

Q324 RESEARCH UPDATE
BIO-PATH HOLDINGS, INC. (NASDAQ: BPTH)
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Market Statistics (As of 9/30/2024)

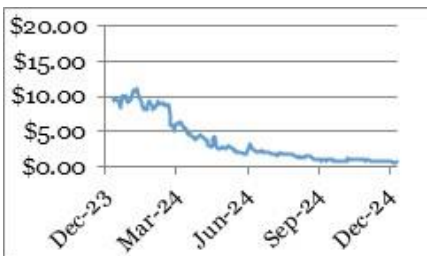
Exchange / Symbol	Nasdaq: BPTH
Price:	\$0.72
Market Cap (\$M):	\$3.1
Enterprise Value (\$M):	\$2.5
Shares Outstanding	4,306,892
Float%	90.9%
Volume 3-mo average (M)	1.20
52 Week Range	0.59-12.00
Industry	Biotechnology

CONDENSED BALANCE SHEET (As of 9/30/24)

Equity (\$M)	(\$0.7)
BV/S	(\$0.17)
Cash (\$M)	\$0.6

CONDENSED INCOME STMTS. (As of 9/30/24)

	Rev	Net Income	Adj. EBITDA	EPS
FY21	\$0.0	(\$10.4)	(\$9.5)	(\$1.55)
FY22	\$0.0	(\$13.9)	(\$12.9)	(\$1.91)
FY23	\$0.0	(\$16.1)	(\$14.9)	(\$33.63)
FY24 E	\$0.0	(\$12.0)	(\$11.3)	(\$3.64)


COMPANY DESCRIPTION

Bio-Path has developed DNAbilize®, a novel technology that has yielded a pipeline of RNAi nanoparticle drugs that can be administered via intravenous transfusion. Bio-Path's lead candidate, prexigebersen (BP1001 targeting the Grb2 protein) is in Phase 2 studies for blood cancers. BP1001-A has begun Phase 1 studies in solid tumors. BP1002, which targets the Bcl-2 protein, is being evaluated for the treatment of blood cancers and solid tumors. An IND should be filed soon for BP1003, developed as a specific STAT3 inhibitor.

Recent Private Placement Raises \$4.0M and Expands Runway for Execution of BPTH's Operational Plans

Ongoing Clinical Trials: The Company has various product candidates in different stages of development and continues to expect near-term results in key cohorts.

Prexigebersen - Bio-Path has completed Phase 1 clinical trials for its lead candidate prexigebersen for acute myeloid leukemia (AML) and other blood cancers and is in the midst of a Phase 2 clinical trial for AML. The Company also recently reported that it is exploring potential treatment applications for obesity and obesity-related cancers with prexigebersen.

BP1001-A – BP1001-A (prexigebersen with enhanced nanoparticle properties) has begun Phase 1 trials for the treatment of solid tumors and recently reported treating the first patient with a second, higher dose cohort in its Phase 1/1b clinical trial, continuing to demonstrate the drug's favorable safety profile.

BP1002 – Bio-Path is conducting two clinical trials for BP1002. A Phase 1 clinical trial of BP1002 in patients with advanced lymphoid malignancies is ongoing. Also, a Phase 1 is underway for patients with refractory/relapsed AML, including those who have relapsed from venetoclax-based treatment, and recently BPTH reported completion of the second dose cohort of the dose escalation portion of the trial.

BP1003 - BP1003 is in pre-clinical development in a pancreatic patient-derived tumor model. In previous preclinical trials, it has been successful at penetrating pancreatic tumors.

Owning the Breakthrough Technology: Bio-Path has developed a proprietary antisense and liposome delivery technology for DNA drugs, DNAbilize®, potentially solving the challenges of delivering these molecules directly to target cells without side effects. DNAbilize® is Bio-Path's novel and patented method for producing antisense DNA therapeutics for a broad spectrum of indications, including cancer. This technology overcomes certain drawbacks and challenges of the more traditional methods.

Strategic Relationships: The original technology platform was licensed from The MD Anderson Cancer Center; BPTH maintains a strong relationship with the Cancer Center as well numerous leading cancer centers across the US, with several hosting clinical trials.

Strong IP Position: Bio-path has a strong IP position with composition of matter and method patents for antisense targets and manufacturing, which helps ensure technology preservation and offers protection against competitors.

Cash Runway: The Company reported \$0.6M as cash on hand as of 9/30/24; subsequent to quarter-end, the Company raised ~ \$4.0 M of additional funds for working capital through a private placement that closed 10/10/24.

Valuation: Using comparable companies' EV/R&D multiple - we gauge that Bio-Path is significantly undervalued next to its peers with numerous drug candidates in the pipeline and its lead drug candidate quickly approaching Phase 2 milestones that could indicate potential for approval. See page 12 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.

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.

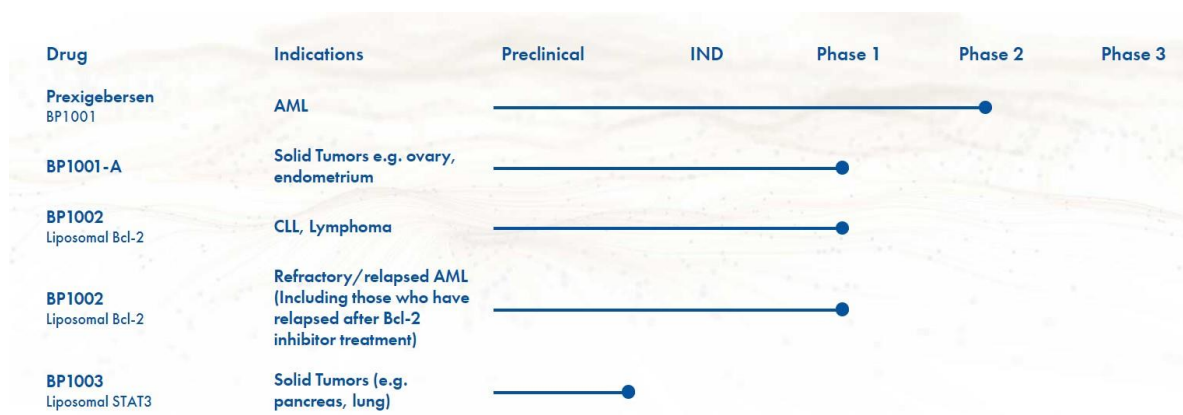
With the rise of “personalized therapy” as an important topic of research over the last several years, multiple companies have performed clinical trials using antisense oligonucleotides (AONS) as RNA-modulating therapeutics. The results have been disappointing, primarily due to toxicity induced by either 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 US-issued patents and 54 issued foreign patents related to its DNAbilize® platform including its use in the treatment of cancers, autoimmune diseases and infectious diseases; there are five pending US patents as well as 46 additional allowed patent applications in foreign jurisdictions.

Clinical Pipeline

Bio-Path has several product candidates in various stages of development that target multiple indications. The following exhibit highlights several of the drug candidates in the pipeline.

Exhibit 2: Product Candidates in Development



Source: Company Reports

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.

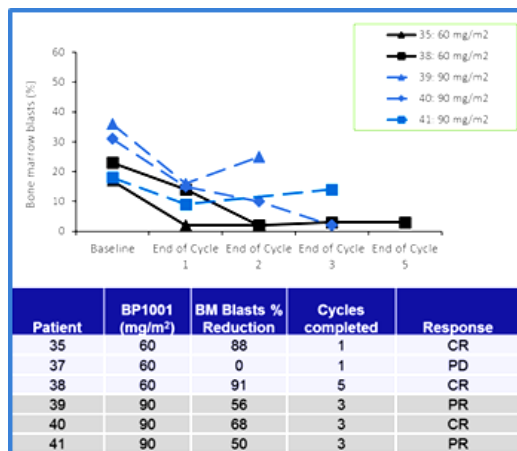
Exhibit 3: Decrease in Disease-causing Proteins

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

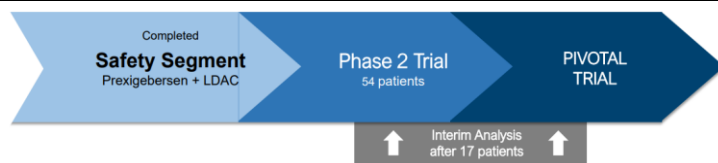


Source: Company Reports

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 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 Combo 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 are 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 is being conducted at multiple US clinical sites and is targeted to include an interim assessment of 19 evaluable patients in each cohort; however, protocol allows BPTH to conduct interim efficacy analysis sooner at its discretion. 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).

In August 2023, the Company reported interim data analysis for 14 newly diagnosed patients in Cohort 1; they were treated with at least one cycle of prexigebersen, decitabine, and venetoclax combination therapy. Details were as follows:

- All patients, median age 75, were adverse risk by 2017 European Leukemia Net (ELN) guidelines (n=10) or secondary AML (n=4)
- Prexigebersen was well-tolerated, and any noted adverse events were consistent with decitabine and venetoclax treatment and/or AML
- Twelve patients (86%) achieved complete remission (CR/Cri) and two (14%) achieved partial remission (PR)
- In total, 100% of the evaluable patients had a response to treatment
- Most notable is that the 86% CR/Cri rate is significantly higher than those for newly diagnosed patients treated with frontline combination treatment of decitabine and venetoclax (62%)

The Company at the same time reported interim results for 14 refractory/relapsed AML patients in Cohort 2; they were treated with at least one cycle of prexigebersen, decitabine, and venetoclax combination therapy. We note that:

- All patients, median age 56.5, were adverse risk by 2017 European Leukemia Net (ELN) guidelines (n=11) or secondary AML (n=2)
- Prexigebersen was well-tolerated, and any noted adverse events were consistent with decitabine and venetoclax treatment and/or AML
- Eight patients (57%) achieved complete remission (CR/Cri) and two (14%) achieved partial remission, and three (22%) achieved stable disease
- In total, 93% of evaluable patients had a response to treatment
- Most notable is that the 57% CR/Cri rate is significantly higher than those refractory/relapsed patients treated with combination treatment of decitabine and venetoclax (21%)

For both cohorts, results are further highlighted by the high-risk rating of Bio-Path's evaluable patient pools and the inclusion of secondary AML patients, a very difficult class of patients to treat. The Company recently also reported noticeably extended treatment durability in elderly patients, which underscores prexigebersen's potential to treat fragile AML patients for longer periods. Given the superiority of these interim review results, BPTH plans to pursue the FDA

expedited programs for Fast Track and Breakthrough Therapy designations. The Company is also contemplating expanding operations to Europe, as it believes there are more potential patients for Stage 2 of this Phase 2 trial.

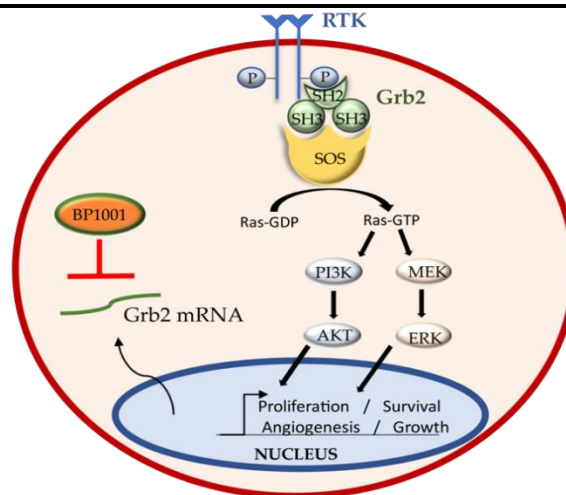
During the second quarter, BPTH additionally announced the development of a new molecular biomarker package that can accompany treatment with prexigebersen. The biomarker package can assist in identifying patients with a genetic profile more likely to respond to the treatment, which increases the likelihood of success for the program. This approach has become more common in recent years related to oncology programs as the role of biomarkers has demonstrated increasing value within the process of cancer treatments.

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. The first patient was dosed in December 2022, and in July 2023, the Company announced successful completion of the first dose cohort in the Phase 1/1b trial. The first patient was treated with the second, higher dose in August 2024 and was reported to have experienced tumor reduction and continued stable disease.

The Phase 1/1b clinical trial initially is scheduled to include 9 evaluable patients being treated with prexigebersen-A monotherapy in a standard 3+3 design, which starts with a dose of 60 mg/m². The approved treatment cycle is two doses per week over 4 weeks, resulting in 8 doses administered over 28 days. The dosing will then continue under the same structured dosing with 90 mg/m² and 135 mg/m².

Three patients that were enrolled in the first dose cohort had all undergone extensive previous chemotherapies and/or surgeries for their disease prior to enrollment and included one patient with hepatic lesions (and lung metastases) and two had advanced gynecologic lesions. No patient demonstrated any treatment related adverse events. 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 combination therapy with the appropriate frontline treatment. Data readout from this study is expected in early 2025.

Exhibit 6: BP1001-A Inhibits Tumor Progression at Grb2 Protein Level



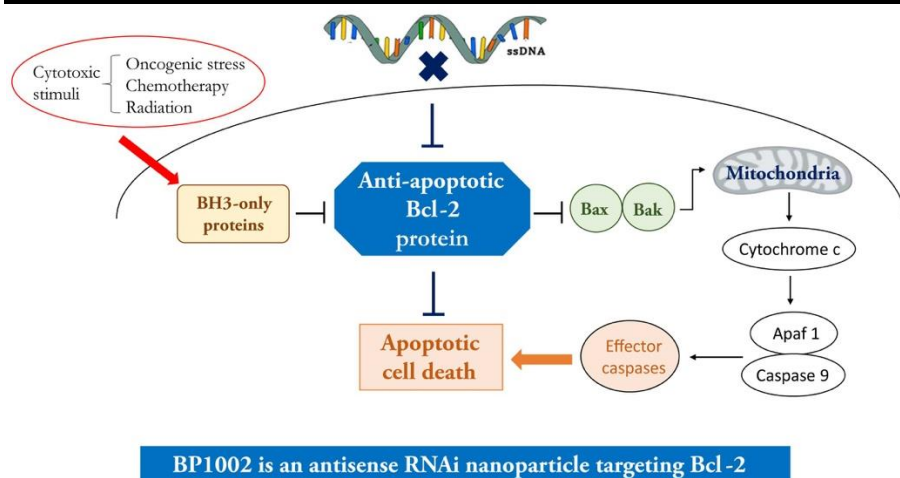
Source: Company Reports

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/m². Per recent disclosures, the approved treatment cycle is two doses per week over 4 weeks, resulting in 8 doses administered over 28 days. In January 2024, the Company announced the safe completion of the initial cohort of the dose escalation portion of the Phase I trial; BP1002 will advance to the next cohort with expectations that the increased levels of the drug will prove even more efficacious in the sickest of sick patients making up this population. Enrollment is now open for the next dose cohort at 40 mg/m².

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 AML, which was reviewed and cleared by the FDA in August 2021. The Company will have the benefit of the experience of 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 it was announced in October 2022 that the first patient had been enrolled and dosed in the Phase 1 portion of this study. Then in December 2023, the Company announced the safe completion of the first dose cohort in which there were no dose limiting toxicities. In April 2024, BPTH additionally announced the completion of the second dose cohort as well. The clinical trial will pause for a brief data review by the FDA prior to testing continuing at the next planned higher dose of 60 mg/m². 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.

Exhibit 7: BP1002 Inhibits Protein Synthesis of Bcl-2

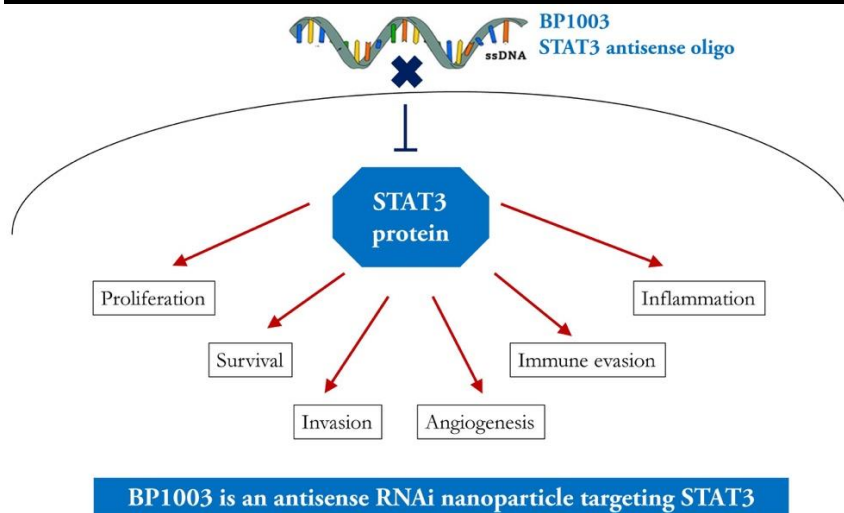


Source: Company Reports

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.

After an extended period of testing, BPTH has identified a method for oligo detection in plasma that it believes will enable the Company to complete final safety testing needed to complete an investigational new drug application or an IND, for submission to the FDA. Management is particularly excited to launch first in-human validation of this cutting-edge therapy, in an especially challenging cancer indication that has limited treatment options. Additionally, the Company has the advantage of world-leading gastrointestinal cancer expert Dr. Jason Fleming being part of its Scientific Advisory Board.

Exhibit 8: BP1003 Targets Inhibition of the STAT3



Source: Company Reports

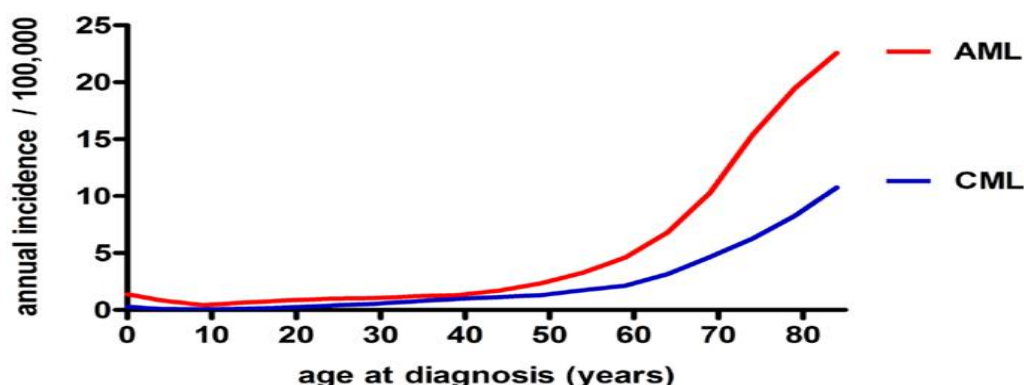
Prexigebersen as a Potential Treatment for Obesity and Obesity-related Cancers – Bio-Path believes that the development of prexigebersen for the treatment of obesity and obesity-related cancers could be accelerated towards approval given the large amount of safety data from other trials. While this is in the initial stages of preparation for preclinical development, the application appears direct. The RNAi target of prexigebersen is the Grb2 protein, which is involved in activating the RAS/ERK pathway for cell growth. In obesity, two such pathways are related to leptin and insulin. Activation of leptin or insulin receptors can stimulate the RAS/ERK pathway via Grb2.

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 of immature blasts in the bone marrow. AML is characterized by the rapid accumulation of immature myeloid cells in the blood, resulting in a drop of the other cell types, such as red blood cells and platelets, and it is the most common acute leukemia in adults. It is estimated by the National Cancer Institute that approximately 20,000 new AML cases occur each year. Also, the incidence of both AML and CML dramatically increases with age (Exhibit 9), and most patients are 60 or older. Particularly in the elderly, who often cannot tolerate aggressive therapies, there remains a dire unmet need for an effective, non-toxic therapy.

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, with the cure rate for older adults being between 5 to 15%. Thus, 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. For those that cannot receive a standard course of chemotherapy, the average survival rate is 5 – 10 months.

Exhibit 9: Annual Incidence of AML and CML in U.S. by Age



Source: Company Reports

Financial Overview

Research and Development Expense. The research and development expense for the three months ended September 30, 2024, was \$1.3 million, a decrease of \$1.0 million compared to the three months ended September 30, 2023. The decrease in research and development expense was primarily due to lower manufacturing expenses related to drug product releases as well as a decrease in expense related to the clinical trial for BP1001 in AML due to timing of patient enrollment during the quarter.

Exhibit 10: R&D Expenditure Breakup

	Three Months Ended September 30,	
	2024	2023
Research and development expense	\$ 1,283	\$ 2,247
Non-cash stock-based compensation expense	34	45
Total research and development expense	\$ 1,317	\$ 2,292

Source: Company Reports

General and Administrative Expense. The Company reported general and administrative expense for the three months ended September 30, 2024, of \$1.3 million, an increase of \$0.3 million over the three months ended September 30, 2023. The increase was primarily due to increased legal fees and salaries and benefits expense.

Exhibit 11: G&A Expenditure Breakup

	Three Months Ended September 30,	
	2024	2023
General and administrative expense	\$ 1,223	\$ 851
Non-cash stock-based compensation expense	94	133
Total general and administrative expense	\$ 1,317	\$ 984

Source: Company Reports

Net Loss. Net loss for the three months ended September 30, 2024, was \$2.1 million, or \$0.70 per share, as compared to a net loss \$3.2 million, or \$6.36 per share, for the three months ended September 30, 2023.

Subsequent Event. On 10/8/24, the Company raised approximately \$4.0 million in net proceeds from a private placement offering with a certain institutional and accredited investor; per management, current cash on hand is sufficient to fund operations according to plan for the next 12 months.

VALUATION SUMMARY

EV/R&D Approach: Using comparable companies' EV/R&D multiple - we believe that Bio-Path is significantly undervalued to its peers with numerous drug candidates in the pipeline and its lead drug candidate is quickly approaching approval.

Desired Multiple	4.0x	6.0x	8.0x
FY24 R&D Est.	\$7,000	\$7,000	\$7,000
EV	\$28,000	\$42,000	\$56,000
Net Debt	\$0	\$0	\$0
Equity Value	\$28,000	\$42,000	\$56,000
No. of Shares FY24	3,300	3,300	3,300
Equity Value	\$8.48	\$12.73	\$16.97

Applying an EV/R&D of 4x to 8x, with a midpoint of 6x, results in a price on the low end of approximately \$8.50.

Name	Ticker	Price	Sh	Mrkt Cap	EV	Revenue Est.	R&D Est.	EV/Rev	EV/R&D
						Current FY	Current FY		
BeyondSpring, Inc.	BYSI	\$ 1.55	40.3	\$ 62.5	\$ 62.1	n/a	\$ 20.8	n/a	3.0x
Collectar Biosciences, Inc.	CLRB	\$ 0.31	41.3	\$ 12.8	\$ (7.9)	n/a	\$ 26.1	n/m	n/m
Compass Therapeutics, Inc.	CMPX	\$ 1.67	137.6	\$ 229.8	\$ 79.2	\$ 0.8	\$ 39.3	99.0x	2.0x
Cumberland Pharmaceuticals, Inc.	CPIX	\$ 2.42	14.0	\$ 33.9	\$ 34.3	n/a	\$ 5.8	n/a	5.9x
Curis, Inc.	CRIS	\$ 3.81	8.5	\$ 32.4	\$ 49.9	\$ 9.8	\$ 39.0	5.1x	1.3x
Allogene Therapeutics, Inc.	ALLO	\$ 2.14	209.7	\$ 448.7	\$ 224.5	\$ 31.4	\$ 197.3	7.2x	1.1x
Entero Therapeutics, Inc.	ENTO	\$ 0.59	4.7	\$ 2.8	\$ 64.5	n/a	\$ 6.5	n/a	9.9x
Nuvectis Pharma, Inc.	NVCT	\$ 4.71	19.3	\$ 90.9	\$ 72.5	n/a	\$ 11.7	n/a	6.2x
Phio Pharmaceuticals Corp.	PHIO	\$ 2.70	1.1	\$ 3.0	\$ (2.4)	n/a	\$ 5.3	n/m	n/m
Sonnet BioTherapeutics Holdings, Inc.	SONN	\$ 1.91	0.8	\$ 1.5	\$ (1.9)	n/a	\$ 6.3	n/m	n/m
Bio-Path Holdings, Inc.	BPTH	\$ 0.72	4.3	\$ 3.1	\$ 2.5	n/a	\$ 7.0	n/a	0.4x

Average	\$ 91.8	\$ 57.5	37.1x	4.2x
Median	\$ 33.1	\$ 56.0	7.2x	3.0x

BALANCE SHEET

Bio-Path Holdings, Inc. (NasdaqCM: BPTH)				
Consolidated Balance Sheets (\$000s)				
Fiscal Year: December				
ASSETS	FY2021	FY2022	FY2023	Q32024
Assets				
Cash and Cash Equivalents	23,774	10,384	1,052	562
Prepaid Drug Product	523	3,587	632	531
Other Current Assets	1,843	1,644	1,358	1,806
Total Current Assets	26,140	15,615	3,042	2,899
Fixed Assets				
Property and Equipment, net	225	158	76	42
Right of Use operating asset	203	198	102	24
Total Assets	\$ 26,568	\$ 15,971	\$ 3,220	\$ 2,965
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current Liabilities				
Accounts Payable	106	667	457	1,036
Accrued Expenses	770	909	1,346	2,313
Current Portion of lease liabilities	82	108	103	26
Total Current Liabilities	958	1,684	1,906	3,375
Warrant Liability	-	-	863	302
Long Term Liabilities				
Non Current lease liabilities	153	113	10	-
Total Long Term Liabilities	153	113	10	-
Shareholders' Equity				
Preferred Stock Convertible	-	-	-	-
Common Stock - Par Value	7	8	1	4
Additional Paid-in Capital	103,111	105,695	108,047	114,032
Accumulated Deficit	(77,661)	(91,529)	(107,607)	(114,748)
Stockholders Equity	25,457	14,174	441	(712)
Minority Interest	-	-	-	-
Total Stockholders Equity	25,457	14,174	441	(712)
Total Liabilities and Shareholders' Equity	\$ 26,568	\$ 15,971	\$ 3,220	\$ 2,965
Liquidity				
Current Ratio	27.3x	9.3x	1.6x	0.9x
Quick Ratio	27.3x	9.3x	1.6x	0.9x
Working Capital	\$ 25,182	\$ 13,931	\$ 1,136	\$ (476)
Leverage				
Net Debt to Equity	n/a	n/a	n/a	n/a
Net Debt to Capital	n/a	n/a	n/a	n/a

Source: Company Reports, Stonegate Capital Partners

INCOME STATEMENT

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

Fiscal Year: December

	FY 2021	FY 2022	FY 2023	FY 2024
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	4,533	4,736	4,235	5,000
Research and development	5,910	9,165	11,608	7,000
Total operating expenses	10,443	13,901	15,843	12,000
Income (loss) from operations	(10,443)	(13,901)	(15,843)	(12,000)
Other income / (expense)				
Change in fair value warrant liability	-	-	(271)	-
Loss on extinguishment of warrant liability	-	-	-	-
Interest income	3	33	36	-
Total other (income) / expense	3	33	(235)	-
Pre-tax income (loss)	(10,440)	(13,868)	(16,078)	(12,000)
Income taxes (benefit)	-	-	-	-
Net income (loss)	\$ (10,440)	\$ (13,868)	\$ (16,078)	\$ (12,000)
Deemed dividend related to warrant conversion	-	-	-	-
Net income (loss) attributable to common	(10,440)	(13,868)	(16,078)	(12,000)
Basic and diluted EPS (loss)	\$ (1.55)	\$ (1.91)	\$ (33.63)	\$ (3.64)
Weighted Average Basic and Diluted Shares Outstanding	6,725	7,276	478	3,300
EBITDA	(10,282)	(13,723)	(15,665)	(11,850)
Adjusted EBITDA	(9,461)	(12,872)	(14,931)	(11,250)

Growth Rate Analysis Y/Y

General and administrative	4.7%	4.5%	-10.6%	18.1%
Research and development	-10.2%	55.1%	26.7%	-39.7%
Net income (loss)	4.1%	-32.8%	-15.9%	25.4%
EPS	45.1%	-22.8%	-1664.4%	89.2%
EBITDA	4.4%	-33.5%	-14.2%	24.4%
Weighted Average Basic and Diluted Shares Outstanding	74.8%	8.2%	-93.4%	590.2%

Source: Company Reports, Stonegate Capital Partners estimates

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