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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017
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 ☒

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

Indicate by check mark whether the 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 ☒ No ☐

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting company ☒

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

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

As of March 22, 2018, there were 11,340,756 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 $34,842,973 million as of June 30, 2017, 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, after adjustment for the 1-for-10 reverse stock split that occurred effective as of 5:00 p.m. Eastern Time on February 8, 2018. 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 variations of these 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 RNAi nano particle 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. DNAbilize® is a registered trademark of the Company.

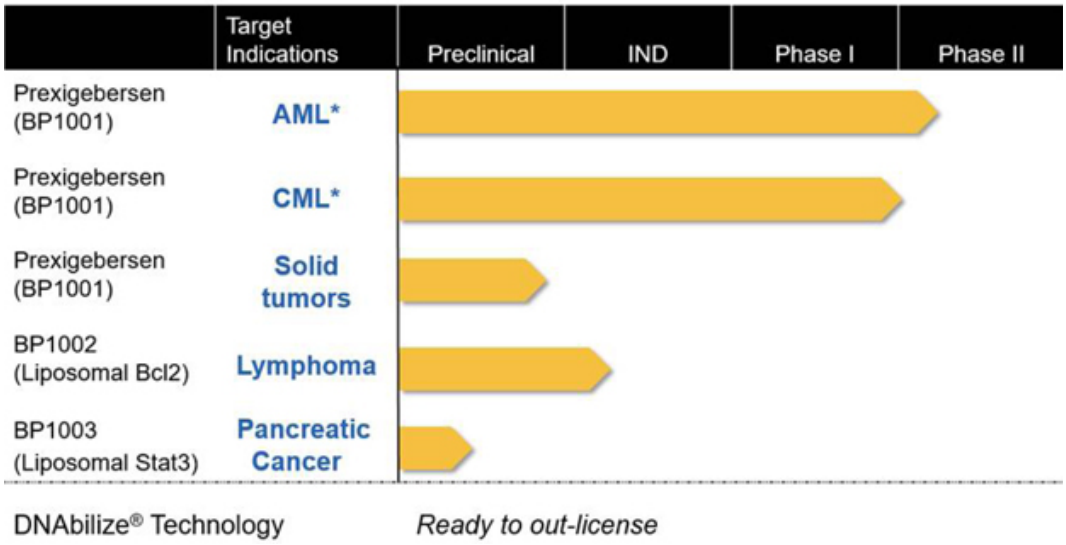
Using DNAbilize® as a platform for drug development and manufacturing, we currently have three antisense drug candidates in development to treat a total of five different disease indications. Our lead drug candidate, prexigebersen (pronounced prex" i je ber' sen), is in the efficacy portion of a Phase II clinical trial for acute myeloid leukemia (AML), and a Phase IIa clinical trial, which is the safety segment of a Phase II clinical trial, for blast phase and accelerated phase chronic myelogenous leukemia (CML) is open for enrollment. 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 Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. We are currently preparing an Investigational New Drug (IND) application for BP1002 in addition to completing additional IND enabling studies. We intend to initiate a Phase I clinical trial of BP1002 in refractory or relapsed lymphoma patients once we receive approval from the FDA.

Our third drug candidate, Liposomal Stat3 ("BP1003"), targets the Stat3 protein and is currently in preclinical development in a pancreatic patient-derived tumor model. Previous preclinical models have shown BP1003 to successfully penetrate pancreatic tumors and to significantly enhance the efficacy of standard frontline treatments. We intend to initiate IND enabling studies of BP1003 in 2018.

We have certain intellectual property as the basis for our current drug products in clinical development, prexigebersen and BP1002. We also 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 certain technology relating to the original delivery technology platform. We are developing RNAi antisense nano particle drug candidates based on our own patented technology 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. On July 19, 2017, we announced that the United States Patent and Trademark Office ("USPTO") issued a notice of allowance for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases. Our pipeline for development of antisense therapeutics is set forth in the table below:

Figure 1. Bio-Path Pipeline for Development of Therapeutics



* Received orphan drug designation from the U.S. FDA for AML and CML and from the European Medicines Agency (EMA) for AML

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 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 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 is in 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) in refractory AML patients 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 had over 50% bone marrow blasts.

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, New Jersey Hematology Oncology Associates, West Virginia University/Mary Babb Randolph Cancer Center, and MD Anderson. To date, over 50 potential patients have been pre-screened for the efficacy portion of the Phase II trial, 26 patients have been screened, 23 patients have been enrolled and 17 patients have been deemed evaluable with six additional patients currently undergoing treatment. We expect the 19 patient pre-specified analysis to be completed in early 2018, at which time we will address the assessment of these patients.

In addition to the Phase II trial for AML, on December 29, 2017, we announced the initiation of our Phase Ib/IIa clinical trial, which is the safety portion of the Phase II clinical trial of prexigebersen for the treatment of CML in accelerated and blast phase patients. The trial is being conducted at MD Anderson as a potential salvage therapy for accelerated and blast phase CML patients. Two cohorts of three evaluable patients each will be enrolled to evaluate two doses (60 mg/ m^2 and 90 mg/ m^2) of prexigebersen in combination with the front-line treatment dasatinib.

Our second drug candidate, BP1002, targets the protein Bcl-2. Bcl-2 is an anti-apoptotic member of the Bcl-2 family of proteins that regulate cell death. Amplified expression of Bcl-2 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 Bcl-2 gene from chromosome 18 into the heavy chain immunoglobin locus on chromosome 14, resulting in uncontrolled high level expression of Bcl-2 protein. Overexpression of Bcl-2 results in deregulated cell survival in affected cells. Initial IND enabling studies for BP1002 have been completed, although an additional second species study has been requested by the FDA. We anticipate being able to file an IND to open a Phase I clinical trial for refractory or relapsed lymphoma in 2018. The clinical trial would evaluate the safety of BP1002 in several dose escalating cohorts to determine a maximum tolerated dose and/or optimal biologically active dose.

Our third drug candidate, BP1003, targets the Stat3 protein and is currently in preclinical development in a pancreatic patient-derived tumor model. Previous preclinical models have shown BP1003 to successfully penetrate pancreatic tumors and to significantly enhance the efficacy of standard frontline treatments. We intend to initiate IND enabling studies of BP1003 in 2018.

Strategy

Our strategy is to develop our lead candidates, prexigebersen, BP1002 and BP1003, for multiple indications where the pathways involving Grb2, Bcl-2 or Stat3, respectively, are utilized to promote cancer growth, proliferation and survival. 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 efficacy portion of the Phase II trial for AML is ongoing. On December 29, 2017, we announced the initiation of the Phase IIa clinical trial for blast and accelerated phase CML patients with prexigebersen in combination with dasatinib.

(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 have completed initial IND enabling studies and filed these in a briefing package with the FDA. The FDA requested an additional study be prepared for submission of an IND to start a Phase I trial in refractory or relapsed 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 dual-site, open-label, dose-escalating trial involving between 15-30 patients. The filing of the IND to open the Phase I trial is expected in 2018.

(4) **Develop BP1003 for pancreatic cancer and solid tumors**. Our third drug candidate, BP1003, targets the Stat3 protein and is currently in preclinical development in a pancreatic patient-derived tumor model. Previous preclinical models have shown BP1003 to successfully penetrate pancreatic tumors and to significantly enhance the efficacy of standard frontline treatments. Bio-Path intends to initiate IND enabling studies of BP1003 in 2018.

(5) **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. On July 19, 2017, we announced that the USPTO issued a notice of allowance for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases.

(6) **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.

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	Approved	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
	Nusinersen	SMN1	Approved	Spinal muscular atrophy

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

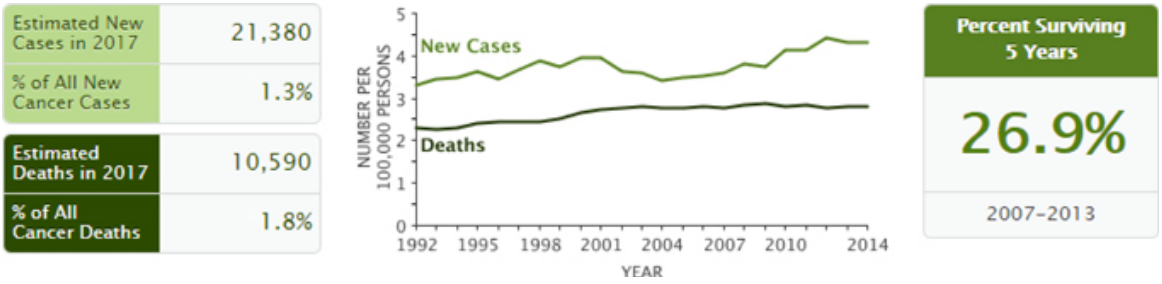
Prexigebersen is targeted at the protein Grb2. Antisense inhibition of Grb2 interrupts the signals between mutated and activated receptors that connect to a well-known cancer associated switch called Ras protein. Inhibition of Grb2 does not cause cell death and thus does not result in adverse events 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 of AML, CML, MDS and Acute Lymphoblastic Leukemia (ALL). We are currently prioritizing our efforts on AML and CML and have begun the Phase II/Phase IIa, respectively, 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)

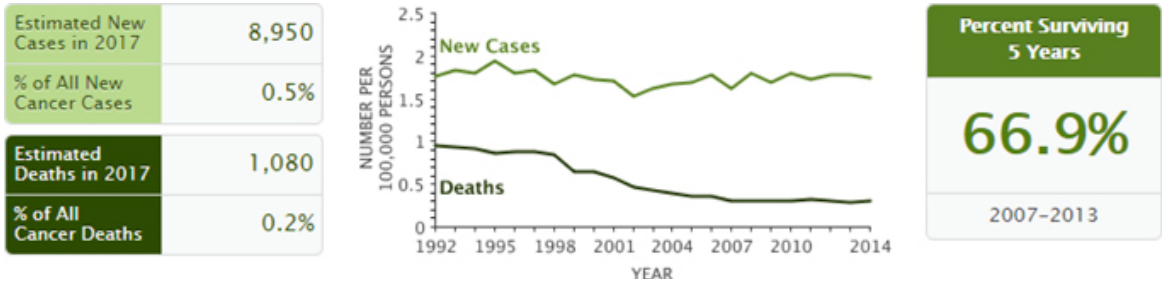
AML – Background and Common Treatments. AML is the rapid accumulation of immature myeloid cells in the blood, resulting in a drop of the other cell types such as red blood cells and platelets. The expansion of immature monocytes leaves the patient unable to fight infection. If AML is left untreated, 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 to 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. In April of 2017, the U.S. Food and Drug Administration (FDA) approved the first targeted-therapy to treat adults with AML. Rydapt (midostaurin) is used in combination with chemotherapy to treat newly diagnosed adults who have a mutation in a gene called FLT3. In August of 2017, the FDA approved Vyxeos (liposomal daunorubicin and cytarabine) for the treatment of newly diagnosed adults with therapy related AML (t-AML) or AML with myelodysplasia related changes (AML-MRC). In September of 2017, the FDA approved Mylotarg (gemtuzumab ozogamicin) for the treatment of adults with newly diagnosed AML whose tumors express the CD33 antigen (CD33-positive AML). Finally, the FDA also approved Mylotarg for the treatment of relapsed or refractory patients aged 2 years and older with CD33-positive AML. Despite this unusually high number of approvals for AML treatments in one year, these therapies target small sub-populations within the AML patient community, leaving the majority of newly diagnosed and relapsed and refractory elderly patients without new options. The 5-year survival rate for people with AML is approximately 27%**.** AML remains 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



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 to 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 4. 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 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 7). 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:

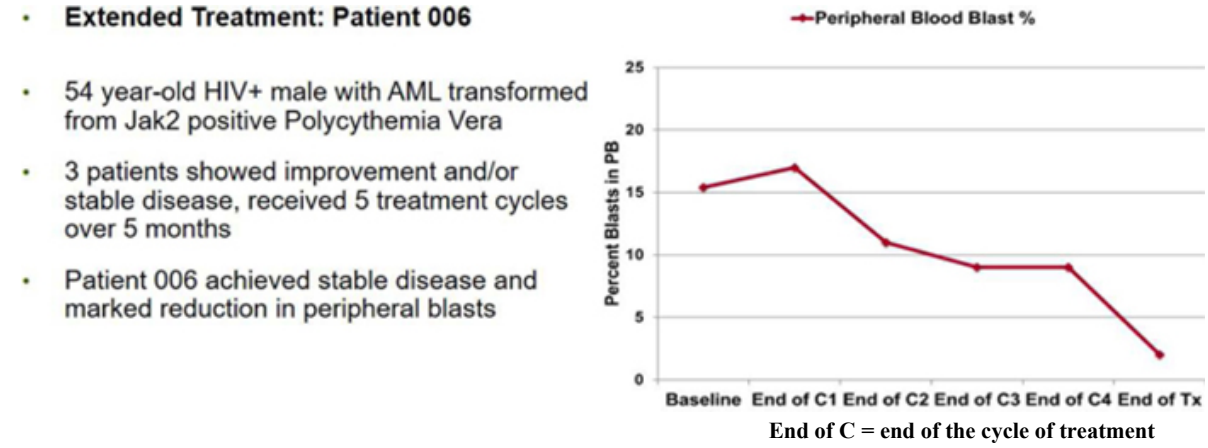
Data from the Phase I Clinical Trial

- 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 5).

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



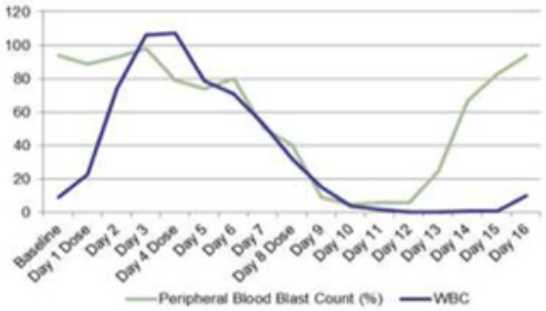
End of C = end of the cycle of treatment

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 6).

Figure 6. Prexigebersen Monotherapy Reversed Blast Phase Crisis in a Patient in the Phase I Clinical Trial for Prexigebersen

- **Patient 002**: 32 year-old, Hispanic male with myeloid blast crisis of CML
- Prior therapies consisted of:
  - Gleevec
  - Dasatinib
  - Nilotinib
  - DCC-2036
  - Cytarabine/Fludarabine/
  - Dasatinib/Gemtuzumab
  - PHA-739358
  - Clofarabine/Dasatinib



- Patient taken off therapy, CNS disease was assumed (not confirmed) and intrathecal Ara-C was administered - patient succumbed due to disease progression prior to going back on treatment

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 7. 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

Subject	Prexigebersen (mg/m^2)	Cohort	Grb2 Decrease (EOT)	pERK Decrease (EOT)
22	20	3	57%	0%
23	20	3	28%	45%
24	20	3	47%	35%
25	40	4	54%	91%
26	40	4	0%	0%
27	40	4	34%	27%
28	60	5	30%	54%
29	60	5	65%	0%
30	60	5	43%	47%
31	90	6	0%	0%
32	90	6	91%	63%
34	90	6	40%	0%

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.

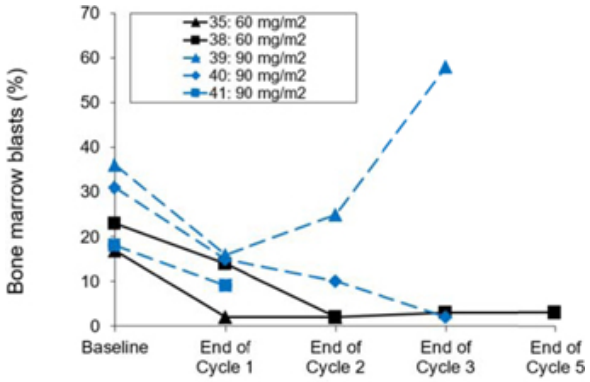
In April 2015, we received orphan drug designation by the FDA for prexigebersen in AML. Orphan drug status provides Bio-Path with seven years of exclusivity after receiving formal marketing approval, as well as additional development incentives. The FDA grants this designation to certain drugs that target diseases affecting fewer than 200,000 people in the United States ("U.S."). 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 had over 50% decrease in bone marrow blast counts (Figure 8). 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 8. Five out of six patients in cohorts 7 and 8 receiving the combination prexigebersen + LDAC have greater than 50% decrease in bone marrow blasts



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. The eighth cohort, patients 039, 040 and 041, were treated with combination therapy of 90 mg/m^2.

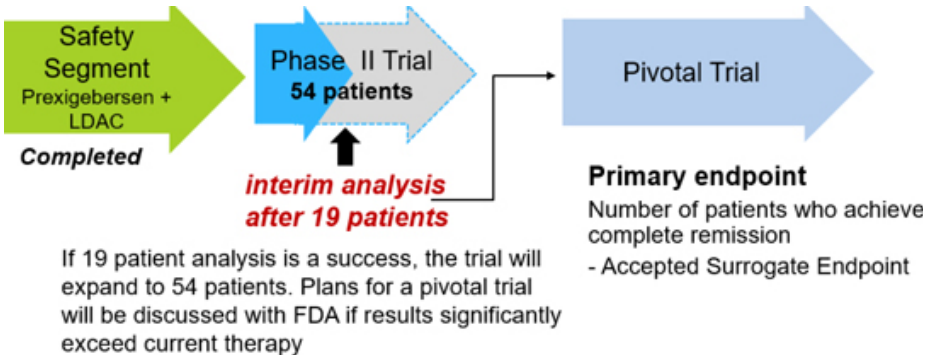
Table 2. Summary Cohorts 1-8 Prexigebersen Clinical Trial Phase I and IB

Patients	Diagnosis	Peripheral or bone marrow blasts %			Reason	Cycles Completed
		Baseline	Nadir	Off-Tx	Discontinued	
1	CML	93	82	97	DLT	<1
6	AML	15	2	5	PD	5
7	MDS	8	4	6	PD	5
10	AML	23	10	10	PD	1
11	CML	24	7	50	PD	1
14	AML	33	5	21	PD	1
15	AML	51	31	72	PD	1
20	AML	76	5	23	PD	1
21	AML	71	43	74	PD	2
22	AML	1	0	2	PD	2
23	MDS	NE	NE	NE	WD	1
24	MDS	0	0	2	PD	5
25	AML	10	3	19	PD	2
26	AML	16	none	80	PD	1
27	AML	93	92	97	PD	1
28	AML	96	none	98	PD	1
29	AML	33	7	27	PD	1
30	AML	51	17	84	PD	1
31	AML	17	NE	17	PD	1
32	AML	24	NE	40	PD	2
34	AML	66	ND	ND	PD	1
35	AML	17	2	ND	CR	1
37	AML	25	25	ND	PD	1
38	AML	23	2	NA	CR	5
39	AML	36	16	58	SD	3
40	AML	31	2	2	CR	3
41	AML	18	9	NA	SD	3

Nadir: the lowest point, Off-TX: off treatment, DLT: dose limiting toxicity, PD: progressive disease, SD: stable 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 9). 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, New Jersey Hematology Oncology Associates, West Virginia University/Mary Babb Randolph Cancer Center, and MD Anderson. To date, over 50 potential patients have been pre-screened for the efficacy portion of the Phase II trial, 26 patients have been screened, 23 patients have been enrolled and 17 patients have been deemed evaluable with six additional patients currently undergoing treatment. We expect the 19 patient pre-specified analysis to be completed in early 2018, at which time we will address the assessment of these patients.

Figure 9. Trial Design



In addition to the Phase II trial for AML, on December 29, 2017, we announced the initiation of our Phase Ib/IIa clinical trial, which is the safety portion of the Phase II clinical trial, of prexigebersen for the treatment of CML in accelerated and blast phase patients. The trial is being conducted at MD Anderson as a potential salvage therapy for accelerated and blast phase CML patients. Two cohorts of three evaluable patients each will be enrolled to evaluate two doses (60 mg/ m^2 and 90 mg/ m^2) of prexigebersen in combination with the front-line treatment dasatinib.

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.

In recently completed preclinical models, prexigebersen effectively penetrated ovarian tumors and has demonstrated clinical benefit both as a monotherapy and in combination with standard frontline therapies. Bio-Path plans to initiate a Phase I clinical trial of prexigebersen targeting several solid tumors types in 2018.

BP1002

BP1002, also known by its scientific name as Liposomal Bcl-2, 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% to 60% of solid tumors.

Bcl-2 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 Bcl-2 prevents the induction of apoptosis in response to cellular insults such as treatment with chemotherapeutic agents. Bcl-2 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. Bcl-2 is also overexpressed in a wide variety of solid tumors (it is estimated to be over-expressed in 40% of cancers). For example, Bcl-2 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 40% being indolent lymphomas such as follicular lymphoma (FL) and approximately 60% being the more aggressive lymphomas such as 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

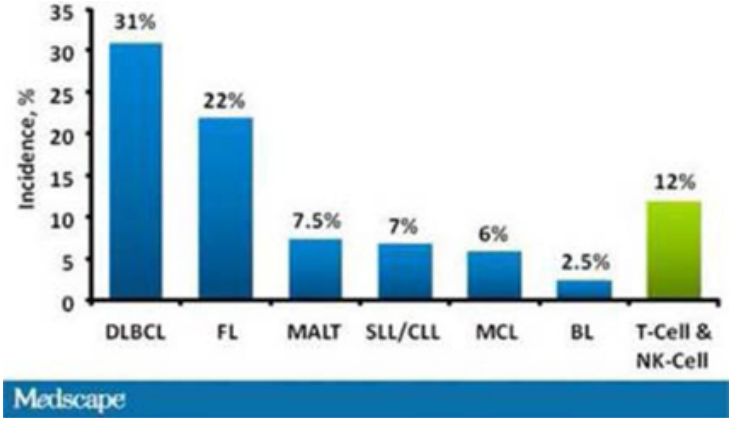
Trial	Number of Patients	Regimen Tested	Overall Response Rate	Median Response Duration
Marcus, et al (2008)	321	R-CVP vs CVP	81% R-CVP 57% CVP (P < .0001)	34 mos TTP R-CVP 15 mos TTP CVP (P < .0001)
Hiddemann et al (2005)	428	R-CHOP vs CHOP	96% R-CHOP 90% CHOP (P < .01)	Not reported
Tsimberidou et al (2002)	73	FMD with interferon-α	97%	Not reported
Rummel et al (2009)	549	BR vs R-CHOP	93.8% BR 93.5% R-CHOP	55 mos PFS BR 35 mos PFS R-CHOP

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%20Journal/v19n3/187.pdf

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 are currently preparing an IND application for BP1002 in addition to completing additional IND enabling studies. We intend to initiate a Phase I clinical trial of BP1002 in refractory or relapsed lymphoma patients once we receive approval from the FDA. The clinical trial will evaluate the safety of BP1002 in several dose escalating cohorts to determine a maximum tolerated dose and/or optimal biologically active dose. 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 10).

Figure 10. 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

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. Bcl-2 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 Bcl-2 could be transformative in this indication. Toxicity in competing therapeutics using small molecule inhibitors of Bcl-2 occurs due to non-specificity of the inhibitors. Bcl-2 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 Bcl-2 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 Bcl-2 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 Bcl-2 expression is driving cell survival. The introduction of a new, non-toxic, and specific Bcl-2 inhibitor could be a major advance in cancer therapeutics.

BP1003

BP1003 is our third liposome delivered antisense drug candidate. BP1003 is a DNAbilize® RNAi nanoparticle containing antisense DNA targeting Stat3, a protein associated with increased pancreatic adenocarcinoma (PDAC) severity and poor survival in the majority of pancreatic tumors. We hypothesized that the natural lipid delivery vesicle would have unique characteristics that would allow for penetration of the fibrotic stroma to reach the cancer cells. Our preclinical work demonstrated that BP1003 was successful in crossing the scar tissue matrix and delivering antisense drug into the tumor tissue. Subsequent studies evaluating the combination of BP1003 with gemcitabine, the frontline therapy for pancreatic cancer, suggest that the regimen has synergistic anti-tumor effects. In November of 2017 we announced that we intend to initiate IND enabling studies of BP1003 in 2018.

Stat3 expression has been associated with increased severity of disease and poor survival in numerous cancers including approximately 82 to 100% of pancreatic tumors, 80% of non-small cell lung cancers (NSCLC), 82% of prostate tumors, 77% of cervical cancers, 50% of breast cancers, 57% of colon cancers and 97% of stage III and IV ovarian cancers. We believe that a therapeutic that shuts down the Stat3 protein can have significant clinical impact for all solid tumors that express Stat3.

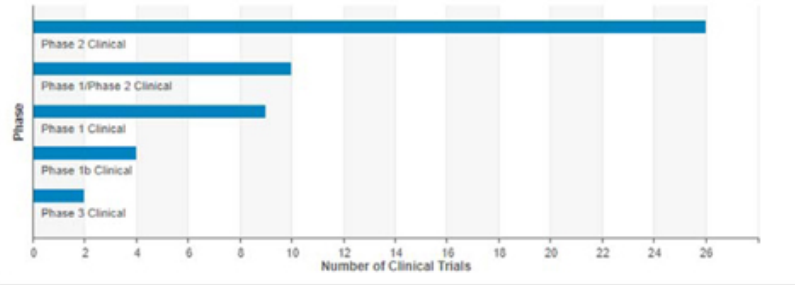
Our lead indication for BP1003 is pancreatic cancer due to the severity of this disease and the lack of effective, life-extending treatments. PDAC is a cancer of the exocrine cells of the pancreas. Approximately 50,000 people per year are diagnosed, 40,000 (80%) of whom will die. It is projected that in the next 10 to 15 years, PDAC will become the second most lethal cancer behind lung cancer. This is due to rapid advancements that have been made in the treatment of other cancers, as well as the rise of type II diabetes, a risk factor for development of PDAC.

Because most people have advanced PDAC at the time of diagnosis, survival rates are very low. Typical survival for a metastatic or advanced patient is only 6 to 9 months from diagnosis. Treatment of this disease is hampered by the location of the pancreas, which is difficult to reach with conventional therapies and the fibrotic nature of the tumors, which protects them from penetration by chemotherapeutics. We believe a novel and unconventional therapeutic is needed to overcome these barriers to treatment.

While competition for therapeutics that target the Stat3 pathway exist, the competition for specific Stat3 inhibitors is very small. Most compounds under development target the pathway upstream of Stat3 or inhibit Stat1 and Stat5 in addition to Stat3 and thus induce serious toxic side effects. For example, Ionis Pharmaceuticals, Inc. has developed an antisense DNA-based Stat3 inhibitor called IONIS-STAT3-2.5Rx. It is being evaluated in clinical trials by AstraZeneca under the name AZD9150 for solid tumors, squamous carcinoma of the head and neck and diffuse large B-cell lymphoma. However, due to the toxicity of the DNA chemistry, thrombocytopenia continues to limit the systemic delivery and efficacy of such compounds for the treatment of cancer. We believe BP1003 avoids these complications.

The competitive landscape for clinical trials treating advanced and metastatic pancreatic cancer patients in the US is slim (Figure 11). Most candidates are fraught with serious side effects that can make completion of therapy a challenge for this fragile patient population. We believe that the excellent safety profile of the DNAbilize® chemistry, the novel lipid formula that allows for penetration of the tumor stroma, and the ability to target a single protein with precision, makes BP1003 an ideal candidate for combination with the frontline treatments to extend survival while maintaining quality of life for the patient.

Figure 11. U.S. Clinical Trials for Advance Metastatic PDAC Patients in Combination with Frontline Treatments



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. On July 19, 2017, we announced that the USPTO issued a notice of allowance for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases.

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 both the years ended December 31, 2017 and 2016 were $5.5 million.

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 trials in AML and CML, 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 U.S. 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 expired in 2017.

We have expanded our intellectual property portfolio by filing patent applications that are applicable to our technology and business strategy. Our patent portfolio currently includes an issued patent (No. 9,744,187) in the U.S. that covers the manufacturing method, formulation and antisense composition for new targets in preclinical development, a patent pending for combinations of antisense drugs with frontline therapeutics, and four additional pending patents for composition and methods of use of specific drug targets. We announced on July 19, 2017 that the USPTO issued a notice of allowance for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases. There can be no assurances that patents related to our existing patent 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 U.S., 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 U.S. 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 9 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, lymphoma, ovarian and breast cancer, solid tumors, and other cancers 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.

Government Regulation

Overview

Government authorities in the U.S., 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.

U.S. Drug Development Process

In the U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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.

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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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.

On February 8, 2018, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-10, and our common stock began trading on the split-adjusted basis on The Nasdaq Capital Market at the commencement of trading on February 9, 2018. All common stock share and per share amounts in this Annual Report on Form 10-K have been adjusted to give effect to the 1-for-10 reverse stock split, retrospectively.

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, 2017, we had accumulated net losses of $39.2 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, BP1002 and BP1003. 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.

As of December 31, 2017, we had $6.0 million in cash on hand, compared to $9.4 million as of December 31, 2016. We have determined that the Company does not have enough cash on hand to meet obligations and fund operations for the next 12 months from the date of this Annual Report on Form 10-K. We expect to finance our foreseeable cash requirements through cash on hand, 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. If we are unable to obtain funding due to unfavorable terms or market conditions, management has determined that it can reduce spending on its day-to-day operations, sell laboratory assets and temporarily delay planned activities if needed. However, our ability to continue as a going concern is dependent upon obtaining funding through one or more sources described above within the next 12 months to meet our planned obligations and pay our liabilities. Our ongoing future capital requirements will further 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, BP1002 and BP1003;
- 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 report of our independent registered public accounting firm contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern.

The report of our independent registered public accounting firm relating to our December 31, 2017 consolidated financial statements contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern. As discussed in Note 2 to the consolidated financial statements included herein, we have suffered recurring losses from operations and have a net capital deficiency that raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

We have determined that the Company does not have enough cash on hand to meet obligations and fund operations for the next 12 months from the date of this Annual Report on Form 10-K. We expect to finance our foreseeable cash requirements through cash on hand, 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. If we are unable to obtain funding due to unfavorable terms or market conditions, management has determined that it can reduce spending on its day-to-day operations, sell laboratory assets and temporarily delay planned activities if needed. However, our ability to continue as a going concern is dependent upon obtaining funding through one or more sources described above within the next 12 months to meet our planned obligations and pay our liabilities.

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 cancers 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 U.S. 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.

On December 22, 2017, the U.S. government enacted legislation referred to as the Tax Cuts and Jobs Act (the "Tax Act"). Under the Tax Act, net operating losses generated prior to 2018 will continue to be governed by the net operating loss tax rules as they existed prior to the adoption of the new Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Accordingly, our net operating losses could expire unused and be unavailable to offset future income tax liabilities, if any. Under the Tax Act, net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such net operating losses is limited to 80% of current year taxable income. We continue to examine the impact that this provision of the Tax Act, among other provisions, may have on our business.

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;
- the authority of our Board to fill vacancies occurring on the Board;
- 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 U.S. 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 also 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. 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 for AML was dosed. On December 29, 2017, we announced the initiation of our Phase Ib/IIa clinical study of prexigebersen for the treatment of CML in accelerated blast phase patients. In addition, prexigebersen is in preclinical studies for solid tumors, including breast cancer and ovarian cancer. 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 U.S. 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 U.S. 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 U.S. 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 U.S., 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 for AML and CML 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 U.S. 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 U.S.

In the U.S., 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. Our patent portfolio currently includes an issued patent (No. 9,744,187) in the U.S. that covers the manufacturing method, formulation and antisense composition for new targets in preclinical development, a patent pending for combinations of antisense drugs with frontline therapeutics, and four additional pending patents for composition and methods of use of specific drug targets. We announced on July 19, 2017 that the USPTO issued a notice of allowance for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases. Our success depends in large part on our ability to obtain and maintain patent protection both in the U.S. 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 U.S. are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the USPTO for the entire time prior to issuance as a U.S. 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 U.S. patent position. Furthermore, we may not have identified all U.S. 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 U.S. 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 U.S. 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 U.S. patent law in a way that may weaken our ability to obtain patent protection in the U.S. 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 expired in 2017. Our patent portfolio currently includes an issued patent (No. 9,744,187) in the U.S. that covers the manufacturing method, formulation and antisense composition for new targets in preclinical development, a patent pending for combinations of antisense drugs with frontline therapeutics, and four additional pending patents for composition and methods of use of specific drug targets. We announced on July 19, 2017 that the USPTO issued a notice of allowance for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases. We are actively reviewing and preparing additional patent applications to expand our patent portfolio, but there can be no assurances that patents related to our existing patent 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 U.S. 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. From January 1, 2016 through December 31, 2017, our stock price has fluctuated from a low of $1.81 to a high of $31.90, after adjustment for the 1-for-10 reverse stock split that occurred effective as of 5:00 p.m. Eastern Time on February 8, 2018. 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. The liquidity of the shares of our common stock may be further affected adversely by the 1-for-10 reverse stock split that we implemented effective as of 5:00 p.m. Eastern Time on February 8, 2018, due to the reduced number of shares that are outstanding.

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.

In the past, we have received a notice of non-compliance from the Listing Qualifications Department of The Nasdaq Stock Market LLC with respect to the $1.00 minimum closing bid price requirement. Although we regained compliance with the minimum closing bid price requirement after implementing a 1-for-10 reserve stock split effective as of 5:00 p.m. Eastern Time on February 8, 2018, there can be no assurance that we will be able to meet the minimum closing bid price requirement or other listing requirements in the future.

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. On February 8, 2018, we effected a 1-for-10 reverse stock split. All share prices below have been adjusted retroactively to account for the reverse stock split.

	High	Low
Fiscal Year Ended December 31, 2016		
First Fiscal Quarter	$ 26.80	$ 12.40
Second Fiscal Quarter	$ 31.90	$ 18.60
Third Fiscal Quarter	$ 19.90	$ 12.50
Fourth Fiscal Quarter	$ 15.00	$ 9.50
Fiscal Year Ended December 31, 2017		
First Fiscal Quarter	$ 13.50	$ 7.00
Second Fiscal Quarter	$ 8.30	$ 3.30
Third Fiscal Quarter	$ 4.90	$ 2.50
Fourth Fiscal Quarter	$ 5.85	$ 1.81

Holders

As of March 22, 2018, there were 11,340,756 shares of our common stock outstanding and approximately 256 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.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Not applicable.

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 RNAi nano particle 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 charge 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. DNAbilize® is a registered trademark of the Company.

Using DNAbilize® as a platform for drug development and manufacturing, we currently have three 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), is in the efficacy portion of a Phase II clinical trial for AML and a Phase IIa clinical trial, which is the safety segment of a Phase II clinical trial, for blast phase and accelerated phase CML is open for enrollment. Prexigebersen is also in preclinical studies for solid tumors, including breast cancer and ovarian cancer.

Our second drug candidate, BP1002, targets the protein Bcl-2, which is responsible for driving cell proliferation in up to 60% of all cancers. We are currently preparing an Investigational New Drug (IND) application for BP1002 in addition to completing additional IND enabling studies. We intend to initiate a Phase I clinical trial of BP1002 in refractory or relapsed lymphoma patients once we receive approval from the FDA.

Our third drug candidate, BP1003, targets the Stat3 protein and is currently in preclinical development in a pancreatic patient-derived tumor model. Previous preclinical models have shown BP1003 to successfully penetrate pancreatic tumors and to significantly enhance the efficacy of standard frontline treatments. We intend to initiate IND enabling studies of BP1003 enabling studies in 2018.

We have certain intellectual property as the basis for our current drug products in clinical development, prexigebersen and BP1002. We also currently maintain the License Agreement with MD Anderson, under which we license from MD Anderson certain technology relating to the original delivery technology platform. We are developing RNAi antisense nano particle 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. On July 19, 2017, we announced that the USPTO issued a notice of allowance for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases.

As of December 31, 2017, we had an accumulated deficit of $39.2 million. Our net loss was $7.0 million and $6.8 million for the years ended December 31, 2017 and 2016, 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, 2017, the Company has recorded $50,000 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, 2017 to the Year Ended December 31, 2016

Revenue. Our revenue was $37,000 for the year ended December 31, 2017. We had $13,000 revenue in the year ended December 31, 2016. 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 both the years ended December 31, 2017 and 2016. The following table sets forth our research and development expenses (in thousands):

	Year ended December 31,	
	2017	**2016**
Research and development expense	$ 5,162	$ 5,115
Non-cash stock-based compensation expense	318	359
Total research and development expense	$ 5,480	$ 5,474

General and Administrative Expenses. Our general and administrative expense was $3.5 million for the year ended December 31, 2017, an increase of $0.5 million compared to the year ended December 31, 2016. The increase in general and administrative expense was primarily due to increased legal fees, audit fees and director fees. The following table sets forth our general and administrative expenses (in thousands):

	Year ended December 31,	
	2017	**2016**
General and administrative expense	$ 3,048	$ 2,589
Non-cash stock-based compensation expense	475	425
Total general and administrative expense	$ 3,523	$ 3,014

Net Operating Loss. Our net loss from operations was $9.0 million for the year ended December 31, 2017, an increase of $0.5 million compared to the year ended December 31, 2016.

Change in Fair Value of Warrant Liability. The change in fair value of the warranty liability for the year ended December 31, 2017 resulted in non-cash income of $2.4 million, an increase of $0.7 million compared to the year ended December 31, 2016.

Loss on Extinguishment of Warrant Liability. The loss on extinguishment of the warrant liability for the year ended December 31, 2017 resulted in a non-cash loss of $0.4 million. There was no gain or loss on extinguishment of the warrant liability for the year ended December 31, 2016.

Net Loss. Our net loss for the year ended December 31, 2017 was $7.0 million, an increase of $0.3 million compared to the year ended December 31, 2016.

Deemed Dividend Related to Warrant Conversion. The deemed dividend related to the warrant conversion was $1.0 million for the year ended December 31, 2017. The Company did not have a deemed dividend for the year ended December 31, 2016.

Net Loss Attributable to Common Stockholders. Our net loss attributable to common stockholders for the year ended December 31, 2017 was $8.1 million, an increase of $1.3 million compared to the year ended December 31, 2016.

Net Loss per Share. Net loss per share, both basic and diluted, was $0.80 per share for the year ended December 31, 2017, compared to $0.73 per share for the year ended December 31, 2016. Net loss per share is calculated using the weighted average number of shares of common stock outstanding during the applicable periods and excludes stock options and warrants because they are antidilutive.

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 $6.0 million at December 31, 2017, a decrease of $3.4 million compared to December 31, 2016. We do not believe that our available cash at December 31, 2017 will be sufficient to fund our liquidity and capital expenditure requirements for the next 12 months. The Company's ability to continue as a going concern is dependent upon obtaining funding through one or more sources as described above within the next 12 months to meet its planned obligations and pay its liabilities.

Cash Flows

For the Year Ended December 31, 2017

Operating Activities. Net cash used in operating activities for the year ended December 31, 2017 was $8.0 million. Net cash used in operating activities consisted primarily of the net loss for the period of $7.0 million and an increase in current assets of $0.2 million. Our net cash used in operating activities is partially offset by non-cash stock-based compensation expense of $0.8 million and technology license amortization and depreciation expenses of $0.4 million. The change in fair value of the warranty liability of $2.4 million partially offset by loss on extinguishment of the warranty liability of $0.4 million, did not have an impact on net cash used in operating activities during the period.

Investing Activities. Net cash used in investing activities for the year ended December 31, 2017 consisted of capital expenditures totaling $0.5 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, 2017 was $5.1 million. Net cash provided by financing activities consisted of $3.6 million from the 2017 Registered Direct Offering and $1.5 million from the warrant exercises, both as described below.

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, 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. The change in fair value of the warrant liability of $1.7 million did not have an impact on net cash used in operating activities during the period.

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.

2017 Shelf Registration Statement

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 (File No. 333-215205) (the "2017 Shelf Registration Statement"), at which time the offering of unsold securities under a previous shelf registration statement on Form S-3 filed with the SEC, which was declared effective by the SEC on January 13, 2014 (File No. 333-192102) (the "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℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") described below and (ii) up to 544,178 shares of our common stock pursuant to the exercise of warrants that were issued in a registered direct offering in 2014 and in the 2016 Registered Direct Offering, 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.

"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, 2017, 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 588,235 shares of our common stock and warrants to purchase up to 294,118 shares of our common stock for gross proceeds of approximately $10.0 million under the 2014 Registration Statement (the "2016 Registered Direct Offering"). We also issued warrants to purchase up to 25,000 shares of common stock in a private placement to H.C. Wainwright & Co., LLC and its designees as compensation for its services as a placement agent in connection with the 2016 Registered Direct Offering (together with the warrants to purchase up to 294,118 shares, the "2016 Warrants"). 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.

Warrant Exercises

On May 21, 2017, the Company entered into Warrant Exercise Agreements (the "Exercise Agreements") with certain holders (the "Exercising Holders") of the 2016 Warrants and warrants to purchase up to 250,000 shares of common stock that we issued in January 2014 (the "2014 Warrants," and together with the 2016 Warrants, the "Original Warrants"). The Exercising Holders owned, in the aggregate, Original Warrants exercisable for 441,176 shares of our common stock. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their Original Warrants with respect to 430,000 shares of our common stock underlying such Original Warrants for a reduced exercise price equal to $3.80 per share (the "Reduced Exercise Price"). The Exercising Holders also subsequently exercised their Original Warrants for the remaining 11,176 shares of our common stock underlying such Original Warrants for the Reduced Exercise Price. In connection with the execution of the Exercise Agreements, we issued to each Exercising Holder a new warrant (each, a "New Warrant") to purchase shares of our common stock equal to the number of shares of our common stock received by such Exercising Holder upon exercise of such Exercising Holder's Original Warrants. The terms of the New Warrants are substantially similar to the terms of the Original Warrants, except that the New Warrants (i) became exercisable immediately upon issuance for a period of five years from the closing date of the Exercise Agreements; (ii) have an exercise price equal to $6.00 per share and (iii) included revised language substantially similar to the language in the Warrant Amendments described above regarding fundamental transactions and net cash settlement. The net proceeds to the Company from the exercise of the New Warrants by the Exercising Holders, after deducting financial advisory fees and expenses and our offering expenses, were approximately $1.5 million.

2017 Registered Direct Offering

On November 3, 2017, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell an aggregate of 1,333,333 shares of our common stock and warrants to purchase up to 666,667 shares of our common stock for gross proceeds of approximately $4.0 million under the 2017 Registration Statement (the "2017 Registered Direct Offering"). We also issued warrants to purchase up to 16,000 shares of common stock in a private placement to Roth Capital Partners, LLC as compensation for its services as a placement agent in connection with the 2017 Registered Direct Offering. The 2017 Registered Direct Offering closed on November 6, 2017. The net proceeds to the Company from the 2017 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 $3.6 million.

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, BP1002 and BP1003. 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, 2017, we did not have any material off-balance sheet arrangements.

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 U.S. 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, 2017, $5.7 million of our cash balances was not covered by the FDIC. As of December 31, 2016 we had $9.4 million in cash on-hand, of which approximately $9.1 million was not covered by the FDIC. To date, the Company has not incurred any losses on its cash balances.

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, 2017, other assets totaled $0.8 million for our technology license, comprised of $2.5 million in value acquiring our technology license and our intellectual property, less accumulated amortization of $1.7 million. 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, 2016 other assets totaled $0.9 million, comprised of $2.5 million in value acquiring our technology licenses and our intellectual property, less accumulated amortization of $1.6 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 both the years ended December 31, 2017 and 2016, we had $5.5 million of costs classified as 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 Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 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 beginning after December 15, 2017, including interim periods within that reporting period. The Company adopted the standard on January 1, 2018 using the modified retrospective method of adoption and determined that it will not have a material effect on our consolidated financial statements as the Company currently does not have significant contracts with customers.

In February 2016, the FASB issued ASU 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 May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation: Scope of Modification Accounting. The new standard requires an entity to apply modification accounting provisions if the value, vesting conditions or classification of the award changes. The new guidance must be applied on a prospective basis and is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. Management is currently evaluating the impact of future adoption of the new standard on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of the new standard applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. Part II of the new standard replaces the indefinite deferrals for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities. ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Management early adopted the new standard during fiscal year 2017 and notes the adoption did not have a significant impact on the Company's consolidated financial statements.

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

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY 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, 2017. 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, 2017. Based on this evaluation, management believes that, as of December 31, 2017, 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.

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	69	Chief Executive Officer; President; Chief Financial Officer; Treasurer; Chairman of the Board; Director
Heath W. Cleaver, CPA	44	Director – Audit Committee (Chair); Compensation Committee; Nominating/Corporate Governance Committee (Chair)
Mark P. Colonnese	62	Director – Audit Committee; Compensation Committee (Chair); Nominating/Corporate Governance Committee
Douglas P. Morris	62	Director; Director of Investor Relations
Paul D. Aubert	48	Director – Audit Committee

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 preclinical 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. Mr. Nielsen previously served 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.

Heath W. Cleaver, CPA. Mr. Cleaver has served as a director of Bio-Path since 2014. Since July 2017, Mr. Cleaver has served as the Chief Financial Officer of Compressor Engineering Corporation, a privately-held independent manufacturer of engine and compressor replacement parts. Mr. Cleaver was previously a consultant providing turn-around management and capital raising services to companies in the oil and gas service sector from 2016 to 2017. 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.

Mark P. Colonnese. Mr. Colonnese has served as a director of Bio-Path since 2017. From 2015 to February 2018, Mr. Colonnese served as Executive Vice President & Chief Financial Officer of Aviragen Therapeutics, Inc., a Nasdaq-listed biotechnology company focused on the discovery and development of direct-acting antivirals to treat infections that have limited therapeutic options and affect a significant number of patients globally. Mr. Colonnese previously served as Chief Financial Officer of Stealth Biotherapeutics Inc. from 2014 to 2015 and as Executive Vice President & Chief Financial Officer of Transgenomic, Inc. from 2012 to 2014. From 1999 to 2012, Mr. Colonnese served in various roles at Salutria Pharmaceuticals, LLC and its predecessor company, AtheroGenics, Inc., including as Executive Vice President; Commercial Operations and Chief Financial Officer, and Senior Vice President, Finance and Administration. Mr. Colonnese holds a B.S. magna cum laude in Accounting from Ithaca College and an M.B.A. from Fairleigh Dickinson 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.

Paul D. Aubert. Mr. Aubert was appointed to the Board on February 1, 2018. Mr. Aubert has served as the sole Shareholder of a private law practice since June 2014. He also serves as a part-time General Counsel to four companies, including one in the medical device space. From February 2012 through May 2014, Mr. Aubert served as General Counsel of Pernix Therapeutics Holdings, Inc., a Nasdaq-listed specialty pharmaceutical company. Before that, he was a Shareholder in the Corporate and Securities practice group at Winstead PC, a national law firm headquartered in Dallas, Texas, from 2007 to 2012. Mr. Aubert also served as an attorney in the Corporate and Securities practice groups of several national and international law firms prior to joining Winstead in 2004, including at Andrews Kurth LLP from 1999 to 2004, Weil, Gotshal & Manges LLP from 1998 to 1999 and Jones Walker LLP from 1996 to 1998. Mr. Aubert holds a Juris Doctor and an M.B.A. from Tulane University in New Orleans, Louisiana and a B.A. in History from Louisiana State University - Baton Rouge.

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 Heath W. Cleaver, Mark P. Colonnese and Paul D. Aubert 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. Cleaver, Colonnese and Aubert. Mr. Cleaver currently serves as 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. Cleaver and Colonnese, both of whom are independent under the rules of The Nasdaq Stock Market. The Compensation Committee meets as necessary. Mr. Colonnese is the chair of the Compensation Committee.

Nominating/Corporate Governance Committee

The Nominating/Corporate Governance Committee's charter provides that the responsibilities of such committee include:

- evaluating, identifying and recommending nominees to the Board;
- considering written recommendations from our stockholders for nominees to the Board;
- recommending directors to serve as committee members and chairs;
- reviewing and developing corporate governance guidelines, policies and procedures for the Board;
- reviewing disclosure by the Company of matters within the Nominating/Corporate Governance Committee's mandate; and
- reviewing and evaluating the Nominating/Corporate Governance Committee's charter and efficacy.

The Nominating/Corporate Governance Committee is responsible for, among other things, identifying and recommending potential candidates for nomination to the Board. The Nominating/Corporate Governance Committee receives advice from the Board and will consider written recommendations from the stockholders of the Company respecting individuals best suited to serve as directors, and, when necessary, develops its own list of appropriate candidates for directorships. For a description of the procedures to be followed by stockholders of the Company in submitting recommendations to be considered by the Nominating/Corporate Governance Committee, see the discussion set forth below under the heading titled, "Stockholder Nominations for Directors."

The Nominating/Corporate Governance Committee is comprised of Messrs. Cleaver and Colonnese, both of whom are independent under the rules of The Nasdaq Stock Market. The Nominating/Corporate Governance Committee meets at least annually, and otherwise as necessary. Mr. Cleaver is the chair of the Nominating/Corporate Governance Committee.

Scientific Advisory Board

The Scientific Advisory Board assists management and the Board on an advisory basis with respect to the research, development, clinical, regulatory and commercial plans and activities relating to research, manufacture, use and/or sale of our drug candidates and products. The Scientific Advisory Board meets on an *ad hoc* basis and may attend meetings of the Board at the Board's request. The current members of the Scientific Advisory Board are Jorge Cortes, M.D., who serves as chairman, and D. Craig Hooper, Ph.D.

Availability of Committee Charters and Other Information

The charters for our Audit Committee, Compensation Committee, and Nominating/Corporate Governance Committee, as well as our Corporate Governance Guidelines, Employee Code of Business Conduct and Ethics and Code of Business Conduct and Ethics for Members of the Board, are available under the section titled "Corporate Governance" on the Investors page of the Company's website, *www.biopathholdings.com*. We intend to disclose any changes to or waivers from the Employee Code of Business Conduct and Ethics that would otherwise be required to be disclosed under Item 5.05 of Form 8-K on our website. The information on our website is not, and shall not be deemed to be, a part of this Annual Report on Form 10-K or incorporated into any other filings we make with the SEC.

We also make available on our website, free of charge, access to our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports, as well as other documents that we file with or furnish to the SEC pursuant to Sections 13(a) or 15 (d) of the Exchange Act, as soon as reasonably practicable after such documents are filed with, or furnished to, the SEC.

Nomination Process

It is our Board's responsibility to nominate members for election to the Board and to fill vacancies on the Board that may occur between annual meetings of stockholders. The Nominating/Corporate Governance Committee assists the Board by identifying and reviewing potential candidates for Board membership consistent with criteria approved by the Board. The Nominating/Corporate Governance Committee also annually recommends qualified candidates (which may include existing directors) for approval by the Board of a slate of nominees to be proposed for election to the Board at the annual meeting of stockholders.

In the event of a vacancy on the Board between annual meetings of our stockholders, the Board may request that the Nominating/Corporate Governance Committee identify, review and recommend qualified candidates for Board membership for Board consideration to fill such vacancies, if the Board determines that such vacancies will be filled. Our First Amended and Restated Bylaws (the "Bylaws") allow for up to fifteen directors. The Board is permitted by the Bylaws to change the number of directors by a resolution adopted by the Board.

When formulating its recommendations for potential Board nominees, the Nominating/Corporate Governance Committee seeks and considers advice and recommendations from management, other members of the Board and may seek or consider advice and recommendations from consultants, outside counsel, accountants or other advisors as the Nominating/Corporate Governance committee or the Board may deem appropriate.

Board membership criteria are determined by the Board, with input from the Nominating/Corporate Governance Committee. The Board is responsible for periodically determining the appropriate skills, perspectives, experiences and characteristics required of Board candidates, taking into account our needs and current make-up of the Board. This assessment should include appropriate knowledge, experience, and skills in areas deemed critical to understanding the Company and our business; personal characteristics, such as integrity and judgment; and the candidate's commitments to the boards of other companies. Each Board member is expected to ensure that other existing and planned future commitments do not materially interfere with the member's service as a director and that he or she devotes the time necessary to discharge his or her duties as a director.

Stockholder Nominations for Directors

The Nominating/Corporate Governance Committee will consider candidates for director nominees that are recommended by our stockholders in the same manner as Board recommended nominees, in accordance with the procedures set forth in our Bylaws. Any such nominations should be submitted to the Nominating/Corporate Governance Committee c/o Secretary, Bio-Path Holdings, Inc., 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401 before the deadline set forth in the Bylaws and under the heading, "Stockholder Proposals for 2018 Annual Meeting" below, and should be accompanied by the following information:

- appropriate biographical information, a statement as to the qualifications of the nominee and any other information relating to such nominee that is required to be disclosed pursuant to Regulation 14A under the Exchange Act (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected); and

- the Proposing Stockholder Information (as defined in the Bylaws).

Involvement in Certain Legal Proceedings

There have been no events under any bankruptcy act, no criminal proceedings and any judgments or injunctions material to the evaluation of the ability and integrity of any director or executive officer during the last ten years.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and officers, and persons who own more than 10% of our common stock, to file initial reports of ownership and reports of changes in ownership (Forms 3, 4, and 5) of common stock with the SEC. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all such forms that they file.

To our knowledge, based solely on our review of the copies of such reports received by us and on written representations by certain reporting persons that no reports on Form 5 were required, we believe that during the fiscal year ended December 31, 2017, all Section 16(a) filing requirements applicable to our officers, directors and 10% stockholders were complied with in a timely manner.

ITEM 11. EXECUTIVE COMPENSATION

The Compensation Committee oversees our compensation programs for executives and all employees. The Compensation Committee understands that for the Company and its stockholders to achieve long-term success, the compensation programs need to attract, retain, develop and motivate a strong leadership team. As a result, our executive compensation programs are designed to pay for performance, enable talent attraction, retain top talent and closely align the interests of our executives with those of our stockholders. 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, 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.

This section provides important information on our executive compensation programs for our named executive officers ("NEOs"). In fiscal year 2016, we had the following NEOs:

- Peter H. Nielsen, Chairman of the Board, Chief Executive Officer; Chief Financial Officer and President; and
- Ulrich W. Mueller, Ph.D., Chief Operating Officer and Secretary. Dr. Mueller resigned from his positions as Chief Operating Officer and Secretary on September 5, 2017.

Summary Compensation Table

The following table sets forth information with respect to the compensation of our NEOs for the fiscal years ended December 31, 2017 and 2016.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Peter H. Nielsen, CEO,	2017	$ 475,000	$ 118,750	-	$ 208(2)	$ 593,958
CFO, President, Chairman, Director	2016	$ 456,250	$ 140,000	1,255,034	$ 208(2)	$ 1,851,492
Ulrich W. Mueller, COO,	2017	$ 243,306	$ 75,375	191,804	$ 9,972(3)	$ 520,457
Secretary (5)	2016	$ 322,500	$ 69,825	1,059,910	$ 13,970(4)	$ 1,466,205

(1) The amounts reported in this column reflect the aggregate grant date fair value of equity awards granted during the year computed in accordance with FASB ASC Topic 718. See Note 10 to our consolidated financial statements included in this Annual Report on Form 10-K and for the fiscal year ended December 31, 2016 for assumptions made by us in such valuation.

(2) The amounts reported represent life insurance premiums paid by the Company for Mr. Nielsen.

(3) The amounts reported represent $240 for life insurance premiums paid by the Company for Dr. Mueller and $9,732 for matching contributions under our 401(k) plan.

(4) The amounts reported represent $320 for life insurance premiums paid by the Company for Dr. Mueller and $13,650 for matching contributions under our 401(k) plan.

(5) Dr. Mueller resigned from his positions as Chief Operating Officer and Secretary on September 5, 2017.

Outstanding Equity Awards at December 31, 2017

The following table sets forth certain information with respect to outstanding stock option awards of the NEOs for the fiscal year ended December 31, 2017.

Name (1)	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Mr. Nielsen (2)	150,000	-	-	$ 14.00	Oct 2018
Mr. Nielsen (3)	150,000	-	-	$ 4.60	Aug 2023
Mr. Nielsen (4)	23,000	32,200	-	$ 27.50	April 2026

(1) Dr. Mueller resigned from his positions as Chief Operating Officer and Secretary on September 5, 2017. All unvested options held by Mr. Mueller at such time were forfeited at the time of such resignation. All vested options held by Mr. Muller at such time expired following a period of three months after the date of such resignation.

(2) All of these options granted are fully vested.

(3) All of these options granted are fully vested.

(4) Such options vest over a four-year period from the date of grant, April 5, 2016, with one-fourth (1/4) of the options vesting on the first anniversary of each such grant, and the remaining options vesting thereafter in equal monthly increments equal to one-forty-eighth (1/48) of the options over the next three years, based on continuing service to the Company.

DIRECTOR COMPENSATION

The following table presents summary information for the year ended December 31, 2017 regarding the compensation of the members of our Board.

Name	Fees Earned or Paid in Cash	Option Awards	All Other Compensation	Total
Heath W. Cleaver	$ 36,500(1)	$ 15,817(2)	$ 500(3)	$ 52,817
Mark P. Colonnese	$ 12,500(1)	$ 7,478(2)	$ 1,000(3)	$ 20,978
Douglas P. Morris (4)	$ —	$ 15,817(5)	$ 79,520(6)	$ 95,337
Michael J. Garrison (7)	$ 29,000(1)	$ 15,817(2)	$ -	$ 44,817
Amy P. Sing (7)	$ 27,500(1)	$ 15,817(2)	$ -	$ 43,317

(1) These amounts reflect cash fees paid to or earned by our non-employee directors for attending Board or committee meetings during the year ended December 31, 2017.

(2) During 2017, our non-employee directors who were eligible earned or received an annual grant of an option to purchase 2,500 shares of our common stock which was the only grant received by such directors during 2017. The amounts in this column reflect the aggregate grant date fair value of equity awards granted during the year computed in accordance with FASB ASC Topic 718. See Note 10 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for assumptions made by us in such valuation.

(3) The amounts reported represent amounts earned for Board services preformed beyond the normal scope of their Board or committee responsibilities.

(4) Mr. Morris was hired by the Company in 2016 as the Company's Director of Investor Relations. Accordingly, Mr. Morris is not considered a non-employee director and does not receive compensation for his services as a member of the Board.

(5) Option awards granted to Mr. Morris reflect compensation received by Mr. Morris in his capacity as the Company's Director of Investor Relations.

(6) This amount reflects compensation received by Mr. Morris in his capacity as the Company's Director of Investor Relations, which includes base salary and certain other benefits.

(7) Mr. Garrison and Dr. Sing resigned from their respective Board positions on August 10, 2017. All unvested options held by Mr. Garrison and Dr. Sing, respectively, were forfeited at the time of such resignations.

The following table reflects the aggregate number of outstanding options (including unexercisable options) held by our directors as of December 31, 2017:

Director	Number of shares underlying outstanding options
Heath W. Cleaver	10,000
Mark P. Colonnese	2,500
Douglas P. Morris (1)	172,778

(1) Mr. Morris's outstanding options include 165,278 options earned while serving as an executive officer of the Company. Mr. Morris ceased serving in his officer capacities in June 2014. However, Mr. Morris was hired by the Company in 2016 as the Company's Director of Investor Relations. Accordingly, Mr. Morris is not considered a non-employee director.

Narrative to Director Compensation Table

In 2017, our non-employee directors received cash and equity compensation in accordance with our non-employee director compensation structure. Directors who are also employed by the Company do not receive compensation for services as a director. We amended our compensation structure for all non-employee directors in August 2017 to include per diem compensation for Board or committee members who spend significant time performing Board or committee service beyond the normal scope of their Board or committee responsibilities. During 2017, our compensation structure for all non-employee directors was as follows:

Cash Compensation Program

Non-employee directors receive as compensation the following amounts: (i) an annual cash retainer in the amount of $5,000; (ii) $3,000 for each required meeting of the Board attended in person; (iii) $1,500 for each meeting of the Board conducted by telephonic or other electronic communications of duration of 15 minutes or longer; and (iv) $500 for each meeting of the Board of duration less than 15 minutes conducted by telephonic or other electronic communications. Board members must attend meetings in person or by telephonic or other electronic communications to receive the applicable cash compensation.

Each non-employee director of the Board who is a member of a Board committee also receives as compensation the following amounts: (i) $2,000 for each committee meeting attended in person; (ii) $1,500 for each committee meeting conducted by telephonic or other electronic communications of duration of 15 minutes or longer; and (iii) $500 for each committee meeting of duration less than 15 minutes conducted by telephonic or other electronic communications. Committee members must attend meetings in person or by telephonic or other electronic communications to receive the applicable compensation.

In addition to the foregoing cash compensation for Board and committee members, non-employee directors of the Board who spend significant time performing Board or committee service beyond the normal scope of their Board or committee responsibilities may receive up to $2,500 per diem at the discretion of the Chief Executive Officer of the Company.

Equity Compensation Program

Each non-employee director of the Board also receives as compensation an annual stock option grant (a "Grant") of 2,500 shares of our common stock (the "Option Shares"). The exercise price of the Option Shares is determined by the Board and the Option Shares vest over a four-year period from the date of the Grant, with one-fourth (1/4) of the Option Shares vesting on the first anniversary of each such Grant (i.e., 625 Option Shares), and the remaining Option Shares vesting thereafter in equal monthly increments equal to one-forty-eighth (1/48) of the Option Shares over the next three years (i.e., approximately 52.08 Option Shares per month), based on continuing service to the Company.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information regarding shares of our common stock beneficially owned at March 15, 2018 by: (i) each of our NEOs and directors; (ii) all executive officers and directors as a group; and (iii) each person known by us to beneficially own 5% or more of the outstanding shares of our common stock. The information in this table is based solely on statements in filings with the SEC or other reliable information.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Peter H. Nielsen (1) (2)	845,194	7.24%
Douglas P. Morris (1) (3)	332,628	2.89%
Heath W. Cleaver (1) (4)	6,458	*
Mark P. Colonnese (1)	-	*
Paul D. Aubert (1)	-	*
All officers and directors as a group (5)	1,184,280	10.00%

*Less than 1%

(1) These are our NEOs and directors.

(2) Includes 516,444 shares owned of record and 328,750 shares issuable upon the exercise of options that are exercisable within 60 days.

(3) Includes 160,982 shares held by Hyacinth Resources, LLC and 2,410 shares held by Sycamore Ventures, LLC. Mr. Morris disclaims beneficial ownership of the shares held by Sycamore Ventures, LLC except to the extent of his pecuniary interest therein. Also includes 169,236 shares issuable upon the exercise of options that are exercisable within 60 days.

(4) All 6,458 shares are issuable upon the exercise of options that are exercisable within 60 days.

(5) Includes 679,836 shares owned of record and 504,444 shares issuable upon the exercise of options currently exercisable or will be exercisable within 60 days.

Equity Compensation Plan Information

There are no equity compensation plans that have not been approved by our stockholders. The following table contains information about our equity compensation plans in effect as of December 31, 2017 (in thousands, except per share amount).

Plan Category	Number of shares of common stock to be issued upon exercise of outstanding options, warrants and rights (1)	Weighted-average exercise price of outstanding options, warrants and rights	Number of shares of common stock remaining available for future issuance under equity compensation plans (2)
Equity compensation plans approved by stockholders	642	$ 11.60	1,692
Equity compensation plans not approved by stockholders	—	—	—

(1) All of the shares shown in this column as securities to be issued upon exercise of outstanding options, warrants and rights were subject to outstanding stock option awards as of December 31, 2017 that were granted under the First Amended Bio-Path Holdings, Inc. 2007 Stock Incentive Plan, as amended (the "2007 Stock Incentive Plan"). The Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (the "2017 Stock Incentive Plan") was approved by our stockholders at our annual meeting of stockholders on December 21, 2017. There were no securities to be issued upon exercise of outstanding options, warrants and rights outstanding under the 2017 Stock Incentive Plan as of December 31, 2017.

(2) The shares shown in this column as remaining available for future issuance as of December 31, 2017 are under each of the 2007 Stock Incentive Plan and the 2017 Stock Incentive Plan and total 492 and 1,200, respectively. The 2007 Stock Incentive Plan expired in January 2018.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

It is our policy that we will not enter into any transactions required to be disclosed under Item 404 of Regulation S-K promulgated by the SEC unless the Audit Committee first reviews and approves the transactions. The Audit Committee is required to review on an ongoing basis, and pre-approve all related party transactions before they are entered into, including those transactions that are required to be disclosed under Item 404 of Regulation S-K. Related party transactions involving a director must also be approved by the disinterested members of the Audit Committee. It is the responsibility of our employees and directors to disclose any significant financial interest in a transaction between the Company and a third party, including an indirect interest. All related party transactions shall be disclosed in our filings with the SEC as required under SEC rules.

In addition, pursuant to our codes of ethics, all employees, officers and directors of ours and our subsidiaries are prohibited from engaging in any relationship or financial interest that is an actual or potential conflict of interest with us without approval. Employees and officers are required to provide written disclosure to their supervisors as soon as they have any knowledge of a transaction or proposed transaction with an outside individual, business or other organization that would create a conflict of interest or the appearance of one. Directors are required to disclose such information to the Board or as otherwise required by law.

For our last two fiscal years, there has not been nor is there currently proposed any transaction or series of similar transactions to which we were or are to be a party in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at the end of our last two fiscal years, and in which any of our directors, executive officers, persons who we know hold more than 5% of our common stock, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest other than: (i) compensation agreements and other arrangements, which are described elsewhere in this Annual Report on Form 10-K and (ii) the transactions described in the following paragraph.

We have entered into indemnity agreements with certain of our officers and directors which provide, among other things, that we will indemnify such officer or director, under the circumstances and to the extent provided for therein, for expenses, damages, judgments, fines and settlements he or she may be required to pay in actions or proceedings which he or she is or may be made a party by reason of his or her position as a director, officer or other agent of the Company, and otherwise to the fullest extent permitted under applicable law, our Certificate of Incorporation and our Bylaws.

Director Independence

The following members of the Board have been identified as independent under the standards of The Nasdaq Stock Market: Heath W. Cleaver, Mark P. Colonnese and Paul D. Aubert. Presently, there are no directors on any of our committees who are not independent under the standards of The Nasdaq Stock Market.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

We received notice from Mantyla McReynolds, LLC ("Mantyla McReynolds") on July 28, 2016, that Mantyla McReynolds merged with BDO USA, LLP ("BDO"), and that as a result, Mantyla McReynolds would not stand for reappointment as our independent registered public accounting firm. On July 29, 2016, we engaged BDO as our new independent registered public accounting firm for and with respect to the fiscal year ending December 31, 2016. The engagement of BDO was approved by our Audit Committee on July 29, 2016 and ratified by our stockholders on December 15, 2016.

For the interim period from January 1, 2016 through July 28, 2016, Mantyla McReynolds, as our independent registered public accounting firm during such time, billed the approximate fees set forth in the first table below. During the interim period from July 29, 2016 through December 31, 2016, and for the fiscal year ended December 31, 2017, BDO, as our independent registered public accounting firm during such time, billed the approximate fees set forth in the second table below. The Board has considered the respective services provided by Mantyla McReynolds and BDO and has concluded that such services are compatible with the independence of Mantyla McReynolds and BDO as our principal accountants during the respective periods.

For fiscal years 2017 and 2016, no hours expended on Mantyla McReynolds's or BDO's engagement to audit our financial statements were attributed to work performed by persons other than full-time, permanent employees of Mantyla McReynolds or BDO, as applicable.

The table below sets forth the aggregate fees billed to the Company by Mantyla McReynolds for services rendered for the interim period from January 1, 2016 through July 28, 2016 (in thousands).

	January 1, 2016 – July 28, 2016
Audit fees (1)	$ 86
Audit-related fees (2)	—
Tax fees (3)	—
Other fees (4)	—
Total	$ 86

(1) Audit fees consist of fees billed for professional services rendered for the audit of our consolidated financial statements and internal control over financial reporting, reviews of the interim condensed consolidated financial statements included in quarterly filings, and services that are normally provided by Mantyla McReynolds in connection with statutory and regulatory filings or engagements, including consents, except those not required by statute or regulation.

(2) Audit-related fees consist of fees billed by Mantyla McReynolds for assurance and related services. These fees include services provided in conjunction with due diligence services and employee benefit plan audits.

(3) Tax fees consist of fees billed for professional services rendered by Mantyla McReynolds for state and federal tax compliance and advice, and tax planning.

(4) Other fees consist of fees billed by Mantyla McReynolds for professional services other than those relating to audit fees, audit-related fees and tax fees.

The table below sets forth the aggregate fees billed to the Company by BDO for services rendered in the fiscal year ended December 31, 2017 and for the interim period from July 29, 2016 through December 31, 2016 (in thousands).

	December 31, 2017	July 29, 2016 – December 31, 2016
Audit fees (1)	$ 232	$ 71
Audit-related fees (2)	—	—
Tax fees (3)	4	3
Other fees (4)	—	—
Total	$ 236	$ 74

(1) Audit fees consist of fees billed for professional services rendered for the audit of our consolidated financial statements (with respect to 2017 and 2017) and internal control over financial reporting (with respect to 2016), reviews of the interim condensed consolidated financial statements included in quarterly filings, services associated with equity offerings, including with respect to registration statements filed by the Company, and services that are normally provided by BDO in connection with statutory and regulatory filings or engagements, including consents, except those not required by statute or regulation.

(2) Audit-related fees consist of fees billed by BDO for assurance and related services. These fees include services provided in conjunction with due diligence services and employee benefit plan audits.

(3) Tax fees consist of fees billed for professional services rendered by BDO for state and federal tax compliance and advice, and tax planning.

(4) Other fees consist of fees billed by BDO for professional services other than those relating to audit fees, audit-related fees and tax fees.

Pre-Approval Policies and Procedures

The Audit Committee has not adopted any blanket pre-approval policies and procedures. Instead, the Audit Committee will pre-approve the provision of all audit or non-audit services.

ITEM 15. EXHIBITS

1. *Financial Statements*. The financial statements and information required by "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K appear on pages F-1 through F-18 of this report. The Index to Consolidated Financial Statements appears on page F-1.

2. *Financial Statement Schedules*. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

3. Exhibits.

Exhibit Number	Exhibit
2.1	Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 27, 2007).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on January 6, 2015).
3.2	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 9, 2018).
3.3	First Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 7, 2017).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K filed on March 16, 2015).
4.2	Warrant Agreement, dated April 25, 2008, by and between the Company and Randeep Suneja, M.D. (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K filed on March 31, 2014).
4.3	Form of Warrant issued to Maxim Group LLC, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K on January 21, 2014).
4.4	Form of Warrant issued to certain investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 29, 2016).
4.5	Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.5 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2016).
4.6	Form of New Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 22, 2017).
4.7	Form of Warrant Amendment (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 19, 2017).
4.8	Form of Warrant issued to certain investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 6, 2017).
4.9*	Form of Warrant issued to Roth Capital Partners, LLC
10.1+	Employment Agreement – Peter H. Nielsen (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 19, 2008).

10.2+	Amended 2007 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed on December 10, 2008).
10.3+	First Amendment to First Amended 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013).
10.4	Patent and Technology License Agreement, dated as of November 2, 2007, by and between the Company and the Board of Regents of The University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2013).
10.5	Amendment No. 1 to the Patent and Technology Agreement, dated as of May 11, 2009, by and between the Company and the Board of Regents of the University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2013).
10.6	Form of Securities Purchase Agreement by and between the Company, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 21, 2014).
10.7	Form of Waiver, Consent and Amendment to that certain Securities Purchase Agreement by and between Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K on January 21, 2014).
10.8+	First Amendment to Employment Agreement, dated March 26, 2014 – Peter H. Nielsen (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 26, 2014).
10.9	Lease Agreement dated April 16, 2014 by and between the Company and Pin Oak North Parcel TT, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2014).
10.10	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 16, 2015).
10.11	Controlled Equity Offering[SM] Sales Agreement, dated June 24, 2015, by and between the Company and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on June 25, 2015).
10.12	Form of Securities Purchase Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 29, 2016).
10.13	Form of Warrant Exercise Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 22, 2017).
10.14	Form of Securities Purchase Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 6, 2017).
10.15	Form of Leak-Out Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 6, 2017).
10.16+	Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 27, 2017).
10.17	Form of Incentive Stock Option Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 27, 2017).
10.18	Form of Non-Qualified Stock Option Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on December 27, 2017).

10.19	Form of Restricted Share Unit Award Agreement (Time-Vested) under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on December 27, 2017).
10.20	Form of Restricted Share Unit Award Agreement (Performance-Based) under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on December 27, 2017).
10.21	Form of Restricted Share Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on December 27, 2017).
10.22	Form of Stock Appreciation Right Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed on December 27, 2017).
21.1*	Subsidiaries of Bio-Path Holdings, Inc.
23.1*	Consent of BDO USA, LLP.
31*	Certification of Principal Executive Officer/Principal Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
32*	Certification of Principal Executive Officer/Principal Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

+ Management contract or compensatory plan.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

BIO-PATH HOLDINGS, INC.

Dated: April 2, 2018

By: /s/ Peter H. Nielsen
Peter H. Nielsen
President
Chief Executive Officer
Chief Financial Officer
Principal Accounting Officer

In accordance with the Securities Exchange Act, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Company and in the capacities and on the dates indicated.

Date	**Title**	**Signature**
April 2, 2018	President/Chief Executive Officer/ Chief Financial Officer/ Principal Accounting Officer/Director	/s/ Peter H. Nielsen Peter H. Nielsen
April 2, 2018	Director	/s/ Heath W. Cleaver Heath W. Cleaver
April 2, 2018	Director	/s/ Mark P. Colonnese Mark P. Colonnese
April 2, 2018	Director	/s/ Douglas P. Morris Douglas P. Morris
April 2, 2018	Director	/s/ Paul D. Aubert Paul D. Aubert

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Bio-Path Holdings, Inc.
Bellaire, Texas

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Bio-Path Holdings, Inc. (the "Company") and subsidiary as of December 31, 2017 and 2016, the related consolidated statements of operations, shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiary at December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2017**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2016.

Salt Lake City, Utah
April 2, 2018

BIO-PATH HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	As of December 31, 2017	As of December 31, 2016
Assets		
Current assets		
Cash	$ 5,965	$ 9,375
Prepaid drug product for testing	1,117	376
Other current assets	353	902
Total current assets	7,435	10,653
Fixed assets		
Furniture, fixtures & equipment	984	708
Less accumulated depreciation	(330)	(94)
	654	614
Other assets		
Technology licenses	2,500	2,500
Less accumulated amortization	(1,731)	(1,571)
	769	929
Total Assets	$ 8,858	$ 12,196
Liabilities & Shareholders' Equity		
Current liabilities		
Accounts payable	$ 52	$ 69
Accrued expenses	739	969
Deferred revenue	-	12
Total current liabilities	791	1,050
Warrant liability	-	2,906
Total Liabilities	791	3,956
Shareholders' equity		
Preferred stock, $.001 par value; 10,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $.001 par value; 200,000 shares authorized; 11,339 and 9,564 shares issued and outstanding, respectively	11	10
Additional paid in capital	47,213	40,364
Accumulated deficit	(39,157)	(32,134)
Total shareholders' equity	8,067	8,240
Total Liabilities & Shareholders' Equity	$ 8,858	$ 12,196

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,	
	2017	**2016**
Revenue	$ 37	$ 13
Operating expenses		
Research and development	5,480	5,474
General and administrative	3,523	3,014
Total operating expenses	9,003	8,488
Net operating loss	$ (8,966)	$ (8,475)
Other income (loss)		
Change in fair value of warrant liability	2,374	1,713
Loss on extinguishment of warrant liability	(440)	-
Interest income	9	12
Total other income	1,943	1,725
Net loss	$ (7,023)	$ (6,750)
Deemed dividend related to warrant conversion	(1,038)	-
Net loss attributable to common stockholders	$ (8,061)	$ (6,750)
Net loss per share, basic and diluted	$ (0.80)	$ (0.73)
Basic and diluted weighted average number of common shares outstanding	10,081	9,270

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2017	**2016**
Cash flow from operating activities		
Net loss	$ (7,023)	$ (6,750)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization	160	161
Depreciation	251	43
Stock-based compensation	793	784
Change in fair value of warrant liability	(2,374)	(1,713)
Loss on extinguishment of warrant liability	440	-
(Increase) decrease in assets		
Prepaid drug product for testing	(741)	184
Other current assets	549	(723)
Increase (decrease) in liabilities		
Accounts payable and accrued expenses	-	(146)
Deferred revenue	(12)	12
Net cash used in operating activities	(7,957)	(8,148)
Cash flow from investing activities		
Purchases of furniture, fixtures & equipment	(538)	(338)
Net cash used in investing activities	(538)	(338)
Cash flow from financing activities		
Net proceeds from sale of common stock	3,567	9,007
Net proceeds from exercise of warrants	1,518	-
Net cash provided by financing activities	5,085	9,007
Net increase (decrease) in cash	**(3,410)**	**521**
Cash, beginning of year	9,375	8,854
Cash, end of year	$ 5,965	$ 9,375
Supplemental disclosure of non-cash activities		
Non-cash financing activities		
Warrants transferred to equity upon modification	$ 797	$ -
Conversion of warrant liability to equity	$ 175	$ -
Capital expenditures included in accrued expense	$ -	$ 247

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)

Description	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Additional Paid in Capital Shares to be Issued	Accumulated Deficit	Total
Balance at December 31, 2015	**8,976**	**$ 9**	**$ 35,193**	**$ -**	**$ (25,384)**	**$ 9,818**
Issuance of common stock, net of fees	588	1	4,387			4,388
Stock-based compensation			784			784
Net loss					(6,750)	(6,750)
Balance at December 31, 2016	**9,564**	**$ 10**	**$ 40,364**	**$ -**	**$ (32,134)**	**$ 8,240**
Issuance of common stock, net of fees	1,333	1	3,566			3,567
Exercise of warrants	442	-	1,518			1,518
Warrants transferred to equity upon modification			797			797
Conversion of warrant liability to equity			175			175
Stock-based compensation			793			793
Deemed dividend related to warrant modification			(1,038)			(1,038)
Modification of warrant exercise price			1,038			1,038
Net loss					(7,023)	(7,023)
Balance at December 31, 2017	**11,339**	**$ 11**	**$ 47,213**	**$ -**	**$ (39,157)**	**$ 8,067**

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Unless the context requires otherwise, references in these Notes to the Consolidated Financial Statements 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."

1. Organization and Business

The Company is a clinical and preclinical stage oncology focused RNAi nano particle drug development company utilizing a novel technology that achieves systemic delivery of antisense drug substances for target specific protein inhibition for any gene product that is over-expressed in disease. The Company's 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 *in vivo*, incorporated inside of a neutral charge lipid bilayer. The Company believes 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 targeted 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), targets the protein Grb2 and is in the efficacy portion of a Phase II clinical trial for acute myeloid leukemia (AML), and the safety segment of a Phase II clinical trial for blast phase and accelerated phase chronic myelogenous leukemia (CML) is open for enrollment. 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 Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. We are currently preparing an Investigational New Drug (IND) application for BP1002 in addition to completing additional IND enabling studies. We intend to initiate a Phase I clinical trial of BP1002 in refractory or relapsed lymphoma patients once we receive approval from the FDA.

Our third drug candidate, Liposomal Stat3 ("BP1003"), targets the Stat3 protein and is currently in preclinical development in a pancreatic patient-derived tumor model. Previous preclinical models have shown BP1003 to successfully penetrate pancreatic tumors and to significantly enhance the efficacy of standard frontline treatments. We intend to initiate IND enabling studies of BP1003 in 2018.

Bio-Path Subsidiary was founded in May 2007 as a Utah corporation. In February 2008, Bio-Path Subsidiary completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. The Company's operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for a limited number of product candidates.

In June 2015, the Company established an "at the market" ("ATM") program through which it may offer and sell up to $25.0 million of its common stock from time to time, at Bio-Path's discretion, through an investment banking firm, acting as sales agent. Sales of Bio-Path common stock under the ATM program will be made directly on or through The Nasdaq Capital Market, among other methods. Pursuant to the Securities Purchase Agreement (as defined below), the Company is subject to certain restrictions on its ability to offer and sell shares of common stock under the ATM program. To date, the Company has not offered or sold any shares of its common stock under the ATM program.

In June 2016, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain healthcare focused institutional investors pursuant to which the Company agreed to sell an aggregate of 588,235 shares of the Company's common stock and warrants (the "2016 Registered Warrants") to purchase up to 294,118 shares of the Company's common stock for gross proceeds of approximately $10.0 million (the "2016 Registered Direct Offering"). The 2016 Registered Direct Offering closed on July 5, 2016. The Company also issued warrants (the "2016 Placement Warrants," and together with the 2016 Registered Warrants, the "2016 Warrants") to purchase up to 25,000 shares of the Company's common stock in a private placement to H.C. Wainwright & Co., LLC and its designees as compensation for its services as a placement agent in connection with the 2016 Registered Director Offering. The net proceeds to the Company from the 2016 Registered Direct Offering, after deducting the placement agent's fees and expenses and the Company's offering expenses, and excluding the proceeds from the exercise of the warrants issued in the offering, were approximately $9.3 million. These proceeds were partially offset by additional financing costs incurred of $0.3 million.

On May 21, 2017, the Company entered into Warrant Exercise Agreements (the "Exercise Agreements") with certain holders (the "Exercising Holders") of the 2016 Warrants and warrants to purchase up to 250,000 shares of common stock that we issued in January 2014 (the "2014 Warrants," and together with the 2016 Warrants, the "Original Warrants"). The Exercising Holders owned, in the aggregate, Original Warrants exercisable for 441,176 shares of our common stock. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their Original Warrants with respect to 430,000 shares of our common stock underlying such Original Warrants for a reduced exercise price equal to $3.80 per share (the "Reduced Exercise Price"). The Exercising Holders also subsequently exercised their Original Warrants for the remaining 11,176 shares of our common stock underlying such Original Warrants for the Reduced Exercise Price. In connection with the execution of the Exercise Agreements, we issued to each Exercising Holder a new warrant (each, a "New Warrant") to purchase shares of our common stock equal to the number of shares of our common stock received by such Exercising Holder upon exercise of such Exercising Holder's Original Warrants. The terms of the New Warrants are substantially similar to the terms of the Original Warrants, except that the New Warrants (i) became exercisable immediately upon issuance for a period of five years from the closing date of the Exercise Agreements; (ii) have an exercise price equal to $6.00 per share and (iii) included revised language substantially similar to the language in the Warrant Amendments described below regarding fundamental transactions and net cash settlement. As noted below, this modified language results in the New Warrants qualifying for equity treatment on the Company's Consolidated Balance Sheet. The net proceeds to the Company from the exercise of the New Warrants by the Exercising Holders, after deducting financial advisory fees and expenses and our offering expenses, were approximately $1.5 million.

On June 13, 2017, the Company entered into amendments (the "Warrant Amendments") with holders (the "Holders") of the remaining 2016 Warrants, which amended the terms of their 2016 Warrants exercisable for 127,941 shares of our common stock. The Warrant Amendments provide that (i) the Holders' right to require the Company to purchase the outstanding warrants upon the occurrence of certain fundamental transactions will not apply if the fundamental transaction is a result of a transaction that has not been approved by the Board of Directors and (ii) in the event the Company does not have an effective registration statement registering the issuance of the underlying shares of our common stock to the Holders, there is no circumstance that would require the Company to net cash settle the outstanding warrants. As such, the changes made in the Warrant Amendments allow for equity treatment of the remaining 2016 Warrants. As a result of the Exercise Agreements and the Warrant Amendments, the Company's Warrant Liability was extinguished, allowing the New Warrants and the remaining 2016 Warrants, as amended, to be treated as equity for all filings beginning with the quarter ended June 30, 2017.

The Exercise Agreements for the 2014 Warrants resulted in the holders receiving $1.0 million in incremental value over the value of the warrants at the exchange date. This incremental value was recorded as a deemed dividend in additional paid-in capital due to the absence of retained earnings and increased the net loss available to common stockholders on the Consolidated Statements of Operations. The Exercise Agreements for the 2016 Warrants resulted in warrants with a fair value of $0.4 million being extinguished and resulted in the recognition of a loss on extinguishment of warrants of $0.4 million. Additionally, the Warrant Amendments resulted in the reclassification of the remaining 2016 Warrants with a fair value of $0.2 million from liability presentation to equity treatment on the Consolidated Balance Sheet.

On November 3, 2017, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell an aggregate of 1,333,333 shares of our common stock and warrants to purchase up to 666,667 shares of our common stock for gross proceeds of approximately $4.0 million under the 2017 Registration Statement (the "2017 Registered Direct Offering"). We also issued warrants to purchase up to 16,000 shares of common stock in a private placement to Roth Capital Partners, LLC as compensation for its services as a placement agent in connection with the 2017 Registered Direct Offering. The 2017 Registered Direct Offering closed on November 6, 2017. The net proceeds to the Company from the 2017 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 $3.6 million.

On February 8, 2018, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-10, and our common stock began trading on the split-adjusted basis on The Nasdaq Capital Market at the commencement of trading on February 9, 2018. All common stock share and per share amounts in this Annual Report on Form 10-K have been adjusted to give effect to the 1-for-10 reverse stock split, retrospectively.

As of December 31, 2017, the Company had $6.0 million in cash on hand, compared to $9.4 million as of December 31, 2016. Management has completed its analysis of the Company's cash needs and determined that it does not have enough cash on hand to meet obligations and fund operations for the next 12 months from the report date included herein. We expect to finance our foreseeable cash requirements through cash on hand, 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. If the Company is unable to obtain funding due to unfavorable terms or market conditions, management has determined that it can reduce spending on its day-to-day operations, sell laboratory assets and temporarily delay planned activities if needed. However, these conditions raise substantial doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent upon obtaining funding within the next 12 months to meet its planned obligations and pay its liabilities.

As the Company has not begun its planned principal operations of commercializing a product candidate, the Company's activities are subject to significant risks and uncertainties, including the potential requirement to secure additional funding, the outcome of the Company's clinical trials, and failing to operationalize the Company's current drug candidates before another company develops similar products.

2. Summary of Significant Accounting Policies

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.

Revenue Recognition — We have not generated significant revenues to date. 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, 2017, the Company has recorded $50,000 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.

Cash and Cash Equivalents — The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

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, 2017, approximately $5.7 million of our cash balances was not covered by the FDIC. As of December 31, 2016 we had approximately $9.4 million in cash on-hand, of which approximately $9.1 million was not covered by the FDIC. To date, the Company has not incurred any losses on its cash balances.

Furniture, fixtures and equipment — Furniture, fixtures and equipment are stated at cost and depreciated using the straight line method over the estimated useful lives of the assets. Depreciation expense was $0.3 million and $43,000 for the years ended December 31, 2017 and 2016, respectively.

The estimated useful lives are as follows:

Computers and equipment – 3 years
Furniture and fixtures – 7 years
Scientific equipment –7 years
Leasehold improvements – Lesser of useful life or lease term

Major additions and improvements are capitalized, while costs for minor replacements, maintenance, and repairs that do not increase the useful life of an asset are expensed as incurred.

Long Lived Assets — Our long lived assets consist of furniture, fixtures and equipment, leasehold improvements 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, 2017, other assets totaled $0.8 million for our technology license, comprised of $2.5 million in value acquiring our technology license and our intellectual property, less accumulated amortization of $1.7 million. 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. The Company did not have any impairments for the years ended December 31, 2017 and 2016. 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, 2016 other assets totaled $0.9 million, comprised of $2.5 million in value acquiring our technology licenses and our intellectual property, less accumulated amortization of $1.6 million.

Research and Development Costs — Costs and expenses that can be clearly identified as research and development are charged to expense. 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 both the years ended December 31, 2017 and 2016, we had $5.5 million of costs classified as research and development expense.

Stock-Based Compensation — The Company has accounted for stock-based compensation under the provisions of generally accepted accounting principles ("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.

Net Loss Per Share — Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Although there were warrants and stock options outstanding during 2017 and 2016, no potential common shares shall be included in the computation of any diluted per-share amount when a loss exists, as it would be anti-dilutive. Consequently, diluted net loss per share as presented in the financial statements is equal to basic net loss per share for the years 2017 and 2016. The calculation of diluted earnings per share for 2017 did not include 562,041 shares and 1,277,784 shares issuable pursuant to the exercise of vested common stock options and outstanding warrants, respectively, as of December 31, 2017 as the effect would be anti-dilutive. The calculation of diluted earnings per share for 2016 did not include 544,167 shares and 595,118 shares issuable pursuant to the exercise of vested common stock options and outstanding warrants, respectively, as of December 31, 2016 as the effect would be anti-dilutive.

Use of Estimates — The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States ("U.S.") requires management to make estimates and assumptions that affect the amounts reported in the Company's consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends as well as on various other assumptions that the Company believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from the Company's estimates. These estimates include accrued clinical trial costs, stock-based compensation expense, valuation of warrants and valuation of deferred tax assets.

Income Taxes — Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Liquidity — Since its inception, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure, and has not generated significant revenues from its planned principal operations. The Company does not anticipate generating significant revenues for the foreseeable future. The Company's activities are subject to significant risks and uncertainties.

The Company has experienced significant losses since its inception, including net losses of $7.0 million and $6.8 million for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, the Company had an accumulated deficit of $39.2 million and $6.0 million in cash and cash equivalents. The Company has no debt commitments. Substantially all of the Company's net losses have resulted from costs incurred in connection with its research and development activities and its general and administrative expenses to support operations. The Company's net losses may fluctuate significantly from quarter to quarter and year to year.

The Company's available cash at December 31, 2017 will not be sufficient to fund liquidity and capital expenditure requirements for the next twelve months from the date of issuance of these financial statements. The Company expects to continue to incur net losses for the foreseeable future in connection with its ongoing activities, including conducting clinical trials, manufacturing development and seeking regulatory approval of its drug candidates, prexigebersen, BP1002 and BP1003. Accordingly, the Company will continue to require substantial additional capital to fund its projected operating requirements. Such additional capital may not be available when needed or on terms favorable to the Company. In addition, the Company may seek additional capital due to favorable market conditions or strategic considerations, even if it believes it has sufficient funds for our current and future operating plan. There can be no assurance that the Company will be able to continue to raise additional capital through the sale of securities in the future. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, financial condition and future prospects.

Recent Accounting Pronouncements — From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) 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 Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 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 beginning 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. The Company adopted the standard on January 1, 2018 using the modified retrospective method of adoption and determined that it will not have a material effect on our consolidated financial statements as the Company currently does not have significant contracts with customers.

In February 2016, the FASB issued ASU 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 May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation: Scope of Modification Accounting*. The new standard requires an entity to apply modification accounting provisions if the value, vesting conditions or classification of the award changes. The new guidance must be applied on a prospective basis and is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. Management is currently evaluating the impact of future adoption of the new standard on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11*, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* Part I of the new standard applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. Part II of the new standard replaces the indefinite deferrals for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities. ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Management early adopted the new standard during fiscal year 2017 and notes the adoption did not have a significant impact on the Company's consolidated financial statements.

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

3. Prepaid Drug Product for Testing

Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future clinical 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. The Company made payments to its contract drug manufacturing and raw material suppliers totaling $0.4 million in late 2015 and all of 2016 pursuant to drug supply contracts for the manufacture and delivery of prexigebersen for testing in a Phase II clinical trial. This amount was carried on the Balance Sheet as of December 31, 2016 at cost as Prepaid Drug Product for Testing. The Company recognized certain expenses and incurred additional installment costs during 2017, with advanced payments totaling $1.1 million, which are carried on the Balance Sheet as of December 31, 2017 as Prepaid Drug Product for Testing (See Note 13).

4. Other Current Assets

As of December 31, 2017, Other Current Assets included prepaid expenses of $0.4 million, comprised primarily of prepayments made to the Company's clinical research organization for our clinical trial for prexigebersen in CML of $0.2 million, prepaid insurance of $0.1 million and other prepaid expenses of $0.1 million. As of December 31, 2016, Other Current Assets included prepaid expenses of $0.9 million.

5. Property and Equipment

The following table summarizes property and equipment as of December 31, 2017 and 2016:

		December 31,	
	Estimated Useful Lives	**2017**	**2016**
	(in years)	**(in thousands)**	
Leasehold improvements	2 to 3	$ 432	$ 393
Computers and office equipment	3	63	77
Furniture and fixtures	7	46	46
Scientific equipment	7	443	192
Total		984	708
Less: Accumulated depreciation		(330)	(94)
Net property and equipment		$ 654	$ 614

6. Accounts Payable

As of December 31, 2017, Current Liabilities included accounts payable of $0.1 million, comprised primarily of amounts owed for legal and professional fees and manufacturing development. As of December 31, 2016, Current Liabilities included accounts payable of $0.1 million.

7. Accrued Expense

As of December 31, 2017, Current Liabilities included accrued expenses of $0.7 million, comprised primarily of accrued clinical and preclinical expenses of $0.4 million, employee vacation and bonus expenses of $0.1 million, an annual license maintenance fee of $0.1 million and other accrued expenses of $0.1 million. As of December 31, 2016, Current Liabilities included accrued expense of $1.0 million, comprised primarily of accrued employee vacation and bonus expenses of $0.4 million, laboratory expenses of $0.2 million, clinical and preclinical expenses of $0.2 million, an annual license maintenance fee of $0.1 million and other accrued expenses of $0.1 million.

8. Warrant Liability

In connection with the 2016 Registered Direct Offering, the Company issued warrants to purchase up to 294,118 shares of the Company's common stock at $23.00 per share to certain healthcare focused institutional investors, as well as warrants to purchase up to 25,000 shares of the Company's common stock at $24.60 per share to H.C. Wainwright & Co., LLC and its designees as compensation for its services as the placement agent. When issued, the 2016 Warrants contained a provision for net cash settlement in the event of certain fundamental transactions involving the Company (defined in the 2016 Warrants to include, among other things, the Company's approval and consummation of a merger with another entity, the Company's approval and consummation of the sale of all or substantially all of the Company's assets or the occurrence of certain other change of control transactions).

Due to this provision and in accordance with ASC 480-10 (Distinguishing Liabilities from Equity), the 2016 Warrants were classified as a liability and recorded at fair value as calculated using the Binomial Lattice Model. The estimated fair value of the Warrant Liability for the 2016 Warrants on the closing date, July 5, 2016, was $4.6 million.

As of December 31, 2017, and December 31, 2016, the fair values of the Warrant Liability were none and $2.9 million, respectively. The net change in fair value of $2.4 million and $1.7 million for the years ended December 31, 2017 and 2016, respectively, are shown as other income on the Company's Consolidated Statements of Operations. As discussed in Note 1, certain of the 2016 Warrants were extinguished as a result of the Exercise Agreements and resulted in recognition of a loss on extinguishment of warrants of $0.4 million. Additionally, warrants with a fair value of $0.2 million were reclassified to equity as a result of the Warrant Amendments.

9. Fair Value Measurements

In accordance with ASC 820 (Fair Value Measurements and Disclosures), the Company uses various inputs to measure the 2016 Warrants on a recurring basis to determine the fair value of the liability. ASC 820 also establishes a hierarchy categorizing inputs into three levels used to measure and disclose fair value. The hierarchy gives the highest priority to quoted prices available in active markets and the lowest priority to unobservable inputs. An explanation of each level in the hierarchy is described below:

Level 1 – Unadjusted quoted prices in active markets for identical instruments that are accessible by the Company on the measurement date

Level 2 – Quoted prices in markets that are not active or inputs which are either directly or indirectly observable

Level 3 – Unobservable inputs for the instrument requiring the development of assumptions by the Company

The Company's Warranty Liability was extinguished as of June 30, 2017 (See Note 1).

The following table summarizes the Company's 2016 Warrants measured at fair value within the hierarchy on a recurring basis as of December 31, 2016:

	Fair Value Measurements at December 31, 2016 (in thousands)			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Warrant liability	$ -	$ -	$ 2,906	$ 2,906

The following table summarizes changes to the fair value of the Level 3 2016 Warrants for the year ended December 31, 2017:

	Fair Value of Warrant Liability
	(in thousands)
Balance at December 31, 2016	$ 2,906
Change in fair value	(2,374)
Extinguished	(357)
Reclassified to equity	(175)
Balance at December 31, 2017	$ -

The following table summarizes changes to the fair value of the Level 3 2016 Warrants for the year ended December 31, 2016:

	Fair Value of Warrant Liability
	(in thousands)
Balance at December 31, 2015	$ -
Issuance	4,619
Change in fair value	(1,713)
Balance at December 31, 2016	$ 2,906

The Company utilized the Binomial Lattice Model for estimating the fair value of the 2016 Warrants using the following assumptions on the reclassification dates of June 13, 2017 and May 21, 2017 and as of December 31, 2016:

	As of June 13, 2017	As of May 21, 2017	As of December 31, 2016
Risk-free interest rate	1.51%	1.78%	1.93%
Expected volatility	88%	89%	98%
Expected term in years	4.6	4.6	5.0
Dividend yield	-%	-%	-%

10. Stockholders' Equity

Issuances of Common Stock – In July 2016, the Company issued a total of 588,235 shares of the Company's common stock and investor warrants to purchase 294,118 shares of the Company's common stock for aggregate gross proceeds of $10.0 million. The warrants are exercisable for a period of five years from the date of issuance. The exercise price of the investor warrants is $23.00 per share. The Company also issued warrants to purchase 25,000 shares of the Company's common stock to the placement agent for the transaction. The warrants are exercisable for a period of five years from the date of issuance. The exercise price of the placement agent warrants is $24.60 per share.

On November 3, 2017, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell an aggregate of 1,333,333 shares of our common stock and warrants to purchase up to 666,667 shares of our common stock for gross proceeds of approximately $4.0 million under the 2017 Registration Statement. We also issued warrants to purchase up to 16,000 shares of common stock in a private placement to Roth Capital Partners, LLC as compensation for its services as a placement agent in connection with the 2017 Registered Direct Offering. The 2017 Registered Direct Offering closed on November 6, 2017. The net proceeds to the Company from the 2017 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 $3.6 million.

Warrant Exercises – On May 21, 2017, the Company entered into the Exercise Agreements with the Exercising Holders of the Original Warrants to purchase up to 250,000 shares of common stock that we issued in January 2014. The Exercising Holders owned, in the aggregate, Original Warrants exercisable for 441,176 shares of our common stock. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their Original Warrants with respect to 430,000 shares of our common stock underlying such Original Warrants for a reduced exercise price equal to $3.80 per share. The Exercising Holders also subsequently exercised their Original Warrants for the remaining 11,176 shares of our common stock underlying such Original Warrants for the Reduced Exercise Price. In connection with the execution of the Exercise Agreements, we issued to each Exercising Holder a New Warrant to purchase shares of our common stock equal to the number of shares of our common stock received by such Exercising Holder upon exercise of such Exercising Holder's Original Warrants. The terms of the New Warrants are substantially similar to the terms of the Original Warrants, except that the New Warrants (i) became exercisable immediately upon issuance for a period of five years from the closing date of the Exercise Agreements; (ii) have an exercise price equal to $6.00 per share and (iii) included revised language substantially similar to the language in the Warrant Amendments described above regarding fundamental transactions and net cash settlement. The net proceeds to the Company from the exercise of the New Warrants by the Exercising Holders, after deducting financial advisory fees and expenses and our offering expenses, were approximately $1.5 million.

Stockholders' Equity totaled $8.1 million as of December 31, 2017 compared to $8.2 million as of December 31, 2016. There were 11,339,032 shares of common stock issued and outstanding as of December 31, 2017. There were no preferred shares outstanding as of December 31, 2017.

11. Stock-Based Compensation Plan

The 2017 Plan – On December 21, 2017, the Company's stockholders approved the Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (the "2017 Plan"), which replaced the First Amended 2007 Stock Incentive Plan, as amended (the "2007 Plan"). The 2007 Plan expired by its terms in January 2018, however, no awards were made under the 2007 Plan upon approval of the 2017 Plan. The 2017 Plan provides for the grant of Incentive Stock Options, Non-Qualified Stock Options, Restricted Shares, Restricted Share Units, Stock Appreciation Rights, Performance-Based Awards and other stock-based awards, or any combination of the foregoing to the Company's employees, non-employee directors and consultants. As of December 31, 2017, the total number of shares reserved and available for grant and issuance pursuant to the 2017 Plan is 1,200,000 shares, subject to the terms of the 2017 Plan. Under the 2017 Plan, the exercise price of awards is determined by the Board of Directors or the compensation committee of the Board of Directors, and for options intended to qualify as qualified Incentive Stock Options, may not be less than the fair market value as determined by the closing stock price at the date of the grant. Each option and award under the 2017 Plan shall vest and expire as determined by the Board of Directors or the compensation committee. Options expire no later than ten years from the date of grant. All grants provide for accelerated vesting if there is a change of control, as defined in the 2017 Plan.

Stock option awards granted for the years 2017 and 2016 were estimated to have a weighted average fair value per share of $6.00 and $20.90, respectively. The fair value calculation is based on stock options granted during the year using the Black-Scholes option-pricing model on the date of grant. In addition, for all stock options granted, exercise price was determined based on the fair market value as determined by the closing stock price at the date of the grant. For stock options granted during 2017 and 2016 the following weighted average assumptions were used in determining fair value:

	2017	2016
Risk-free interest rate	2.06%	1.37%
Expected volatility	99%	109%
Expected term in years	6.1	6.1
Dividend yield	-%	-%

The Company determines the expected term of its stock option awards using the simplified method based on the weighted average of the length of the vesting period and the term of the exercise period. Expected volatility is determined by the volatility of the Company's historical stock price over the expected term of the grant. The risk-free interest rate for the expected term of each option granted is based on the U.S. Treasury yield curve in effect at the time of grant.

Option activity under the 2007 Plan for the year ended December 31, 2017, was as follows (in thousands, except as noted):

	Options	Weighted-Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Year Ended December 31, 2017				
Outstanding at December 31, 2016	707	$ 13.30	5.2	$ 2,241
Granted	68	7.50	9.3	
Forfeited	(87)	16.50		
Expired	(46)	21.30		
Outstanding at December 31, 2017	642	$ 11.60	4.0	$ -
Vested and expected to vest December 31, 2017	627	$ 11.50	3.8	$ -
Exercisable at December 31, 2017	562	$ 10.70	3.3	$ -

The aggregate intrinsic value represents the total pretax intrinsic value (the difference between the Company's closing stock price on December 31, 2017 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2017. This amount changes based on the fair market value of the Company's stock.

Option activity under the 2007 Plan for the year ended December 31, 2016, was as follows (in thousands, except as noted):

	Options	Weighted-Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Year Ended December 31, 2016				
Outstanding at December 31, 2015	575	$ 10.50	5.3	$ 1,972
Granted	132	25.40	9.3	
Exercised	-	-		
Forfeited	-	-		
Outstanding at December 31, 2016	707	$ 13.30	5.2	$ 2,241
Vested and expected to vest December 31, 2016	673	$ 12.70	5.0	$ 2,239
Exercisable at December 31, 2016	544	$ 10.10	4.1	$ 2,236

The aggregate intrinsic value represents the total pretax intrinsic value (the difference between the Company's closing stock price on December 31, 2016 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2016. This amount changes based on the fair market value of the Company's stock.

Stock-Based Compensation Expense – Total stock-based compensation expense for the year ended 2017 was $0.8 million which consisted of research and development expense of $0.3 million and general and administrative expense of $0.5 million. As of December 31, 2017, future stock-based compensation expense for all outstanding unvested options was $0.9 million, which is expected to be recognized over a weighted-average vesting period of 2.3 years. Total stock-based compensation expense for the year ended 2016 was $0.8 million which consisted of research and development expense of $0.4 million and general and administrative expense of $0.4 million.

12. Warrants

A summary of warrants outstanding and exercisable as of December 31, 2017 (in thousands, except as noted):

	Warrants Outstanding			Warrants Exercisable	
Year Issued	**Number Outstanding**	**Weighted Average Remaining Contractual Life (in years)**	**Weighted Average Exercise Price (per share)**	**Number Exercisable**	**Weighted Average Exercise Price (per share)**
2008	1	0.3	$ 9.00	1	$ 9.00
2014	25	1.1	47.40	25	47.40
2016 (Note 10)	128	4.0	23.30	128	23.30
2017 (Note 10)	1,124	4.7	$ 5.10	1,108	5.10
	1,278	4.5	$ 7.70	1,262	$ 7.80

13. Commitments and Contingencies

Technology License – The Company has negotiated exclusive licenses from MD Anderson to develop drug delivery technology for antisense and siRNA drug products. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense and an annual license maintenance fee. The annual license maintenance fee attributable to the License Agreement totaling $0.1 million is included in Current Liabilities as of December 31, 2017 and December 31, 2016.

Operating Lease – In April 2014, the Company entered into a five-year lease agreement for administrative office space located in Bellaire, Texas. The term of the lease began on August 1, 2014 and terminates on July 31, 2019. The remaining lease payments due under this lease as of December 31, 2017 are $0.1 million.

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 and will require Bio-Path to pay $2,500 per month over the term of the lease. The remaining lease payments due under this lease as of December 31, 2017 are $40,000.

A summary of future payments under operating leases as of December 31, 2017:

For the Year Ending December 31,	(in thousands)
2018	116
2019	61
Total	$ 177

Drug Supplier Project Plan – The amounts paid for manufacture of the Company's Grb2 drug substance and prexigebersen that have not been expensed total $1.1 million and is carried on the balance sheet as of December 31, 2017 as Prepaid Drug Product for Testing (See Note 3). Total commitments for the Company's drug supplier project plan are $1.6 million as of December 31, 2017, comprised of $1.0 million to the manufacturer of prexigebersen and BP1002, $0.4 million for manufacture of our Grb2 drug substance and $0.2 million for manufacturing development. We expect to incur $1.2 million of these commitments over the next 12 months.

14. Benefit Plan

The Company initiated a contribution savings plan under Section 401(k) of the Internal Revenue Code in 2016. Under the plan, all eligible employees may contribute up to the statutory allowable amount governed by the Internal Revenue Service for any calendar year. We make matching contributions equal to 100% of the first 3% and 50% of the next 2% of each employee's base salary up to the allowable amount which is fully vested on the date the matching contributions are made. For the years ended December 31, 2017 and 2016, matching contributions totaled $47,000 and $48,000, respectively.

15. Income Taxes

At December 31, 2017, the Company had a net operating loss carryforward for federal income tax purposes of $35.8 million which begins to expire in varying amounts in tax year 2026. During the years ended December 31, 2017 and 2016, the Company raised additional equity capital. IRC Section 382 imposes certain limitations on the use of a net operating losses to offset future taxable income when an ownership change has occurred. The Company has yet to determine whether an ownership change occurred in 2017 or 2016. If an ownership change is determined to have occurred, additional limitations on the Company's net operating losses incurred prior to the ownership change may apply. The Company has a research and development tax credit carryforward of $1.5 million for federal income tax purposes that begins to expire in varying amounts in tax year 2028.

In assessing the ability to realize its deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers evidence such as the reversal of deferred tax liabilities, projected future results of operations, and tax planning strategies in making this assessment. Based upon the level of historical taxable income, significant book losses during the current and prior periods, and projections for future results of operations over the periods in which the deferred tax assets are deductible, among other factors, management continues to conclude that the Company does not meet the "more likely than not" requirement of ASC 740 in order to recognize deferred tax assets. As such, a valuation allowance has been recorded to offset the Company's net deferred tax assets at December 31, 2017. The Company recorded a decrease in the valuation allowance of $1.4 million for the year ended December 31, 2017.

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the "2017 Tax Act"). The 2017 Tax Act significantly changes corporate income tax laws in the U.S. including reducing the corporate income tax rate from a maximum of 35% to a flat rate of 21%, effective January 1, 2018. As a result of the reduction in the corporate income tax rate under the 2017 Tax Act, an adjustment has been recorded to the deferred tax asset of $4.9 million.

Due to the uncertainty surrounding the realization of the benefits of its deferred assets, including NOL carryforwards, the Company has provided a 100% valuation allowance on its deferred tax assets at December 31, 2017 and 2016. The changes in the valuation allowance were decreases of $9.5 million and $11.0 million for the years ended December 31, 2017 and 2016, respectively.

The components of the Company's deferred tax asset are as follows:

	December 31,	
	2017	2016
	(in thousands)	
Deferred tax assets – non-current		
Accrued bonuses	$ -	$ -
Accrued vacation	17	32
Net operating loss (NOL) carryover	7,516	9,166
Technology licenses amortization	36	60
Research & development tax credits	1,542	1,259
Share based expense	387	443
Other	5	9
Fixed asset depreciation	15	-
Total deferred tax asset	9,518	10,969
Less: valuation allowance	(9,518)	(10,965)
Net deferred tax asset	-	4
Deferred tax liability- non-current	-	(4)
Net deferred tax asset	$ -	$ -

Reconciliation between income taxes at the statutory tax rate (34%) and the actual income tax provision for continuing operations follows:

	December 31,		
	2017	2016	2015
		(in thousands)	
Loss before income taxes	$ (7,023)	$ (6,750)	$ (5,467)
Tax (benefit) @ statutory tax rate	(2,388)	(2,295)	(1,859)
Effects of:			
Exclusion of incentive stock option expense	86	117	89
R&D tax credits	(283)	(252)	(132)
Increase (decrease) in valuation allowance	(1,447)	3,001	1,899
FMV of warrants	(658)	(582)	-
Prior year adjustments	5	6	-
Carryforward adjustment	(252)	5	3
Rate change on net deferred tax asset	4,937	-	-
Provision for income taxes	$ -	$ -	$ -

As of December 31, 2017, the Company had no unrecognized income tax benefits. The Company's policy for classifying interest and penalties associated with unrecognized income tax benefits is to include such items as tax expense. No interest or penalties have been recorded as of the year ended December 31, 2017, and no interest or penalties have been accrued as of December 31, 2017 and 2016.

The Company's open years for Internal Revenue Service (IRS) examination purposes due to normal statute of limitation are 2014, 2015 and 2016. However, since the Company has operating loss carryforwards, the IRS has the ability to make adjustments to items that originate in a year otherwise barred by the statute of limitations under Section 6501 of the Internal Revenue Code of 1986, as amended (the "code"), in order to redetermine tax for an open year to which those items are carried. Therefore, in a year in which a net operating loss deduction was claimed, the IRS may examine the year in which the net operating loss was generated and adjust it accordingly for purposes of assessing additional tax in the year the net operating loss was claimed. The Company is not currently under examination by the IRS or any other taxing authorities.

16. Subsequent Event

On February 8, 2018, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-10, and our common stock began trading on the split-adjusted basis on The Nasdaq Capital Market at the commencement of trading on February 9, 2018 (See Note 1).

Exhibit 4.9

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

COMMON STOCK PURCHASE WARRANT

BIO-PATH HOLDINGS, INC.

Warrant Shares: 160,000 Initial Exercise Date: May 6, 2018

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant"), dated as of November 6, 2017, certifies that, for value received, Roth Capital Partners, LLC or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after May 6, 2018 (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on May 3, 2022 (the "Termination Date") but not thereafter, to subscribe for and purchase from Bio-Path Holdings, Inc., a Delaware corporation (the "Company"), up to 160,000 shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Securities Purchase Agreement (the "Purchase Agreement"), dated November 3, 2017, among the Company and the purchasers signatory thereto.

Section 2. Exercise.

a) Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire

transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within five (5) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be **$**0.45, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a

Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in

interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period, in each case, following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to

the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without

limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of the Warrant that are not in compliance with the Beneficial Ownership Limitation, except to the extent the Holder relies on the number of outstanding shares of Common Stock that was provided by the Company. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of the Warrant that are not in compliance with the Beneficial Ownership Limitation, except to the extent the Holder relies on the number of outstanding shares of Common Stock that was provided by the Company. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of

this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

f) No Net Cash Settlement. Without limiting the cashless exercise provision in Section 2(c), the liquidated damages provision in Section 2(d)(i) or the buy-in provision in Section 2(d)(iv), in the event that the Company does not have an effective registration statement registering, or the prospectus contained therein is not available for the issuance of, the Warrant Shares to the Holder, there is no circumstance that would require the Company to net cash settle the warrants.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Reserved.

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this

Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend (other than cash dividends) or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock

is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction (other than a Fundamental Transaction not approved by the Company's Board of Directors), the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that for the avoidance of doubt, if the Fundamental Transaction is not approved by the Company's Board of Directors, Holder shall not have the option to require the Company to purchase this Warrant. "Black Scholes Value" means the value of this Warrant based on the Black and Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public

announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds within five Business Days of the Holder's election (or, if later, on the effective date of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for, the Company (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and the Successor Entity may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to

the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If while the Warrant is outstanding (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

h) Voluntary Adjustment By Company. The Company may at any time during the term of this Warrant, with the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate

by the Board of Directors of the Company unless such reduction would result the Company violating any rules of its principal trading market.

Section 4. Transfer of Warrant.

a) Transferability. Pursuant to Rule 5110(g)(1), neither this Warrant nor any Warrant Shares issued upon exercise of this Warrant shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which this Warrant is being issued, except the transfer of any security:

i. by operation of law or by reason of reorganization of the Company;

ii. to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period;

iii. if the aggregate amount of securities of the Company held by the Holder or related person do not exceed 1% of the securities being offered;

iv. that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or

v. the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period.

Subject to compliance with the foregoing restriction, any applicable securities laws and the conditions set forth in Section 4(d) hereof and to the provisions of Section 4.1 of the Purchase Agreement, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an

assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

d) Transfer Restrictions. If, at the time of the surrender of this Warrant in connection with any transfer of this Warrant, the transfer of this Warrant shall not be either (i) registered pursuant to an effective registration statement under the Securities Act and under applicable state securities or blue sky laws or (ii) eligible for resale without volume or manner-of-sale restrictions or current public information requirements pursuant to Rule 144, the Company may require, as a condition of allowing such transfer, that the Holder or transferee of this Warrant, as the case may be, comply with the provisions of Section 5.7 of the Purchase Agreement.

e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of

the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain

all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Purchase Agreement.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant or the Purchase Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Purchase Agreement.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

BIO-PATH HOLDINGS, INC.

By: _____
Name:
Title:

NOTICE OF EXERCISE

TO: BIO-PATH HOLDINGS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

EXHIBIT B

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder's Signature: _____

Holder's Address: _____

Exhibit 21.1

SUBSIDIARIES OF REGISTRANT

Bio-Path, Inc., a Utah corporation

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Bio-Path Holdings, Inc.
Bellaire, Texas

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-215205 and 333-221610) and Form S-8 (File Nos. 333-156054 and 333-223111) of Bio-Path Holdings, Inc. of our report dated April 2, 2018, relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ BDO USA, LLP
Salt Lake City, Utah
April 2, 2018

Exhibit 31

CERTIFICATION OF

PRINCIPAL EXECUTIVE OFFICER AND

PRINCIPAL FINANCIAL OFFICER

I, Peter H. Nielsen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bio-Path Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared; and

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant’s board of directors:

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 2, 2018

By: /s/ Peter H. Nielsen
Peter H. Nielsen
Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Bio-Path Holdings, Inc. (the "Company") for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (the "Report"), I Peter H. Nielsen, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 2, 2018

By: /s/ Peter H. Nielsen
Peter H. Nielsen
Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.