214-987-4121





# STONEGATE CAPITAL PARTNERS

## **MARKET STATISTICS**

Exchange / Symbol	NASDAQ:BPTH
Price:	\$1.81
Market Cap (mm):	\$3.2
Enterprise Value (mm):	\$0.9
Shares Outstanding (mm):	1.8
Float (%):	96.8%
Volume (3-mo. average, mm):	.02
52 week Range:	\$1.16-\$61.80
Industry:	Biotechnology

#### **CONDENSED BALANCE SHEET**

(\$mm, except per share data)

<b>Balance Sheet Date:</b>	9/30/2018
Cash & Cash Equivalent:	\$2.3
Cash/Share:	\$2.06
Equity (Book Value):	\$3.0
Equity/Share:	\$2.69

#### **CONDENSED INCOME STATEMENTS**

(\$mm, except per share data)

FY - 12/31	Rev	Net Income	Adj. EBITDA	EPS		
FY15	\$0.00	(\$5.47)	(\$4.91)	(\$12.18)		
FY16	\$0.01	(\$6.75)	(\$7.49)	(\$14.56)		
Fy17	\$0.04	(\$8.06)	(\$7.76)	(\$15.99)		
Fy18E	\$0.00	(\$9.09)	(\$8.10)	(\$15.69)		

## LARGEST SHAREHOLDERS

Sabby Management, LLC	34,000
Peter H. Nielsen	25,800
University of Texas Investment Mgmt.	19,100
Renaissance Technologies, Corp.	11,100
Hyacinth Resources, LLC	8,000
The Vanguard Group, Inc.	7,300
Geode Capital Management, LLC	2,600
Wilcoxson Wealth Management	2,200

## STOCK CHART



## **COMPANY DESCRIPTION**

Bio-Path Holdings, Inc. (Bio-Path) is a clinical stage biotechnology company that focuses on developing nucleic acid cancer therapeutics using its proprietary nanoparticle RNAi antisense technology called DNAbilize®. This technology safely distributes nucleic acid based drugs systemically throughout the body via intravenous infusion. Bio-Path's lead product candidate, prexigebersen (BP1001) is in Phase 2 clinical studies for the treatment of acute and chronic myeloid leukemia (AML and CML), and the Company has plans to enroll a Phase 1 in solid tumors in 2019. The Company's second DNAbilize® drug candidate, Liposomal Bcl-2 (BP1002), for the treatment of lymphoma, leukemia, colon, prostate and breast cancers, has completed initial preclinical studies for non-Hodgkin's lymphoma and completed one additional safety study per FDA request. Bio-Path is targeting a broad Phase 1 clinical trial in lymphoma and CLL, with plans to submit an IND application, anticipated by first quarter 2019. Bio-Path's third drug candidate, BP1003, is currently in preclinical development in a pancreatic patient-derived tumor model with plans to initiate IND enabling studies in 2019. BPTH is headquartered in Bellaire, Texas, and has 13 employees.

## **SUMMARY**

In clinical studies, Bio-Path's therapeutic platform has delivered a strong, effective therapeutic payload, with no evidence of toxicity; this novel target-based platform has the potential to transform the landscape of cancer treatment as well as other diseases with well-defined targets.

- Bio-Path's pipeline continues to expand with new cancer indications, and once its DNAbilize® platform is proven successful for cancer, the core technology can easily be expanded to address new therapeutic areas, including autoimmune diseases.
- In contrast to other lipid delivery technologies that have dose-limiting toxicities,
  DNAbilize®, Bio-Path's next generation oligonucleotide-based technology, enables the
  delivery of high doses of therapeutics to target cells, while demonstrating no evidence of
  toxicity. This lack of toxicity enables the development of therapies to address patients,
  particularly within the growing elderly population, who are unable to withstand
  aggressive regimens, and therefore, have limited options.
- Bio-Path has completed Phase 1 clinical trials for its lead candidate prexigebersen for AML, CML and other blood cancers, and is in the midst of a Phase 2 clinical trial for AML and a Phase 2a clinical trial for CML. Importantly, the Company recently announced interim data, reporting that prexigebersen plus LDAC was well-tolerated and showed early anti-leukemic activity in almost 50% of evaluable AML patients; the anti-leukemia activity has recently been revised upward to 60%. Notably, in March 2018 data from the Phase 1/1b study relating to the treatment of hematological malignancies was published in *The Lancet Haematology* with expert commentary from Dr. Xavier Thomas included; additionally, the interim data for the AML Phase 2 was accepted for poster presentation at the American Society of Hematology (ASH) annual meeting 2018.
- The clinical targets for BP1002 are lymphoma and CLL, and potentially breast cancer, colon cancer, and prostate cancer. This novel, non-toxic, specific Bcl-2 inhibitor could be a significant advance in cancer therapeutics, with the potential to treat 40% to 60% of solid tumors, according to Bio-Path estimates.
- Bio-Path has announced its third drug candidate, BP1003, for the treatment of
  pancreatic cancer; BP1003 targets the Stat3 protein and is currently in preclinical
  development in a pancreatic patient-derived tumor model, with previous preclinical
  models having shown BP1003 to successfully penetrate pancreatic tumors.
- With Q318 results, management noted that cash on hand of ~\$2.3M was sufficient to continue progress towards key milestones for 2019, and subsequent to quarter-end, BPTH raised an additional \$2.8M in January 2019 and effected a 1-for-20 reverse stock split as of 1/17/19 (share counts and per share amounts in this report adjusted accordingly).
- With promising clinical data and several programs in the pipeline addressing sizable markets with unmet needs, our comparables analysis shows that BPTH appears undervalued at current levels. See page 7 for further details.



### **BUSINESS OVERVIEW**

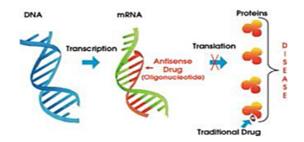
Bio-Path was founded based on antisense and neutral lipid technology licensed from The University of Texas M.D. Anderson Cancer Center. The Company maintains an exclusive license agreement. Bio-Path has subsequently developed its own neutral lipid nanoparticle RNAi technology that is patented and is the basis for development of its DNAbilize® technology platform. Bio-Path plans to develop therapeutics using this proprietary platform, both independently and by partnering with others, to address a broad range of diseases.

With DNAbilize® as the drug development and manufacturing platform, Bio-Path is focusing on three drug candidates that address multiple disease indications, including several types of cancers, with an initial focus on hematological malignancies. Bio-Path's lead product candidate, prexigebersen (BP1001), is in Phase 2 studies to treat patients with acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and multiple types of solid tumors, including breast and ovarian cancers. Prexigebersen has received orbhan drug status for AML and CML from the FDA, and for AML from the European Medicines Agency. Another DNAbilize® drug candidate, Liposomal Bcl-2 (BP 1002), which is also a liposomal antisense drug, is currently in preparation for a Phase 1 clinical trial in lymphoma and CLL with an Investigational New Drug (IND) application, and just recently, the Company announced its third drug candidate, BP1003, for the treatment of pancreatic cancer. BP1003 targets the Stat3 protein and is currently in preclinical development in a pancreatic patient-derived tumor model, with previous preclinical models having shown BP1003 to successfully penetrate pancreatic tumors, while significantly enhancing the efficacy of standard frontline treatments.

## **TECHNOLOGY**

Simply put, DNAbilize<sup>®</sup> is based on blocking the expression of proteins that cause disease (RNA interference, or RNAi). Bio-Path's novel and patented technology enables the development and the delivery of systemic antisense DNA treatments for multiple types of cancers, including solid tumors and hematological cancers, as well as other types of diseases.

Exhibit 1: How DNAbilize® Works



Source: Company Reports

DNA has two strands—the sense strand and the antisense strand. The antisense strand, which is also known as the template strand, is the DNA that carries the genetic information necessary to make proteins because it is the template for messenger RNA (mRNA) synthesis. The synthesis of RNA from DNA is called transcription (the DNA is transcribed into RNA). Outside the cell nucleus, the mRNA sequence is next translated into a protein. Bio-Path's DNAbilize® technology works by delivering short strands of antisense DNA (antisense oligonucleotides) into the cell which correspond to the target mRNA and hybridize, blocking protein synthesis. DNAbilize® technology is an RNA-modulating therapeutic that disrupts the expression of proteins that are responsible for the disease.

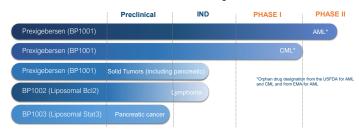
- **No toxicity** Unlike many traditional therapies, DNAbilize® does not introduce a toxic agent into the body to kill the cells. The P-ethoxy DNA does not induce hepatotoxicity or thrombocytopenia, but simply blocks protein production.
- Higher cellular uptake Neutral lipids form structures
  that are similar to cell membranes, enabling a more efficient
  delivery in higher doses to the diseased cells through the
  blood and lymphatic system, as compared with other lipid
  delivery technologies with dose limiting toxicities.
- **Systemic treatment** The technology provides systemic distribution of nucleic acid drugs throughout the body with a simple intravenous transfusion.
- Microscopic-sized liposomes enable penetration into tumors for delivery of drug - Testing in animals has shown a 10- to 30-fold increase in tumor cell penetration compared to other methods of drug delivery.
- Proven target inhibition- DNAbilize<sup>®</sup> is a sequencespecific drug, targeting the protein that is causing the disease. It inhibits only the target protein, and no off-target effects have been observed.

With the rise of "personalized therapy" as an important topic of research over the last several years, multiple companies have performed clinical trials using antisense oligonucleotides (AONS) as RNA-modulating therapeutics. The results have been disappointing, primarily due to toxicity induced by either the DNA backbone or the lipid delivery. These therapies have historically used positively charged lipids to form complexes between lipids and the targeted molecules. Due to their instability in plasma and hepatic clearance, these approaches have been dose limiting. While many companies have focused on overcoming the limitations posed by DNA instability or lipid delivery, Bio-Path's DNAbilize® drug delivery and antisense technology successfully overcomes the limitations of AONS therapies by combining a neutral charge P-ethoxy DNA backbone. This combination enables the delivery of high doses of drugs, while minimizing toxicity. DNAbilize® could prove to be the first antisense therapeutic to effectively treat hematological and systemic diseases relating to the blood and lymph systems.



#### **CLINICAL TRIALS**

Exhibit 2: Product Candidates in Development



Source: Company Reports

Bio-Path has three product candidates in various stages of development that target multiple indications. The Company's lead drug, prexigebersen, targets Grb2, a protein that bridges activated and mutated cellular kinases (altering cellular functionality) and the proteins involved in the process of cell proliferation. Inhibiting Grb2 function impairs developmental processes and blocks the transformation and proliferation of the diseased cancer cells.

Phase 1 Clinical Trial - Prexigebersen for AML, CML and MDS- This Phase 1 trial, which was conducted at M.D. Anderson Cancer Center, was designed to determine the safety and tolerance of escalating doses of prexigebersen in AML, CML and MDS patients who were refractory or resistant to current therapies, having failed an average of 6 prior therapies. The original IND outlined for a maximum dose of 50 mg/m2, but because there had been no evidence of significant toxicity, in November 2012, the FDA permitted a change in protocol allowing for higher doses. In October 2014, three patients were then treated with 90 mg/m2, with no evidence of significant toxicity.

#### Summary of results:

- Data demonstrated that Bio-Path's technology successfully delivered the antisense drug substance to the cell and across the cell membrane into the interior of the cell, where expression of the target protein (Grb2) was blocked
- Of the 18 evaluable patients with circulating blasts, 83% showed decreased circulating blasts/ anti-leukemic activity
- 63% of evaluable patients showed greater than 50% reduction of circulating blasts
- The drug was well tolerated, with no dose limiting toxicities observed

As shown in Exhibit 3, the Grb2 levels decreased in 11 of 13 patient samples by the end of treatment. Inhibition of the disease-causing protein has the effect of down regulating the disease; phosphorylated (pErk), a protein downstream of the Ras protein, was decreased in 58% of the samples. This potentially enables prexigebersen to be used in combination with current frontline therapies, and also as a potential standalone treatment. These results marked a milestone for antisense therapies, with development efforts that have been hindered by safety concerns and problems with delivery into the interior of the cell.

Exhibit 3: Decrease in Disease-causing Proteins

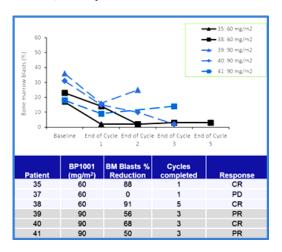
Subject Number	Cohort	BP1001 dose (mg/m²)	Grb2 Decrease (Day 15)	pErk Decrease (Day 15)	Grb2 Decrease (EOT)	pErk Decrease (EOT)
022	3	20	0%	0%	57%	0%
023	3	20	0%	3%	28%	45%
024	3	20	56%	28%	47%	35%
025	4	40	63%	82%	54%	91%
026	4	40	47%	0%	0%	0%
027	4	40	NS1	NS <sup>1</sup>	34%	27%
028	5	60	0%	0%	30%	54%
029	5	60	57%	51%	65%2	0%2
030	5	60	54%	55%	43%	47%
031	6	90	0%	0%	0%	0%
032	6	90	85%	54%	91%	63%
033	6	90	13%	13%	53%	2%
034	6	90	42%	42%	40%	0%

Source: Company Reports

Phase 1b/2 Clinical Trial – Safety Trial of Prexigebersen in Combination with Low-dose Cytarabine Treating AML - The Company completed the safety segment of the Phase 2 clinical trials, which demonstrated anti-leukemic activity with no adverse events and no negative synergies using prexigebersen

with LDAC (low-dose cytarabine).

Exhibit 4: Five of Six Patients Achieved Remission



Source: Company Reports

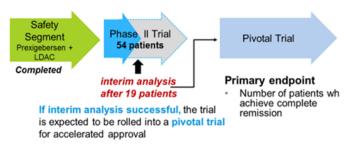
There were two cohorts, with three patients in each cohort, one group receiving 60 mg/m² and one group receiving 90 mg/m². As illustrated in Exhibit 4, of the six evaluable patients from the trial, three patients achieved complete remission and two patients achieved partial remission. This corroborates the decrease of Grb2 protein and the positive effect on bone marrow blasts observed in the Phase 1 trial.



## Phase 2 Clinical Trial - Efficacy Trial of Prexigebersen Combined with Low-dose Cytarabine for Treating AML -

The Phase 2 efficacy trial of prexigebersen in combination with low-dose cytarabine for the treatment of AML is underway. The efficacy trial is taking place in 10 leading cancer centers throughout the U.S., with additional trial sites to be opened in the EU, in order to accelerate enrollment. The trial will compare safety profile, pharmacokinetics, pharmacodynamics, and efficacy of 60 mg/m² of prexigebersen combined with LDAC vs. the response rates documented for LDAC alone. The study involves newly diagnosed, previously untreated patients, who are not eligible for, or who have opted to forego, high-intensity chemotherapy or have elected to have a low intensity regimen.

Exhibit 5: Phase 2 Efficacy Trial Design for AML Prexigebersen Combination Therapy



#### Source: Company Reports

The primary endpoint is complete remission, including patients achieving incomplete hematologic recovery and complete remission with incomplete platelet recovery. Secondary endpoints will assess aspects relating to safety and efficacy of prexigebersen. The first patient was dosed in November 2016. The trial design includes approximately 54 previously untreated AML patients.

Pre-specified interim results were reported April 3, 2018, which included the following:

- Of the 17 evaluable patients (17 instead of 19 since criteria had been met), 4 achieved complete responses, 1 achieved a leukemia free, 1 had significantly reduced bone marrow blasts, and 3 achieved stable disease
- In total, 47% of the evaluable patients showed some form of response, including 4 with complete remission, or 23%, and 4 with stable disease; these significant results were recently selected for posted presentation at the ASH annual meeting in December 2018

Based on recommendations from the principal investigators conducting the study, Bio-Path amended the protocol to change the dosing schedule to that used in the Phase 1b study in relapsed and refractory AML patients (larger dose of prexigebersen was administered prior to LDAC treatment starting day 10 vs. LDAC treatment starting day 4), and the first patient has been dosed in this Stage 2 as just recently reported. Also per investigators' recommendations, BPTH has begun a decitabine cohort as part of this trial based on recently released data on this compound. Ultimately, if the results with advanced protocols for this trial exceed the statistically determined thresholds, Bio-Path may be able to seek accelerated approvals.

# Phase 2a - Prexigebersen for Chronic Myeloid Leukemia

- The Company began enrolling patients in a Phase 2a study to determine the dose-limiting toxicity and maximal tolerated dose of prexigebersen combined with dasatinib in patients with Philadelphia chromosome positive CML in accelerated blast phase in December 2017. The trial is being conducted at The University of Texas M.D. Anderson Cancer Center and will have two cohorts of 3 evaluable patients, and each will be enrolled to evaluate two doses (6omg/m² and 9omg/m²) of prexigebersen in combination with dasatinib.

Based on previous clinical data involving CML patients, prexigebersen demonstrated the potential to provide the 33% of patients who are resistant to the current standard of care for CML, Gleevec® (imatinib), with an alternative treatment.

# Summary of results:

- Prexigebersen has demonstrated the ability to decrease the proliferation of Gleevec®-resistant CML cells in a dosedependent manner
- Prexigebersen pretreatment enhanced the inhibitory effects of Sprycel® (dasatinib) in CML cells, leading to cell death
- Five CML blast phase patients were enrolled in the first cohort (5 mg/m² dose of prexigebersen) of the Phase 1 clinical study. Two CML patients, who had drug resistant mutations, showed significant reductions in circulating blasts during treatment
- One patient's blasts were reduced from 89% to 12%, while another patient's blasts were reduced from 24% to 7%

For 2019, additional sites are planned to be added and enrollment planned to be opened across both phases of the disease, which will include imatinib-resistant chronic phase patients.

## Pre-clinical -Prexigebersen for Treatment of Solid

Tumors - Bio-Path believes that solid tumors with activated or mutated tyrosine kinases as targets for prexigebersen would have a high degree of success. The Company is investigating prexigebersen for the treatment of solid tumors in advanced ovarian, uterine, triple negative breast, and potentially pancreatic cancers. In preclinical studies, leaders in the field of ovarian and breast cancer at M.D. Anderson are currently assessing prexigebersen in the treatment of solid tumors, and the results from these preclinical studies will be used to evaluate the efficacy of prexigebersen, both as a monotherapy and in combination with front line therapies, in the treatment of solid tumors. Preclinical studies supporting the potential of prexigebersen in the treatment of solid tumors in gynecologic malignancies were presented in a poster at the annual meeting of the American Association for Cancer Research just recently in April 2018. Bio-Path plans to begin enrollment at several leading cancer centers of a Phase 1 clinical trial in 2019.

It is notable that in March 2018, Bio-Path announced that data on BP1001 from its Phase 1/1b study for the treatment of hematological malignancies was published in *The Lancet Haematology*, lending significant third-party recognition to prexigebersen's therapeutic potential.



BP1002 – Liposomal Bcl-2 Antisense - BP1002 is a neutral-charge, liposome-incorporated antisense drug designed to inhibit protein synthesis of Bcl-2, a protein that promotes the survival of cells and inhibits apoptosis. The Company recently announced the results of preclinical in-vitro and in-vivo studies supporting BP1002 as a potential treatment in aggressive non-Hodgkin's lymphoma (NHL). In two animal studies, none of the control group mice survived beyond 39 days. In the BP1002 arm of the study, a combined 87% of the mice survived until the end of the 5-week study. In 2018, Bio-Path completed one additional safety study per FDA request and is preparing for a broad Phase 1 clinical trial of BP1002 in patients with lymphoma and CLL, anticipating an IND application filing by Q1 2019.

**BP1003** — BP1003 targets the Stat3 protein, and it is currently in preclinical development in a pancreatic patient-derived tumor model. In previous preclinical work, models have shown BP1003 successful at penetrating pancreatic tumors and notably enhancing the efficacy of standard frontline treatments. Per a recent announcement, BPTH intends to initiate IND enabling studies of BP1003 in 2019 and has welcomed world-leading gastrointestinal cancer expert Dr. Jason Fleming to it Scientific Advisory Board.

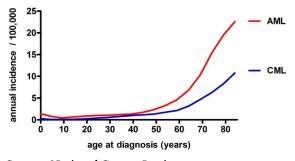
#### **Collaborations**

Bio-Path is collaborating with respected academic and clinical institutions to expand indications in oncology and outside of cancer, which we view as further validation of Bio-Path's DNAbilize® technology. M.D. Anderson is developing clinical and preclinical programs that address cancers with significant unmet needs including pancreatic, triple negative and inflammatory breast and advanced ovarian cancers. Thomas Jefferson University has launched a program to establish DNAbilize® technology for glioblastoma immunotherapy. Beyond oncology, UT Southwestern is developing a clinical and preclinical pipeline for systemic lupus erythematosus.

## **MARKET OPPORTUNITY**

Bio-Path's initial targets are myeloid neoplasms, a subset of hematologic malignancies that include acute myeloid leukemia and chronic myeloid leukemia, which are defined according to the percentage immature blasts in the bone marrow. The incidence of AML and CML dramatically increases with age (Exhibit 6). Particularly in the elderly, who often cannot tolerate aggressive therapies, there remains a dire unmet need for an effective, non-toxic therapy.

Exhibit 6: Annual Incidence of AML and CML in U.S. by Age



Source: National Cancer Institute

Although there have been two specialized drug approvals, AML treatment has generally remained unimproved in the last 20 years and consists of induction cytotoxic chemotherapy. Even with these highly toxic chemotherapies, less than 30% of AML patients survive long-term. The prognosis for patients over 65 is dismal. Treatment failure often occurs due to therapy-related complications, such as infections and toxicity, and there is a high disease relapse rate after a first remission in AML therapy.

CML is characterized by the overproduction and accumulation of mature, functionally impaired myeloid cells, primarily granulocytes. The incidence of the disease dramatically rises with age. Without treatment, chronic phase CML generally turns into blast crisis, and the disease becomes similar to AML. Blast crisis CML is highly resistant to treatment, and median survival of patients is approximately 4–8 months.

## **RISKS**

**Competition** - Bio-Path would be unable to compete effectively if its technology or its pipeline were to be rendered noncompetitive or obsolete by novel technologies or products that are more effective or less costly.

Clinical trials - The path to commercialization requires multiple clinical trials. If the Company is unable to prove safety and efficacy of its product candidates, the result could be increased costs and a delay in generating revenue. Given that the clinical trials process can be both lengthy as well as costly, BPTH will likely need to continue raising additional capital to fund its pipeline activities.

**Funding** – To date, the Company has incurred significant losses from operations and reported an accumulated deficit of (\$45.8M) as of 9/30/18. Management expects to incur significant operating losses as it continues product research and development and clinical trials. Therefore, the Company will likely source additional financing to fund its R&D programs in the near-term. If the Company raises money through convertible debt or equity, there is risk of shareholder dilution. Additionally, Bio-Path may not find the necessary capital under favorable terms depending on the timing and the amount of funds needed. In January 2019, BPTH announced a completed offering of public stock with the gross proceeds of ~\$1.1M to be used for working capital and general corporate purposes as well as a 1-for-20 reverse stock split (effective 1/17/19). Additionally, the Company announced a \$1.7M registered direct offering expected to close on or about 1/23/19 including ~648K shares (share counts in this report have been adjusted accordingly).

**Reimbursement** - Even if Bio-Path's drug candidates are approved, they may not gain market acceptance among patients, healthcare payors and the medical community due to the pricing or reimbursement status of the drug candidates, and as a result, the Company's topline could suffer.



# **INCOME STATEMENT**

Consolidated Statements of Income (in thousands \$, except per share amounts)

Fiscal Year: December

	FY 2015	FY 2016	FY 2017	FY 2018 E
Revenues			- /	
Product revenues	\$ -	\$ 13	\$ 37	\$ -
Total product revenues	\$ -	\$ 13	\$ 37	\$ -
Cost of revenues				
Cost of product revenues	-	-	-	-
Total cost of revenues	-	-	-	-
Gross (loss) profit	-	13	37	-
Operating expenses				
General and administrative	2,465	3,014	3,523	3,500
Research and development	3,020	5,474	5,480	5,600
Total operating expenses	5,485	8,488	9,003	9,100
Income (loss) from operations	(5,485)	(8,475)	(8,966)	(9,100
Other income / (expense)				
Change in fair value warrant liability	-	1,713	2,374	-
Loss on extinguishment of warrant liability	-	- 1	(440)	-
Interest income	18	12	9	8
Total other (income) / expense	18	1,725	1,943	8
Pre-tax income (loss)	(5,467)	(6,750)	(7,023)	(9,092
Income taxes (benefit)	-	-	-	-
Net income (loss)	\$ (5,467)	\$ (6,750)	\$ (7,023)	\$ (9,092
Deemed dividend related to warrant conversion	-	-	(1,038)	-
Net income (loss) attributable to common	(5,467)	(6,750)	(8,061)	(9,092
Basic and diluted EPS (loss)	\$ (12.18)	\$ (14.56)	\$ (15.99)	\$ (15.69
Veighted Average Basic and Diluted Shares Outstanding*	449	464	504	580
EBITDA	(5,283)	(8,271)	(8,555)	(8,650
Adjusted EBITDA	(4,914)	(7,487)	(7,762)	(8,100
Growth Rate Analysis Y/Y				
General and administrative	-9.2%	22.3%	16.9%	-0.7%
Research and development	65.3%	81.3%	0.1%	2.2%
Net income (loss)	-21.0%	-23.5%	-4.0%	-29.5%
EPS	-2306.6%	-19.6%	-9.8%	1.9%
EBITDA	-20.9%	-56.6%	-3.4%	-1.1%

-95.0%

3.3%

8.7%

15.0%

Source: Company Reports, Stonegate Capital Partners estimates

Weighted Average Basic and Diluted Shares Outstanding\*

\*Includes 1-for-20 reverse stock split effective 1/17/19



#### **VALUATION**

We are projecting total operating expenses of approximately \$9.1M, and we have assumed that Bio-Path finishes the FY18E year with a net loss attributable to common of approximately (\$9.1M), or (\$15.69) per share, with approximately 580K weighted average shares outstanding. This activity supports BPTH's main objectives for the year, with its lead candidate prexigebersen in Phase 2 for AML and CML and likely to begin enrolling a Phase 1 in solid tumors in 2019 as well, a second drug candidate being readied to start a Phase 1, and a third drug candidate recently announced in preclinical development. Notably, in January 2019, the Company raised ~\$2.8M in gross proceeds for working capital and general corporate purposes and effected a 1-for-20 reverse stock split as of 1/17/19. However, we believe the biggest risk to the BPTH story is their continuing ability to raise equity/debt as needed moving forward to fund the Company's development pipeline.

Below we have presented a comparables analysis as an appropriate tool for outlining the current opportunity for BPTH investors. We have selected a peer group of clinical stage biotech and pharmaceutical companies with minimal to no current revenues and all with at least one or more candidates focused in the oncology realm, and we note that Bio-Path Holdings, Inc. trades well below both the median and averages of these comps.

Given the valuations afforded to the comps, three product candidates under development addressing sizable target markets with unmet medical needs and supported by novel and proprietary technology platform, and the recent impressive results presented at the ASH annual meeting December 2018, it appears that BPTH is clearly undervalued at current levels.

Exhibit 7: Comparables Analysis (all figures in \$M)

								Rev	enues
Name	Ticker	P	rice	Sh	Mr	kt Cap	EV	20	019E
Arvinas Holding Company, LLC	PRTK	\$	16.41	32.4	\$	531.7	\$ 758.5	\$	13.5
Cannabics Pharmaceuticals, Inc.	CNBX	\$	0.42	131.9	\$	55.4	\$ 48.8	\$	-
Cumberland Pharmaceuticals, Inc.	CPIX	\$	5.84	15.5	\$	90.5	\$ 54.6	\$	50.1
HedgePath Pharmaceuticals, Inc.	HPPI	\$	0.04	370.0	\$	14.8	\$ 17.7	\$	-
ImmuPharma Plc	IMM	\$	0.13	139.5	\$	18.1	\$ 7.0	\$	0.1
Odonate Therapeutics, Inc.	ODT	\$	16.91	26.8	\$	453.2	\$ 292.7	\$	-
Onconova Therapeutics, Inc.	ONTX	\$	1.93	5.7	\$	11.0	\$ (11.4)	\$	4.0
Redx Pharam Plc	REDX	\$	0.10	126.5	\$	12.7	\$ 3.9	\$	-
Spotlight Innovation, Inc.	STLT	\$	0.01	35.8	\$	0.2	\$ 5.9	\$	-
Bio-Path Holdings, Inc.	ВРТН	\$	1.81	1.8	\$	3.2	\$ 0.9	\$	

									EV/Revs
Name	Ticker	Ticker Price Sh		Mı	kt Cap	EV		2019E	
Arvinas Holding Company, LLC	PRTK	\$	16.41	32.4	\$	531.7	\$	758.5	56.2x
Cannabics Pharmaceuticals, Inc.	CNBX	\$	0.42	131.9	\$	55.4	\$	48.8	n/a
Cumberland Pharmaceuticals, Inc.	CPIX	\$	5.84	15.5	\$	90.5	\$	54.6	1.1X
HedgePath Pharmaceuticals, Inc.	HPPI	\$	0.04	370.0	\$	14.8	\$	17.7	n/a
ImmuPharma Plc	IMM	\$	0.13	139.5	\$	18.1	\$	7.0	53.8x
Odonate Therapeutics, Inc.	ODT	\$	16.91	26.8	\$	453.2	\$	292.7	n/a
Onconova Therapeutics, Inc.	ONTX	\$	1.93	5.7	\$	11.0	\$	(11.4)	-2.9x
Redx Pharam Plc	REDX	\$	0.10	126.5	\$	12.7	\$	3.9	n/a
Spotlight Innovation, Inc.	STLT	\$	0.01	35.8	\$	0.2	\$	5.9	n/a
	Average				\$	132.0	\$	130.9	27.1x
	Median				\$	18.1	\$	17.7	27.5x
Bio-Path Holdings, Inc.	ВРТН	\$	1.81	1.8	\$	3.2	\$	0.9	n/a

Source: Company Reports, Stonegate Capital Partners, Capital IQ



## **IN THE NEWS**

January 2019 – BPTH announces two raises totaling ~\$2.8M, with proceeds to be used for working capital and general corporate purposes, as well as a 1-for-20 reverse stock split

**December 2018** – Company presents interim data from Phase 2 study evaluating prexigebersen as a treatment for AML at the 60<sup>th</sup> annual American Society of Hematology meeting

**September 2018** – BPTH completes a registered direct offering of ~2.2M common shares and warrants for gross proceeds of ~\$1.5M

August 2018 – Company announces first patient dosed in expansion of Phase 2 trial of prexigebersen in AML

April 2018 - Pre-clinical studies supporting the potential of prexigebersen in the treatment of solid tumors in gynecologic malignancies were presented at the annual meeting of the American Association for Cancer Research

**March 2018** – Positive interim data from Phase 2 prexigebersen plus LDAC for treatment of AML announced

**February 2018** – 1-for-10 reverse stock split effective for BPTH

**December 2017** – Initiation of Phase 2a clinical study of prexigebersen for treatment of CML in accelerated and blast phase patients

**November 2017** - Company announces \$4M registered direct offering as well as the selection of its third drug candidate, BP1003, for the treatment of pancreatic cancer

**July 2017** - BPTH received Notice of Allowance for key U.S. composition of matter patent related to DNAbilize®

**April 2017** - Announced results of preclinical in- vitro and in-vivo studies supporting the potential of BP1002 in the treatment of aggressive NHL

**November 2016 -** Dosing of first patient in the efficacy portion of the Phase 2 trial for AML announced

#### **BIO-PATH HOLDINGS GOVERNANCE**

Peter Nielsen, President, Chief Executive Officer, Chief Financial Officer — Peter Nielsen co-founded Bio-Path Holdings in 2007. Since the Company's founding, Mr. Nielsen has been responsible for advancing its lead product candidate into Phase 2 studies, for introducing additional candidates into Bio-Path's pipeline, and for overseeing the Company's IPO. Prior to co-founding Bio-Path, Mr. Nielsen served as a senior level executive for several companies, where his responsibilities included developing and implementing strategies for growth. Before he became involved with the biotechnology sector, Mr. Nielsen served as a lieutenant in the U.S. Naval Nuclear Power program, where he was Director of the physics department. He also worked in product development for Ford Motor Company. Mr. Nielsen's educational background includes degrees in engineering and mathematics, and an MBA from the University of California at Berkeley.

William Hahne, M.D., Vice President of Clinical Research — Dr. Hahne joined Bio-Path in 2017. Previously, he was a medical consultant for multiple organizations focused on oncology. He also held a number of management and executive-level positions in clinical research and medical affairs at biotechnology and global pharmaceutical companies, including Celator Pharmaceuticals, Celsion Corp., Glaxco Inc., Hoechst Marion Rousel, and Eisai, Inc. Dr. Hahne has a BA in chemistry from Grinnell College. He received his medical degree from Cornell University and completed his residency in general surgery at Emory University Affiliated Hospitals in Atlanta, Georgia.

Ana Tari Ashizawa, Ph.D., MBA, Director of Research — Dr. Ashizawa is a scientific co-founder of Bio-Path Holdings. As an expert in neutral lipid delivery technology, she was instrumental in the development of the Company's technology. Previously, she was an Associate Professor at the University of Texas M.D. Anderson Cancer Center and the University of Florida, Gainesville. She earned a doctorate in biochemistry from the University of Tennessee and an MBA from University of Florida.

**Anthony Price, MBA, Director, Finance and Accounting** – Mr. Price joined the Company in 2014. Previously, he was Associate Director of Finance and Accounting for Lexicon Pharmaceuticals, Inc. and held various financial and accounting management positions for Building Materials Holding Corporation. He has a Bachelor of Science in business administration-finance from California State University, Fresno and an MBA from Colorado State University.

#### **Board of Directors:**

Peter Nielsen – Chairman Mark P. Colonnese – Director Heath Cleaver – Director Douglas P. Morris – Director



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## **CONTACT INFORMATION**

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