Bio-Path Holdings INC

STONEGATE CAPITAL PARTNERS

September 30, 2022

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MARKET STATISTICS

Exchange / Symbol	NASDAQ:BPTH
Price:	$3.25
Market Cap (mm):	$23.3
Enterprise Value (mm):	$6.90
Shares Outstanding (mm):	7.16
Float (%):	99%
Volume (3-mo. average, mm):	0.03
52 week Range:	$2.68-$5.40
Industry:	Biotechnology

CONDENSED BALANCE SHEET

($mm, except per share data)

Balance Sheet Date:	6/30/2022
Cash & Cash Equivalent:	$17.0
Cash/Share:	$2.38
Equity (Book Value):	$19.7
Equity/Share:	$2.73

CONDENSED INCOME STATEMENTS

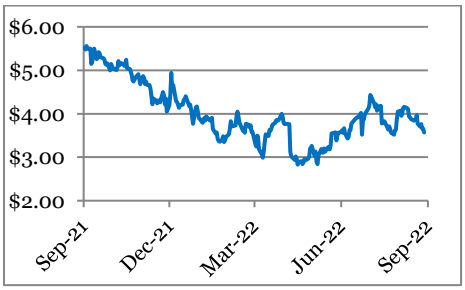
($mm, except per share data)

FY - 12/31	Rev	Net Income	Adj. EBITDA	EPS
Fy19	$0.00	($8.60)	($7.78)	($3.24)
Fy20	$0.00	($10.88)	($10.18)	($2.83)
Fy21	$0.00	($10.44)	($9.46)	($1.55)
Fy22E	$0.00	($13.00)	($11.75)	($1.78)

LARGEST SHAREHOLDERS

The Vanguard Group, Inc.	221,512
Geode Capital Management, LLC	67,519
BlackRock, Inc.	48,469
Peter H. Nielsen	25,823
Renaissance Technologies, LLC	18,000
Northern Trust Global Investments	17,327
State Street Global Advisors, Inc.	13,033
Dimensional Fund Advisors, L.P. (U.S.)	12,960
Morgan Stanley & Company, LLC	9,564
UBS Financial Services, Inc.	2,164

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 myeloid leukemia (AML), and the Company's Investigational New Drug (IND) for a Phase 1 in solid tumors in was cleared in October 2021 (BP1001-A, Bio-Path's fourth drug candidate). The Company's second DNAbilize® drug candidate, Liposomal Bcl-2 (BP1002), for the treatment of lymphoma, chronic lymphocytic leukemia (CLL), colon, prostate and breast cancers, has had an IND application for a Phase 1 clinical trial cleared by the FDA in lymphoma and CLL patients, with dosing beginning in the Phase 1 in November 2020, and in August 2021 an additional IND filing was given clearance for refractory/relapsed AML patients. Bio-Path's third drug candidate, BP1003, is currently in preclinical development in a pancreatic patient-derived tumor model with plans to pursue IND-enabling studies and file an IND 2022, and having a goal of entering first-in-human trials shortly thereafter.

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. BPTH has five patents related to its DNAbilize® platform including its use in the treatment of cancers, autoimmune diseases and infectious diseases, and six pending patents.
- 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 and other blood cancers, and is in the midst of a Phase 2 clinical trial for AML. Importantly, in March 2019 the Company 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 82% of the responding patients were secondary AML patients, historically a very difficult class to treat. Given the new data, BPTH developed a revised registration-directed clinical development plan (see page 4) and most recently reported successful completion of the safety cohort in Stage 2 of the Phase 2 trial testing the triple combination treatment of prexigebersen/decitabine/venetoclax.
- 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 preclinical data, BPTH now believes that BP1002 likely could be used to treat CLL and AML 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.
- Bio-Path is developing a 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.
- The Company most recently reported that cash on hand as of 6/30/22 is sufficient to fund operations according to plan for at the next 12 months.
- With promising clinical data and several programs in the pipeline addressing sizable markets with unmet needs, BPTH remains undervalued relative to comparable companies at similar stages of development. See page 8 for further details.

BUSINESS OVERVIEW

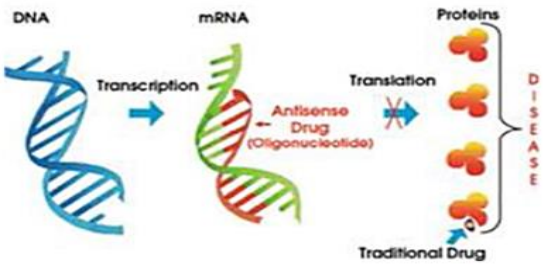
Bio-Path was founded based on antisense and neutral lipid technology licensed from The University of Texas M.D. Anderson Cancer Center. The Company maintains an exclusive license agreement. Bio-Path has subsequently developed its own neutral lipid nanoparticle RNAi technology that is patented and is 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. BPTH is headquartered in Bellaire, Texas, and has 10 employees.

With DNAbilize® as the drug development and manufacturing platform, Bio-Path is focusing on four 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. BPTH has added a fourth drug candidate, BP1001-A targeting multiple types of solid tumors, including breast and ovarian cancers, for which an IND was recently cleared to initiate a Phase 1/1b trial. Prexigebersen has received orphan drug status for AML from the FDA and from the European Medicines Agency. Another DNAbilize® drug candidate, Liposomal Bcl-2 (BP1002), which is also a liposomal antisense drug, has begun dosing in a Phase 1 clinical trial in lymphoma and CLL following an IND being cleared by the FDA; additionally, BPTH believes that BP1002 has applications in treating venetoclax AML and CLL patients who have relapsed and had an additional IND cleared in August 2021 for refractory/relapsed AML patients. The Company also has 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.

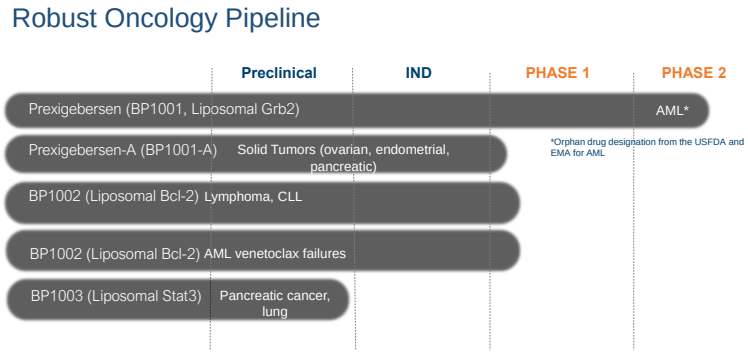
- **No toxicity -** Unlike many traditional therapies, DNAbilize® does not introduce a toxic agent into the body to kill the cells. The P-ethoxy DNA does not induce hepatotoxicity or thrombocytopenia, but simply blocks protein production.
- **Higher cellular uptake -** Neutral lipids form structures 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.

As most recently reported, BPTH has five issued patents related to its DNAbilize® platform including its use in the treatment of cancers, autoimmune diseases and infectious diseases, and six pending patents.

CLINICAL TRIALS

Exhibit 2: Product Candidates in Development



*Orphan drug designation from the USFDA and EMA for AML

Source: Company Reports

Bio-Path has several 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 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 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.

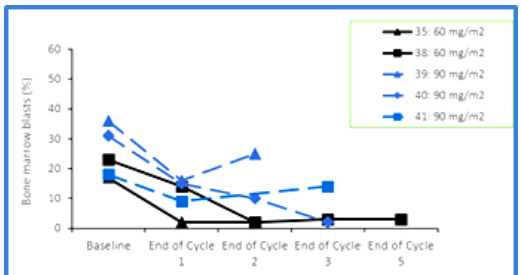
Exhibit 3: Decrease in Disease-causing Proteins

Subject Number	Cohort	BP1001 dose (mg/m^2)	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/m^2)	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/m^2 and one group receiving 90 mg/m^2. 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 compares 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. As of August 2019, Bio-Path amended the Phase 2 trial to include patients with high risk myelodysplastic syndrome (MDS) and refractory/relapsed AML patients.

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 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 original 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 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 noted that the efficacy profile had 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 82% 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 82%. 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:

- 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; additionally, efficacy studies for prexigebersen + decitabine + venetoclax 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
- Amend the protocol of the Phase 2 for untreated AML 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.

BPTH announced August 2019 that patient dosing had begun in the amended Phase 2 trial. In November 2019, BPTH disclosed that safety testing in Stage 2 of the Phase 2 clinical trial for AML and MDS had been completed. This safety segment included 6 evaluable patients treated with the combination of prexigebersen and decitabine and resulted in 50% of the patients having a response, with 33% of these showing complete responses with incomplete hematologic recovery, and 17% showing partial response (complete response rate to decitabine alone is ~20%). With this safety study complete, BPTH has also moved forward with the first six evaluable patients in testing the combination of prexigebersen + decitabine + venetoclax; the Company announced in August 2020, that a patient had been enrolled and dosed (patient is in the relapsed/refractory cohort). On April 5, 2021, Bio-Path reported successful completion of the safety cohort for testing this triple combination and thus will move forward with efficacy testing. Results showed a clean side effect profile and lack of toxicity, which will be especially important when treating *de novo* fragile AML patients with higher sensitivities. The Company also noted that out of the six evaluable patients treated with the triple combination, five responded (83%) to the treatment, including four achieving complete response (67%) and one complete response with incomplete hematologic recovery (17%); these results far exceeded complete response rates for the combination decitabine + venetoclax across comparable treatment categories, and no dose limiting toxicities were noted related to prexigebersen.

The efficacy segment of the trial will be conducted at 10 US clinical sites, with 9 already committed to date, and will include an interim assessment of 19 evaluable patients in each cohort. While 54 evaluable patients will be included in two cohorts testing relapsed/refractory AML patients (using triple combination) as well as those who are venetoclax resistant/intolerant (using prexigebersen + decitabine), a total of 98 evaluable patients will be included in the cohort for previously untreated AML patients (includes triple combination).

Prexigebersen-A for Treatment of Solid Tumors - Bio-Path believes that solid tumors with activated or mutated tyrosine kinases as targets for prexigebersen (referred to as BP1001-A for solid tumors) would have a high degree of success. The Company is investigating this fourth drug candidate BP1001-A 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 BP1001-A in the treatment of solid tumors, and the results from these preclinical studies will be used to evaluate the efficacy of BP1001-A, both as a monotherapy and in combination with front line therapies, in the treatment of solid tumors. Pre-clinical studies supporting the potential of BP1001-A 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 in April 2018. Bio-Path filed an IND in late 2019 that was cleared in October 2021 and thus anticipates beginning enrollment at several leading cancer centers of a Phase 1 clinical trial 2Q 2022.

The Phase 1/1b clinical trial initially will include 6 evaluable patients being treated with prexigebersen-A monotherapy in a standard 3+3 design, which starts with a dose of 60 mg/m^2. The approved treatment cycle is two doses per week over 4 weeks, resulting in 8 doses administered over 28 days. The Phase 1b portion of the study will commence after successful completion of prexigebersen-A monotherapy cohorts and will assess the safety and efficacy of prexigebersen- A.

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 previously 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 in preparation for a broad Phase 1 clinical trial of BP1002 in patients with lymphoma and CLL.

BPTH's IND application was reviewed and cleared by the FDA, and a patient in the Phase 1 trial received the first dosage in November 2020. The Phase 1 clinical trial initially includes 6 evaluable patients at several leading cancer centers across the U.S. being treated with BP1002 monotherapy in a standard 3+3 design, which starts with a dose of 20 mg/m^2. Per recent disclosures, the approved treatment cycle is two doses per week over 4 weeks, resulting in 8 doses administered over 28 days.

Additionally, with the approval of frontline therapy venetoclax (approved for AML and CLL) and most recently updated interim data, BPTH filed an additional IND for registration of BP1002 for the treatment of refractory/relapsed acute myeloid leukemia patients, which was reviewed and cleared by the FDA in August 2021. The Company will have the benefit of the experience from the modified Phase 2 AML clinical program now including 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. The trial design of the Phase 1/1b is the same as that of the previously approved IND for BP1002 described above, and the Phase 1b portion of the study will commence after completion of the monotherapy cohorts to assess the safety and efficacy of BP1002 in combination with decitabine in refractory/relapsed AML patients, likely 2Q 2022.

BP1003 – BP1003 targets inhibition of the STAT3 (Signal Transducer and Activator of Transcription 3) 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. STAT3 is recognized as a critical mediator of tumor immune evasion and is found in many types of cancer, including NSCLC, AML and PDAC. Activation of STAT3 typically correlates with poor clinical outcomes, high grade disease and metastasis, and has been linked with resistance to chemotherapy.

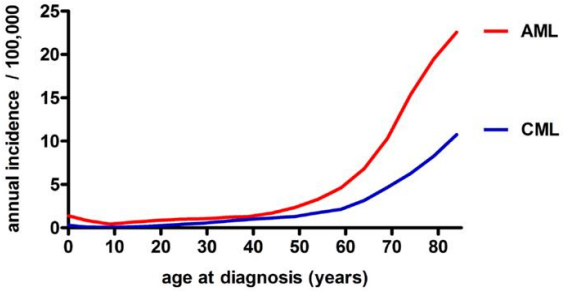
BPTH intends to pursue IND-enabling studies of BP1003 and file in 2022, with a goal to enter first-in-human trials shortly thereafter. Additionally, the Company has the advantage of world-leading gastrointestinal cancer expert Dr. Jason Fleming being part of its Scientific Advisory Board.

Collaborations
Bio-Path collaborates 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. Most notably, the Company recently worked with Dr. Jason Fleming and M.D. Anderson to investigate whether liposomal Grb2 antisense or liposomal STAT3 antisense would be internalized within a pancreatic patients-derived xenograft (PDX) model; once internalization was confirmed, the team further investigated efficacy against pancreatic PDX in the presence and absence of gemcitabine. Results were incorporated into the BP1001-A IND and also included in the pre-IND BP1003 briefing package submitted to the FDA.

MARKET OPPORTUNITY

Bio-Path's initial targets are myeloid neoplasms, a subset of hematologic malignancies such as 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.

RISKS

COVID-19 – The severity and continuation of the COVID-19 outbreak could ultimately cause significant disruptions to the Company's ongoing clinical trial processes. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed given the progression of the COVID-19 pandemic.

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 ~($84.0M) as of 6/30/22. 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. Management most recently reported cash on hand of $17M to fund operations for the next 12 months and will need to raise funding additional funding for operations.

On July 13, 2020, Bio-Path entered into an ATM (at-the-market) agreement with H.C. Wainwright & Co., LLC; sales of common shares can be sold under the Company's shelf registration statement on Form S-3 filed with the SEC and effective June 2019, with a supplement also filed July 2020 and an amendment March 2022, for an aggregate offering price of up to $10.0M, with some limitations as long as Bio-Path's public float remains less than $75M. The Company's previous sales agreement with Cantor Fitzgerald & Co. was terminated July 12, 2020.

As of 3/31/22, BPTH had offered and sold 1,328,800 shares of common stock under the H.C. Wainwright agreement for gross proceeds of approximately $8.4M.

In February 2021 the Company entered into a placement agency agreement with Roth Capital Partners, and as of the closing on 2/18/21 of the 2021 Registered Direct Offering, BPTH received ~$12.2M in net proceeds.

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 2019	FY 2020	FY 2021	FY 2022 E
Revenues				
Product revenues	$ -	$ -	$ -	$ -
Total product revenues	**$ -**	**$ -**	**$ -**	**$ -**
Cost of revenues				
Cost of product revenues	-	-	-	-
Total cost of revenues	-	-	-	-
Gross (loss) profit	**-**	**-**	**-**	**-**
Operating expenses				
General and administrative	4,108	4,330	4,533	5,000
Research and development	4,585	6,578	5,910	8,000
Total operating expenses	8,693	10,908	10,443	13,000
Income (loss) from operations	**(8,693)**	**(10,908)**	**(10,443)**	**(13,000)**
Other income / (expense)				
Change in fair value warrant liability	-	-	-	-
Loss on extinguishment of warrant liability	-	-	-	-
Interest income	94	26	3	-
Total other (income) / expense	94	26	3	-
Pre-tax income (loss)	**(8,599)**	**(10,882)**	**(10,440)**	**(13,000)**
Income taxes (benefit)	-	-	-	-
Net income (loss)	**$ (8,599)**	**$ (10,882)**	**$ (10,440)**	**$ (13,000)**
Deemed dividend related to warrant conversion	**-**	**-**	**-**	**-**
Net income (loss) attributable to common	**(8,599)**	**(10,882)**	**(10,440)**	**(13,000)**
Basic and diluted EPS (loss)	**$ (3.24)**	**$ (2.83)**	**$ (1.55)**	**$ (1.78)**
Weighted Average Basic and Diluted Shares Outstanding	2,657	3,847	6,725	7,300
EBITDA	(8,463)	(10,757)	(10,282)	(12,750)
Adjusted EBITDA	(7,779)	(10,180)	(9,461)	(11,750)
Growth Rate Analysis Y/Y				
General and administrative	21.6%	5.4%	4.7%	10.3%
Research and development	-12.0%	43.5%	-10.2%	35.4%
Net income (loss)	-0.2%	-26.5%	4.1%	-24.5%
EPS	77.5%	12.6%	45.1%	-14.7%
EBITDA	-3.7%	-27.1%	4.4%	-24.0%
Weighted Average Basic and Diluted Shares Outstanding	345.1%	44.8%	74.8%	8.6%

Source: Company Reports, Stonegate Capital Partners estimates

VALUATION

We are projecting total operating expenses of approximately $13.0M and assuming that Bio-Path finishes the FY222E year with a net loss attributable to common of approximately ($13.0M), or ($1.78) per share, with approximately 7.3M weighted average shares outstanding. This activity level should support BPTH's main objectives for the remainder of 2022 and well into the 2023 year, with its lead candidate prexigebersen in Phase 2 for AML and targeted to begin enrolling a Phase 1 in solid tumors in 2022 (BP1001-A), a second drug candidate that has begun dosing in a Phase 1, and a third drug candidate in preclinical development, moving towards IND-enabling studies. The Company most recently reported that cash on hand as of 6/30/22 is sufficient to fund operations according to plan for at least the next 12 months.

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	Revenue Est. Current FY
BeyondSpring, Inc.	BYSI	$ 1.30	38.9	$ 50.6	$ (18.5)	$ 0.7
Compass Therapeutics, Inc.	CMPX	$ 3.11	100.9	$ 313.8	$ 185.5	n/a
CTI BioPharma Corp.	CTIC	$ 5.81	114.4	$ 664.7	$ 677.7	$ 56.1
Cumberland Pharmaceuticals, Inc.	CPIX	$ 2.21	14.7	$ 32.5	$ 33.4	n/a
Curis, Inc.	CRIS	$ 0.86	91.8	$ 78.9	$ (23.5)	$ 10.9
CytoDyn, Inc.	CYDY	$ 0.50	809.9	$ 405.0	$ 437.5	n/a
First Wave BioPharma, Inc.	FWBI	$ 4.22	1.4	$ 5.9	$ 5.2	n/a
Magenta Therapeutics, Inc.	MGTA	$ 1.75	58.4	$ 102.2	$ (5.6)	n/a
Nuvectis Pharma, Inc.	NVCT	$ 12.00	12.7	$ 152.4	$ 105.6	n/a
Paratek Pharmaceuticals, Inc.	PRTK	$ 2.38	54.9	$ 130.7	$ 319.9	$ 151.6
Sonnet BioTherapeutics Holdings, I	SONN	$ 0.20	60.6	$ 12.1	$ 7.3	$ 0.4
Bio-Path Holdings, Inc.	**BPTH**	**$ 3.60**	**7.2**	**$ 25.8**	**$ 4.3**	**n/a**

Name	Ticker	Price	Sh	Mrkt Cap	EV	EV/Revs Current FY
BeyondSpring, Inc.	BYSI	$ 1.30	38.9	$ 50.6	$ (18.5)	n/a
Compass Therapeutics, Inc.	CMPX	3.11	100.9	313.8	$ 185.5	n/a
CTI BioPharma Corp.	CTIC	$ 5.81	114.4	$ 664.7	$ 677.7	12.1x
Cumberland Pharmaceuticals, Inc.	CPIX	$ 2.21	14.7	$ 32.5	$ 33.4	n/a
Curis, Inc.	CRIS	$ 0.86	91.8	$ 78.9	$ (23.5)	n/a
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First Wave BioPharma, Inc.	FWBI	$ 4.22	1.4	$ 5.9	$ 5.2	n/a
Magenta Therapeutics, Inc.	MGTA	$ 1.75	58.4	$ 102.2	$ (5.6)	n/a
Nuvectis Pharma, Inc.	NVCT	$ 12.00	12.7	$ 152.4	$ 105.6	n/a
Paratek Pharmaceuticals, Inc.	PRTK	$ 2.38	54.9	$ 130.66	$ 319.9	2.1x
Sonnet BioTherapeutics Holdings, I	SONN	$ 0.20	60.6	$ 12.1	$ 7.3	18.3x
	Average			**$ 177.2**	**$ 156.8**	**10.8x**
	Median			**$ 102.2**	**$ 33.4**	**12.1x**
Bio-Path Holdings, Inc.	**BPTH**	**$ 3.60**	**7.2**	**$ 25.8**	**$ 4.3**	**n/a**

Source: Company Reports, Stonegate Capital Partners, Capital IQ

IN THE NEWS

September 2022 – BPTH presents at H.C. Wainwright 24th Annual Global Investment Conference

April 2022 – BPTH presents at 2022 American Association for Cancer Research Annual Meeting, and Aline Sherwood joins the Board of Directors, replacing Martina Molsbergen

January 2022 – BPTH participating in H.C. Wainwright BioConnect 2022 Virtual Conference

December 2021 – BPTH presents data from ongoing Phase 2 study of prexigebersen at the 63rd Annual American Society of Hematology Meeting

October 2021 – Bio-Path announces clearance of IND for Phase 1/1b Trial of Prexigebersen-A in solid tumors

August 2021 – Company reports clearance of IND application for BP1002 in refractory/relapsed acute myeloid leukemia patients

June 2021 – Bio-Path announces that a new patent has been granted related to the Company's BP1003 program

April 2021 – Company reports successful completion of safety cohort of triple combination of prexigebersen, decitabine, and venetoclax in Stage 2 of Phase 2 AML clinical trial; BPTH also announces that Company has presented BP1002 data at 2021 American Association for Cancer Research Annual Meeting as well as published an analysis highlighting the potential of BP1001 within the antisense oligonucleotide drug delivery landscape in the journal *Biomedicines*

February 2021 – BPTH receives third US patent grant related to manufacture of platform technology; Company announces closing of $13M public stock offering

November 2020 – Company announces that first patient has been dosed in Phase 1 clinical trial of BP1002

October 2020 – Bio-Path receives notice of allowance for strategic patent for prexigebersen in combination with front line cytidine analogues or Bcr-Abl tyrosine kinase inhibitors in a variety of cancers

September 2020 – BPTH presents a corporate overview at the virtual H.C. Wainwright 22nd Annual Global Investment Conference

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.

Douglas P. Morris, Director of Investor Relations – Doug Morris is a co-founder of Bio-Path and a co-founding director. Mr. Morris has a number of administrative responsibilities, including working with retail broker/dealers in raising capital for small cap companies, and interfacing with existing shareholders. Mr. Morris has a Bachelor of Arts from Brigham Young University and is working towards a Master of Public Administration from the University of Southern California.

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*
Paul Aubert - *Director*
Heath Cleaver – *Director*
Douglas P. Morris – *Director*
Aline Sherwood - *Director*

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