

Bio-Path Holdings

An Oncology-Focused
Biotechnology Company

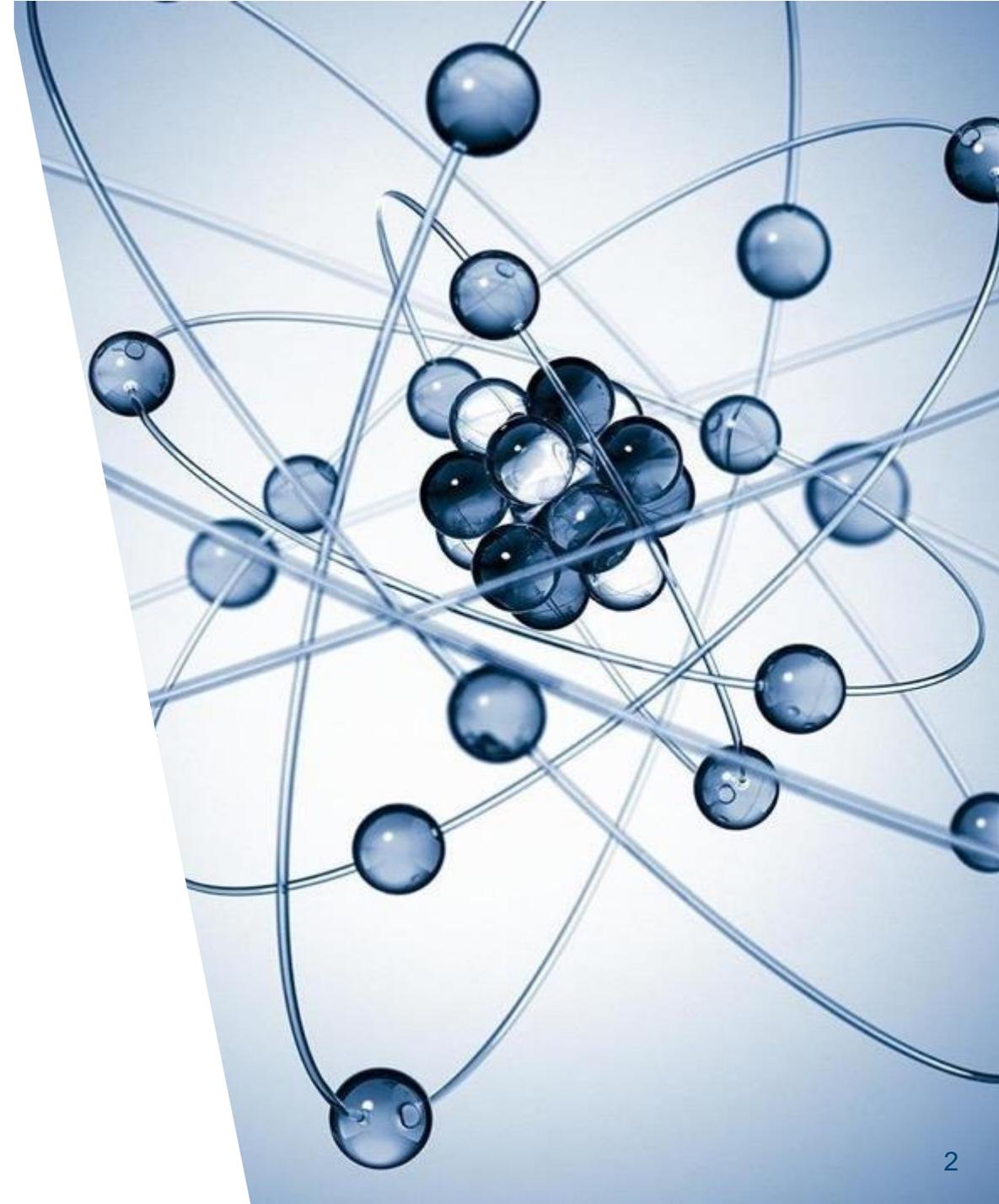
March 2021



Forward looking statements

This Presentation contains forward-looking statements with respect to business conducted by Bio-Path Holdings, Inc. By their nature, forward-looking statements and forecasts involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future.

The Company does not undertake to update any forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially and investors should use their own judgment to evaluate risks. Stockholders are encouraged to review the risk factors contained in the Company's most recent Annual Report on Form 10-K and in other reports the Company files with the Securities and Exchange Commission from time to time.



Introducing Bio-Path Holdings

Advanced Oligonucleotide Therapeutics with
High Efficiency Systemic Delivery

Publicly traded
NASDAQ
BPTH

Employees,
Contractors &
Consultants
14

Established
Houston, TX
2007

DNAbilize[®] Technology, next generation single-stranded DNA antisense
Robust clinical pipeline with novel oncology targets

Technology Highlights

Robust Oncology Pipeline

Preclinical

IND

PHASE 1

PHASE 2

Prexigebersen (BP1001, Liposomal Grb2)

AML*

Prexigebersen-A (BP1001-A) Solid Tumors (ovarian, endometrial, pancreatic)

*Orphan drug designation from the USFDA and EMA for AML

BP1002 (Liposomal Bcl-2) Lymphoma, CLL

BP1002 (Liposomal Bcl-2) AML venetoclax failures

BP1003 (Liposomal Stat3) Pancreatic cancer, lung

DNAbilize[®] Technology

Proven As Safe, Robust and Targeted Method for Treating Disease

No Toxicity

With human patients to date in prexigebersen clinical trial.

- DNAbilize[™] liposome structure is similar to the cellular membrane
- P-ethoxy DNA does not induce hepatotoxicity or thrombocytopenia

Systemic Treatment

I.V. delivery to the main organs via blood flow.

High Cellular Uptake

Liposome structure is similar to the cellular membrane enhancing cellular uptake.

Nanoparticle Liposomes

Enable penetration into tumors for delivery of drug.

Proven Target Inhibition

Demonstrated that DNAbilize[®] method inhibits target protein, proving delivery technology works.



No Toxicity



Systemic Treatment



High Cellular uptake



Nanoparticle liposomes



Proven target inhibition

Prexigebersen Phase 1 Clinical Trial Conclusions

Results support that Grb2 is a potential therapeutic target for haematological malignancies

- Favorable safety profile strongly suggests that prexigebersen has a very different toxicity profile than other antisense oligonucleotide analogues, which have been associated with serum transaminase activation, thrombocytopenia, and activated partial thrombin time prolongation.
- The tolerability of BP1001 may prove useful in clinical combination settings
- Results published in The Lancet Haematology with Expert Commentary

The Lancet Haematology

“Liposomal Grb2 antisense oligodeoxynucleotide (BP1001) in patients with refractory or relapsed haematological malignancies: a single-centre, open-label, dose-escalation, phase 1/1b trial.”

Volume 5, No. 4, e136–e146, April 2018

Stage 1 of the Phase 2 Efficacy Trial Design for AML Prexigebersen Combination Therapy

- Treatment of untreated AML patients who are induction therapy ineligible and unfit for stem cell transplant
- Efficacy trial conducted at 6 leading cancer centers in the U.S., including the MD Anderson Cancer Center
- Primary Endpoint: # patients who achieve CR, (accepted surrogate endpoint)



With this Phase 2 design, plans for a pivotal trial would be discussed with FDA if the Interim Analysis significantly exceed current therapy

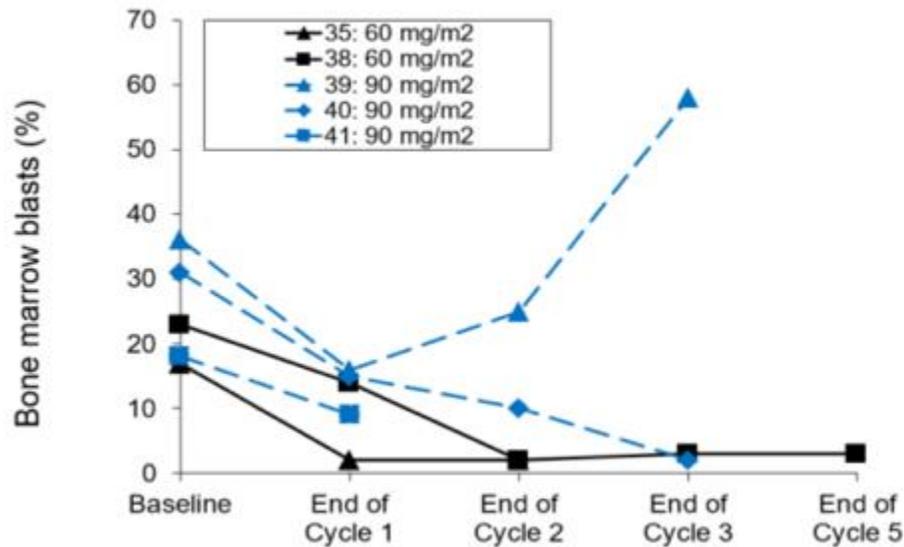
Safety Segment Phase 2 Prexigebersen + LDAC Combination Therapy Showed Excellent Results

Relapsed/refractory AML patients

- 3 evaluable patients per cohort, 2 cohorts, n=6
- Dose 60 mg/m² and 90 mg/m² respectively
- Received drug 2x week for 4 weeks per treatment cycle

Results

- 3 patients achieved **CR** (and 2 were eligible for bone marrow transplant)
- 2 patients achieved **50% or greater bone marrow blast reduction with stable disease**
- Average age of Patients was 73.5 years old
- No Adverse Effects attributed to prexigebersen
- No MTD reached

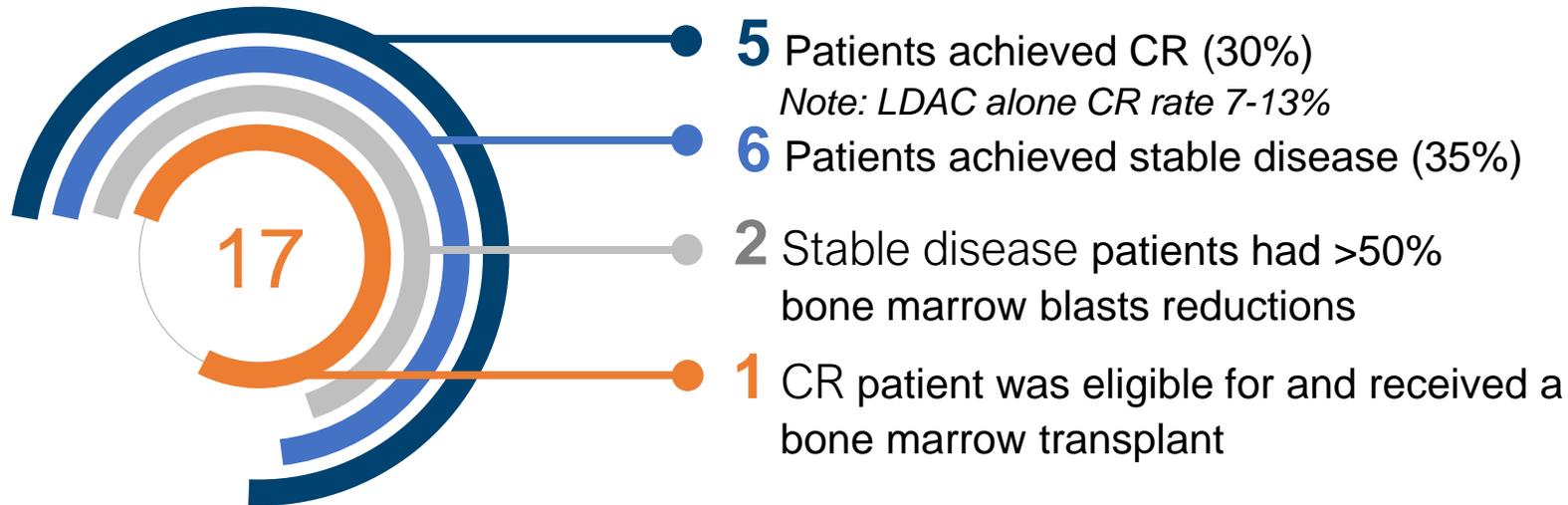


Patient	BP1001 (mg/m ²)	BM Blasts % Reduction	Cycles completed	Response
35	60	88	1	CR
37	60	0	1	PD
38	60	91	5	CR
39	90	56	3	SD w/ ≥50% bmb reduction
40	90	68	3	CR
41	90	50	3	SD w/ ≥50% bmb reduction

71% average reduction bone marrow blasts in responding patients

Results of Stage 1 Interim Analysis

Patient evaluation summary



Importantly, no toxicity associated with prexigebersen

Based on the recommendations of the study PIs, protocol amendments have been made for Stage 2 in the ongoing study

- A cohort of refractory/resistant AML patients added
- LDAC cohort discontinued
- Triple combination treatment of prexigebersen/decitabine/venetoclax
- Resulted in 2 cohorts, one with untreated AML and a second with refractory/resistant AML being treated with the triple combination
- A third cohort was added to treat AML refractory/resistant and venetoclax intolerant patients with prexigebersen and decitabine



Of the evaluable patients 65% showed some form of response, including CR and stable disease, to the combination treatment

Prexigebersen-A Phase 1 Study in Solid Tumors

- Prexigebersen-A is a modified product that incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties
- Prexigebersen-A efficacy against ovarian tumors was enhanced when combined with paclitaxel
- Prexigebersen-A in combination with gemcitabine is efficacious against pancreatic tumors
- Clinical Plans
 - Open a Phase 1 study of prexigebersen-A in patients with advanced or recurrent solid tumors, including ovarian and uterine, pancreatic and breast cancer
 - Second - open Phase 1b studies of prexigebersen-A + paclitaxel in recurrent ovarian or endometrial tumors and prexigebersen + gemcitabine in patients with metastatic pancreatic tumors

BP1002 – A Phase 1 Study in Lymphoma and CLL

- BP1002 is an RNAi antisense nanoparticle targeting Bcl-2
- BP1002 decreased viability of lymphoma cells (11 of 15 lymphoma cell lines)
- By blocking Bcl-2 protein expression, BP1002 allows chemotherapy and radiation to activate apoptosis
- BP1002 extended survival of mice bearing lymphoma xenografts
- Focus in CLL will be on patients who have relapsed on venetoclax treatment
- Phase 1 clinical trial is open for lymphoma and CLL and the first patient has been dosed.



BP1003 Targeting STAT3

- BP1003 has efficacy against non-small cell lung cancer, AML, and pancreatic cancer cells
- BP1003 + gemcitabine combination is efficacious in pancreatic cancer-derived tumors in animals
- IND enabling studies during 2020 - 2021
- Goal is to submit a new IND in 2021
- Conduct a Phase 1 study of BP1003 in patients with refractory, metastatic solid tumors (pancreatic, non-small cell lung cancer)

Experienced Leadership Team



Peter Nielsen

**Co-Founder, President,
Chief Executive Officer
and Chief Financial
Officer**

**Officer and Director
since founding
Company in 2007**

**Manufacturing
development and
evolution of engineered
product design**



Michael Hickey

**Director Clinical
Program Management**

**20+ years experience across
all phases of drug
development**

**Point of escalation Amgen
for South East regional CRO
monitoring**



**Ana Tari Ashizawa,
PhD, MBA**

**Sr Vice President,
Research, Development
& Clinical Design**

**Key member of the
research team that
developed our
liposomal delivery
technology**



**Anthony Price,
MBA**

**Sr Vice President,
Finance, Accounting
& Administration**

**Former Associate Director
of Accounting and Finance
at Lexicon Pharmaceuticals**

Scientific Advisory Board



Jorge Cortes, M.D.
Chairman

- Director, Cancer Center at Augusta University
- Georgia Research Alliance Eminent Scholar in Cancer
- Formerly, Jane and John Justin Distinguished Chair in Leukemia Research, Chief of the AML and CML sections, and Deputy Chair of the Department of Leukemia at The University of Texas MD Anderson Cancer Center



D. Craig Hooper,
Ph.D.

- Professor of Cancer Biology and Neurological Surgery and the Section Chief for Translational Research, Tumor Division, in the Department of Neurological Surgery at Thomas Jefferson University
- His work has led to novel immune therapies for rabies infection, neuro-inflammation, and cancer with 10 issued U.S. patents and 19 international patents that have been licensed to five companies in the U.S. and abroad
- He is the founding president of the Jefferson Chapter of the National Academy of Inventors and a fellow of the National Academy of Inventors.



Ana Tari Ashizawa,
PhD, MBA

- Senior Vice President
Research, Development and Clinical Design
Bio-Path Holdings, Inc.



Jason B. Fleming,
M.D., F.A.C.S.

- Newly appointed Chair of the Department of Gastroenterology at H. Lee Moffitt Cancer Center and Research Institute.
- Professor with tenure in the Department of Surgical Oncology at the University of Texas MD Anderson Cancer Center in Houston.
- Served as as chief of Pancreas Surgery and executive director of Perioperative Services and created the first xenograft program in gastrointestinal cancer.
- Received the Castle Connolly Top Doctor award every year since 2013
- President's Faculty Recognition Award for Outstanding Contribution to the University of Texas MD Anderson Cancer Center in 2016.

IP and Financial Snapshot

Intellectual Property

- Original patents licensed from MD Anderson
- New composition and methods of use patent issued covers DNAbilize[®] technology, solely owned by Bio-Path
 - Four patents issued
 - Four additional patents pending

Financial Snapshot

- **Ticker:** NASDAQ: BPTH
- **Cash:** \$12.1 million as of September 30, 2020. Another \$4.6 million was raised in the 4th quarter, 2020 and \$20 million raised in the 1st quarter 2021
- **Market Cap:** \$45 million as of February 28, 2021
- **Burn rate:**
 - Approximately \$3 million per quarter

Accomplishments in 2020

- Successfully completed preclinical efficacy studies for the triple combination treatment of prexigebersen, decitabine and venetoclax in AML cell lines, suggesting significant enhancement in the efficacy of the frontline treatment.
- Presented a poster at the 2020 American Association for Cancer Research (AACR) Annual Meeting in April that summarized the Phase 1 study design of BP1002 (liposomal Bcl-2 antisense) for the treatment of lymphomas and chronic lymphocytic leukemia.
- Appointed Ernst & Young LLP (“EY”), a ‘Big Four’ accounting firm, as the Company’s new independent registered public accounting firm.
- Presented a poster highlighting the clinical trial design of its Phase 2 study of BP1001 (prexigebersen) at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place in May 2020.
- In August of 2020 we completed dosing of the first patient in the Stage 2, Phase 2 clinical trial in AML using the triple combination of prexigebersen/decitabine/venetoclax.
- In October 2020 the United States Patent and Trademark Office issued a Notice of Allowance for U.S. Patent Application No. 16/333,221 entitled “Combination Therapy with Liposomal Antisense Oligonucleotides.” This will be our third issued patent, plus four additional pending patents.
- Completed enrollment and dosing in November 2020 of the first patient in a Phase 1 clinical trial evaluating the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia (CLL) patients.
- The Company entered into an At-The-Market Offering Agreement with H. C. Wainwright & Co. to which the Company can sell shares of common stock up to \$7 million.
- Subsequent to the end of the third quarter 2020, the Company sold \$4.6 million in common stock through the Offering Agreement with Wainwright. This followed \$29.3 million raised in 2019.
- The Company established a new Board Business Development Committee, focused on what we expect to be increased potential licensing opportunities.

Bio-Path Holdings

Thank you

Bio-Path Holdings, Inc.

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