

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): December 29, 2015

BIO-PATH HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36333

(Commission File Number)

87-0652870

(IRS Employer Identification No.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas

(Address of principal executive offices)

77401

(Zip Code)

(832) 742-1357

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 5.07 Submission of Matters to a Vote of Security Holders.

Bio-Path Holdings, Inc. (the "Company") held its 2015 annual meeting (the "2015 Annual Meeting") of stockholders of the Company on December 29, 2015 in The Woodlands, Texas. At the 2015 Annual Meeting, the Company's stockholders: (i) elected each of the five persons listed below under Proposal 1 to serve as a director of the Company until its 2016 annual meeting of stockholders; and (ii) ratified and approved the appointment of Mantyla McReynolds LLC as the Company's registered independent public accounting firm for the Company's fiscal year ending December 31, 2015. The following describes the results of the voting at the 2015 Annual Meeting:

Proposal 1: The election of directors to serve until the 2016 annual meeting of stockholders of the Company:

Name of Nominee	Shares Voted "For"	Shares Voted "Against"	Shares Withheld	Shares Abstained	Broker Non-Votes
Peter H. Nielsen	25,474,864	--	1,813,984	--	45,681,062
Michael J. Garrison	25,798,895	--	1,489,953	--	45,681,062
Heath W. Cleaver	25,955,858	--	1,332,990	--	45,681,062
Amy P. Sing, M.D.	26,421,862	--	866,986	--	45,681,062
Douglas P. Morris	24,008,861	--	3,279,987	--	45,681,062

Proposal 2: Ratification and approval of the appointment of Mantyla McReynolds LLC as the Company's independent registered public accounting firm for its fiscal year ending December 31, 2015:

Shares Voted "For"	Shares Voted "Against"	Shares Withheld	Shares Abstained	Broker Non-Votes
67,735,036	4,921,614	--	313,260	--

Item 7.01 Regulation FD Disclosure.

At the 2015 Annual Meeting, Peter H. Nielsen, President and Chief Executive Officer of the Company, presented highlights of the Company from 2015. A copy of the slide presentation used for Mr. Nielsen's presentation is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Slide Presentation dated December 29, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIO-PATH HOLDINGS, INC.

Dated: December 30, 2015

By: /s/ Peter H. Nielsen
Peter H. Nielsen
President and Chief Executive Officer

EXHIBIT INDEX

Exhibit
Number

Description

99.1 Slide Presentation dated December 29, 2015



Annual Meeting Presentation Highlights from 2015

"A New Paradigm in Drug Delivery"



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.

2015 Overview

- ❖ Core Organization
 - Scientific Advisory Board
- ❖ Corporate Development
 - PR and Marketing
 - New Patent
 - DNAbilize™
- ❖ BP1001 (Liposomal Grb2) in the clinic
- ❖ ASH 2015
- ❖ Plans and milestones
- ❖ Financial snapshot

Core Organization

Peter Nielsen

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

- Officer and Director since founding Company in 2007

Ulrich Mueller, PhD

Chief Operating Officer

- Previously Vice President at the Fred Hutchinson Center Research Center
- Former Managing Director Office of Technology Commercialization at MD Anderson

Ana M. Tari, PhD & MBA

Director, Preclinical Operations & Research

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

Tara Sadeghi, PhD

Director, Clinical Operations

- Assistant Director of the Cord Blood Bank Regulatory and Quality Assurance office at The University of Texas M. D. Anderson
- Over 24 years of drug development and clinical operations experience across all phases of clinical development (Phases I through III)

Suzanne Kennedy, PhD

Director, Corporate Development

- Over 15 years of marketing, business development, and research & development experience in the biotech industry

Scientific Advisory Board

Jorge Cortes, M.D.

Chairman

- M.D. from la Facultad de Medicina, Universidad Nacional Autónoma de México
- 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 MDACC
- Has consulted leading pharmaceutical companies such as AstraZeneca on development of prenyltransferase inhibitors, GlaxoSmithKline on the use of topotecan in MDS and CMML, and Rhône-Poulenc Rorer on the use of PEG-Asparaginase in adult ALL.

Amy P. Sing, M.D.

Member, Bio-Path's Board of Directors

- M.D. from the Stanford University School of Medicine
- Currently Senior Director of Medical Affairs at Genomic Health, Inc.
- Former Senior Medical Director at Genentech, Inc., had an integral role in the Avastin™ program.
- Former Senior Director of Medical and Regulatory Affairs at Seattle Genetics

Recruiting additional members

Corporate Development



- ❖ Brought on corporate marketing and branding Firm, 6 Degrees, to increase Bio-Path profile and outreach
 - Increase Bio-Path visibility in media
 - Develop partnerships with influential journalists
 - Strategic planning for conferences and investor presentations
- ❖ Development of drug product marketing plan
- ❖ Website upgrade with improved SEO and branding
- ❖ Increasing press releases as Bio-Path reaches milestones
- ❖ New composition of matter and process patent filed
- ❖ New tradename and trademark for DNAbilize™ technology and for Bio-Path Holdings logo

Press Releases for 2015 (17)

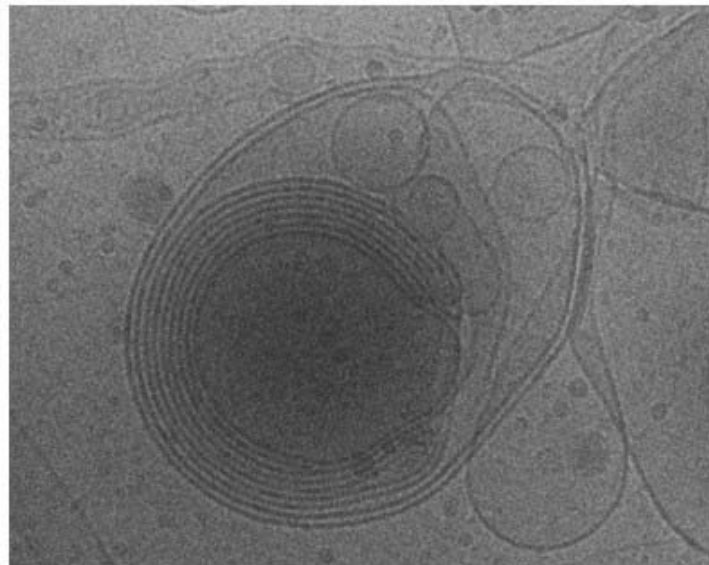
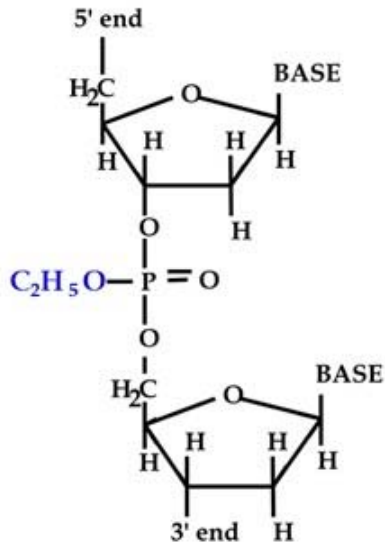
- ❖ Bio-Path Holdings' Data from Phase I and Safety Segment of Phase II Clinical Trials in Blood Cancers Presented at 57th American Society of Hematology (ASH) Annual Meeting
- ❖ Bio-Path Holdings Reports Third Quarter 2015 Operational and Financial Results
- ❖ Bio-Path Holdings' Data to be presented at 57th American Society of Hematology (ASH) Annual Meeting
- ❖ Bio-Path Holdings to Present at the 14th Annual BIO Investor Forum
- ❖ Bio-Path Holdings Announces Successful Completion of Cohort 7 of Phase Ib of Clinical Trial Evaluating Liposomal Grb-2 in Acute Myeloid Leukemia
- ❖ Bio-Path Holdings to Present at the 17th Annual Rodman & Renshaw Global Investment Conference
- ❖ Bio-Path Holdings Forms Scientific Advisory Board to Support Advancement of Liposomal Grb-2 in Blood Cancers
- ❖ Bio-Path Holdings Reports Second Quarter 2015 Operational and Financial Results
- ❖ Bio-Path Holdings Announces "At the Market" Offering with Cantor Fitzgerald
- ❖ Bio-Path Holdings Reports First Quarter 2015 Operational and Financial Results
- ❖ Bio-Path Holdings Appoints Tara Sadeghi as Director of Clinical Operations
- ❖ Bio-Path Holdings Granted Orphan Drug Designation for Liposomal Grb-2 in Acute Myeloid Leukemia
- ❖ Bio-Path Holdings' Drug Delivery Technology to be featured in a Presentation at IBC's 17th Annual TIDES Oligonucleotide and Peptide Therapeutics Conference
- ❖ Bio-Path Holdings Reports Fiscal Year 2014 Operational and Financial Results
- ❖ Bio-Path Holdings Starts Phase II Study with Liposomal Grb-2 in AML Patients
- ❖ Bio-Path Holdings' Liposomal Grb-2 Featured in Peer-Reviewed Journal "Expert Opinion on Drug Delivery"
- ❖ Bio-Path Holdings to Present at the Biotech Showcase 2015 Conference in San Francisco, CA

Conference Program 2016

- ❖ Biotech Showcase EDB Group - *January*
- ❖ The 18th Annual BIO CEO & Investor Conference – *February*
- ❖ 28th Annual ROTH Conference- *March*
- ❖ TIDES- Oligonucleotides in Therapeutics conference - *May*
- ❖ BIO International Convention - *June*
- ❖ ASCO 2016 - *June*
- ❖ Rodman & Renshaw 18th Annual Healthcare Conference - *Sept*
- ❖ BIO Investor Forum - *October*
- ❖ Therapeutic Area Partnerships (TAP) - *November*
- ❖ ASH 2016 - *December*

New Trade Name and Patent

- ❖ **DNabilize™ Technology** – a platform technology utilizing the P-ethoxy stabilized DNA backbone with neutral liposomal incorporation of antisense DNA
- ❖ New Composition of Matter and Process Patent filed for the manufacturing of DNabilize™ DNA



BP1001 in Clinical Testing

- ❖ Grb2 is a protein that bridges activated tyrosine kinases to the Ras signaling pathway
- ❖ Phase I clinical trial:
 - First 6 cohorts completed
 - Preliminary results show drug has been well tolerated in patients with AML, CML, and MDS with no signs of toxicity and signs of anti-leukemia activity
- ❖ Safety segment of Phase II (Phase Ib) trial for Acute Myeloid Leukemia (AML) in combination with frontline therapy ongoing
 - Phase II efficacy trial to follow
 - Phase II trial in Chronic Myelogenous Leukemia (CML) planned
- ❖ Additional indications in triple negative and inflammatory breast cancers being developed and in other solid tumors

Summary of Phase I and Ib Clinical Trial Results for BP1001

- ❖ AML, CML, ALL & MDS Patients Refractory or Resistant to Current Therapies
- ❖ Dose escalating, treatment cycle 8 doses over 4 weeks

Results through cohort 6 (90 mg/m²)

- Patients averaged 6 prior therapies
- Of 15 of 20 evaluable patients' blasts demonstrated anti-leukemia activity
- 8 patients stabilized for extended treatments
- 2 patients (010 and 014) transient improvement leukemia cutis lesions
- Drug was **well-tolerated**
- ❖ Of the 18 evaluable with circulating blasts, 83% had a response to the drug
- ❖ Cohort 7 (Phase II safety segment) receiving LDAC + 60 mg/m² BP1001, 2 patients, 035 and 038 achieved complete remission.

Patients	Diagnosis	Peripheral or bone marrow (BM)* Blast %			Cycles Completed
		Baseline	Nadir	Off-Tx	
01	CML	93	82	97	<1
06	AML	15	2	5	5
07	MDS	8*	4*	6*	5
010**	AML	23*	10*	10*	1
011	CML	24	7	50	1
014**	AML	33	5	21	1
015	AML	51	31	72	1
020	AML	76	5	23	1
021	AML	71	43	74	2
022	AML	1	0	2	2
023	MDS	NE*	NE*	NE*	1***
024	MDS	0*	0*	2*	5
025	AML	10	3	19	2
026	AML	16	none	80	1
027	AML	93	92	97	1
028	AML	96	none	98	1
029	AML	33	7	27	1
030	AML	51	17	84	1
031	AML	17	NE	17	1
032	AML	24	NE	40	2
034	AML	66	ND	ND	1
★ 035	AML	17	2	ND	1
037	AML	25	25	ND	1
★ 038	AML	23	2	ongoing	4

Cohort 7 {

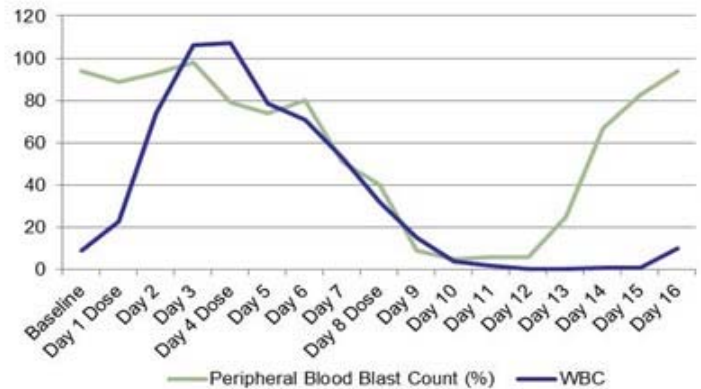
★ Complete remission

Response to Treatment for Select Patients 002 and 006

❖ **Patient 002:** 32 year-old, Hispanic male with myeloid blast crisis of CML

❖ Prior therapies consist of:

- Gleevec
- Dasatinib
- Nilotinib
- DCC-2036
- Cytarabine/Fludarabine/
- Dasatinib/Gemtuzumab
- PHA-739358
- Clofarabine/Dasatinib

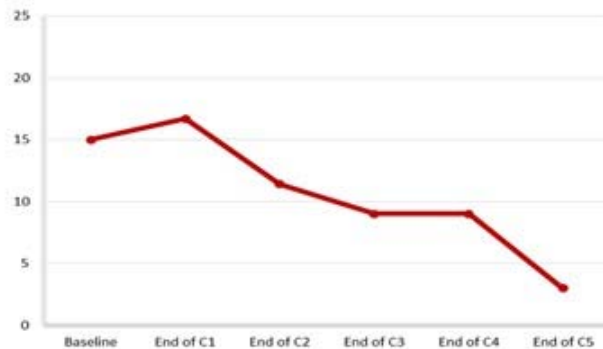


❖ Patient taken off therapy, CNS disease was assumed (not confirmed) and intrathecal Ara-C was administered - patient succumbed due to disease progression prior to going back on treatment

Extended Treatment: Patient 006

- ❖ 54 year-old HIV+ male with AML transformed from Jak2 positive Polycythemia Vera
- ❖ 3 patients showed improvement and/or stable disease, received 5 treatment cycles over 5 months
- ❖ Patient 006 achieved stable disease and marked reduction in peripheral blasts

Peripheral Blood % Blast



% Decrease of Target Grb2 Protein and pErk protein

- Grb2 levels decreased 50% in 11 of 13 samples by end of treatment (EOT)
- pErk levels decreased an average of 52% in 7 of 13 samples by EOT.

Subject Number	Grb2 Decrease (Day 15)	pErk Decrease (Day 15)	Grb2 Decrease (EOT)	pErk Decrease (EOT)
022	0	0	57	0
023	0	3	28	45
024	56	28	47	35
025	63	82	54	91
026	47	0	0	0
027	NS ¹	NS ¹	34	27
028	0	0	30	54
029	57	51	65 ²	0 ²
030	54	55	43	47
031	0	0	0	0
032	85	54	91	63
033	13	13	53	2
034	42	42	40	0



NS¹ = no sample collected

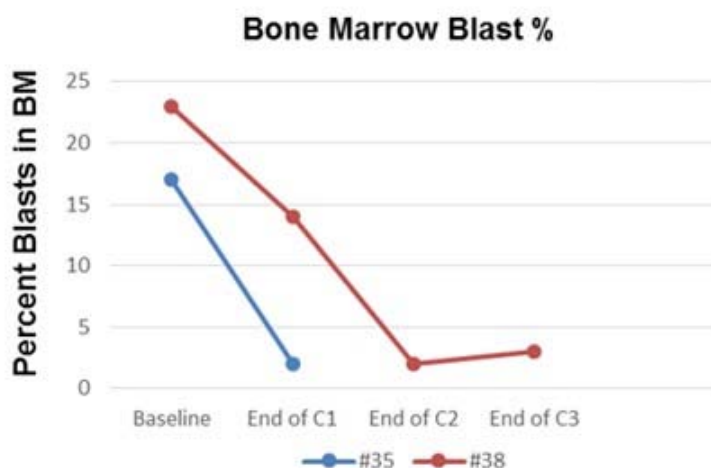
²Fewer cells used in analysis because sample had less cells

Results of Phase II Cohort 7 Combination LDAC + BP1001 Therapy

- ❖ Safety evaluation of combination low-dose cytarabine (LDAC) with BP1001 in refractory and relapsed patients.
- ❖ Three (3) evaluable patients were treated twice a week for 4 weeks with 60 mg/m² of BP1001 and LDAC
- ❖ Total of 8 doses in combination with the standard regimen of LDAC.
 - Two out of three patients achieved *complete remission*
- ❖ Cohort 8 patients being treated with 90 mg/m² of BP1001 in combination with frontline LDAC is ongoing.

Results were consistent with previous cohorts, showing BP1001 to be safe, well tolerated with significant anti-leukemia activity

Percent Blasts in Bone Marrow for Patients in Safety Study Phase II Cohort 7



Patients	Diagnosis	Peripheral or bone marrow (BM)* Blast %			Cycles Completed
		Baseline	Nadir	Off-Tx	
035	AML	17	2	ND	1
037	AML	25	25	ND	1
038	AML	23	2	ongoing	4

ASH 2015 Presentation

Safety, Pharmacokinetics, and Efficacy Of BP-100-1.01 (Liposomal Grb-2 Antisense Oligonucleotide) In Patients With Refractory Or Relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL), and Myelodysplastic Syndrome (MDS)

Maro Obanian, DO^{1}, Hagop M. Kantarjian, MD², Farhad Ravandi, MD¹, Gautam Borthakur, MD³, Guillermo Garcia-Manero, MD¹, Michael Andreeff, MD, PhD⁴, Elias Jabbour, MD¹, Marina Konopleva, MD, PhD^{1*}, Miranda Lim, Sherry Pierce, Susan O'Brien, MD¹, Alfonso Quintas-Cardama, MD^{1,3*}, Bradley G. Somer, MD^{5*}, Ana Tari, PhD^{6*}, Srdan Verstovsek, MD, PhD⁷, William G. Wierda, MD^{8*} and Jorge Cortes, MD¹*

Highlights:

- Patient 035, an 86-year old female patient with AML, achieved CR after 1 cycle of BP-100-1.01 and Ara-C drug combination.
- Patient 038, a 69-year old male patient with AML, achieved CR after 2 cycles of BP-100-1.01 and Ara-C drug combination.

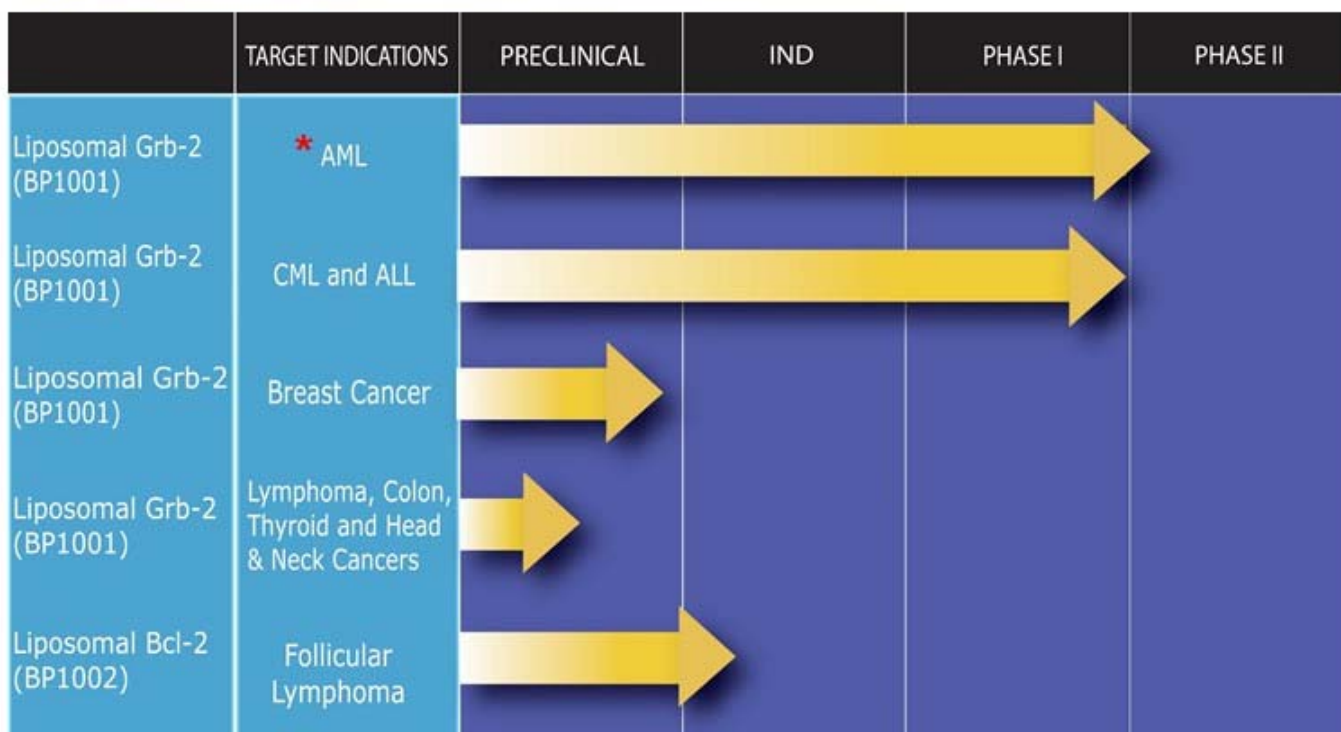
Plans For Phase II Clinical Trials of BP1001

- ❖ The proposed clinical program is to evaluate BP1001 in AML first in a Phase II clinical trial in combination with frontline therapy
- ❖ The current safety segment of the Phase II (Phase Ib) trial is evaluating 2 cohorts at 2 dose levels, 3 patients per cohort, to test for any potential negative synergies of using BP1001 together with frontline therapy
- ❖ Phase II efficacy trial:
 - Planned to have approximately 55 patients with an interim analysis after 19 patients
 - If successful, the trial will be rolled into a pivotal trial for accelerated approval
 - Expected to be conducted at leading cancer centers in the US, including the MD Anderson Cancer Center
 - Primary endpoint for the study is the number of patients who achieve complete remission
 - Includes CRi (incomplete blood count recovery) and CRp (platelet recovery)
- ❖ Phase II trial in CML expected to start in early 2016

Accomplishments 2015 and Future Development for 2016

- ❖ Significant corporate development in 2015:
 - Phase II safety segment (Phase Ib) dosing for the combination therapy for BP1001 near completion
 - IND package for BP1002 (Liposomal Bcl2) in preparation to begin a clinical trial
 - Promising new targets in preclinical development (lymphoma, pancreatic, brain)
 - Expanding pipeline with new target drug candidates, new drug indication outside of cancer
 - BP1001 being developed for triple negative and inflammatory breast cancers
 - \$25 Million ATM financing in place
- ❖ Value propositions for 2016:
 - Enrollment of first 19 patients in Phase II with an interim analysis to be completed with potential for switch to registration trial for accelerated approval
 - Initiation of safety segment for Phase II (Phase Ib) in CML for combination therapy
 - Expanding pipeline and collaborations on new and creative drug candidates
 - Continued new manufacturing and target IP

Clinical Pipeline



*BP1001 for AML has received orphan-drug designation from the U.S. FDA

Financial Snapshot

Ticker: NASDAQ: BPTH

Shares: 89.8M shares outstanding Sept 30, 2015

Market Cap: approximately \$145 MM

Capital Raised: \$30.6 MM

Cash: \$9.9 MM as of Sept 30, 2015

Burn rate: approximately \$1,000,000 per quarter excluding the clinical trial costs

Financing: \$25 million ATM program in place