Bio-Path Holdings INC

STONEGATE CAPITAL PARTNERS

April 17, 2019

Laura S. Engel, CPA
laura@stonegateinc.com
214-987-4121

MARKET STATISTICS

Exchange / Symbol	NASDAQ:BPTH
Price:	$20.81
Market Cap (mm):	$52.2
Enterprise Value (mm):	$51.2
Shares Outstanding (mm):	2.5
Float (%):	82.7%
Volume (3-mo. average, mm):	4.2
52 week Range:	$1.61-$73.52
Industry:	Biotechnology

CONDENSED BALANCE SHEET

($mm, except per share data)

Balance Sheet Date:	12/31/2018
Cash & Cash Equivalent:	$1.0
Cash/Share:	$0.40
Equity (Book Value):	$1.2
Equity/Share:	$0.49

CONDENSED INCOME STATEMENTS

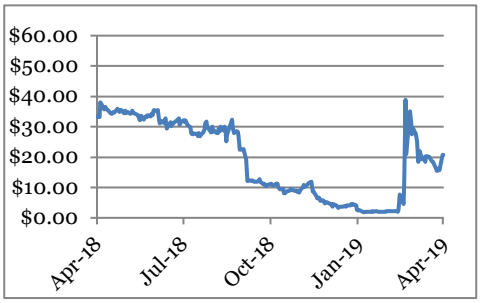
($mm, except per share data)

FY - 12/31	Rev	Net Income	Adj. EBITDA	EPS
FY16	$0.01	($6.75)	($7.49)	($14.56)
Fy17	$0.04	($8.06)	($7.76)	($15.99)
Fy18	$0.00	($8.58)	($7.61)	($14.38)
Fy19E	$0.00	($9.15)	($8.30)	($3.32)

LARGEST SHAREHOLDERS

Sabby Management, LLC	237,600
Empery Asset Management	163,000
Anson Group	106,700
Armistice Capital, LLC	92,300
Schonfeld Strategic Advisors, LLC	56,800
Sassicala Capital Advisers, LLC	49,200
Peter H. Nielsen	25,800
Renaissance Technologies Corp.	23,000
University of Texas Inv. Management	19,100
Virtu Financial, LLC	16,500

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 early 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 8 employees.

SUMMARY

- 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 an update to interim data, reporting that prexigebersen plus LDAC continues to be well-tolerated and now has shown early anti-leukemic activity (revised upwards) in almost 65% of evaluable AML patients; notably, it was observed that 68% of the responding patients were secondary AML patients, historically a very difficult class to treat. Given the new data, BPTH has a developed a revised registration-directed clinical development plan detailed on page 4 of this report.
- The clinical targets for BP1002 have initially been 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. And given the most recent clinical data, BPTH now believes that BP1002 likely could be used to treat AML and CLL patients who have relapsed following treatment with Venetoclax. Venetoclax works against the anti-apoptotic protein Bcl-2 by neutralizing the protein's BH3 domain, but some patients relapse due to BH3 domain mutation over time. However, BP1002's activity is based on blocking the Bcl-2 messenger RNA and does not target the BH3 domain; hence, it would likely be able to treat these patients who have relapsed on Venetoclax.
- 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.
- For Q418/FY18 results, management reported cash on hand of ~$1.0M, 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. Additionally, an $18.5M registered direct offering closed 3/14/19; thus, cash on hand is sufficient to achieve key milestones for the Company's programs throughout the upcoming year and beyond.
- With promising clinical data and several programs in the pipeline addressing sizable markets with unmet needs, our comparables analysis shows that BPTH remains undervalued at current levels. See page 8 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 orphan 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, has been in preparation for a Phase 1 clinical trial in lymphoma and CLL with an Investigational New Drug (IND) application, and now BPTH believes that it also has applications in treating Venetoclax AML and CLL patients who have relapsed. 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® 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

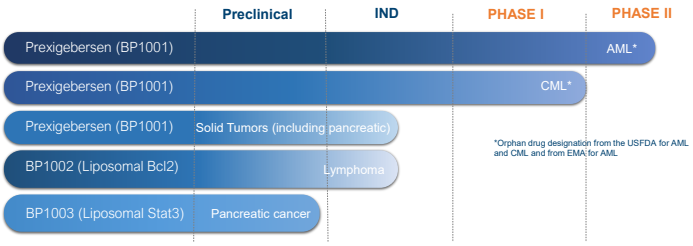
DNA has two strands—the sense strand and the antisense strand. The antisense strand, which is also known as the template strand, is the DNA that carries the genetic information necessary to make proteins because it is the template for messenger RNA (mRNA) synthesis. The synthesis of RNA from DNA is called 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® is a sequence-specific 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.

BP1001 - 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 myelodysplastic syndrome (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 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.

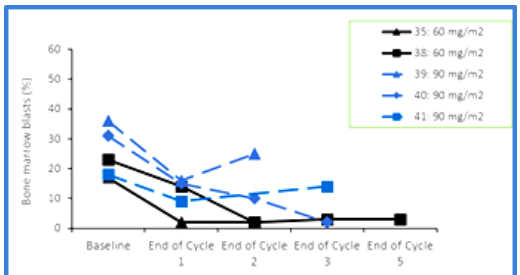
Exhibit 3: Decrease in Disease-causing Proteins

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	NS[1]	NS[1]	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



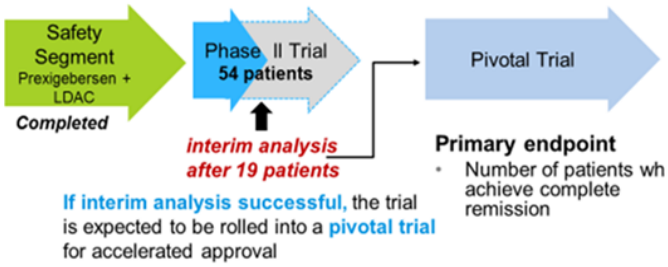
Patient	BP1001 (mg/m²)	BM Blasts % Reduction	Cycles completed	Response
35	60	88	1	CR
37	60	0	1	PD
38	60	91	5	CR
39	90	56	3	PR
40	90	68	3	CR
41	90	50	3	PR

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 has been 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 *de novo* 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: Initial 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). Also per investigators' recommendations, BPTH has begun a Stage 2 decitabine cohort as part of this trial based on recently released data on this compound for *de novo* AML patients.

In March 2019, a clinical update to the previously reported interim Phase 2 data was released by the Company and highlighted the following:

- Following updated data from the 17 evaluable patients as well as a meeting with principal investigators, BPTH now notes that the efficacy profile has increased to 65% with 11 of the 17 patients having a response
- This includes 5, or 29%, of patients achieving complete response (including one with complete response with incomplete hematologic recovery) and 1 morphologic leukemia free state
- Six showed stable disease responses, including two patients with greater than 50% reduction in bone marrow blasts
- It was observed that 68% of these patients were secondary AML patients, which is recognized as an extremely difficult group to treat

The above results are even more impressive when compared to the historical 7 – 13% varying complete response rates noted when treating this patient population with LDAC alone. Furthermore, we note that for the newly approved Venetoclax plus LDAC treatment regime, patients reported a 42% complete response rate and complete response with incomplete hematologic response, but that study had only 46% secondary AML patients involved vs. Bio-Path's 68%. The Company sees these results, specifically as they relate to Venetoclax, creating the opportunity for combining prexigebersen with the combination of Venetoclax plus decitabine for the treatment of *de novo* AML patients.

Thus, BPTH has released a **new registration-directed clinical development plan** that includes the following steps:

- Add untreated high risk MDS patients to the current prexigebersen + decitabine Phase 2 AML (*de novo* patients) cohort, as high-risk MDS patients could potentially benefit from the combination therapy in lieu of the typical treatment with hypomethylating agents alone
- Cancel the Phase 2 prexigebersen + LDAC cohort for AML *de novo* patients given the more recent preference by oncologists towards decitabine
- Add a cohort of prexigebersen + decitabine in refractory/relapsed AML patients, including relapsed/refractory high risk MDS patients; additionally, efficacy studies are underway for prexigebersen + decitabine + Venetoclax to confirm incremental efficacy benefit of the triple combination in a small safety assessment
- Following a successful safety assessment, initiate the triple combination cohort for the treatment of refractory/relapsed AML plus high risk MDS patients
- Amend the protocol of the Phase 2 for untreated AML and high risk MDS patients to initiate a triple combination trial registration-directed trial (prexigebersen + decitabine + Venetoclax) to determine if more durable responses and longer survival is observed as compared to using the decitabine and Venetoclax combination alone.

And one expectation from these changes to the Phase 2 protocol is that several of the Venetoclax patients will relapse, and subsequently BP1002 can be introduced, replacing Venetoclax, and enabling continued patient treatment with the new triple combination.

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 (60mg/m^2 and 90mg/m^2) 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 dose-dependent 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/m^2 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. Pre-clinical 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 in recent months has been preparing for a broad Phase 1 clinical trial of BP1002 in patients with lymphoma and CLL, anticipating an IND application filing early 2019.

However, with the approval of frontline therapy Venetoclax (approved for AML and CLL) and most recently updated interim data, BPTH now plans to file for registration of BP1002 for the treatment of Venetoclax relapses in both CLL and AML patients, and the Company will have the benefit of the experience from the modified Phase 2 AML clinical program now to include Venetoclax as well. Venetoclax works against the anti-apoptotic protein Bcl-2 by neutralizing the protein's BH3 domain, but some patients relapse due to BH3 domain mutation over time. BP1002's activity is based on blocking the Bcl-2 messenger RNA and does not target the BH3 domain; hence, it would likely be able to treat these patients who have relapsed on Venetoclax treatment.

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.

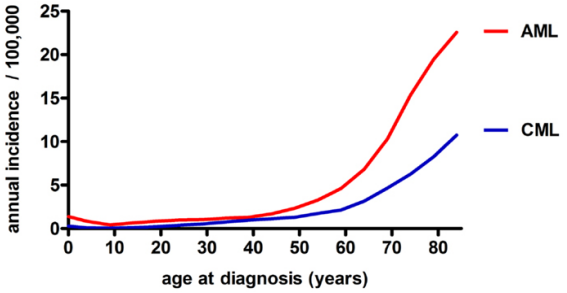
Collaborations

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 a few 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 ($47.7M) as of 12/31/18. Management expects to incur significant operating losses as it continues product research and development and clinical trials. Therefore, the Company will likely continue to source additional financing to fund its R&D programs through to commercialization. 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 did announce 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 completed a $1.7M registered direct offering including ~648K shares. Finally, BPTH announced an $18.5M registered direct offering of common stock that closed 3/14/19. We do note that on 4/12/19, Bio-Path filed Form RW with the SEC requesting consent to the withdrawal of the Company's registration statement on Form S-1 that was originally filed December 2018.

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

Bio-Path Holdings, Inc. (NasdaqCM: BPTH)
Consolidated Statements of Income (in thousands $, except per share amounts)
Fiscal Year: December

	FY 2016	FY 2017	FY 2018	FY 2019 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	3,014	3,523	3,379	3,500
Research and development	5,474	5,480	5,211	5,800
Total operating expenses	8,488	9,003	8,590	9,300
Income (loss) from operations	**(8,475)**	**(8,966)**	**(8,590)**	**(9,300)**
Other income / (expense)				
Change in fair value warrant liability	1,713	2,374	-	-
Loss on extinguishment of warrant liability	-	(440)	-	-
Interest income	12	9	7	145
Total other (income) / expense	1,725	1,943	7	145
Pre-tax income (loss)	**(6,750)**	**(7,023)**	**(8,583)**	**(9,155)**
Income taxes (benefit)	-	-	-	-
Net income (loss)	**$ (6,750)**	**$ (7,023)**	**$ (8,583)**	**$ (9,155)**
Deemed dividend related to warrant conversion	**-**	**(1,038)**	**-**	**-**
Net income (loss) attributable to common	**(6,750)**	**(8,061)**	**(8,583)**	**(9,155)**
Basic and diluted EPS (loss)	**$ (14.56)**	**$ (15.99)**	**$ (14.38)**	**$ (3.32)**
Weighted Average Basic and Diluted Shares Outstanding	464	504	597	2,758
EBITDA	(8,271)	(8,555)	(8,164)	(8,850)
Adjusted EBITDA	(7,487)	(7,762)	(7,610)	(8,300)
Growth Rate Analysis Y/Y				
General and administrative	22.3%	16.9%	-4.1%	3.6%
Research and development	81.3%	0.1%	-4.9%	11.3%
Net income (loss)	-23.5%	-4.0%	-22.2%	-6.7%
EPS	-19.6%	-9.8%	10.1%	76.9%
EBITDA	-56.6%	-3.4%	4.6%	-8.4%
Weighted Average Basic and Diluted Shares Outstanding	3.3%	8.7%	18.4%	361.9%

Source: Company Reports, Stonegate Capital Partners estimates

VALUATION

We have projected total operating expenses of approximately $9.3M, and we have assumed that Bio-Path finished the FY19E year with a net loss attributable to common of approximately ($9.1M), or ($3.32) per share, with approximately 2.8M weighted average shares outstanding. This activity level should support BPTH's main objectives for the 2019 year, with its lead candidate prexigebersen in Phase 2 for AML and CML and targeted 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 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. Additionally, an $18.5M registered direct offering closed 3/14/19 per a recent press release. And as previously mentioned, subsequent to the March offering, on 4/12/19 Bio-Path filed Form RW with the SEC requesting consent to the withdrawal of the Company's registration statement on Form S-1 that was originally filed December 2018.

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 a novel and proprietary technology platform, and the impressive results recently announced, it appears that BPTH remains clearly undervalued at current levels.

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

Name	Ticker	Price	Sh	Mrkt Cap	EV	Revenues 2019E
Arvinas Holding Company, LLC	PRTK	$ 22.18	32.3	$ 716.4	$ 531.3	$ 13.8
Cannabics Pharmaceuticals, Inc.	CNBX	$ 0.34	131.9	$ 44.8	$ 39.1	$ -
Cumberland Pharmaceuticals, Inc.	CPIX	$ 6.05	15.4	$ 93.2	$ 76.9	$ 50.1
HedgePath Pharmaceuticals, Inc.	HPPI	$ 0.06	370.4	$ 22.2	$ 23.6	$ -
ImmuPharma Plc	IMM	$ 0.13	139.5	$ 18.1	$ 7.3	$ 0.1
Odonate Therapeutics, Inc.	ODT	$ 23.94	26.7	$ 639.2	$ 501.5	$ -
Onconova Therapeutics, Inc.	ONTX	$ 3.88	5.9	$ 22.9	$ 5.9	$ 8.5
Redx Pharam Plc	REDX	$ 0.08	126.5	$ 10.1	$ 1.5	$ -
Spotlight Innovation, Inc.	STLT	$ 0.01	35.8	$ 0.2	$ 6.0	$ -
Bio-Path Holdings, Inc.	**BPTH**	**$ 20.81**	**2.5**	**$ 52.2**	**$ 51.2**	**$ -**

Name	Ticker	Price	Sh	Mrkt Cap	EV	EV/Revs 2019E
Arvinas Holding Company, LLC	PRTK	$ 22.18	32.3	$ 716.4	$ 531.3	38.6x
Cannabics Pharmaceuticals, Inc.	CNBX	$ 0.34	131.9	$ 44.8	$ 39.1	n/a
Cumberland Pharmaceuticals, Inc.	CPIX	$ 6.05	15.4	$ 93.2	$ 76.9	1.5x
HedgePath Pharmaceuticals, Inc.	HPPI	$ 0.06	370.4	$ 22.2	$ 23.6	n/a
ImmuPharma Plc	IMM	$ 0.13	139.5	$ 18.1	$ 7.3	55.9x
Odonate Therapeutics, Inc.	ODT	$ 23.94	26.7	$ 639.2	$ 501.5	n/a
Onconova Therapeutics, Inc.	ONTX	$ 3.88	5.9	$ 22.9	$ 5.9	0.7x
Redx Pharam Plc	REDX	$ 0.08	126.5	$ 10.1	$ 1.5	n/a
Spotlight Innovation, Inc.	STLT	$ 0.01	35.8	$ 0.2	$ 6.0	n/a
	Average			**$ 174.1**	**$ 132.6**	**24.2x**
	Median			**$ 22.9**	**$ 23.6**	**20.1x**
Bio-Path Holdings, Inc.	**BPTH**	**$ 20.81**	**2.5**	**$ 52.2**	**$ 51.2**	**n/a**

Source: Company Reports, Stonegate Capital Partners, Capital IQ

IN THE NEWS

April 2019 – Bio-Path files Form RW with the SEC requesting consent to the withdrawal of the Company's registration statement on Form S-1 originally filed December 2018

March 2019 – BPTH announces clinical update to interim analysis of Phase 2 prexigebersen in AML; the Company also reports an $18.5M registered direct offering of common stock that closed 3/14/19

February 2019 – Company regains compliance with the minimum bid price requirement for continuing Nasdaq listing; BPTH also announces that the Company will present at the 2019 AACR Annual Meeting beginning 3/29/19

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 – Interim data presented from Phase 2 study evaluating prexigebersen as a treatment for AML at the 60th 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 study of prexigebersen for treatment of CML in accelerated and blast phase patients

BPTH 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*

IMPORTANT DISCLOSURES AND DISCLAIMERS

The following disclosures are related to Stonegate Capital Partners (SCP) research reports.

ANALYST DISCLOSURES - I, Laura S. Engel, CPA, hereby certify that the view expressed in this research report accurately reflects my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING, REFERRALS, AND FEES FOR SERVICE - SCP does not provide nor has it received compensation for investment banking services on the securities covered in this report. SCP does not expect to receive compensation for investment banking services on the securities covered in this report. SCP has a non-exclusive Advisory Services agreement to provide research coverage, retail and institutional awareness, and overall Investor Relations support for which it is compensated $3,000 per month. SCP may engage outside consultants, SCP or SMC employees to assist in the preparation of this report or other reports released by SCP. The principles of SCP may review and or alter the content of SCP research reports based on their sole discretion. While the SCP analyst may receive input from the Company during the preparation of the report, ultimately the unbiased opinions expressed in the report are those of the analyst. Stonegate Capital Markets "SCM" (Member FINRA) is an affiliate of SCP and may seek to receive future compensation for investment banking or other business relationships with the covered companies mentioned in this report. In certain instances, SCP has contracted with SCM to produce research reports for its client companies. SCP pays SCM a monthly retainer for said services.

POLICY DISCLOSURES - SCP analysts are restricted from holding or trading securities in the issuers that they cover. SCP and SCM do not make a market in any security nor do they act as dealers in securities. Each SCP analyst has full discretion on the content and valuation discussion based on his or her own due diligence. Analysts are paid in part based on the overall profitability of SCP. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by SCP for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article. No employee of SCP serves on the Company's Board of Directors. Research analyst and/or a member of the analyst's household do not own shares of this security. The research analyst and/or a member of the analyst's household do not serve as an officer, director, or advisory board member of the Company. This security is eligible for sale in one or more states. This security is subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities. SCP or its affiliates do not beneficially own 1% or more of an equity security of the Company. SCP does not have other actual, material conflicts of interest in the securities of the Company. Stonegate relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Stonegate does not offer or provide personalized advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions.

ADDITIONAL INFORMATION - Please note that this report was originally prepared and issued by SCP for distribution to their market professional and institutional investor customers. Recipients who are not market professional or institutional investor customers of SCP should seek the advice of their independent financial advisor prior to making any investment decision based on this report or for any necessary explanation of its contents. The information contained herein is based on sources, which we believe to be reliable, but is not necessarily complete and its accuracy cannot be guaranteed. Because the objectives of individual clients may vary, this report is not to be construed as an offer or the solicitation of an offer to sell or buy the securities herein mentioned. This report is the independent work of SCP and is not to be construed as having been issued by, or in any way endorsed or guaranteed by, any issuing companies of the securities mentioned herein. The firm and/or its employees and/or its individual shareholders and/or members of their families and/or its managed funds may have positions or warrants in the securities mentioned and, before or after your receipt of this report, may make or recommend purchases and/or sales for their own accounts or for the accounts of other customers of the firm from time to time in the open market or otherwise. While we endeavor to update the information contained herein on a reasonable basis, there may be regulatory, compliance, or other reasons that prevent us from doing so. The opinions or information expressed are believed to be accurate as of the date of this report; no subsequent publication or distribution of this report shall mean or imply that any such opinions or information remains current at any time after the date of this report. All opinions are subject to change without notice, and we do not undertake to advise you of any such changes. Reproduction or redistribution of this report without the expressed written consent of SCP is prohibited. Additional information on any securities mentioned is available on request.

RATING & RECOMMENDATION - SCP does not rate the securities covered in its research. SCP does not have, nor has previously had, a rating for any securities of the Company. SCP does not have a price target for any securities of the Company.

CONTACT INFORMATION

Bio-Path Holdings, Inc.
Douglas P. Morris, Director of Investor Relations
4710 Bellaire Blvd.
Suite 210
Bellaire, Texas 77401
Phone:(832) 742-1357
www.biopathholdings.com

Investor Relations
Stonegate Capital Partners
8201 Preston Rd.
Suite 325
Dallas, Texas 75225
Phone: 214-987-4121
www.stonegateinc.com