Bio-Path Holdings INC

STONEGATE CAPITAL PARTNERS

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## MARKET STATISTICS

| | |
|---|---|
| **Exchange / Symbol** | NASDAQ:BPTH |
| **Price:** | $1.69 |
| **Market Cap (mm):** | $19.2 |
| **Enterprise Value (mm):** | $14.9 |
| **Shares Outstanding (mm):** | 11.3 |
| **Float (%):** | 94% |
| **Volume (3-month average):** | 292,600 |
| **52 week Range:** | $1.54-$5.85 |
| **Industry:** | Biotechnology |

## CONDENSED BALANCE SHEET

($mm, except per share data)

| | |
|---|---|
| **Balance Sheet Date:** | 3/31/2018 |
| **Cash & Cash Equivalent:** | $4.3 |
| **Cash/Share:** | $0.38 |
| **Equity (Book Value):** | $6.3 |
| **Equity/Share:** | $0.55 |

## CONDENSED INCOME STATEMENTS

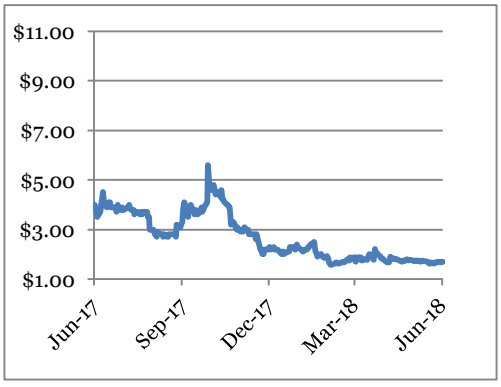
($mm, except per share data)

| FY - 12/31 | Rev | Net Income | Adj. EBITDA | EPS |
|---|---|---|---|---|
| FY15 | $0.00 | ($5.47) | ($4.91) | ($0.61) |
| FY16 | $0.01 | ($6.75) | ($7.49) | ($0.73) |
| Fy17 | $0.04 | ($8.06) | ($7.76) | ($0.80) |
| Fy18E | $0.00 | ($10.13) | ($7.85) | ($0.85) |

## LARGEST SHAREHOLDERS

| | |
|---|---|
| Peter H. Nielsen | 516,400 |
| UT Investment Management Co. | 383,100 |
| The Vanguard Group, Inc. | 233,800 |
| Hyacinth Resources, LLC | 161,000 |
| Renaissance Technologies Corp. | 136,700 |
| Sabby Management, LLC | 85,000 |
| Garrison Capital Advisors, LLC | 67,300 |
| Geode Capital Management, LLC | 52,500 |

## 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 potentially in 2018. 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 will complete one additional safety study per FDA request. Bio-Path is targeting a broad Phase 1 clinical trial in lymphoma, planned to start in 2018. 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 2018. BPTH is headquartered in Bellaire, Texas, and currently has 9 full-time 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 treated to date. 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.
- The clinical targets for BP1002 are lymphoma, 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 recently 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.
- Q118 results include a net loss attributable to common stockholders of (1.9M) for the quarter ended 3/31/18 vs. ($0.4M) for the prior year. Operating expenses in total were comparable year-over-year. Management states that cash on hand of approximately $4.3M is sufficient to fund key milestones for 2018; however, the Company will be seeking additional funding in the upcoming year for 2019.
- Bio-Path effected a 1-for-10 reverse stock split on 2/8/18 to increase the per share trading price above the NasdaqCM $1.00 minimum bid price for continued listing.
- With promising clinical data and several programs in the pipeline addressing sizable markets with unmet needs, our valuation analysis for the BP1001 for AML and CML programs alone results in an estimated range of $11-$14/share, with a mid-point of approximately $13. 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 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, is currently in preparation for a Phase 1 clinical trial in lymphoma 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® 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*

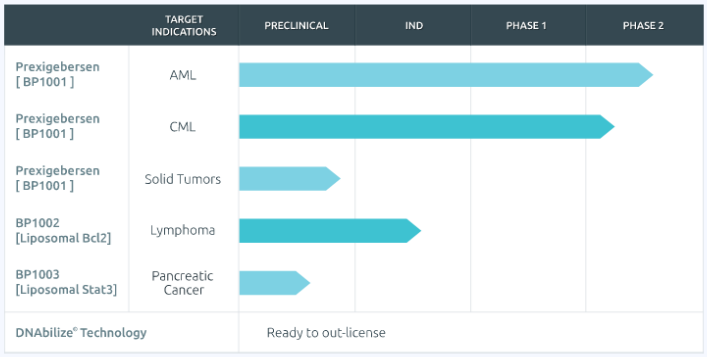
DNA has two strands—the sense strand and the antisense strand. The antisense strand, which is also known as the template strand, is the DNA that carries the genetic information necessary to make proteins because it is the template for messenger RNA (mRNA) synthesis. The synthesis of RNA from DNA is called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

**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.

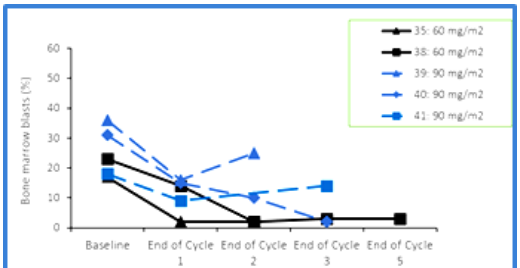
*Exhibit 3: Decrease in Disease-causing Proteins*

| 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 | 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*



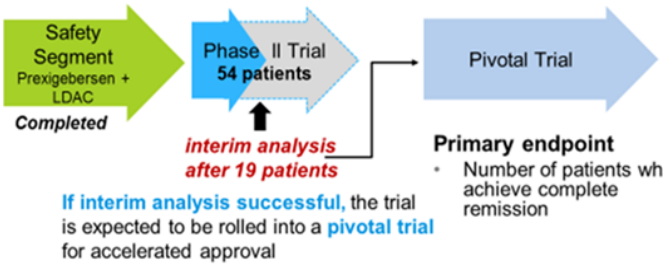

| Patient | BP1001 (mg/m²) | BM Blasts % Reduction | Cycles completed | Response |
|---|---|---|---|---|
| 35 | 60 | 88 | 1 | CR |
| 37 | 60 | 0 | 1 | PD |
| 38 | 60 | 91 | 5 | CR |
| 39 | 90 | 56 | 3 | PR |
| 40 | 90 | 68 | 3 | CR |
| 41 | 90 | 50 | 3 | PR |

*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 is underway. The efficacy trial will take place in 10 leading cancer centers throughout the U.S., with six sites currently enrolling patients. 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

Based on recommendations from the principal investigators conducting the study, Bio-Path intends to amend 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, the investigators have recommended the inclusion of a decitabine cohort 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 (60mg/m² and 90mg/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 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/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%

**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 of a Phase 1 clinical trial potentially by year-end 2018.

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 will complete one additional safety study per FDA request and prepare for a broad Phase 1 clinical trial of BP1002 in patients with lymphoma.

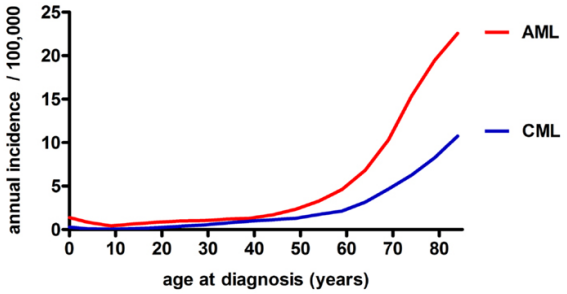
**BP1003 –** BP1003 targets the Stat3 protein, and it is currently in preclinical development in a pancreatic patient-derived tumor model. In previous preclinical work, models have shown BP1003 successful at penetrating pancreatic tumors and notably enhancing the efficacy of standard frontline treatments. Per a recent announcement, BPTH intends to initiate IND enabling studies of BP1003 in 2018.

**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. Management states that cash on hand of approximately $4.3M is sufficient to fund key milestones for 2018; however, the Company will be seeking additional funding in the upcoming year for 2019.

**Funding** – To date, the Company has incurred significant losses from operations and reported an accumulated deficit of ($41.1M) as of 3/31/18. 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.

**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 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 | - | - | (440) | - |
| Interest income | 18 | 12 | 9 | 10 |
| Total other (income) / expense | 18 | 1,725 | 1,943 | 10 |
| **Pre-tax income (loss)** | **(5,467)** | **(6,750)** | **(7,023)** | **(9,090)** |
| Income taxes (benefit) | - | - | - | - |
| **Net income (loss)** | **$ (5,467)** | **$ (6,750)** | **$ (7,023)** | **$ (9,090)** |
| **Deemed dividend related to warrant conversion** | **-** | **-** | **(1,038)** | **(1,038)** |
| **Net income (loss) attributable to common** | **(5,467)** | **(6,750)** | **(8,061)** | **(10,128)** |
| **Basic and diluted EPS (loss)** | **$ (0.61)** | **$ (0.73)** | **$ (0.80)** | **$ (0.85)** |
| Weighted Average Basic and Diluted Shares Outstanding | 8,976 | 9,270 | 10,081 | 11,896 |
| EBITDA | (5,283) | (8,271) | (8,555) | (8,650) |
| Adjusted EBITDA | (4,914) | (7,487) | (7,762) | (7,850) |
| | | | | |
| **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% | -29.4% |
| EPS | -20.3% | -19.6% | -9.8% | -6.5% |
| EBITDA | -20.9% | -56.6% | -3.4% | -1.1% |
| Weighted Average Basic and Diluted Shares Outstanding | 0.5% | 3.3% | 8.7% | 18.0% |

*Source: Company Reports, Stonegate Capital Partners estimates*

## 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 ($10.1M), or ($0.85) per share, with approximately 11.9M weighted average shares outstanding. This activity will support 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 this year as well, a second drug candidate being readied to start a Phase 1, and a third drug candidate recently announced in preclinical development. Management states that cash on hand of approximately $4.3M is sufficient to fund key milestones for 2018; however, the Company will be seeking additional funding in the upcoming year for 2019. Thus, we assume a capital raise prior to year-end.

We believe that an appropriate tool for analyzing the longer-term opportunity for Bio-Path is through a discounted cash flows analysis. Exhibit 7 presents a summary of the detailed analysis we performed based on certain assumptions for the Company's AML and CML programs with the most advanced clinical work, providing sensitivity for discount rates and terminal growth rates. Given the still fairly early stages of the other programs, we have not factored them into the analysis at this point, although we note that several indications show significant promise to move forward quickly following success of Bio-Path's lead candidate prexigebersen.

We have assumed that commercialization of BP1001 for AML begins in 2020 and for CML in 2021, given the Company's current progress in clinical trials and the orphan drug designation. We have incorporated a US population of 20,000 patients for AML and 8,000 for CML, and we have doubled those figures to incorporate the European population. We show market penetration ramping up to 30% of the total population by 2025; we used an average price of $120,000 per patient per year in the US, with significantly discounted pricing in the EU. We factor in a probability of commercialization of ~30%.

We have made conservative assumptions on Bio-Path's changes in working capital, depreciation and amortization, as well as capex going forward. We have incorporated a tax rate of 35% beginning in 2021. The Company reported a tax loss carryforward of ~$36M as of 12/31/17 as well as a $1.5M tax credit R&D carryforward.

A mid-range discount rate of 25% has been included, which we feel is appropriate given the stages of the programs, regulatory hurdles both in the U.S. and abroad, and the need for reimbursement approvals. We have incorporated terminal values ranging from 0% - 4%. Our discounted cash flows analysis for the AML and CML BP1001 programs results in the range of valuation of approximately $11 - $14, with a midpoint of approximately $13. BPTH currently trades at $1.69 per share.

Again, we point out that this analysis covers the potential of the BP1001 for AML and CML programs only at this point, with several other promising programs in the pipeline that could follow just years behind given continued impressive results from the clinic; additionally, the DNAbilize® technology has applications in several other disease areas outside cancer and can likely be out-licensed as well. Furthermore, we note that while we feel that we have attempted to include conservative assumptions within our analysis, downside to any one of those inputs can significantly lower the estimated ranges, and in keeping with that idea, it is appropriate for investors revisit the risks associated with clinical stage development companies in the process of seeking initial FDA approval and drug commercialization.

*Exhibit 7: Summarized DCF Analysis*

| | | Terminal Growth Rates | | | | |
|---|---|---|---|---|---|---|
| | | 0% | 1% | 2% | 3% | 4% |
| Discount Rate | 23.0% | $15 | $15 | $15 | $16 | $16 |
| | 24.0% | $13 | $14 | $14 | $14 | $15 |
| | 25.0% | $12 | $12 | $13 | $13 | $13 |
| | 26.0% | $11 | $11 | $12 | $12 | $12 |
| | 27.0% | $10 | $10 | $11 | $11 | $11 |

*Source: Company Reports, Stonegate Capital Partners, Capital IQ*

## CORPORATE TIMELINE

***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

***October 2016*** - Received orphan drug designation for prexigebersen in the EU for the indication of AML

***April 2015*** - Received orphan drug designation from the FDA for prexigebersen in AML

***February 2015*** - Began enrollment into the combination therapy Phase 1b clinical trial for prexigebersen in patients with AML

***August 2013*** - Clinical confirmation received that treating patients with BP1001 inhibits the Grb2 disease-causing target protein in patients with blood cancers

***November 2011*** - Announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb2, Bio-Path had requested that the FDA allow higher dosing

***July 2010*** - BPTH initiated Phase 1 clinical trial of BP1001

***March 2010*** - FDA accepted IND for Bio-Path's lead cancer drug candidate liposomal BP1001 allowing it to proceed into clinical trials

***March 2010*** - Common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market under the ticker symbol BPTH

***February 2008*** - Company completed a reverse merger with Bio-Path subsidiary

***February 2006*** - Company becomes publicly traded

## 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.

**Suzanne Kennedy, Ph.D., Director of Corporate Development –** Dr. Kennedy joined Bio-Path in 2014. Prior to joining the Company, she was in global marketing at QIAGEN and Thermo Fisher and Director of Research and Development for MO BIO Laboratories. She earned a doctorate from Virginia Commonwealth University in microbiology and immunology.

**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*
**Paul D. Aubert** - *Director*
**Mark P. Colonnese** – *Director*
**Heath Cleaver** – *Director*
**Douglas P. Morris** – *Director*

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