhance the uptake of charged antisense DNA molecules into cells as compared to no lipid, still do not efficiently transfer antisense DNA into cells due to serum protein interactions and subsequent cell toxicity. The antisense field has attempted to work around these issues by either avoiding a delivery method completely, or by utilizing polyethylene glycol (PEG) as a positive charged based carrier of DNA into cells. PEG showed promise in extending the time of circulation of antisense DNA *in vivo* and avoiding clearance by the liver. However, adverse effects have been demonstrated by PEG carriers, including hypersensitivity, activation of blood clotting, embolism and anaphylaxis. To date, the only known lipid delivery method that has not shown any adverse effects in clinical trials is the neutral lipid method utilized by DNAbilize™.

PREXIGEBERSEN

Prexigebersen is targeted at the protein Grb2. Antisense inhibition of Grb2 interrupts the signals between mutated and activated receptors that connect to a well-known cancer associated switch called Ras protein. Inhibition of Grb2 does

not cause cell death and thus does not result in adverse events typically observed with receptor inhibitors or Ras pathway inhibitors. We believe that prexigebersen has the potential to be an ideal combination for any number of cancer therapeutics where the Ras pathway is aberrantly activated and patient fitness is a major concern.

We have completed our Phase I clinical trials for prexigebersen for indications for AML, CML, MDS and Acute Lymphoblastic Leukemia (ALL). We are currently prioritizing our efforts on AML and CML and have begun the Phase Ib/Phase II clinical trials for these indications. Priorities for additional indications, including MDS or ALL, are expected to be addressed in the future as the results of our Phase II and work in solid tumors progresses.

Indications for Acute Myeloid Leukemia (AML) and Chronic Myelogenous Leukemia (CML)

AML – Background and Common Treatments. AML is the rapid accumulation of immature myeloid cells in the blood, resulting in a drop of the other cell types such as red blood cells and platelets. The expansion of immature monocytes leaves the patient unable to fight infection. If AML is left untreated, it usually results in death within three months. AML incidence increases with age, with more than 50% of the cases in people age 60 or older. AML is the most common acute leukemia in adults, and the National Cancer Institute estimates that approximately 20,000 new cases occur each year (Figure 3). The cure rate is between 5-15% in older adults, and those who cannot receive the standard course of chemotherapy have an average survival rate of five to ten months. The standard induction therapy for AML is Cytarabine with anthracycline, which has not been improved upon for the last 20 years. The last drug approval for AML was in 1990 (Figure 4). Of those patients who are able to receive the standard induction therapy, about 75% will likely relapse. AML is an area of high unmet need for both the relapsed and the de novo elderly population who are typically ineligible for induction therapy.

Figure 3. Basic Statistics for AML

Figure 4. FDA Drug Approvals for AML over the Last 48 Years

Source:http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCo

CML – Background and Common Treatments. CML is characterized by expansion in the blood and bone marrow of mature myeloid cells and their precursors. It can show no symptoms and is often detected during a routine blood test. If left untreated, after several years it will progress to an accelerated phase and eventually blast crisis where it becomes an acute leukemia. With the introduction of drugs such as Gleevec, the life expectancy of patients treated in the chronic phase has been significantly improved, and only 1-1.5% of patients ever go into blast crisis. However, for those patients who do progress into blast crisis, there are currently few treatment options. Myeloid cells in blast crisis have accumulated genetic abnormalities that resist traditional treatment methods that kill leukemic cells. Patients in blast crisis have an average survival rate of seven to eleven months. New treatments for this critical population are necessary.

Figure 5. Basic Statistics for CML

Prexigebersen Development and Treatment for AML and CML. Our lead liposome delivered antisense drug candidate, prexigebersen, has been clinically tested in patients having AML, CML, MDS and ALL in a Phase I trial. During the Phase I trial, 80% of the evaluable patients had refractory or relapsed AML, having failed at least 6 prior therapies. In our study, 83% of patients showed decreased circulating blasts and anti-leukemic activity and eight patients stabilized for extended treatments.

Phase I Clinical Trials

The Phase I clinical trial was a dose-escalating study to determine the safety and tolerance of escalating doses of prexigebersen. The study determined an optimal biologically active dose for further development. The pharmacokinetics of prexigebersen in patients from the study are being evaluated. In addition, patient blood samples from the trial were tested using a new assay developed by us to measure down-regulation of the target protein, the critical scientific data that demonstrated the delivery technology does in fact successfully deliver the antisense drug substance to the cell and across the cell membrane into the interior of the cell where expression of the target protein is blocked. The clinical trial was conducted at MD Anderson.

The original IND granted by the U.S. Food and Drug Administration (FDA) in March 2010 allowed us to proceed with a Phase I clinical trial having five cohorts culminating in a maximum dose of 50 mg/m^2. However, in November 2012, we announced that since there had been no evidence of significant toxicity from treatment of patients with prexigebersen, we requested the FDA to allow higher dosing in patients. The principal investigator for the clinical trial, in consultation with our management team, advised us that with the absence of any real toxicity barriers, we should continue to evaluate higher doses of prexigebersen. The absence of significant toxicity provided a significant opportunity for us to test higher doses in patients in order to find a dose that provides maximum potential benefit and duration of anti-leukemia effect. These actions were approved and a revised protocol was submitted allowing higher dosing. We announced in October 2014 that we completed Cohort 6, successfully treating three patients at a dose 90 mg/m^2. There has been no evidence of significant toxicity from treatment of patients with prexigebersen in our Phase I clinical trial.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of our delivery technology platform in human patients. We have developed two new assays to be able to provide scientific proof of concept of the delivery technology. The first involves a novel detection method for the drug substance in blood samples that will be used to assess the pharmacokinetics of the drug. The second involves a method to measure down-regulation of the target protein in a patient blood sample that was achieved. The latter measurement will provide critical proof that DNAbilize™ neutral liposome delivery technology delivered the drug substance to the cell and was

able to transport it across the cell membrane into the interior to block cellular production of the Grb2 protein.

In this regard, in August 2013 we announced that our DNAbilize™ liposomal delivery technology achieved a major milestone in the development of antisense therapeutics based on a scientific assay confirming that treating patients with our drug candidate prexigebersen inhibits the Grb2 disease-causing target protein in patients with blood cancers (Figure 8). Inhibition of the disease-causing protein has the effect of down regulating the disease. This will allow for prexigebersen to be used potentially in combination with current frontline treatments. This discovery also points to the potential use of a liposomal antisense treatment as a standalone treatment to transform and manage a disease that has a disease-causing protein as a chronic disorder. This accomplishment is a potentially significant breakthrough for antisense therapeutics, whose development, to date, as a class of therapeutics has been severely limited by a lack of a systemic delivery mechanism that can safely distribute the drug throughout the body and deliver the antisense drug substance across the cell membrane into the interior of the cell. Further, we expect that scientific proof of principle for DNAbilize™ may lead to licensing and business development opportunities, supporting our business model.

The principal investigator for the Phase I clinical trial is a leading expert in the treatment of CML, AML, MDS and ALL. Because the results of the first trial produced unexpected and clinically interesting results in some patients, the principal investigator prepared an abstract of the results of the first cohort that was accepted for presentation at the American Society of Hematology (ASH) annual meeting in December 2011. Results that demonstrated potential anti-leukemia benefits in treated patients were included in the presentation. Subsequently, in fall 2013 the principal investigator prepared an abstract of updated information on the results of the clinical trial through Cohort 5, which was accepted for presentation at the ASH annual meeting in December 2013. Highlights (which have been updated to include patients from Cohort 6) of the presentation prepared by the principal investigator for the meeting included:

Data from the Phase I Clinical Trial

- Among 20 evaluable patients, 15 demonstrated anti-leukemia activity with reduction in peripheral or bone marrow blasts from baseline.
- Five patients demonstrated transient improvement and/or stable disease, three of whom received a total of five cycles each.
- Two patients, in addition to achieving market blast percentage declines, also experienced transient improvements in leukemia cutis lesions.

Disease Stabilization in MDS and AML

- Two patients with MDS, a 53-year-old male and a 72-year-old female, both achieved disease stabilization and continued therapy for five cycles before disease progression.
- A 54-year-old HIV positive male with AML achieved stable disease and marked reduction in peripheral blasts, continuing therapy for five cycles before disease progression (Figure 6).

Figure 6. AML Patient with HIV Demonstrated Reduction of
Peripheral Blasts and Sustained Improvement Over 5 Cycles of Treatment

End of C = end of the cycle of treatment

Experience in CML-Blast Phase

- Patient with myeloid blast crisis of CML.
- Prior therapies consisted of: imatinib, dasatinib, nilotinib, DCC-2036, cytarabine + fludarabine + dasatinib + gemtuzumab, PHA-739358, clofarabine + dasatinib.
- Upon start of prexigebersen, patient showed a significant reduction in white blood cell (WBC) blasts from 81 percent to 5 percent, but due to leptomeningeal disease progression discontinued therapy before full cycle (Figure 7).

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Figure 7. Prexigebersen Monotherapy Reversed Blast Phase Crisis
in a Patient in the Phase I Clinical Trial for Prexigebersen

Inhibition of Target Grb2 Protein

- Grb2 levels were compared to baseline prior to treatment.
- By end of treatment, prexigebersen decreased Grb2 in 10 out of 12 samples (83%) tested (average reduction 50%).
- Phosphorylated ERK (pERK, extracellular signal related kinase), a protein downstream of the Ras protein, was decreased in 58% of samples.

Figure 8. Grb2 Protein and Downstream pERK are
Downregulated in Prexigebersen Treated Patient's Cells

Grb2 levels decreased in 10 out of 12 patient samples by end of treatment (EOT)

pErk levels decreased in 7 of 12 patient samples by EOT

The Phase I clinical trial is typically ended when a maximum tolerated dose (MTD) is encountered. However, due to the lack of toxicity of the drug, a MTD was not observed. As a result, an optimal biological dose was determined and we completed Cohort 6 of our Phase I clinical trial. It is noted, however, that the lack of toxicity is a major advantage for the drug candidate prexigebersen since it allows higher levels of drug to be administered to the patient, increasing the potential therapeutic benefit.

In April 2015, we received orphan drug designation by the FDA for prexigebersen in AML. Orphan drug status provides Bio-Path with seven years of exclusivity after receiving formal marketing approval, as well as additional development incentives. The FDA grants this designation to certain drugs that target diseases affecting fewer than 200,000 people in the United States. In October 2016, prexigebersen received orphan drug designation for AML in the European Union ("E.U.") from the European Medicines Agency ("EMA"). To receive orphan drug designation from the EMA, a therapy must be intended for the treatment of a life-threatening or chronically debilitating rare condition with a prevalence of less than five in 10,000 in the E.U. Orphan drug designation provides incentives designed to facilitate development, including fee reductions for protocol assistance, scientific advice and importantly, may provide up to ten years of market exclusivity in the E.U. following product approval.

Phase II Clinical Trials

On February 9, 2015, we announced that we began enrollment into the combination therapy Phase Ib clinical trial for prexigebersen in patients with AML. The combination therapy Phase Ib clinical trial consisted of two dosing cohorts of prexigebersen (60 mg/m^2 and 90 mg/m^2) to test the safety profile of treating AML patients with prexigebersen in combination with LDAC. Patients ineligible for intensive induction therapy are currently treated only with LDAC.

On October 9, 2015, we announced the completion of Cohort 7, the first dosing cohort of the Phase Ib clinical trial, consisting of a 60 mg/m^2 dose of prexigebersen in combination with LDAC. On March 3, 2016, we announced the completion of Cohort 8, the second dosing cohort of the Phase Ib clinical trial, consisting of a 90 mg/m^2 dose of prexigebersen in combination with LDAC. On June 6, 2016, we announced that data from Cohort 7 and Cohort 8 of the Phase Ib clinical trial combination therapy of prexigebersen and LDAC showed no dose limiting toxicities. Of the six evaluable patients from the Phase Ib clinical trial, four patients completed more than two cycles of treatment, three patients achieved complete remission and two patients achieved partial remission (Figure 9). Pharmacokinetics of prexigebersen demonstrated a half-life at 60 mg/m^2 of 30 hours, significantly better than the 90 mg/m^2 dose. The final analysis of these data, along with the demonstrated reductions in bone marrow blasts, suggested that 60 mg/m^2 is the appropriate dose for use in the Phase II trial. Administratively, this required Bio-Path to substantially revise documents for the Phase II trial with the 60 mg/m^2 dose and resubmit for approvals with the FDA and site Institutional Review Boards, which delayed the commencement of the Phase II trial.

Figure 9. Five out of six patients in cohorts 7 and 8 receiving the combination prexigebersen + LDAC achieve complete or partial remission

End of C = end of the cycle of treatment

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A summary of the clinical trial results for the Phase I monotherapy for indications of AML, CML, MDS and ALL, and Phase Ib combination therapy for prexigebersen for indications of AML is shown in Table 2 below. The first six cohorts, patients 001 to 034, were treated in the Phase I clinical trial using prexigebersen as a monotherapy. The seventh cohort, patients 035, 037 and 038, were treated in our Phase Ib clinical trial evaluating the combination therapy of 60 mg/m^2 prexigebersen.

Table 2. Summary Cohorts 1-7 Prexigebersen Clinical Trial Phase I and IB

Nadir: the lowest point, Off-TX: off treatment, DLT: dose limiting toxicity, PD: progressive disease, WD: withdraw, CR: complete remission, NE: not enough sample to evaluate, ND: not done, NA: not available

With the completion of Cohort 8, the Phase Ib trial has been completed. Results from the Phase Ib clinical trial demonstrated it is safe to add prexigebersen, which appears to yield better response rates in this AML patient population. On November 2, 2016, we announced that the first patient in the efficacy portion of the Phase II trial was dosed. The full trial design includes approximately 54 evaluable patients with an interim analysis to be performed after 19 patients are treated with the combination. In the event the interim results exceed the primary endpoint in the number of patients that meet or exceed statistically determined thresholds, we may seek to convert the trial into a registration trial for accelerated approval (Figure 10). The multi-site trial is being conducted at leading cancer centers, among them are Weill Medical College of Cornell University, Baylor Scott & White Health, The University of Kansas and MD Anderson.

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Figure 10. Trial Design

Development of new therapeutics for AML and CML in blast crisis can meet currently unmet needs for patients who have very few treatment options due to age, fitness or treatment-resistance of advanced genetically unstable cells. Elderly patients unfit to receive a stem cell transplant or induction therapy face a likelihood of relapse to a more resistant leukemia for which current drug products are not effective. prexigebersen and DNAbilize™ technology offer new hope for achieving remission for fragile populations. We believe that the combination of prexigebersen with frontline chemotherapy can provide a way to treat cancer without added toxicity so that the patient can remain under treatment long enough to reach complete remission.

Indications for Triple Negative Breast Cancer (TNBC) and Inflammatory Breast Cancer (IBC)

TNBC and IBC – Background and Common Treatments. Approximately 15 to 20 percent of breast cancers fall into the category of triple-negative. TNBC tumors do not express estrogen receptors, progesterone receptors, and low human epidermal growth factor receptor 2 (HER2). These negative results mean that the growth of the cancer is not supported by the hormones estrogen and progesterone, or by the presence of HER2 receptors. Therefore, TNBC does not respond to hormonal therapy or therapies that target HER2 receptors. In addition, TNBC tumors are very aggressive. IBC often presents as TNBC and is a rare and very aggressive disease in which cancer cells block lymph vessels in the skin of the breast. This type of breast cancer is called “inflammatory” because the breast often looks swollen and red, or “inflamed.” IBC accounts for 2 to 5% of all breast cancers. IBC tumors are very aggressive and are frequently hormone receptor negative, which means hormone therapies may not be effective. The five-year survival rate for IBC is approximately 40% versus approximately 87% for all breast cancers combined, making IBC a priority area for development of new treatments. The current treatment regimen includes radiation, chemotherapy and surgery. A lack of targeted treatments for these types of breast cancer has led to development of new therapeutics currently in clinical trials. Because of the aggressiveness of these cancers, a systemic treatment is needed. Prexigebersen represents a systemic treatment that targets an important pathway for TNBC and IBC cell growth and has potential to be integral for the treatment of these diseases.

Prexigebersen Development and Treatment for TNBC and IBC. In July 2013, we announced that we were initiating preclinical testing of prexigebersen for TNBC and IBC. Our plan is to develop prexigebersen as a targeted therapy against TNBC and IBC. Our treatment goals are two-pronged: the first is to develop prexigebersen as a tumor reduction agent in combination with other approved drugs in preoperative settings for TNBC and IBC patients, and the second is to develop prexigebersen as a drug to treat and control or eliminate cancer metastasis in TNBC and IBC patients. Both of these treatment goals address high need situations for patients. Once the preclinical studies are completed, we believe that the observations that we learned from the original Phase I trial will help us increase the speed of progress for such Phase I trial in TNBC and IBC, as the toxicity profile of prexigebersen is currently well-established.

Indications for Other Solid Tumors (e.g., Lymphoma, Colon, Thyroid, and Head and Neck Cancers)

Cancers of colon, thyroid, head and neck, and lymphoma are solid tumors which utilize the same signaling pathway as TNBC and IBC, which involve the Grb2 protein. It has been proposed that prexigebersen may have clinical efficacy in these indications due to the overlapping similarity of the mechanisms of their growth and proliferation. As our program for prexigebersen continues to develop, it is anticipated that these indications will be assessed in preclinical research.

BP1002

BP1002, also known by its scientific name as Liposomal Bcl2, is our second liposome delivered antisense drug candidate. BP1002 is intended to target the lymphoma and certain solid tumor markets. Clinical targets for BP1002 include lymphoma, breast cancer, colon cancer, prostate cancer and leukemia. We believe that BP1002 has the potential to treat 40%-60% of solid tumors.

Bcl2 is a protein that is involved in regulating apoptosis, or programmed cell death. Apoptosis is a physiologic mechanism of cell turnover by which cells actively commit suicide in response to aberrant external signals. Over-expression of Bcl2 prevents the induction of apoptosis in response to cellular insults such as treatment with chemotherapeutic agents. Bcl2 is over-expressed in more than 90% of follicular B-cell non-Hodgkin's lymphoma due to a chromosomal rearrangement and is the key factor in the initiation of this malignancy. Bcl2 is also overexpressed in a wide variety of solid tumors (it is estimated to be over-expressed in 40% of cancers). For example, Bcl2 over-expression has been associated with the progression of prostate cancer from hormone dependence to hormone independence and may contribute to the relative drug resistant phenotype typically observed in hormone independent prostate cancer.

Non-Hodgkin's Lymphomas –Background and Common Treatments. There are approximately 56,000 new cases of non-Hodgkin's lymphoma (NHL) per year, with approximately 30% being follicular lymphoma (FL) and approximately 60% being the more aggressive diffuse large B cell lymphoma (DLBCL) type. A consensus on front-line treatment for FL has not been established as many factors are taken into account in the treatment approach (e.g., age, stage of disease, cell surface markers). Rituximab is a treatment of choice for the majority of lymphomas and is typically used in combination with other chemotherapy agents or as a maintenance treatment. Table 3 describes the current treatment options for follicular lymphoma.

Table 3 Summary of Studies Evaluating Frontline Chemotherapies in Follicular Lymphoma

BR = bendamustine, rituximab, CHOP = cyclophosphamide, doxorubicin, vincristine, prednisone, CVP = cyclophosphamide, vincristine, prednisone, FMD = fludarabine, mitoxantrone, dexamethasone, PFS = progression-free survival, R-CHOP = rituximab-cyclophosphamide, doxorubicin, vincristine, prednisone, R-CVP = rituximab-cyclophosphamide, vincristine, prednisone, TTP = time to disease progression.

Source:https://www.moffitt.org/File%20Library/Main%20Nav/Research%20and%20Clinical%20Trials/Cancer%20Control%

BP1002 – Development and Treatment for FL, DLBCL, MALT, MCL AND BL. On December 22, 2014, we announced that we initiated development of BP1002 as a treatment for FL. We intend to file a new IND to begin clinical testing of BP1002 in patients with multiple types of lymphoma in 2017. We anticipate that the Phase I trial will be open to refractory and relapsed patients with FL and other sub-types of NHL, including DLBCL, MALT, MCL and BL (Figure 11).

Figure 11. Non-Hodgkin's Lymphoma Types and Prevalence

BL = Burkitt's lymphoma; CLL = chronic lymphocytic leukemia; DLBCL = diffuse large B-cell lymphoma; FL = follicular lymphoma; MALT = mucosa-associated lymphoid tissue; MCL = mantle cell lymphoma; NK = natural killer; SLL = small lymphocytic lymphoma.

Source: http://www.medscape.org/viewarticle/725127

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Treatments of varying efficacy exist for FL and DLBCL; however, due to the wide variety of subtypes of this disease, a frontline approach is lacking. Bcl2 is over-expressed in 85% of patients due to a translocation between chromosomes 18 and 14, a hallmark of the disease. Therapies that directly and specifically block or inhibit protein synthesis of Bcl2 could be transformative in this indication. Toxicity in competing therapeutics using small molecule inhibitors of Bcl2 occurs due to non-specificity of the inhibitors. Bcl2 is part of a large family of proteins and small molecule inhibitors developed against it typically bind to more than one member of the family. This leads to unexpected off-target adverse effects. A previous attempt at a Bcl2 antisense by Genta Inc. failed to show an improvement in remission or overall survival rates. This antisense was a phosphorothioate DNA with dose-limiting toxicity and it also did not have a lipid delivery mechanism to aid in prevention of clearance by the liver, reducing the levels of antisense reaching diseased cells. We believe that BP1002 overcomes the failures of previous attempts at inhibiting Bcl2 by specifically interrupting the protein expression of one protein and not a family of necessary proteins and does so without inherent toxicity. With BP1002, more drug substance can reach the circulating lymphocytes so that the cancer cells can be treated with a therapeutically relevant dose. We believe BP1002 provides a new tool for cancer treatment for not just lymphomas, but also many cancers for which Bcl2 expression is driving cell proliferation. The introduction of a new, non-toxic, and specific Bcl2 inhibitor could be a major advance in cancer therapeutics.

DNAbilize™

DNAbilize™ technology is available for out-licensing. We intend to apply our drug delivery technology template to new disease-causing protein targets as a means to develop new liposomal antisense drug candidates. A new product identification template was recently approved that defines a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. A significant amount of capital is expected to be allocated to in-license promising protein targets that can be developed as new liposomal antisense drug candidates. As we expand, we will look at indications where a systemic delivery is needed and antisense can be used to slow, reverse or cure a disease, either alone or in combination with another drug.

We are interested in pursuing a wide-ranging, proactive licensing program to include co-development of specific liposomal antisense drug candidates, sub-licensing our delivery template for outside development of liposomal antisense drug candidates or out-licensing a partially-developed drug candidate for final development and marketing.

Research and Development

Our research and development expense primarily consists of third-party clinical and preclinical development activities, salaries and benefits expense and stock-based compensation. As we advance and expand our pipeline of drug candidates, we anticipate our research and development expenses will continue to increase in conjunction with these activities. Research and development expenses incurred for the years ended December 31, 2016, 2015 and 2014 were $5.5 million, $3.0 million and $1.6 million, respectively. Research and development - related party expenses

incurred for the year ended December 31, 2014 were $0.2 million. Research and development - related party expense has been consolidated with research and development expense on our financial statements in 2015 and 2016 as MD Anderson is no longer a greater than 5% stockholder in the Company.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. Accordingly, we have no ability to internally manufacture the drug candidates that we need to conduct our clinical trials. For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of our drug candidates and any future drug candidates for use in our clinical trials. We have entered into agreements with third-party manufacturers for the manufacture of our drug requirements, including agreements for the manufacture of prexigebersen for use in our Phase II clinical trial, a development agreement for BP1002 and an agreement for the manufacture of BP1002 for use in our planned Phase I clinical trial. However, we may face various risks and uncertainties in connection with our reliance on third-party manufacturers, as discussed in “Item 1A. Risk Factors” of this Annual Report on Form 10-K under the heading “Risks Related to Manufacturing Our Drug Candidates.” If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of such approved drug candidates. However, we may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

Sales and Marketing

We currently do not have any commercial drug products or an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drug candidates that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty sales force that calls on a limited but focused group of physicians, we may commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population, we may enter into arrangements with other companies for commercialization. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

Intellectual Property

Patents, trademarks, trade secrets, technology, know-how and other proprietary rights are important to our business. Our success depends in large part on our ability to obtain and maintain patent protection both in the United States and in other countries for our drug candidates and on our ability to operate without infringing the proprietary rights of third parties. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party.

As previously noted, we have entered into the License Agreement with MD Anderson, which relates to the delivery technology platform for antisense nucleic acids, including two single nucleic acid (antisense) drug products, prexigebersen and BP1002. In addition, we may enter into out-license and in-license agreements in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Under the License Agreement, we license rights to certain patents that are necessary or useful for our business. Some of these material patents are set to expire as early as 2017.

We plan to expand our intellectual property portfolio by filing patent applications that are applicable to our technology and business strategy. Our patent portfolio currently includes two pending patent applications in the United States that cover the manufacturing method, formulation and antisense composition for new targets in preclinical development and for combinations of antisense drugs with frontline therapeutics. There can be no assurances that patents related to these applications or applications we may file in the future will be issued or that any issued patents will provide meaningful protection for our drug candidates, which could materially and adversely affect our competitive business position, business prospects and financial condition.

In the United States, individual patents extend for varying periods of time depending on the date of filing of the patent application or the date of patent issuance. Generally, patents issued in the United States are effective for 20 years from the earliest non-provisional filing date. In addition, a patent term can sometimes be extended to recapture a portion of the term effectively lost during the FDA's regulatory review period; however, the restoration period cannot be longer than five years, and the total patent term cannot exceed 14 years following FDA approval.

Employees

We currently employ 12 full-time employees. We also have contractual relationships with additional professionals who perform certain medical officer, regulatory and drug development duties. We believe relations with such professionals and employees are good.

Competition

We are engaged in segments of the pharmaceutical and biotechnology industry that are highly competitive and characterized by rapid and significant technological change. Many large pharmaceutical and biotechnology companies, academic and research institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target AML, CML, breast cancer and other cancer generally. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than our drug candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our drug candidates.

Many of our competitors have:

- significantly greater capital, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates;

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- more experience in drug discovery, development and commercialization, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;

- drug candidates that have been approved or are in late-stage clinical development; and/or

- collaboration arrangements in our target markets with leading companies and research institutions.

Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patent registration for clinical trials, and acquiring technologies complementary to, or necessary for, our drug candidates and programs.

Competitive products and technological developments may render our drug candidates noncompetitive or obsolete before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of any vaccine for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for any of our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

Government Regulation

Overview

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, record keeping, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. The nature and extent to which such regulations will apply to us will vary depending on the nature of any drug candidates we develop. We anticipate that all of our drug candidates will require regulatory approval by governmental agencies prior to commercialization. This process and subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations will require the expenditure of substantial time and financial resources.

United States Drug Development Process

In the United States, drugs are subject to rigorous regulation by the FDA under the Federal Food, Drug and Cosmetic Act (the "FDCA"), and implementing regulations, as well as other federal and state statutes. Failure by us or our collaborators to comply with the applicable United States requirements at any time during the drug candidate development process, approval process or after approval, may subject us to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

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

- completion of preclinical laboratory tests, animal studies and formulation studies according to FDA's Good Laboratory Practice regulations;
- submission of an IND, which must become effective before human clinical trials may begin and which must include approval by an institutional review board at each clinical site before the trials are initiated;
- performance of adequate and well-controlled human clinical trials according to FDA's Good Clinical Practice ("GCP") regulations to establish the safety and efficacy of the proposed drug for its intended use;
- submission to, and acceptance by, the FDA of a new drug application (an "NDA");
- completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice ("cGMP") regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and

- FDA review and approval of the NDA.

Pre-Approval Studies

Once a drug candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of drug candidate chemistry, toxicity and formulation, as well as animal studies. Prior to beginning human clinical trials, an IND sponsor must submit an IND to the FDA, which includes submitting the results of the preclinical tests, together with manufacturing information and analytical data. Some preclinical or nonclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Even after the 30-day time period, the FDA may impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. The IND application process may be extremely costly and substantially delay the development of our drug candidates for certain indications. Moreover, positive results of preclinical tests will not necessarily indicate positive results in subsequent clinical trials in humans. The FDA may require additional animal testing after an initial IND application is approved and prior to Phase III trials.

Clinical trials involve the administration of the IND to volunteers or patients under the supervision of one or more qualified investigators in accordance with FDA's GCP regulations. Clinical trials must be conducted under protocols detailing the objectives of the trial and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, an institutional review board at each institution participating in the clinical trial must review and approve each protocol before any clinical trial commences at that institution. All research subjects must provide informed consent, and informed consent information must be submitted to the institutional review board for approval prior to initiation of the trial. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events or other certain types of other changes occur.

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

- *Phase I:* The drug candidate is initially introduced into human subjects or patients with the disease and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some drug candidates for severe or life-threatening diseases, the initial human testing is often conducted in patients.

- *Phase II:* Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase III:* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, typically at geographically dispersed clinical study sites. These studies are intended to establish the

overall risk-benefit ratio of the drug candidate and provide, if appropriate, an adequate basis for product labeling.

Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. The FDA or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug candidate and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other requirements, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Our business model relies on developing drug candidates through Phase IIa and either entering into out-license agreements with pharmaceutical licensee partners who will be responsible for post-Phase II clinical testing and working with the FDA on necessary regulatory submissions resulting in approval of new drug applications for commercialization, or internally developing a drug candidate through commercialization.

Approval Process

After successful completion of the required clinical trials, an NDA is generally submitted, which is required before marketing of the product may begin in the United States. The NDA must include the results of drug development, preclinical studies and clinical studies, together with other detailed information, including information on the chemistry, manufacture and composition of the drug. The FDA has 60 days from its receipt of the NDA to review the application to ensure that it is sufficiently complete for substantive review before accepting it for filing and may request additional information rather than accept an NDA for filing. If additional information is requested, the NDA must be resubmitted. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The submission of an NDA is also subject to the payment of user fees, which may be waived under certain limited circumstances.

The FDA reviews an NDA that has been accepted for filing to determine, among other things, whether a product is safe and effective for its intended use. The approval process for an NDA is lengthy and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA may also refer applications for drug candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. Before approving an NDA, the FDA will also inspect the facility or facilities where the product is manufactured to determine whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, purity and stability.

There are various programs that are intended to expedite the development and review of drug candidates, and/or provide for approval on the basis of surrogate endpoints, including Fast Track, breakthrough therapy, priority review and accelerated approval. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drug candidates that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs or those that offer meaningful benefits over existing treatments.

Fast Track is a process designed to facilitate the development, and expedite the review of drug candidates to treat serious diseases and fill an unmet medical need. Breakthrough therapy requires preliminary clinical evidence that demonstrates the drug candidate may have substantial improvement on at least one clinically significant endpoint over available therapy. A breakthrough therapy designation conveys all of the Fast Track program features, as well as more intensive FDA guidance on an efficient drug development program. Priority review is designed to give drug candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track, breakthrough therapy and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug candidate and expedite review of the application for a drug candidate designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform post-marketing clinical trials.

If the FDA evaluations of the application and the manufacturing facilities are favorable, the FDA may issue an approval letter or an "approvable" letter. An approvable letter will usually contain a number of conditions that must be met in order to secure final approval of the NDA and authorization of commercial marketing of the drug for certain indications. An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication. As a condition of NDA approval, the FDA may require post-approval testing, including Phase IV trials, and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling or distribution restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems occur after the product reaches the market. The FDA may also refuse to approve the NDA or issue a "not approvable" letter

outlining the deficiencies in the submission and often requiring additional testing or information.

To date, we have not submitted a marketing application for any drug candidate to the FDA or any foreign regulatory agency, and none of our drug candidates have been approved for commercialization in any country. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and for the FDA's review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA regulatory review.

Timing to Approval

We estimate that it generally takes 10 to 15 years or possibly longer to discover, develop and bring to market a new pharmaceutical product in the United States as outlined below:

Phase:	**Objective:**	**Estimated Duration:**
Discovery	Lead identification and target validation.	2 to 4 years
Preclinical	Initial toxicology for preliminary identification of risks for humans; gather early pharmacokinetic data.	1 to 2 years
Phase I	Test for safety, dosage tolerance, absorption, metabolism, distribution and excretion.	1 to 2 years
Phase II	Identify possible adverse effects and safety risks; preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases; determine dosage tolerance and optimal dosage.	2 to 4 years
Phase III	Further evaluate dosage, clinical efficacy and safety in an expanded patient population, typically at geographically dispersed clinical study sites; establish the overall risk-benefit ratio of the drug candidate and provide, if appropriate, an adequate basis for product labeling.	2 to 4 years
FDA approval	Approval by the FDA to sell and market the drug for the approved indication.	6 months to 2 years

A drug candidate may fail at any point during this process. Animal and other non-clinical studies typically are conducted during each phase of human clinical trials.

Our business model is primarily focused on the preclinical to Phase IIa interval. This greatly reduces the time frame for us from in-license of a new, preclinical stage drug candidate to be developed to out-licensing to a pharmaceutical partner.

Post-Approval Studies

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. After approval, some types of changes to the

approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes;
- complying with certain electronic records and signature requirements; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and some state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our drug candidates. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our drug candidates. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

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Foreign Regulations

Whether or not we obtain FDA approval for a drug candidate, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of our products in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application ("CTA"), much like an IND, prior to the commencement of human clinical trials. In the E.U., for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, but typically takes several years and requires significant resources. In all cases, the clinical trials must be conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under E.U. regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the E.U. by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The EMA implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the E.U. This procedure results in a single marketing authorization granted by the European Commission that is valid across the E.U., as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for certain human drugs including those that are: (i) derived from biotechnology processes, such as genetic engineering, or (ii) contain a new active substance indicated for the treatment of certain diseases.

Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement, which is time consuming and expensive. Reimbursement may not be available or sufficient to allow us to sell our future products, if any, on a competitive and profitable basis.

The passage of the Medicare Prescription Drug and Modernization Act of 2003 (the "MMA") imposed requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, which may affect the marketing of our

future products, if any. The MMA also introduced a reimbursement methodology, part of which went into effect in 2004, and a prescription drug plan, which went into effect on January 1, 2006. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the E.U. provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

There have been and we expect that there will continue to be frequent federal and state proposals to impose governmental pricing controls or cost containment measures for prescription drugs. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, contains provisions that may reduce the profitability of drugs, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more of our drug candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Regulations

Pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, under certain conditions a sponsor may be granted marketing exclusivity for a period of five years following FDA approval. During this period, third parties would not be permitted to obtain FDA approval for a similar or identical drug through an Abbreviated NDA, which is the application form typically used by manufacturers seeking approval of a generic drug. The Hatch-Waxman Act also permits a patent extension term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent extension cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus time of active FDA review between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and it must be applied for prior to expiration of the patent and within 60 days of the approval of the NDA.

Prexigebersen previously received orphan drug designations for the treatment of CML in the United States. Orphan designation is available to drugs intended to treat, diagnose or prevent a rare disease or condition that affects fewer than 200,000 people in the United States at the time of application for orphan designation. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan designation qualifies the sponsor of the product for a tax credit and marketing incentives. The first sponsor to receive FDA marketing approval for a drug with an orphan designation is entitled to a seven-year exclusive marketing period in the United States for that product for that indication and, typically, a waiver of the prescription drug user fee for its marketing application. However, a drug that the FDA considers to be clinically superior to, or different from, the approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. Orphan drug exclusive marketing rights may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug.

In October 2016, prexigebersen also received orphan drug designation for AML in the E.U. from the EMA. To receive orphan drug designation from the EMA, a therapy must be intended for the treatment of a life-threatening or chronically debilitating rare condition with a prevalence of less than five in 10,000 in the E.U. Orphan drug designation provides incentives designed to facilitate development, including fee reductions for protocol assistance, scientific advice and importantly, may provide up to ten years of market exclusivity in the E.U. following product approval.

There is no guarantee that any of our other drug candidates will receive orphan drug designation or that, even if such drug candidate is granted such status, the drug candidate’s clinical development and regulatory approval process will not be delayed or will be successful.

Pharmaceutical companies are also subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for any entity or person to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third party payors, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

Company History and Available Information

We were originally incorporated in May 2000 as a Utah corporation under the name Ogden Golf Co. Corporation, but terminated our retail golf store operations in December 2006. In February 2008, we completed a reverse merger with Bio-Path Subsidiary. The name of Ogden Golf Co. Corporation was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on The NASDAQ Capital Market

under the ticker symbol “BPTH.” Effective December 31, 2014, we changed our state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law. Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357.

Our Internet address is *www.biopathholdings.com*. We are not including the information contained in our website as part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such materials with, or furnish it to, the SEC. We also make available on our website our Corporate Governance Guidelines; the charters for our Audit Committee, Nominating/Corporate Governance Committee and Compensation Committee; our Employee Code of Business Conduct and Ethics, which applies to all of our employees, including our executive officers; and our Code of Business Conduct and Ethics for Members of the Board of Directors. All such information is also available in print and free of charge to any of our stockholders who request it. In addition, we intend to disclose on our website any amendments to, or waivers from, our codes of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the SEC.

ITEM 1A. RISK FACTORS

Risks Relating to Our Business

We are a clinical stage biotechnology company with no significant revenue. We have incurred significant operating losses since our inception, and we expect to incur losses for the foreseeable future and may never achieve profitability.

We have incurred significant operating losses since our inception. As of December 31, 2016, we had accumulated net losses of $32.1 million. To date, we have not generated any revenue from the sale of our drug candidates and we do not expect to generate any revenue from sales of our drug candidates for the foreseeable future. We expect to continue to incur significant operating losses and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts.

To achieve profitability, we must successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability.

We will continue to require substantial additional capital for the foreseeable future. If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our drug development programs and commercialization efforts.

We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials, manufacturing and seeking regulatory approval of our drug candidates, prexigebersen and BP1002. In addition, if we obtain regulatory approval of one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

We believe that our available cash at December 31, 2016 will be sufficient to fund our liquidity and capital expenditure requirements for at least the next 12 months. However, our future capital requirements may change and will depend on numerous factors, including:

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;
- the rate of progress, results and costs of completion of the ongoing preclinical trials of prexigebersen and BP1002;
- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical trials of our drug candidates that we may initiate;
- the costs to obtain adequate supply of the compounds necessary for our drug candidates;
- the costs of obtaining regulatory approval of our drug candidates;
- the scope, prioritization and number of drug development programs we pursue;
- the costs for preparing, filing, prosecuting, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies and the costs to develop those products and technologies;
- the costs of future commercializing activities, including product sales, marketing, manufacturing and distribution, of any of our drug candidates or other products for which marketing approval has been obtained;
- our ability to establish strategic collaborations and licensing or other arrangements on terms favorable to us; and
- competing technological and market developments.

There can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. If adequate funds are not available on a timely basis, we may be forced to:

- delay, reduce the scope of or eliminate one or more of our drug development programs;
- relinquish, license or otherwise dispose of rights to technologies, drug candidates or products that we would otherwise seek to develop or commercialize ourselves at an earlier stage or on terms that are less favorable than might otherwise be available; or

- liquidate and dissolve the Company.

If our operating plans change, we may require additional capital sooner than planned. Such additional financing may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan.

The pharmaceutical and biotechnology industry is highly competitive. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete.

We are engaged in segments of the pharmaceutical and biotechnology industry that are highly competitive and characterized by rapid and significant technological change. Many large pharmaceutical and biotechnology companies, academic and research institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target AML, CML, ALL, MDS, breast cancer and other cancer generally. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than our drug candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our drug candidates.

Many of our competitors have:

- significantly greater capital, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates;

- more experience in drug discovery, development and commercialization, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;

- drug candidates that have been approved or are in late-stage clinical development; and/or

- collaboration arrangements in our target markets with leading companies and research institutions.

Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel,

establishing clinical trial sites and patent registration for clinical trials, and acquiring technologies complementary to, or necessary for, our drug candidates and programs.

Competitive products and technological developments may render our drug candidates noncompetitive or obsolete before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of any vaccine for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for any of our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

Our plan to use collaboration arrangements to leverage our capabilities may not be successful.

As part of our business strategy, we may enter into collaborative arrangements for the development and commercialization of our drug candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also successfully enter into collaboration agreements with them on terms attractive to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do.

If we do enter into collaborative arrangements, the success of these collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Furthermore, we may face risks and uncertainties in connection with collaborative arrangements, including:

- inability to integrate the resources or capabilities of collaborators;
- collaborators may prove difficult to work with or less skilled than we originally expected;
- disputes may arise with respect to the ownership of rights to technology developed with collaborators;

- disagreements with collaborators could delay or terminate the research, development or commercialization of products or result in litigation or arbitration;

- difficulty enforcing our arrangements if one of our collaborators fails to perform;

- termination of our collaboration arrangements by collaborators, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;

- collaborators may have considerable discretion in electing whether to pursue the development of any additional drug candidates and may pursue technologies or products either on their own or in collaboration with our competitors that are similar to or competitive with our technologies; and

- collaborators may change the focus of their development and commercialization efforts.

If we are unsuccessful in our collaborative efforts, our ability to develop and market drug candidates could be severely limited.

If we are unable to attract and retain key management, scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.

Our success depends on the availability and contributions of members of our senior management team, scientific team and other key personnel. The loss of services of any of these individuals could delay, reduce or prevent our drug development and other business objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform drug development work will be critical to our success. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other public and private research institutions. We may be unable to attract and retain these individuals, and our failure to do so could materially adversely affect our business and financial condition.

Our employees, agents, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with applicable regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, advisors and commercial partners. Misconduct by these persons could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and

regulations intended 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, sales commission, customer incentive programs and other business arrangements. Such misconduct could involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our business, financial condition and reputation. We currently have codes of business conduct and ethics applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our codes of business conduct and ethics and the other precautions we take to detect and prevent improper activities 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could materially adversely affect our business and financial condition. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

We expect to expand our operations in the future and may face challenges in managing our growth, which may result in disruptions to our operations.

We expect to expand our operations over time. To successfully manage future growth, we may need to implement and improve our managerial, operational and financial resources, and may need to expand our facilities and recruit and train additional qualified personnel. Our expected growth may also require significant financial resources, which may not be available when needed or on terms favorable to us. Our senior management may be required to devote substantial attention to managing growth activities and may be unable to effectively manage the expansion of our operations due to our limited resources, which may result in disruptions to our business operations and could harm our business and financial condition.

If we acquire or license technologies, resources or drug candidates, we will incur a variety of costs and may never realize benefits from the transaction.

If appropriate opportunities become available, we may license or acquire technologies, resources, drugs or drug candidates. We may never realize the anticipated benefits of such a transaction. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the drug candidates we acquire. Future licenses or acquisitions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, the creation of contingent liabilities, material impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our business and financial condition.

Our business has a substantial risk of product liability claims. If we are unable to obtain or maintain appropriate levels of insurance, a product liability claim could adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. Product liability claims could delay or prevent completion of our clinical development programs**.** We currently have product liability insurance, but we may not be able to maintain such insurance on acceptable terms. However, even if we maintain or obtain other product liability insurance, our insurance may not provide adequate coverage against potential liabilities. As a result, we may be unable to obtain or maintain insurance coverage at a reasonable cost to protect against losses that could harm our business and financial condition. If any claims are brought against us, and we are not successful in defending ourselves, those claims could result in damage awards against us, which could materially adversely affect our business and financial condition. Whether or not we are successful in defending against such claims, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims.

We are increasingly dependent on information technology systems to operate our business and a cyber-attack or other breach of our systems, or those of third parties on whom we may rely, could subject us to liability or interrupt the operation of our business.

We are increasingly dependent on information technology systems to operate our business. A breakdown, invasion, corruption, destruction or interruption of critical information technology systems by employees, others with authorized access to our systems or unauthorized persons could negatively impact operations. In the ordinary course of business, we collect, store and transmit confidential information and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. Additionally, we outsource certain elements of our information technology systems to third parties. As a result of this outsourcing, our third party vendors may or could have access to our confidential information making such systems vulnerable. Data breaches of our information technology systems, or those of our third party vendors, may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. For example, the loss of clinical trial data from completed or ongoing clinical trials or preclinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we believe that we have taken appropriate security measures to protect our data and information technology systems, and have been informed by our third party vendors that they have as well, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems, or those of our third party vendors, that could materially adversely affect our business and financial condition.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), if a corporation experiences 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 utilize its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post- change taxable income or taxes may be limited. Our prior and potential future equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change under Section 382 of the Code. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

Provisions of our charter documents or Delaware law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult to change management.

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders might otherwise consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- limitations on our stockholders' ability to call special meetings of stockholders;
- an advance notice requirement for stockholder proposals and nominations for members of our Board;
- the authority of our Board to determine the number of director seats on our Board; and
- the authority of our Board to issue preferred stock with such terms as our Board may determine.

In addition, because we are governed by Delaware law, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Risks Relating to the Development of Our Drug Candidates

We must complete extensive clinical trials to demonstrate the safety and efficacy of our drug candidates. If we are unable to demonstrate the safety and efficacy of our drug candidates, we will not be successful.

To date, none of our drug candidates have been approved for sale in the United States or any foreign country. While antisense therapeutics have been in development for over 20 years, only two antisense drugs have been successfully developed to date. Further, development of liposomal antisense therapeutics, which comprise our drug therapeutics technology, has faced many challenges and generally remains unproven in the treatment of cancers. The success of our business depends primarily on our ability to develop and commercialize our drug candidates successfully. Our drug candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy testing of our drug candidates.

On February 9, 2015, we announced that we began enrollment into the combination therapy Phase Ib clinical trial for prexigebersen in patients with AML. The combination therapy Phase Ib clinical trial consisted of two dosing cohorts of prexigebersen (60 mg/m^2 and 90 mg/m^2) to test the safety profile of treating AML patients with prexigebersen in combination with LDAC. Patients ineligible for intensive induction therapy are currently treated only with LDAC. We recently announced the completion of the Phase Ib trial. Results from the Phase Ib clinical trial demonstrated it is safe to add prexigebersen, which appears to yield better response rates in this AML patient population. Following the safety portion, the trial is expected to be opened in multiple centers to test 54 patients with the combination. An interim analysis is expected to be performed after 19 patients have been treated with the combination therapy. On October 9, 2015, we announced the completion of Cohort 7, the first dosing cohort of the Phase Ib clinical trial, and on March 3, 2016, we announced the completion of Cohort 8, the second dosing cohort of the Phase Ib clinical trial. On June 6, 2016, we announced data from the safety segment of the Phase II combination therapy of prexigebersen and LDAC showed no dose limiting toxicities. On November 2, 2016, we announced that the first patient in the efficacy portion of the Phase II trial was dosed. In addition, (i) we are currently conducting preclinical studies on prexigebersen for TNBC and IBC and (ii) we plan to initiate two other Phase II clinical trials for prexigebersen in CML, among other things. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to move on to further efficacy segments of the Phase II or Phase III clinical trials or commence and complete any other clinical trials for any of our drug candidates. Positive results in preclinical studies of a drug candidate may not be predictive of similar results in human clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the preclinical trials or clinical trials for

our drug candidates may not be predictive of the results we may obtain in later stage trials. The failure of clinical trials to demonstrate safety and efficacy of one or more of our drug candidates will have a material adverse effect on our business and financial condition.

Delays in the commencement of clinical trials of our drug candidates could result in increased costs to us and delay our ability to generate revenues.

Our drug candidates will require continued extensive clinical trials prior to the submission of a regulatory application for commercial sales. Because of the nature of clinical trials, we do not know whether future planned clinical trials will begin on time, if at all. Delays in the commencement of clinical trials could significantly increase our drug development costs and delay any commercialization of our drug candidates. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a drug candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy in past clinical trials to obtain regulatory approval to commence a further clinical trial;
- convincing the FDA that we have selected valid endpoints for use in proposed clinical trials;
- reaching agreements on acceptable terms with prospective contract manufacturers for manufacturing sufficient quantities of our drug candidates; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Delays in the completion of, or the termination of, clinical trials of our drug candidates could result in increased costs to us, and could delay or prevent us from generating revenues.

Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

- regulators or institutional review boards may not authorize us to commence or conduct a clinical trial at a prospective trial site;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect may not be promising;
- we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we currently anticipate and we may lack adequate funding to continue the clinical trial;
- the timing of our clinical trials may be longer than we currently anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner (including delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials);
- inadequacy of or changes in our manufacturing process or compound formulation;

- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;

- the effects of our drug candidates may not be the desired effects or may include undesirable side effects or our drug candidates may have other unexpected characteristics;

- changes in applicable regulatory policies and regulations;

- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

- uncertainty regarding proper dosing;

- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise fail to perform their services in a timely or acceptable manner;

- scheduling conflicts with participating clinicians and clinical institutions;

- failure to construct appropriate clinical trial protocols;

- insufficient data to support regulatory approval;

- inability or unwillingness of medical investigators to follow our clinical protocols; and

- the timing of discussions and meetings with the FDA or other regulatory authorities regarding the scope or design of our clinical trials.

Many of these factors that may lead to a delay, suspension or termination of clinical trials of our drug candidates may also ultimately lead to denial of regulatory approval of our drug candidates. If we experience delays in the completion of, or termination of, clinical trials of any drug candidates in the future, our business, financial condition and the commercial prospects for our drug candidates could be materially adversely affected, and our ability to generate product revenues could be delayed or eliminated.

If we are unable to obtain United States and/or foreign regulatory approval, we will be unable to commercialize our drug candidates.

Our drug candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, record keeping, labeling, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of our drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing will obtain marketing approval. In connection with the clinical trials for our drug candidates, we face risks that:

- the drug candidate may not prove to be efficacious;
- the drug candidate may not prove to be safe;
- the drug candidate may not be readily co-administered or combined with other drugs or drug candidates;
- the results may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies; and
- the FDA or other regulatory agencies may require us to carry out additional studies.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and for the FDA and other countries' regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA regulatory review.

Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product and affect reimbursement by third-party payors. These limitations may limit the size of the market for the product. We may also become subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of foreign regulations. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a drug candidate, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of our products in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application, much like an IND, prior to the commencement of human clinical trials. In the E.U., for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under E.U. regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the E.U. by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The EMA implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the E.U. This procedure results in a single marketing authorization granted by the European Commission that is valid across the E.U., as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for certain human drugs including those that are: (i) derived from biotechnology processes, such as genetic engineering, or (ii) contain a new active substance indicated for the treatment of certain diseases.

Changes in existing laws and regulations affecting the healthcare industry could increase our costs and otherwise adversely affect our business.

Our research and development activities, preclinical studies and clinical trials, and the manufacturing, marketing and labeling of any products we may develop, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries. Changes in existing federal, state and foreign laws and agency regulations may be established that could prevent or delay regulatory approval of our drug candidates or materially increase our costs, including:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our drug candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign current cGMP that would make it more difficult for us to manufacture our drug candidates in accordance with cGMP.

Delays in obtaining or preventing our obtaining regulatory approval of our drug candidates could materially adversely affect our ability to commercialize any of our drug candidates and our ability to receive product revenues or to receive milestone payments or royalties from any product rights we might license to others.

We rely on third parties to conduct clinical trials for our drug candidates, and their failure to timely and properly perform their obligations may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our drug candidates.

We rely on independent contractors, including clinical research organizations, in certain areas that are particularly relevant to our research and drug development plans, such as for data management for the conduct of clinical trials. The competition for these relationships is intense, and we may not be able to maintain our relationships with them on acceptable terms. Independent contractors generally may terminate their engagements at any time, subject to notice. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time conducting research on and trials of our drug candidates and assisting in developing them. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these trials fail to comply with clinical trial protocols or fail to meet expected deadlines, our clinical trials may need to be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or excessive expenditures. If there are delays in testing or regulatory approvals as a result of the failure to perform by our

independent contractors or other outside parties, our drug candidate development costs will increase and we may not be able to attain regulatory approval for or successfully commercialize our drug candidates.

In addition, we have no control over the financial health of our independent contractors. Several of our independent contractors are in possession of valuable and sensitive information relating to the safety and efficacy of our drug candidates, and several others provide services to a significant percentage of the patients enrolled in our clinical trials in which such independent contractors participate. Should one or more of these independent contractors become insolvent, or otherwise are not able to continue to provide services to us, the clinical trial in which such contractor participates could become significantly delayed and we may be materially adversely affected as a result of the delays and additional expenses associated with such event.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.

Prexigebersen has received orphan drug designations for the treatment of CML in the United States. Orphan designation is available to drugs intended to treat, diagnose or prevent a rare disease or condition that affects fewer than 200,000 people in the United States at the time of application for orphan designation. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan designation qualifies the sponsor of the product for a tax credit and marketing incentives. The first sponsor to receive FDA marketing approval for a drug with an orphan designation is entitled to a seven-year exclusive marketing period in the United States for that product for that indication and, typically, a waiver of the prescription drug user fee for its marketing application. However, a drug that the FDA considers to be clinically superior to, or different from, the approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. Orphan drug exclusive marketing rights may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug.

In October 2016, prexigebersen also received orphan drug designation for AML in the E.U. from the EMA. To receive orphan drug designation from the EMA, a therapy must be intended for the treatment of a life-threatening or chronically debilitating rare condition with a prevalence of less than five in 10,000 in the E.U. Orphan drug designation provides incentives designed to facilitate development, including fee reductions for protocol assistance, scientific advice and importantly, may provide up to ten years of market exclusivity in the E.U. following product approval.

There is no guarantee that any of our other drug candidates will receive orphan drug designation or that, even if such drug candidate is granted such status, the drug candidate's clinical development and regulatory approval process will not be delayed or will be successful.

Risks Related to Manufacturing Our Drug Candidates

We rely on third parties for manufacturing of our clinical drug supplies; our dependence on these manufacturers may impair the development of our drug candidates.

We have no ability to internally manufacture the drug candidates that we need to conduct our clinical trials. For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of our drug candidates and any future drug candidates for use in our clinical trials. We have entered into agreements with our third-party manufacturer for the manufacture of our drug requirements, including an agreement for the manufacture of prexigebersen for use in our Phase II clinical trial and a development agreement for BP1002. To date, we have made steady progress with our current third-party manufacturers, overcoming challenges associated with scaling up manufacturing to develop their capabilities to supply us with our necessary quantities of drug supplies for our clinical trials. However, we may face various risks and uncertainties in connection with our reliance on third-party manufacturers, including:

- reliance on third-party manufactures for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third-party manufacturer because of factors beyond our control;
- the possibility of termination or nonrenewal of our manufacturing agreement by the third-party manufacturer at a time that is costly or inconvenient for us;
- the potential that third-party manufacturers will develop know-how owned by such third-party manufacturer in connection with the production of our drug candidates that is necessary for the manufacture of our drug candidates; and
-

reliance on third-party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

Our drug candidates are complicated and expensive to manufacture. If our third-party manufacturers fail to deliver our drug candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development of our drug candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these drug candidates, this process would likely cause a delay in the availability of our drug candidates and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our drug candidates can be manufactured, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available drug candidates.

We may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

There are underlying risks associated with the manufacture of our drug candidates, which have never been manufactured in large scale. Furthermore, we anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA or other regulatory agencies for any of our drug candidates.

To date, our drug candidates have been manufactured in relatively small quantities for preclinical testing and clinical trials by third-party manufacturers, and have never been manufactured in large scale. Additionally, as in the development of any new compound, there are underlying risks associated with their manufacture. These risks include, but are not limited to, cost, process scale-up, process reproducibility, construction of a suitable process plant, timely availability of raw materials, as well as regulatory issues associated with the manufacture of an active pharmaceutical agent. Any of these risks may prevent us from successfully developing our drug candidates. Our failure, or the failure of our third-party manufacturers to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors and reliable product packaging for diverse environmental conditions, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could materially adversely affect our business and financial condition.

If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of such approved drug candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any of our approved drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA or other regulatory authorities must review and approve. If our third-party manufacturers are unable to successfully increase the manufacturing capacity for a drug candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

Identification of previously unknown problems with respect to a drug candidate, manufacturer or facility may result in restrictions on the drug candidate, manufacturer or facility.

The FDA stringently applies regulatory standards for the manufacturing of our drug candidates. Identification of previously unknown problems with respect to a drug candidate, manufacturer or facility may result in restrictions on the drug candidate, manufacturer or facility, including warning letters, suspensions of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, product recalls, fines, injunctions and criminal prosecution. Any of the foregoing could have a material adverse effect on our business and financial condition.

We may experience delays in the development of our drug candidates if the third-party manufacturers of our drug candidates cannot meet FDA requirements relating to current Good Manufacturing Practices.

Our third-party manufacturers are required to produce our drug candidates under FDA cGMP in order to meet acceptable standards for our preclinical testing and clinical trials. If such standards change, the ability of third-party manufacturers to produce our drug candidates on the schedule we require for our preclinical tests and clinical trials may be affected. In addition, third-party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to gain approval for or commercialize our drug candidates. Any difficulties or delays in the manufacturing and supply of our drug candidates could increase our costs or cause us to lose revenue or postpone or cancel clinical trials.

The FDA also requires that we demonstrate structural and functional comparability between the same drug candidate produced by different third-party manufacturers. Because we may use multiple sources to manufacture our drug candidates, we may need to conduct comparability studies to assess whether manufacturing changes have affected the safety, identity, purity or potency of any drug candidate compared to the drug candidate produced by another manufacturer. If we are unable to demonstrate comparability, the FDA could require us to conduct additional clinical trials, which would be expensive and significantly delay commercialization of our drug candidates.

Risks Related to Commercialization

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not generate product revenue.

We have no commercial products, and we do not currently have an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drug candidates that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty sales force that calls on a limited but focused group of physicians, we may commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population, we may enter into arrangements with other companies for commercialization. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

If our future drugs do not achieve market acceptance, we may be unable to generate significant revenue, if any.

Even if our drug candidates obtain regulatory approval, they may not gain market acceptance among physicians, health care payors, patients and the medical community. Factors that we believe could materially affect market acceptance of our drug candidates include:

- the timing of market introduction of competitive drugs;
- the demonstrated clinical safety and efficacy of our drug candidates compared to other drugs and other drug candidates;

- the suitability of our drug candidates to be co-administered or combined with other drugs or drug candidates;
- the durability of our drug candidates in their ability to prevent the emergence of drug-resistant viral mutants;
- the convenience and ease of administration of our drug candidates;
- the existence, prevalence and severity of adverse side effects;
- other potential advantages of alternative treatment methods;
- the effectiveness of marketing and distribution support;
- the cost-effectiveness of our drug candidates; and
- the availability of reimbursement from managed care plans, the government and other third-party payors.

If our approved drug candidates fail to achieve market acceptance, we would not be able to generate significant revenue. In addition, even if our approved drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete;
- unforeseen complications arise with respect to the use of our products; or
- sufficient third-party insurance coverage or reimbursement does not remain available.

If third-party payors do not adequately reimburse patients for any of our drug candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.

Our revenues and profits will depend significantly upon the availability of adequate reimbursement for the use of any approved drug candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third party may depend upon a number of factors, including the third-party payor’s determination that use of an approved drug candidate is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;

- cost effective; and

- neither experimental nor investigational.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic and diagnostic products vary widely from country to country. Some countries require approval of the sale price of a drug candidate before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the approved drug and negatively impact the revenues we are able to generate from the sale of the approved drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval.

Obtaining reimbursement approval for an approved drug from each third-party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of any approved drug candidates to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any approved drug incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage does not imply that any approved drug will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the approved drugs and the clinical setting in which it is used, may be based on payments allowed for lower-cost products or combinations of products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

In the United States, at both the federal and state levels, the government regularly proposes legislation to reform health care and its cost, and such proposals have received increasing political attention. In 2010, Congress passed legislation to reform the U.S. health care system by expanding health insurance coverage, reducing health care costs and making other changes. While health care reform may increase the number of patients who have insurance coverage for the use of any approved drug, it may also include changes that adversely affect reimbursement for approved drugs. In addition, there has been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our drug candidates that obtain approval. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for any of our drug candidates that obtain approval could have a material adverse effect on our business and financial condition.

Risks Related to Intellectual Property

If our patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business.

We have an exclusive license with MD Anderson to several issued patents and other certain technology rights. We have also filed two pending patent applications in the United States that cover the manufacturing method, formulation and antisense composition for new targets in preclinical development. Our success depends in large part on our ability to obtain and maintain patent protection both in the United States and in other countries for our drug candidates. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our drug candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us.

Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be

commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the United States Patent and Trademark Office (the "USPTO") for the entire time prior to issuance as a United States patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications on, our drug candidates. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our United States patent position. Furthermore, we may not have identified all United States and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

The claims of the issued patents that are licensed to us, and the claims of any patents which may issue in the future and be owned by or licensed to us, may not confer on us significant commercial protection against competing products. Additionally, our patents may be challenged by third parties, resulting in the patent being deemed invalid, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different molecule, our patents may not prevent others from directly competing with us.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

Because of the extensive time required for development, testing and regulatory review of a drug candidate, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization of our drug candidates, thereby reducing any advantages of the patent. To the extent our drug candidates based on that technology are not commercialized significantly ahead of the date of any applicable patent, or to the extent we have no other patent protection on such drug candidates, those drug candidates would not be protected by patents, and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the FDCA or trade secret protection.

The Leahy-Smith America Invents Act (the "America Invents Act") was signed into law in September 2011, and many of the substantive changes became effective in March 2013. The America Invents Act reforms United States patent law in part by changing the standard for patent approval from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 2013.

We license patent rights from MD Anderson. If MD Anderson or any third-party owners of intellectual property we may license in the future do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

We are party to an exclusive license with MD Anderson that gives us rights to intellectual property that is necessary or useful for our business. We may enter into additional licenses for third-party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. If applicable, our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of any such patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could materially adversely affect our competitive business position, business prospects and financial condition.

Because our research and development of drug candidates incorporates compounds and other information that is the intellectual property of third parties, we depend on continued access to such intellectual property to conduct and complete our preclinical and clinical research and commercialize the drug candidates that result from this research. Our license with MD Anderson imposes, and we expect that future licenses would impose, numerous obligations on us. For example, under our existing and future license agreements, we may be required to pay (i) annual maintenance fees until a drug candidate is sold for the first time, (ii) running royalties on net sales of drug candidates, (iii) minimum annual royalties after a drug candidate is sold for the first time, and (iv) one-time payments upon the achievement of specified milestones. We may also be required to reimburse patent costs incurred by the licensor, or we may be obligated to pay additional royalties, at specified rates, based on net sales of our drug candidates that incorporate the licensed intellectual property rights. We may also be obligated under some of these agreements to pay a percentage of any future sublicensing revenues that we may receive. Future license agreements may also include

payment obligations such as milestone payments or minimum expenditures for research and development. In addition to our payment obligations under our license with MD Anderson, we are required to comply with reporting, insurance and indemnification requirements under the License Agreement. We expect that any future licenses would contain similar requirements.

If we fail to comply with these obligations or otherwise breach our license agreement with MD Anderson, the licensor may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any approved drug candidate that is covered by the licensed intellectual property. Even if we contest any such termination or claim and are ultimately successful, our financial results and stock price could suffer. In addition, upon any termination of the License Agreement with MD Anderson, we may be required to grant to the licensor a license to any related intellectual property that we developed. For example, the licensors have the right to terminate our license of the intellectual property covered by its licenses to us under certain circumstances, including our failure to make payments to the licensor when due and our uncured breach of any other terms of the licenses. If access to such intellectual property is terminated, or becomes more expensive as a result of renegotiation of our existing license agreement with MD Anderson, our ability to continue development of our drug candidates or the successful commercialization of our drug candidates could be severely compromised and our business could be adversely affected.

Certain patents under the License Agreement are set to expire over the next few years.

Under the License Agreement, we license rights to certain patents that are necessary or useful for our business. Some of these material patents are set to expire as early as 2017. We have filed two pending patent applications in the United States and are actively reviewing and preparing additional patent applications to expand our patent portfolio, but there can be no assurances that patents related to these applications or any applications we may file in the future will be issued or that any issued patents will provide meaningful protection for our drug candidates, which could materially adversely affect our competitive business position, business prospects and financial condition.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities, including any drug candidates resulting from these activities, may infringe or be claimed to infringe patents or other proprietary rights owned by third parties and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, if issued, could be asserted against us. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development or manufacturing of drug candidate that is the subject of the suit. Further, if we are found to have infringed a third- party patent, we could be obligated to pay royalties and/or other payments to the third party related to our drug candidates, which may be substantial, or we could be enjoined from selling our drug candidates that obtain approval.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the USPTO and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our drug candidates and technology. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business and financial condition.

Litigation regarding patents, intellectual property and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents. Under the License Agreement with MD Anderson we are responsible to enforce any patent exclusively licensed thereunder against substantial infringement by third parties. If we fail to enforce a substantial infringement, within a specified number of days, the licensor may bring an action against the infringing party on the licensor's and our behalf and retain all recoveries and/or reduce the license granted under the License Agreement to non-exclusive for the technology infringed. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our drug candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our drug candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our drug candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could materially adversely affect our business and financial condition.

Risks Related to Our Securities

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights. Additionally, sales of a substantial number of shares of our common stock or other securities in the public market could cause our stock price to fall.

We may seek the additional capital necessary to fund our operations through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interests will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us. In addition, sales of a substantial number of shares of our common stock or other securities in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

The trading price of our common stock has been volatile and is likely to be volatile in the future.

The trading price of our common stock has been highly volatile. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on The NASDAQ Capital Market, and there is a limited history on which to gauge the volatility of our stock price on The NASDAQ Capital Market. Since January 1, 2015 through December 31, 2016, our stock price has fluctuated from a low of $0.95 to a high of $3.19. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory approvals of our drug candidates or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other drug development milestones;
- the ability of our drug candidates, if they receive regulatory approval, to achieve market success;
- the performance of third-party manufacturers and suppliers;
- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;

- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates;
- trading volume of our common stock;
- investor perceptions about us and our industry;
- public reaction to our press releases, other public announcements and SEC and other filings;
- the failure of analysts to cover us, or changes in analysts' estimates or recommendations;
- the failure by us to meet analysts' projections or guidance;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors; and
- the other factors described elsewhere in this "Item 1A. Risk Factors" or the section titled "Risk Factors" contained in our other public filings.

The stock prices of many companies in the biotechnology industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company's securities, securities class action litigation often has been initiated against a company. If any class action litigation is initiated against us, we may incur substantial costs and our management's attention may be diverted from our operations, which could materially adversely affect our business and financial condition.

Our common stock is thinly traded and in the future may continue to be thinly traded, and our stockholders may be unable to sell at or near asking prices or at all if they need to sell their shares to raise money or otherwise desire to liquidate such shares.

To date, we have a low volume of daily trades in our common stock on The NASDAQ Capital Market. Our stockholders may be unable to sell their common stock at or near their asking prices or at all, which may result in substantial losses to our stockholders.

The market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the foreseeable future. As noted above, our common stock may be sporadically and/or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction.

Our certificate of incorporation grants our Board of Directors the power to designate and issue additional shares of common and/or preferred stock.

Our authorized capital consists of 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. Our preferred stock may be designated into series pursuant to authority granted by our certificate of incorporation, and on approval from our Board of Directors (the "Board"). The Board, without any action by our stockholders, may designate and issue shares in such classes or series as the Board deems appropriate and establish the rights, preferences and privileges of such shares, including dividends, liquidation and voting rights. The rights of holders of other classes or series of stock that may be issued could be superior to the rights of holders of our common shares. The designation and issuance of shares of capital stock having preferential rights could adversely affect other rights appurtenant to shares of our common stock.

We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us.

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders.

Our management is required to devote substantial time and incur additional expense to comply with public company regulations. Our failure to comply with such regulations could subject us to public investigations, fines, enforcement actions and other sanctions by regulatory agencies and authorities and, as a result, our stock price could decline in value.

As a public reporting company, we are subject to the Sarbanes-Oxley Act of 2002, as well as to the information and reporting requirements of the SEC and other federal securities laws. We are also subject to the rules of The NASDAQ Stock Market. As a result, we incur significant legal, accounting, and other expenses that we would not incur as a private company, including costs associated with our public company reporting requirements and corporate governance requirements. Compliance with these public company obligations places significant additional demands on our limited number of finance and accounting staff and on our financial, accounting and information systems.

In particular, as a public company, our management is required to conduct an annual evaluation of our internal controls over financial reporting and include a report of management on our internal controls in our Annual Reports on Form 10-K. If we are unable to continue to conclude that we have effective internal controls over financial reporting or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

Our common stock may be delisted from The NASDAQ Capital Market which could negatively impact the price of our common stock and our ability to access the capital markets.

The listing standards of The NASDAQ Capital Market provide that a company, in order to qualify for continued listing, must maintain a minimum stock price of $1.00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. If we fail to comply with all listing standards applicable to issuers listed on The NASDAQ Capital Market, our common stock may be delisted. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital. Delisting from The NASDAQ Capital Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease approximately 3,000 square feet of office space for general and administrative purposes in Bellaire, Texas, which is part of the Houston metropolitan area, under a lease agreement that expires on July 31, 2019.

In April 2016, we entered into a lease agreement for approximately 2,100 square feet of lab space located in Bellaire, Texas for research and development purposes. The term of lease began on May 1, 2016 and terminates on April 30, 2019.

We do not own or lease any other real property that is materially important to our business. We believe that our current facilities are adequate for our current needs and that additional space will be available when and as needed.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is listed on The NASDAQ Capital Market under the symbol "BPTH." The following table sets forth the high and low sale prices per share for our common stock, as reported on The NASDAQ Capital Market for the periods indicated:

	High	Low
Fiscal Year Ended December 31, 2015		
First Fiscal Quarter	$2.69	$1.60
Second Fiscal Quarter	$2.03	$0.99
Third Fiscal Quarter	$1.44	$1.00
Fourth Fiscal Quarter	$2.00	$1.11
Fiscal Year Ended December 31, 2016		
First Fiscal Quarter	$2.68	$1.24
Second Fiscal Quarter	$3.19	$1.86
Third Fiscal Quarter	$1.99	$1.25
Fourth Fiscal Quarter	$1.50	$0.95

Holders

As of March 1, 2017, there were 95,645,224 shares of our common stock outstanding and approximately 280 stockholders of record.

Dividends

We have not paid any cash dividends since our inception and do not anticipate or contemplate paying dividends in the foreseeable future.

Performance Graph

The following performance graph and related information shall not be deemed to be “soliciting material” or to be “filed” with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following performance graph compares the cumulative total return on our common stock during the last five fiscal years with the NASDAQ Composite Index (U.S.) and the NASDAQ Biotechnology Index during the same period. The graph shows the value at the end of each of the last five fiscal years, of $100 invested in our common stock. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The statement of operations data for the years ended December 31, 2016, 2015 and 2014, and the balance sheet data as of December 31, 2016 and 2015, have been derived from our financial statements included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2013 and 2012, and the balance sheet data as of December 31, 2014, 2013 and 2012 have been derived from our financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of results to be expected for any future period. The data presented below have been derived from financial statements that have been prepared in accordance with accounting principles generally accepted in the United States of America and should be read with our financial statements, including notes, and with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

Statements of Operations Data	2016	2015	2014	2013	2012
	(in thousands, except per share amounts)				
Revenues and Other Income:					
Revenue	$13	$—	$—	$—	$—
Other income	1,725	18	23	4	1
Total revenues and other income	1,738	18	23	4	1
Expenses:					
Research and development	5,474	3,020	1,630	1,519	1,133
Research and development – related party	—	—	197	116	464
General and administrative	3,014	2,465	2,715	1,634	986
Other expense	—	—	—	1	1
Total expenses	8,488	5,485	4,542	3,270	2,584
Net loss	$(6,750)	$(5,467)	$(4,519)	$(3,266)	$(2,583)
Net loss per share – basic and diluted	$(0.07)	$(0.06)	$(0.05)	$(0.05)	$(0.04)
Basic and diluted weighted average number of common shares outstanding	92,704	89,763	89,282	71,373	59,318
Balance Sheet Data					
Cash, cash equivalents	$9,375	$8,854	$13,859	$3,552	$534
Other current assets	1,278	739	255	115	238
Total assets	12,196	10,755	15,478	5,079	2,344
Total liabilities	3,956	937	562	295	329
Accumulated deficit	(32,134)	(25,384)	(19,917)	(15,398)	(12,131)
Total stockholders' equity	$8,240	$9,818	$14,917	$4,783	$2,015

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements that involve significant risks and uncertainties, which may cause our actual results to differ materially from plans and results discussed in forward-looking statements. We encourage you to review the risks and uncertainties, discussed in "Item 1A. Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements," included elsewhere in this Annual Report on Form 10-K. The risks and uncertainties can cause actual results to differ significantly from those forecasted in forward-looking statements or implied in historical results and trends.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical and preclinical stage oncology focused antisense drug development company utilizing a novel technology that achieves systemic delivery for target specific protein inhibition for any gene product that is over-expressed in disease. Our drug delivery and antisense technology, called DNAbilize™, is a platform that uses P-ethoxy, which is a DNA backbone modification that is intended to protect the DNA from destruction by the body's enzymes when circulating *in vivo,* incorporated inside of a neutral charged lipid bilayer. We believe this combination allows for high efficiency loading of antisense DNA into non-toxic, cell-membrane-like structures for delivery of the antisense drug substance into cells. *In vivo,* the DNAbilize™ delivered antisense drug substances are systemically distributed throughout the body to allow for reduction or elimination of proteins in blood diseases and solid tumors.

Using DNAbilize™ as a platform for drug manufacturing, we currently have two antisense drug candidates in development to treat a total of five different disease indications. Our lead drug candidate, prexigebersen, the unique nonproprietary (generic) drug name for BP1001 designated by the United States Adopted Names Council, targets the protein Grb2 and has entered the efficacy portion of Phase II clinical trials for AML and is preparing to enter the safety segment of a Phase II clinical trial for blast phase and accelerated phase CML. Prexigebersen is also in preclinical studies for solid tumors, including ovarian and breast cancer.

Our second drug candidate, BP1002, targets the protein Bcl2, which is responsible for driving cell proliferation in up to 60% of all cancers. BP1002 is in preparation for an IND application and expected to begin a Phase I clinical trial for lymphoma in 2017.

We currently maintain the License Agreement with MD Anderson, under which we license from MD Anderson the delivery technology platform and prexigebersen and BP1002. We are developing antisense drug candidates to treat cancer and autoimmune disorders where targeting a single protein may be advantageous and result in reduced adverse effects as compared to small molecule inhibitors with off-target and non-specific effects. We have composition of matter and method of use intellectual property for the manufacture of neutral charged DNA-liposome complexes.

As of December 31, 2016, we had an accumulated deficit of $32.1 million. Our net loss was $6.8 million, $5.5 million and $4.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. We expect to continue to incur significant operating losses and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts. To achieve profitability, we must enter into license or development agreements with third parties, or successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. In addition, if we obtain regulatory approval for one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. There can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability.

Financial Operations Overview

Revenue

We have not generated significant revenues to date. Our ability to generate revenues from our drug candidates, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our drug candidates.

During 2016, the Company entered into a fixed fee service agreement with a preclinical stage biotechnology company in connection with a development project involving our DNAbilize™ technology, pursuant to which we agreed to perform certain evaluation services in exchange for $50,000. As of December 31, 2016, the Company has recorded $13,000 in revenue under the agreement. Payments received prior to the Company’s performance of work are recorded as deferred revenue and recognized as revenue once the work is performed.

In the future, we may generate revenue from a combination of product sales, third-party grants, service agreements, strategic alliances and licensing arrangements. We expect that any revenue we generate will fluctuate due to the timing and amount of services performed, milestones achieved, license fees earned and payments received upon the eventual sales of our drug candidates, in the event any are successfully commercialized. If we fail to complete the development of any of our drug candidates or obtain regulatory approval for them, our ability to generate future

revenue will be adversely affected.

Research and development expenses

Research and development expenses consist of costs associated with our research activities, including the development of our drug candidates. Our research and development expenses consist of:

- expenses related to research and development personnel, including salaries and benefits, travel and stock-based compensation;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, clinical investigative sites, laboratories, manufacturing organizations and consultants;
- license fees, including maintenance fees and patent expense paid to MD Anderson in connection with the License Agreement; and
- costs of materials used during research and development activities.

Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with generally accepted accounting policies ("GAAP"). Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

We expect research and development expenses associated with the completion of the associated clinical trials to be substantial and to increase over time. The successful development of our drug candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our drug candidates or the period, if any, in which material net cash inflows from our drug candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;
- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical trials of our drug candidates that we may initiate;

- competing technological and market developments;

- the performance of third-party manufacturers and suppliers;

- the ability of our drug candidates, if they receive regulatory approval, to achieve market success; and

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a drug candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses.

Results of Operations

Comparisons of the Year Ended December 31, 2016 to the Year Ended December 31, 2015

Revenue. Our revenue was $13,000 for the year ended December 31, 2016. We had no revenue in the year ended December 31, 2015. The increase in revenue represents revenue that has been recorded pursuant to a fixed fee service agreement with a preclinical stage biotechnology company in connection with a development project involving our DNAbilize™ technology, pursuant to which we agreed to perform certain evaluation services in exchange for $50,000. Payments received prior to the Company's performance of work are recorded as deferred revenue and recognized as revenue once the work is performed.

Research and Development Expenses. Our research and development expense was $5.5 million for the year ended December 31, 2016, an increase of $2.5 million compared to the year ended December 31, 2015. The increase in research and development expense was primarily due to the release of drug material for our Phase II clinical trial for prexigebersen in AML and associated clinical trial costs as well as increased salaries and benefits expense. The following table sets forth our research and development expenses (in thousands):

	Year ended December 31,	
	2016	2015
Research and development expense	$5,115	$2,886
Non-cash stock-based compensation expense	359	134
Total research and development expense	$5,474	$3,020

General and Administrative Expenses. Our general and administrative expense was $3.0 million for the year ended December 31, 2016, an increase of $0.5 million compared to the year ended December 31, 2015. The increase in general and administrative expense was primarily due to increased third party fees related to corporate communications, stock-based compensation expense and salaries and benefits expense. The following table sets forth our general and administrative expenses (in thousands):

	Year ended December 31,	
	2016	2015
General and administrative expense	$2,589	$2,230
Non-cash stock-based compensation expense	425	235
Total general and administrative expense	$3,014	$2,465

Net Operating Loss. Our net loss from operations was $8.5 million for the year ended December 31, 2016, an increase of $3.0 million compared to the year ended December 31, 2015.

Change in Fair Value of Warrant Liability. The change in fair value of the warrant liability for the year ended December 31, 2016 resulted in non-cash income of $1.7 million.

Net Loss. Our net loss was $6.8 million for the year ended December 31, 2016, an increase of $1.3 million compared the year ended December 31, 2015. Net loss per share, both basic and diluted, was $0.07 per share for the year ended December 31, 2016 compared to $0.06 per share for the year ended December 31, 2015.

Comparisons of the Year Ended December 31, 2015 to the Year Ended December 31, 2014

Research and Development Expenses. Our research and development expense was $3.0 million for the year ended December 31, 2015, an increase of $1.2 million compared to the year ended December 31, 2014. The increase in research and development expense was primarily due to increased clinical trial expenses, manufacturing development, preclinical studies and personnel costs associated with the addition of our support staff hired in the second half of 2014. These were partially offset by a decrease in drug material used in 2015. Research and development – related party expense has been consolidated with research and development expense on our financial statements in 2015 as MD Anderson is no longer a greater than 5% stockholder in the Company. The following table sets forth our research and development expenses (in thousands):

	Year ended December 31,	
	2015	2014
Research and development expense	$2,886	$1,548
Research and development - related party expense	—	197
Non-cash stock-based compensation expense	134	83
Total research and development expense	$3,020	$1,828

General and Administrative Expenses. Our general and administrative expense was $2.5 million for the year ended December 31, 2015, a decrease of $0.3 million compared to the year ended December 31, 2014. The decrease in general and administrative expense was primarily due to decreased management and administrative personnel costs. The following table sets forth our general and administrative expenses (in thousands):

	Year ended December 31,	
	2015	2014
General and administrative expense	$2,230	$2,394
Non-cash stock-based compensation expense	235	321
Total general and administrative expense	$2,465	$2,715

Net Loss. Our net loss was $5.5 million for the year ended December 31, 2015, an increase of $0.9 million compared the year ended December 31, 2014. Net loss per share, both basic and diluted, was $0.06 per share for the year ended December 31, 2015 compared to $0.05 per share for the year ended December 31, 2014.

Liquidity and Capital Resources

Overview

We have not generated significant revenues to date. Since our inception, we have funded our operations primarily through public and private offerings of our capital stock and other securities. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations, debt financings and public or private equity offerings. Additionally, we may seek collaborations and license arrangements for our drug candidates. We may seek to access the public or private equity markets whenever conditions are favorable. We currently have no lines of credit or other arranged access to debt financing.

We had a cash balance of $9.4 million at December 31, 2016, an increase of $0.5 million compared to December 31, 2015. We believe that our available cash at December 31, 2016 will be sufficient to fund our liquidity and capital expenditure requirements for at least the next 12 months.

Cash Flows

For the Year Ended December 31, 2016

Operating Activities. Net cash used in operating activities for the year ended December 31, 2016 was $8.1 million. Net cash used in operating activities consisted primarily of the net loss for the period of $6.8 million, a non-cash decrease in fair value of the warrant liability of $1.7 million, an increase in other current assets of $0.7 million and a decrease in current liabilities of $0.1 million. These were partially offset by non-cash stock-based compensation expense of $0.8 million, a decrease in prepaid drug product for testing of $0.2 million and technology license amortization expense of $0.2 million.

Investing Activities. Net cash used in investing activities for the year ended December 31, 2016 consisted of capital expenditures totaling $0.3 million which were primarily related to equipment purchases for our new research and development laboratory.

Financing Activities. Net cash provided by financing activities for the year ended December 31, 2016 was $9.0 million. Net cash provided by financing activities consisted of net proceeds of $9.3 million from the registered direct offering described below, which closed on July 5, 2016. These proceeds were partially offset by additional financing costs incurred during the period of $0.3 million.

For the Year Ended December 31, 2015

Operating Activities. Net cash used in operating activities for the year ended December 31, 2015 was $5.0 million. Net cash used in operating activities for the year ended December 31, 2015 consisted primarily of the net loss for the period of $5.5 million, an increase in prepaid drug product for testing of $0.4 million and an increase in other current assets of $0.1 million. These are partially offset by a net increase in current liabilities of $0.4 million, non-cash stock-based compensation expense of $0.4 million and technology license amortization expense of $0.2 million.

2014 and 2017 Shelf Registration Statements

On November 5, 2013, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on January 13, 2014 (the "2014 Shelf Registration Statement"). The 2014 Shelf Registration Statement was filed to register the offering and sale of up to $100.0 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units. On December 20, 2016, we filed a shelf registration on Form S-3 with the SEC, which was declared effective by the SEC on January 9, 2017 (the "2017 Shelf Registration Statement"), at which time the offering of unsold securities under 2014 Shelf Registration Statement was deemed terminated pursuant to Rule 415(a)(6) under the Securities Act. The 2017 Registration Statement was filed to register the offering, issuance and sale of (i) up to $125.0 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units, including offers and sales of our common stock under the Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") described below and (ii) up to 5,441,176 shares of our common stock pursuant to the exercise of warrants that were issued in the 2014 Registered Direct Offering and the 2016 Registered Direct Offering, each as described below. The foregoing does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

2014 Registered Direct Offering

On January 15, 2014, we entered into a securities purchase agreement, as amended, with certain investors, pursuant to which we agreed to sell an aggregate of 5.0 million shares of our common stock and warrants to purchase a total of 2.5 million shares of our common stock to such certain investors for gross proceeds of approximately $15.0 million under the 2014 Shelf Registration Statement (the "2014 Registered Direct Offering"). The 2014 Registered Direct Offering closed on January 21, 2014. The net proceeds to the Company from the 2014 Registered Direct Offering, after deducting the placement agent's fees and expenses, our estimated offering expenses, and excluding any potential future proceeds from the exercise of the warrants issued in the offering, were approximately $13.8 million.

"At the Market" Offering

On June 24, 2015, we entered into the Sales Agreement with Cantor Fitzgerald, as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald shares of our common stock. Sales of shares of common stock under the Sales Agreement will be made pursuant to the 2017 Shelf Registration Statement and a related prospectus filed with the SEC on January 10, 2017, for an aggregate offering price of up to $25.0 million. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act. We will pay Cantor Fitzgerald a commission of 3.4% of the aggregate gross proceeds from each sale of shares under the Sales Agreement and have agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. We have also agreed to reimburse Cantor Fitzgerald for certain

specified expenses. Pursuant to the Securities Purchase Agreement described below, we are subject to certain restrictions on our ability to offer and sell shares of our common stock under the Sales Agreement. As of December 31, 2016, we have not offered or sold any shares of common stock under the Sales Agreement.

2016 Registered Direct Offering

On June 29, 2016, we entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain healthcare focused institutional investors pursuant to which we agreed to sell an aggregate of 5,882,352 shares of our common stock and warrants to purchase up to 2,941,176 shares of our common stock for gross proceeds of approximately $10.0 million under the 2014 Registration Statement (the "2016 Registered Direct Offering"). The 2016 Registered Direct Offering closed on July 5, 2016. The net proceeds to the Company from the 2016 Registered Direct Offering, after deducting the placement agent's fees and expenses and our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offering, were approximately $9.3 million. For more information, see Note 1 to the consolidated financial statements included herein.

Future Capital Requirements

We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials, manufacturing and seeking regulatory approval of our drug candidates, prexigebersen and BP1002. Accordingly, we will continue to require substantial additional capital to fund our projected operating requirements. Such additional capital may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan. There can be no assurance that we will be able to continue to raise additional capital through the sale of our securities in the future. Our future capital requirements may change and will depend on numerous factors, which are discussed in detail in "Item 1A. Risk Factors" of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

As of December 31, 2016, we did not have any material off-balance sheet arrangements.

Contractual Obligations and Commitments

The following table sets forth a summary of our commitments as of December 31, 2016 (in thousands):

	Payment Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Leases[1][2]	$291	$ 114	$ 177	$ —	$ —
Technology License Maintenance Agreement	200	100	100	—	—
Total	$491	$ 214	$ 277	$ —	$ —

(1) In April 2014, we entered into a lease for a larger office space, which we occupied as of August 2014. The remaining lease payments due under this lease as of December 31, 2016 are $0.2 million.

(2) In April 2016, the Company entered into a three-year lease agreement for lab space located in Bellaire, Texas. The term of lease began on May 1, 2016 and terminates on April 30, 2019. The remaining lease payments due under this lease as of December 31, 2016 are $0.1 million.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in conformity with GAAP in the United States. The preparation of such financial statements has required our management to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. We consider our critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements, including the following:

Principles of Consolidation — The consolidated financial statements include the accounts of Bio-Path Holdings, Inc., and its wholly-owned subsidiary Bio-Path, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

Concentration of Credit Risk — Financial instruments that potentially subject us to a significant concentration of credit risk consist of cash. The Company maintains its cash balances with one major commercial bank, JPMorgan

Chase Bank. The balances are insured by the Federal Deposit Insurance Corporation (the "FDIC") up to $250,000. As a result, as of December 31, 2016, $9.1 million of our cash balances was not covered by the FDIC. As of December 31, 2015 we had $8.9 million in cash on-hand, of which approximately $8.6 million was not covered by the FDIC.

Long Lived Assets — Our long lived assets consist of furniture, fixtures and equipment, and a technology license. Long lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the asset is measured by a comparison of the asset's carrying amount to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Intangible Assets/Impairment of Long-Lived Assets — As of December 31, 2016, other assets totaled $0.9 million for our technology license, comprised of $2.5 million in value acquiring our technology license and our intellectual property, less accumulated amortization of $1.6 million. The technology value consists of $0.8 million in cash paid to MD Anderson, plus 3.1 million shares of common stock granted to MD Anderson valued at $2.4 million less $0.7 million for impairment expense taken in December of 2011 and June of 2012. This value is being amortized over a 15-year period from November 7, 2007, the date that the technology license became effective. Long-lived assets are reviewed for events of changes in circumstances which indicate that their carrying value may not be recoverable. Approximately $0.2 million will be amortized per year for each future year for the current value of the technology licenses acquired until approximately 2022. As of December 31, 2015 other assets totaled $1.1 million, comprised of $2.5 million in value acquiring our technology licenses and our intellectual property, less accumulated amortization of $1.4 million.

Research and Development Costs — Costs and expenses that can be clearly identified as research and development are charged to expense as incurred. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

The Company estimates its clinical trial expense accrual each period based on a cost per patient calculation which is derived from estimated start-up costs, clinical trial costs based on the number of patients and length of the study and clinical study report costs. These services are performed by the Company's third-party clinical research organizations, laboratories and clinical investigative sites. The expense accrual is recorded in research and development expense each period. Amounts that have been prepaid in advance of work performed are recorded in other current assets.

For the year ended December 31, 2016, we had $5.5 million of costs classified as research and development expense. For the year ended December 31, 2015, we had $3.0 million of costs classified as research and development expense. Research and development – related party expense has been consolidated with research and development expense on our financial statements beginning in 2015 as MD Anderson is no longer a greater than 5% stockholder in the Company. For the year ended December 31, 2014, we had $1.6 million of costs classified as research and development expense and $0.2 million of related party research and development expense.

Stock-Based Compensation — The Company has accounted for stock-based compensation under the provisions of GAAP. The provisions require us to record an expense associated with the fair value of stock-based compensation. We currently use the Black-Scholes option valuation model to calculate stock based compensation at the date of grant. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimate.

Recent Accounting Pronouncements — From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board that are adopted by the Company as of the specified effective date. If not discussed, management believes that the impact of recently issued standards, which are not yet effective, will not have a material impact on the Company's consolidated financial statements upon adoption.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers.* The new standard provides comprehensive guidance for recognizing revenue as goods or services are delivered to the customer in an amount that is expected to be earned from those same goods or services. ASU 2014-09 was scheduled to be effective for annual reporting periods beginning after December 15, 2016, and early adoption was not permitted. In August 2015, the FASB issued ASU No. 2015-14, "Revenue from Contracts with Customers: Deferral of Effective Date", which defers the effective date of ASU 2014-09 by one year. ASU 2014-19 is now effective for annual periods after December 15, 2017 including interim periods within that reporting period. Early application is permitted only for annual periods beginning after December 15, 2016, including interim periods within that reporting period and allows for adoption using a full retrospective method, or a modified retrospective method. We currently anticipate adopting this standard on its effective date under the full retrospective method of adoption. We have not experienced significant issues in our implementation process and we do not anticipate any if we begin to generate revenues from the drug candidates the Company currently has under development.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The new standard requires management to perform interim and annual assessments as to the entity's ability to continue as a going concern and provides related disclosure guidance. ASU 2014-15 is effective for reporting periods ending after December 15, 2016, with early adoption permitted. The Company adopted this pronouncement for the year ended December 31, 2016 and analyzed its operations. The Company has determined that it has enough cash on hand to meet obligations and fund operations for at least the next 12 months from the report date included herein and does not have going concern uncertainty.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. Management is currently evaluating the impact of future adoption of the new standard on the Company's consolidated financial statements.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Stock Compensation.* The new standard simplifies certain aspects of the accounting for share-based payment award transactions by allowing entities to continue to use current GAAP by estimating the number of awards that are expected to vest or, alternatively, entities can elect to account for forfeitures as they occur. Another aspect of the standard requires an entity to recognize all excess tax benefits and deficiencies associated with stock-based compensation as a reduction or increase to tax expense in the income statement. Previously, such amounts were recognized in additional paid-in capital. The new standard is now effective and management adopted the standard effective December 31, 2016 and did not elect to use actual forfeitures as they occur. Management also notes that the adoption of the standard to recognize excess tax benefits and deficiencies related to stock-based compensation in the income statement would not have a material impact on the Company's consolidated financial statements as the Company has a full valuation allowance in place against its deferred tax asset.

Management has reviewed all other recently issued pronouncements and has determined they will have no material impact on the Company's consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. We had cash and cash equivalents of $9.4 million as of December 31, 2016. Although this cash account is subject to fluctuations in interest rates and market conditions, no significant gain or loss on this account is expected to be recognized in earnings. We do not invest in derivative securities.

Capital Market Risk. We currently have no significant revenues and depend on funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMETARY DATA

Our consolidated financial statements, together with the report of our independent registered public accounting firm, are set forth beginning on page F-1 of this Annual Report on Form 10-K. In the calendar year 2008, our fiscal year end was changed from June 30th to December 31st.

ITEM 9. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including the company's principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Our management, including our Chief Executive Officer (who is also our Chief Financial Officer), has reviewed and evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e)

under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Following this review and evaluation, our management determined that as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act, is a process designed by, or under the supervision of, our principal executive officer and our principal financial officer, and effected by our Board, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Management's assessment of the effectiveness of our internal controls is based principally on our financial reporting as of December 31, 2016. In making our assessment of internal control over financial reporting, management used the criteria set forth in *Internal Control - Integrated Framework (*2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our management, with the participation of our Chief Executive Officer (who is also our acting Chief Financial Officer), has evaluated the effectiveness of our internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as of December 31, 2016. Based on this evaluation, management believes that, as of December 31, 2016, our internal control over financial reporting was effective.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. The scope of management's assessment of the effectiveness of internal control over financial reporting includes our consolidated subsidiary.

The effectiveness of our internal control over financial reporting as of December 31, 2016 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their attestation report which is included elsewhere in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Identification of Directors and Executive Officers

Our current directors and officers are set forth below:

Name	Age	Position - Committee
Peter H. Nielsen	68	Chief Executive Officer; President; Chief Financial Officer; Treasurer; Chairman of the Board; Director
Ulrich W. Mueller, Ph.D.	50	Chief Operating Officer; Secretary
Michael J. Garrison	47	Director – Audit Committee; Compensation Committee; Nominating/Corporate Governance Committee
Amy P. Sing, M.D.	59	Director – Audit Committee; Compensation Committee; Nominating/Corporate Governance Committee
Heath W. Cleaver, CPA	43	Director – Audit Committee; Compensation Committee; Nominating/Corporate Governance Committee
Douglas P. Morris	61	Director; Director of Investor Relations

Our current directors will serve until the next annual meeting of stockholders or until their successors are elected or appointed and qualified.

Background Information

Peter H. Nielsen. Mr. Nielsen co-founded Bio-Path and has served as Bio-Path's President, Chief Executive Officer, Chief Financial Officer/Treasurer and Chairman of the Board since 2008. At the time of Bio-Path's establishment in

2007, Mr. Nielsen licensed technology and targets from The University of Texas, MD Anderson Cancer Center and coordinated pre-clinical development, optimization and manufacturing of Bio-Path's lead drug candidate, prexigebersen. Over the next ten years, Mr. Nielsen led the clinical advancement of prexigebersen into Phase II studies, the introduction of additional pipeline candidates and the Company's public market debut. Prior to co-founding Bio-Path, Mr. Nielsen worked with several other companies, leading turnarounds and developing and executing on strategies for growth. In addition to his service as a director of Bio-Path, Mr. Nielsen currently serves as a director of Synthecon, Inc., a company developing 3D cell culture technology. Before entering the biotechnology sector, Mr. Nielsen was a lieutenant in the U.S. Naval Nuclear Power program where he was director of the physics department and was employed at Ford Motor Company in product development. Mr. Nielsen has a broad background in senior management and has significant negotiating experience. He holds engineering, mathematics and M.B.A. finance degrees from the University of California at Berkeley.

Ulrich W. Mueller, Ph.D. Dr. Mueller has served as Bio-Path's Chief Operating Officer and Secretary since 2014. Between 2007 and 2014, Dr. Mueller managed various administrative departments at Fred Hutchinson Cancer Research Center, a leading research center for cancer and other life-threatening diseases. Dr. Mueller most recently served as Fred Hutchinson Cancer Research Center's Vice President, Industry Relations and Clinical Research Support. Between 2000 and 2007, Dr. Mueller served in various capacities at MD Anderson, including as Managing Director, Director of Licensing, and Assistant Director of Business Development. Dr. Mueller holds a Ph.D. in Cell and Molecular Biology from Baylor College of Medicine, a Master's degree in Biology from Texas A&M University, and a Bachelor of Science in Microbiology from New Mexico State University.

Douglas P. Morris. Mr. Morris is a co-founder of Bio-Path and has served as a director of Bio-Path since 2007 and served as an officer from 2007 to June 2014. Mr. Morris also currently serves as a Director of Investment Relations of Bio-Path. Mr. Morris previously served as a co-founder, Managing Member, and Secretary of nCAP Holdings, LLC (nCAP), a privately held technology based company from September 2013 to January 2016. Between 1993 and 2010, Mr. Morris was an officer and director of Celtic Investment, Inc., a financial services company. Mr. Morris has owned and operated Hyacinth Resources, LLC ("Hyacinth"), a business-consulting firm since 1990 and is also a Managing Member of Sycamore Ventures, LLC, a privately held consulting firm. Mr. Morris has a B.A. from Brigham Young University, and attended the University of Southern California Master's program in public administration.

Amy P. Sing, M.D. Dr. Sing has served as a director of Bio-Path since 2014. She served as the Senior Medical Director for US Medical Affairs from January 2011 until August 2016 at Genomic Health, Inc., a leading publicly held biotechnology company that assists physicians and patients in making personalized cancer treatment decisions. From 2004 to 2006, Dr. Sing led oversight of the approved breast cancer drug Avastin Investigator Sponsored Trials (IST) program at Genentech, Inc., a public biotechnology firm providing major contributions to the understanding and development of cancer research. From 2004 to 2011, Dr. Sing worked in various other leadership and research positions at Genentech, Inc. Dr. Sing also led research teams for Seattle Genetics, Inc. from 1999 to 2003 and has received awards from the National Cancer Institute, American Cancer Society and Stanford University. Dr. Sing holds a B.A. from Amherst College and an M.D. from Stanford University.

Michael J. Garrison. Mr. Garrison has served as a director of Bio-Path since 2012. Mr. Garrison is the managing partner of Garrison Capital, LLC, a private holding company with interests in healthcare, technology and hospitality. He is also a principal and serves as President of Body Sculpt Intl, LLC, which operates plastic surgery clinics under the trade name Sono Bello. Mr. Garrison previously spent 10 years in a variety of executive roles with Dell, Inc. including Director of Marketing for the Small & Medium Business division and Country Manager of Dell Philippines. Prior to joining Dell, Inc., Mr. Garrison held general management and corporate development positions with ITT Industries, Inc., a leading industrial manufacturer. Mr. Garrison holds a Master’s degree in Business Administration from Harvard Business School and a Bachelor of Science in Mechanical Engineering from Purdue University.

Heath W. Cleaver, CPA. Mr. Cleaver has served as a director of Bio-Path since 2014. Mr. Cleaver is currently a consultant providing turn-around management and capital raising services to companies in the oil and gas service sector. From 2015 to 2016, Mr. Cleaver served as the Chief Financial Officer of Global Fabrication Services, Inc. In 2014, Mr. Cleaver served as Chief Financial Officer at Tarka Resources, Inc. From 2011 until 2014, Mr. Cleaver served as Chief Financial Officer of Porto Energy Corp. From 2010 until 2011, Mr. Cleaver served as Chief Accounting Officer of Porto Energy Corp. Mr. Cleaver served as Corporate Controller and then as Vice President and Chief Accounting Officer for BPZ Energy from 2006 to 2010. Beginning in 1997 through 2004, Mr. Cleaver served in various accounting roles, including Financial Controller, at Horizon Offshore Contractors, Inc. Mr. Cleaver is a Certified Public Accountant in the state of Texas and holds a Bachelor’s Degree in Business Administration - Accounting from Texas A&M University.

Board of Directors

Our operations are managed under the broad supervision of the Board, which has ultimate responsibility for the establishment and implementation of our general operating philosophy, objectives, goals and policies. Our Board is currently comprised of three independent directors and two non-independent directors. The Board has determined that current directors Michael J. Garrison, Heath W. Cleaver and Amy P. Sing, M.D. are “independent” as independence is defined under the listing standards for The NASDAQ Stock Market. The Board based these determinations primarily on a review of the responses our directors provided to questions regarding employment and compensation history, affiliations and family and other relationships.

Codes of Ethics

We have adopted the Employee Code of Business Conduct and Ethics, which applies to all of our employees, including our executive officers, and the Code of Business Conduct and Ethics for Members of the Board, which applies to members of the Board.

Board Committees

The Board has a standing audit committee (the "Audit Committee"), compensation committee (the "Compensation Committee") and nominating/corporate governance committee (the "Nominating/Corporate Governance Committee"), each of which is governed by a charter. The Board may also establish other committees from time to time as necessary to facilitate the management of the business and affairs of the Company. In addition to the three standing committees, we also have a Scientific Advisory Board that serves an advisory role to management and the Board. The information below summarizes the functions of each of the committees and the Scientific Advisory Board.

Audit Committee

The Audit Committee has been structured to comply with the requirements of Section 3(a)(58)(A) of the Exchange Act. The Board has determined that the Audit Committee members have the appropriate level of financial understanding and industry specific knowledge to be able to perform the duties of the position and are financially literate and have the requisite financial sophistication as required by the applicable listing standards of The NASDAQ Stock Market.

The Audit Committee, as permitted by, and in accordance with, its charter, is responsible to periodically assess the adequacy of procedures for the public disclosure of financial information and review on behalf of the Board, and report to the Board, the results of its review and its recommendation regarding all material matters of a financial reporting and audit nature, including, but not limited to, the following main subject areas:

- financial statement, including management's discussion and analysis thereof;

- financial information in any annual information form, proxy statement, prospectus or other offering document, material change report, or business acquisition report;

- press releases regarding annual and interim financial results or containing earnings guidance;

- internal controls;

- audits and reviews our financial statements; and

- filings with securities regulators containing financial information, including our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q.

The Audit Committee appoints and sets the compensation for the independent registered public accounting firm annually and reviews and evaluates such external auditor. This external auditor reports directly to the Audit Committee. The Audit Committee establishes our hiring policies regarding current and former partners and employees of the external auditor. In addition, the Audit Committee pre-approves all audit and non-audit services undertaken by the external auditor.

The Audit Committee has direct responsibility for overseeing the work of the external auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services, including the resolution of disagreements between the external auditor and management.

The Audit Committee is comprised of Messrs. Garrison and Cleaver and Dr. Sing. Mr. Cleaver is the chair of the Audit Committee. The Board has determined that Mr. Cleaver qualifies as an "audit committee financial expert" under the Exchange Act and that each member of the Audit Committee is an independent director. The Audit Committee meets at least once per fiscal quarter to fulfill its responsibilities under its charter and in connection with the review of the Company's quarterly and annual financial statements.

Compensation Committee

The Compensation Committee's role is to assist the Board in fulfilling its responsibilities relating to matters of human resources and compensation, including equity compensation, and to establish a plan of continuity and development for our senior management. The Compensation Committee operates under a written charter adopted by the Board. The Compensation Committee periodically assesses compensation of our executive officers in relation to companies of comparable size, industry and complexity, taking the performance of the Company and such other companies into consideration. All decisions with respect to the compensation of our Chief Executive Officer are determined and approved either solely by the Compensation Committee or together with other independent directors, as directed by the Board. All decisions with respect to non-CEO executive compensation, and incentive-compensation and equity based plans are first approved by the Compensation Committee and then submitted, together with the Compensation Committee's recommendation, to the members of the Board for final approval. In addition, the Compensation Committee will, as appropriate, review and approve public or regulatory disclosure respecting compensation, including the Compensation Disclosure and Analysis, and the basis on which performance is measured. The Compensation Committee has the authority to retain and compensate any outside adviser as it determines necessary to permit it to carry out its duties. The Compensation Committee has not to date engaged the services of any executive compensation consultant. The Compensation Committee may not form or delegate authority to subcommittees without the prior approval of the Board.

The Compensation Committee is comprised of Messrs. Garrison and Cleaver and Dr. Sing, all of whom are independent under the rules of The NASDAQ Stock Market. The Compensation Committee meets as necessary. Mr. Garrison is the chair of the Compensation Committee.

Nominating/Corporate Governance Committee

The Nominating/Corporat