

Bio-Path Holdings

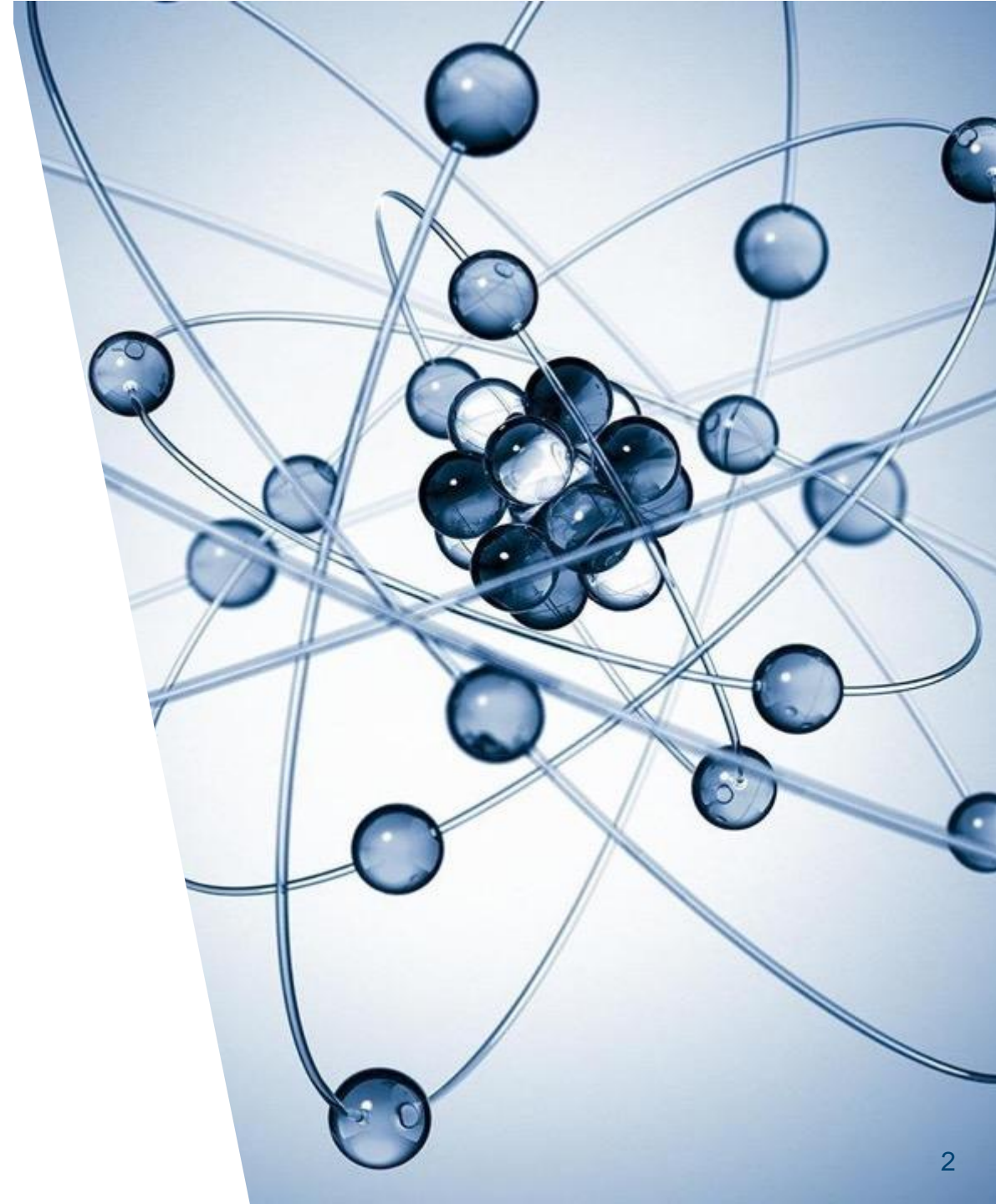
March 2025



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
OTC
BPTH

Employees,
Contractors &
Consultants
14

Established
Houston, TX
2007

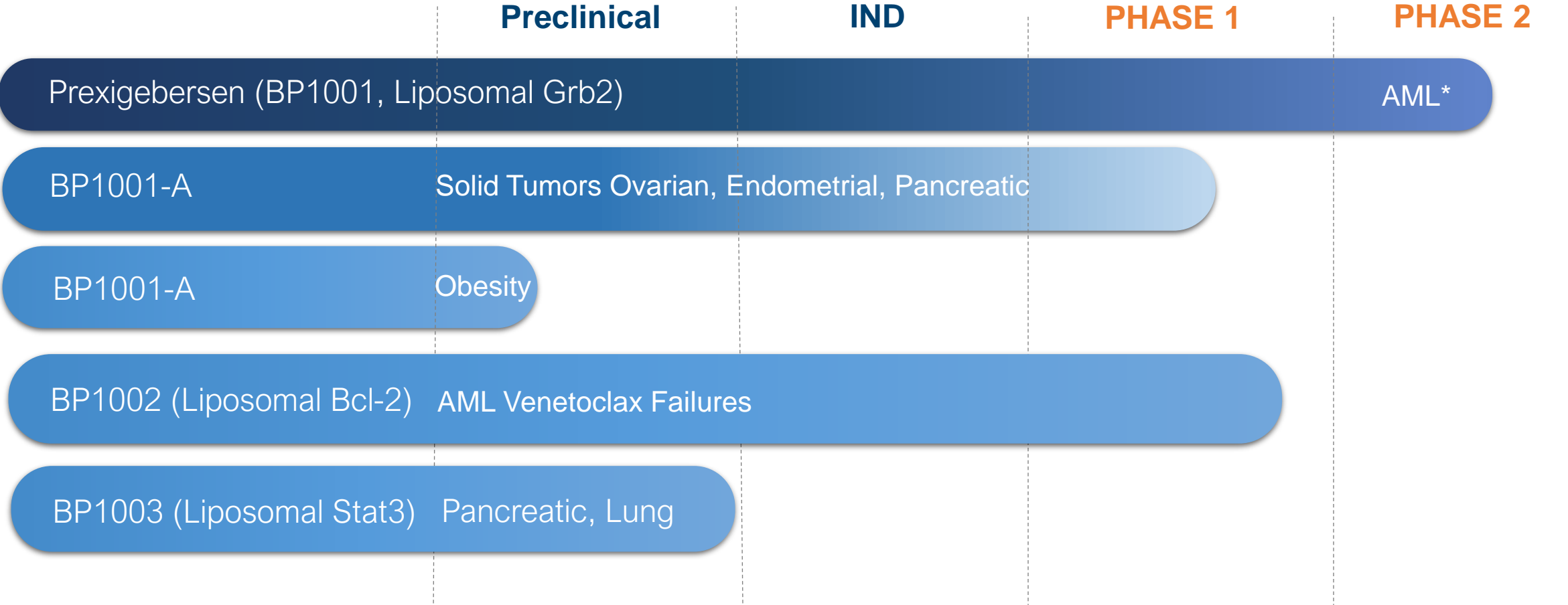
Technology Highlights

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

Business Highlights – Multiple High Value Creating Opportunities

- Interim data from Phase 2 AML clinical trial of prexigebersen demonstrated strong efficacy and safety/tolerability
 - ❖ Results further highlighted by high-risk rating of evaluable patients and inclusion of secondary AML patients, both classes of patients with very difficult to treat disease
- Patient response in Phase 1/1b clinical trial of BP1001-A in solid tumors supports BP1001-A's compelling potential as treatment for advanced solid tumors
 - ❖ First solid tumor patient treated in the second, higher dose cohort experienced tumor reduction, stable disease and allowed rigorous exercise swimming program with improved quality of life
- Phase 1/1b Clinical Trial of BP1002 in Relapsed/Refractory AML had significant patient response
 - ❖ Patient had significant blast count reduction and stable disease in patients having median life expectancy of 3 months.
 - ❖ Potential fast approval!!
- BP1001-A being developed for treatment of obesity and related metabolic diseases in Type 2 diabetes patients
 - ❖ After final testing Bio-Path plans to file an IND to commence a clinical trial by year-end 2025
- Platform technology with composition of matter patents enable development of new patented drug products!!

Robust Pipeline



*Orphan drug designation from the USFDA and EMA for AML

DNAbilize[®] Technology

Proven As Safe, Robust and Targeted Method for Treating Disease

No Toxicity

With human patients to date in prexigebersen and other clinical trials

- 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 substance.

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

Interim Analysis of Phase 2 Clinical Trial of Prexigebersen in AML

August 2024, the Company released encouraging interim results of the Phase 2 clinical trial of prexigebersen for the treatment of acute myeloid leukemia (or AML), in combination with frontline therapy decitabine and venetoclax

- Data show signs of safety and higher efficacy in high-risk AML patients, with adverse risk or secondary AML
- Two cohorts of patients reported for untreated AML and refractory/relapsed AML
- Primary endpoint is the number of patients who achieve complete remission
- 20 untreated patients were evaluable in Cohort 1 comprised of untreated AML patients
 - ❖ 15 of the 20 evaluable patients (or 75%) complete remission, two (or 10%) partial remission (PR) and two (or 10%) stable disease, in total, evaluable patients had 95% response to treatment
 - ❖ The complete remission rate of 75% for the evaluable patients in Cohort 1 is significantly higher than complete remission rates of 62% for untreated patients treated with the frontline combination treatment of decitabine and venetoclax
- 23 refractory/relapsed patients were evaluable in Cohort 2
 - ❖ 12 of the 23 evaluable patients (or 55%) complete remission, 1 patient (or 4%) partial remission, and eight patients (or 35%) stable disease, in total, evaluable patients had a 94% response to treatment
 - ❖ Complete remission rate of 55% for the evaluable refractory and relapsed patients in Cohort 2 is higher than the complete remission rate of 21% for refractory/relapsed patients treated with the combination treatment of decitabine and venetoclax

BP1001-A Phase 1/1b Study in Solid Tumors

- BP1001-A is a modified product that incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties
- BP1001-A efficacy against ovarian tumors and pancreatic tumors has been demonstrated preclinically
- Clinical Plans
 - ❖ Phase 1 study of BP1001-A in patients with advanced or recurrent solid tumors, including ovarian and endometrial, pancreatic and breast cancer
 - ❖ Second - Phase 1b studies of BP1001-A + paclitaxel in recurrent ovarian or endometrial tumors and BP1001-A + gemcitabine in patients with metastatic pancreatic tumors
- Phase 1/1b clinical trial is open
 - ❖ First dosing cohort successfully completed, second higher dosing cohort is open and enrolling
 - ❖ First solid tumor patient treated with second, higher dose of 90 mg/m² experienced tumor reduction and stable disease, which allowed for rigorous exercise program and improved quality of life

BP1002 – Phase 1/1b Study in Relapsed/Refractory AML

Focus On Patients Who Relapsed on Venetoclax Treatment

- Phase 1/1b clinical trial is open for refractory/relapsed AML and three dose cohort levels have been completed
- High expression of BP1002 target Bcl-2 correlates with adverse prognosis for AML patients
- Preclinical studies show BP1002 using RNAi blocks cell production of Bcl-2 as a potent inhibitor against Bcl-2
- Venetoclax is a frontline treatment of AML that blocks Bcl-2
- AML patients that fail frontline venetoclax-based therapy have very poor prognosis with median overall **survival of less than 3 months!!**

Focus of BP1002 in AML will be on patients who have relapsed on venetoclax treatment

BP1001-A Development of Therapeutic Program for Treatment of Obesity in Type 2 Diabetes Patients

- Obesity research suggests BP1001-A, which suppresses the protein Grb2, has the potential to treat insulin resistance, a major contributor to obesity, Type 2 diabetes and other related metabolic diseases
- Bio-Path preclinical studies confirmed the effectiveness of BP1001-A in affecting insulin signaling and its potential efficacy as a therapeutic treatment for obese patients who have Type 2 diabetes
- The failure of leading weight loss medications to induce weight loss in obese patients who have Type 2 diabetes creates a compelling need for an alternative method of lowering blood glucose in obese patients who have Type 2 diabetes
- Bio-Path next step is animal studies to confirm the efficacy of BP1001-A as a potential treatment for obesity and related metabolic diseases in Type 2 diabetes patients.
- Bio-Path's plan is to file an IND to initiate a Phase 1 clinical trial by end of 2025

BP1003 Targeting STAT3

- BP1003 has efficacy against non-small cell lung cancer, AML, pancreatic cancer cells, and solid tumors
- BP1003 + gemcitabine combination is efficacious in pancreatic cancer-derived tumors in animals
- Conducting final IND enabling studies
- Goal is to submit an IND and conduct Phase 1 study of BP1003 in patients with refractory, metastatic solid tumors (pancreatic and 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

**Vice President Clinical
Program Management**

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

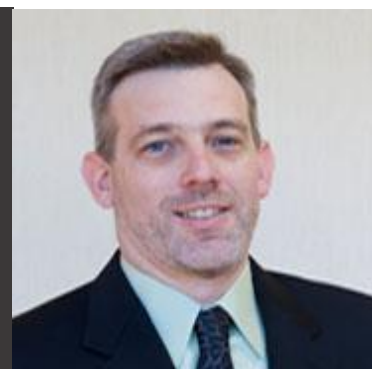
**Point of escalation Amgen
for South East regional CRO
monitoring**



**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**

IP and Financial Snapshot

Intellectual Property

- Original patents licensed from MD Anderson
- New composition and methods of use patents issued covers DNAbilize® technology, solely owned by Bio-Path
- 7 patents issued in the United States and 4 pending applications with 2 being allowed
- 61 foreign patents issued across 26 countries; 35 additional foreign patent applications across 10 jurisdictions with 3 being allowed

Financial Snapshot

- **Ticker:** OTCQB: BPTH
- **Cash:** Approximately \$1.2 million as of December 31, 2024
- **Market Cap:** Approximately \$6.7 million as of December 31, 2024
- **Burn Rate:** Estimated average quarterly burn rate range \$1.2 - \$2.0 million

Bio-Path Holdings

Thank you

Bio-Path Holdings, Inc.

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