Bio-Path Holdings INC

Corporate Presentation
July 2016

"A new path in DNA-powered medicine"

Bio-Path Holdings

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.

DNAbilize™ Technology

Enabling the development and delivery of systemic antisense treatments for a broad spectrum of cancers including hematological malignancies, solid tumors, as well as diseases outside of cancer, without toxicity

Ability to address unmet clinical needs in fragile populations

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Investment Highlights

Broad Vision, Focused Strategy

- Solving the antisense drug delivery challenge with DNAbilize™ Technology
- Original technology licensed from The MD Anderson Cancer Center

Clinical Stage Pipeline

- Lead candidate BP1001, a Liposomal Grb2 Antisense in Phase I/II for acute myeloid leukemia and chronic myeloid leukemia
- Second drug candidate ready for IND to start Phase I

Novel Mechanism of Action

- Demonstrated ability to deliver antisense DNA into target cells and down-regulate the protein in systemic disease
- Lack of toxicity allows for development of drugs for hard to treat diseases and unmet needs among fragile populations

Robust Preclinical Pipeline

- Applications and development in other solid tumors, hematological cancers, and indications outside of cancer

Validating Academic Collaborations

- UT Southwestern evaluating pipeline for systemic lupus erythematosus (SLE)
- MD Anderson evaluating pipeline in pancreatic cancer
- Thomas Jefferson University evaluating DNAbilize™ Technology for glioblastoma immunotherapy

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DNAbilize™ Antisense DNA: A Targeted Method for Treating Disease

- ***Antisense -*** molecules that interfere with the process of producing proteins inside cells (RNAi)
  - Does not use a toxic agent to kill cells, but blocks production of proteins
  - Advantage of specificity because it targets the disease-causing protein

- ***No toxicity -*** In numerous animal studies or human patients in BP1001 clinical trial
  - DNAbilize™ liposome structure is similar to the cellular membrane
  - P-ethoxy DNA does not activate complement or inhibit the clotting cascade

- ***Systemic treatment*** **-** I.V. delivery to the main organs via blood flow

- ***High cellular uptake -*** liposome structure is similar to the cellular membrane

- ***Microscopic-sized liposomes -*** enable penetration into tumors for delivery of drug

- ***Proven target inhibition -*** demonstrated that DNAbilize™ method inhibits target protein, proving delivery technology works

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DNAbilize™ Technology

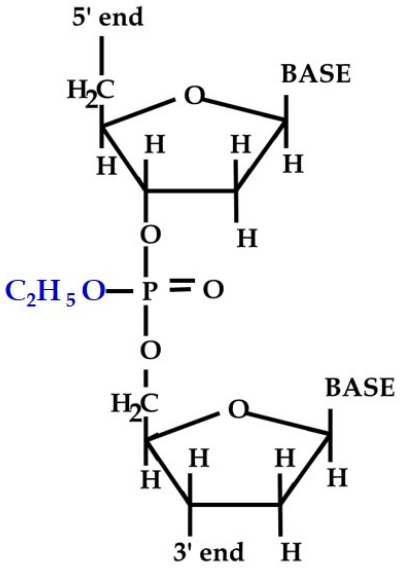
DNAbilize™ Technology is a proprietary antisense and delivery system that solves the antisense industry dilemma

***SAFE*: No toxicity from the DNA modification or the lipid delivery, no AEs observed to date**

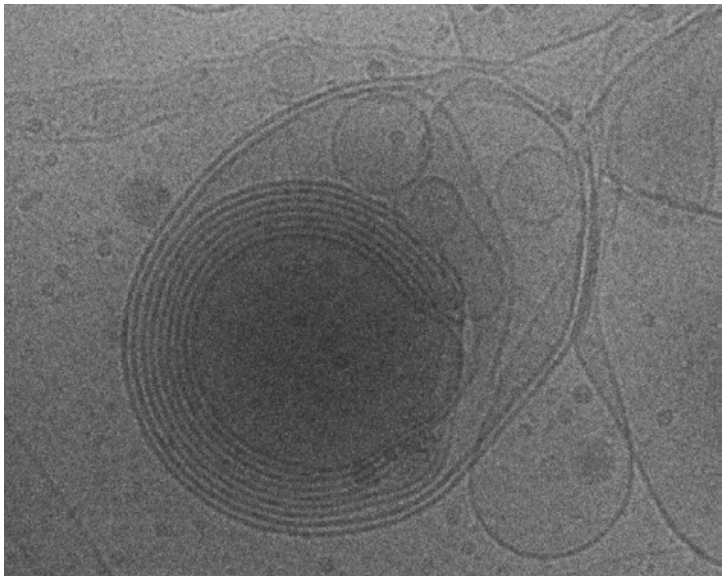
***SYSTEMIC*: Allows for systemic distribution via IV infusion**

***SPECIFIC*: Knock down a single protein, no off-target effects observed**

P-ethoxy backbone

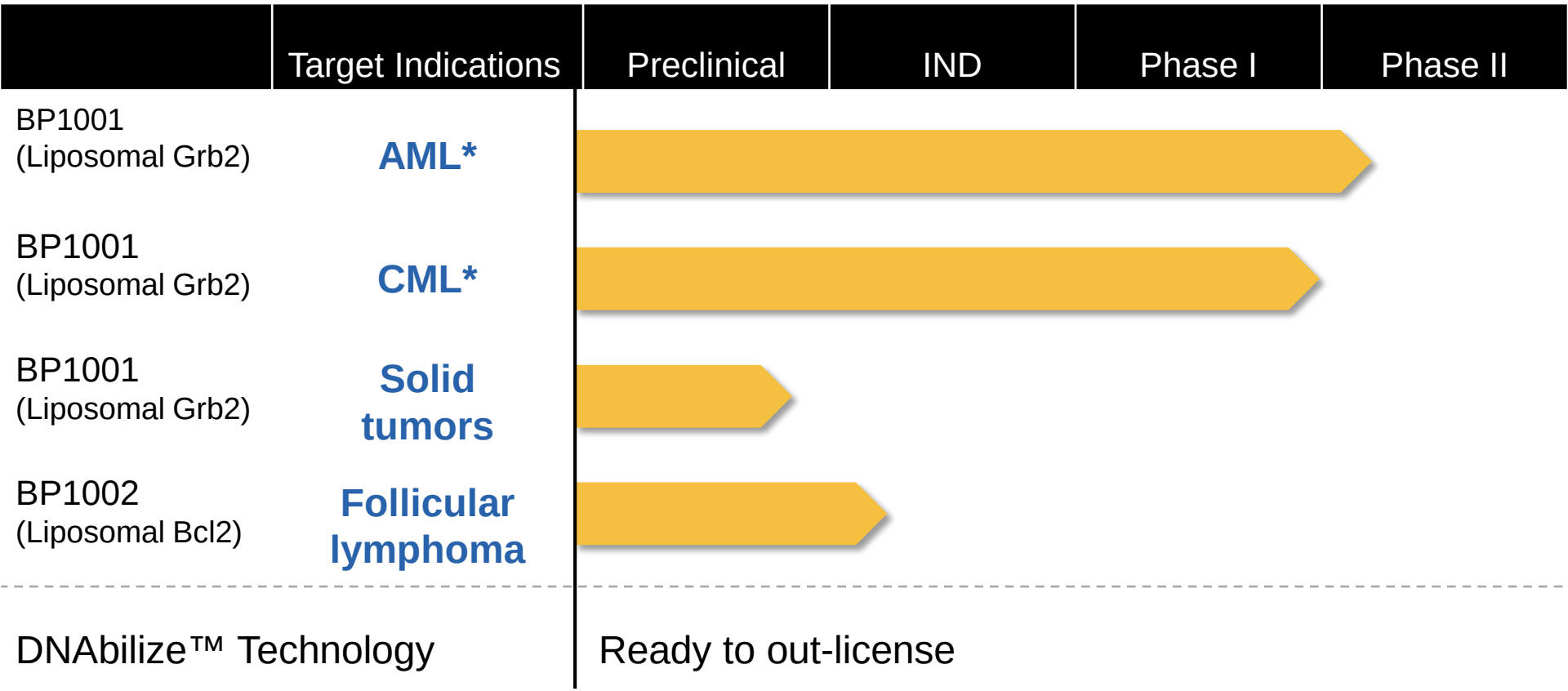


Neutral liposomes



DNAbilize™

Clinical Pipeline



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

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DNAbilize™ Lead Target and Indications: Grb2 and Myeloid Leukemia

BP1001 is an antisense DNA to the bridging protein Grb2

- Ideal target for myeloid leukemia because it shuts down the Ras pathway in receptor activated myeloid cells without exerting adverse effects on Ras signaling through other channels

No toxicity *in vivo* to date

- Acute Myeloid Leukemia: high unmet need for a fragile patient population
  - Average age at diagnosis ≥ 60 years old
  - > 20,000 new cases a year
  - > 10,000 deaths a year
  - Patients typically cannot tolerate induction chemotherapy. Patients have lower response rates and decreased survival

No new AML treatments have been approved in 25 years (Idarubicin)

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Summary of Phase I Monotherapy Clinical Trial Results for BP1001

- AML, CML, & MDS Patients Refractory or Resistant to Current Therapies
- Dose escalating, treatment cycle 8 doses over 4 weeks
- Results through cohort 6 (90 mg/m^2)
  - Patients averaged ***6 prior therapies***
  - ***15 of 20 evaluable patients' blasts demonstrated anti-leukemia activity***
  - 7 patients stabilized for extended treatment
  - Drug was ***well tolerated***
- Of the 18 evaluable with circulating blasts, ***83% had a response to the drug***

Patients	Diagnosis	Peripheral or bone marrow (BM)* Blast %		Reason Discontinued	Cycles Completed
		Baseline	Nadir		
01	CML	93	82	DLT	<1
06	AML	15	2	PD	5
07	MDS	8	4	PD	5
010	AML	23	10	PD	1
011	CML	24	7	PD	1
014	AML	33	5	PD	1
015	AML	51	31	PD	1
020	AML	76	5	PD	1
021	AML	71	43	PD	2
022	AML	1	0	PD	2
023	MDS	NE	NE	WD	1
024	MDS	0	0	PD	5
025	AML	10	3	PD	2
026	AML	16	none	PD	1
027	AML	93	92	PD	1
028	AML	96	none	PD	1
029	AML	33	7	PD	1
030	AML	51	17	PD	1
031	AML	17	NE	PD	1
032	AML	24	NE	PD	2
034	AML	66	ND	PD	1

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BP1001 Knocks Down Grb2 Protein in Target Cells

Grb2 levels decreased in 11 of 13 patient samples by end of treatment (EOT)
pErk levels decreased in 7 of 13 patient samples by EOT

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%	0%
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%

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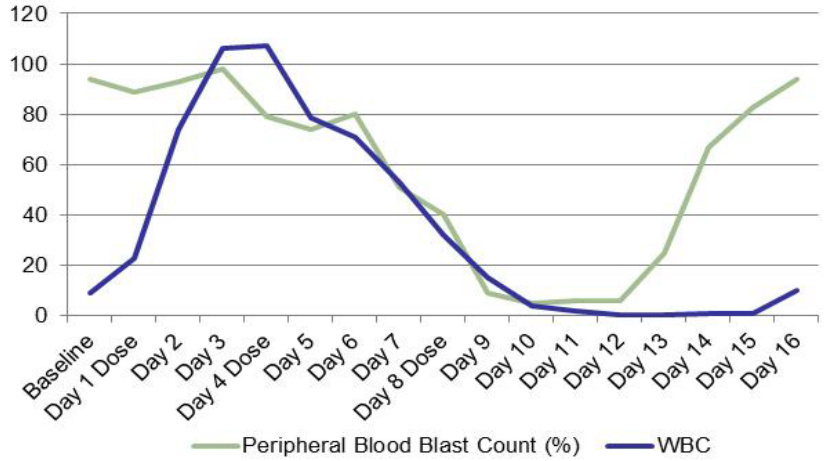
NS[1] = no sample collected
[2]Fewer cells used in analysis because sample had less cells

Response to Treatment for Blast Crisis CML and HIV+ AML

- **<u>Patient 002</u>:** 32 year-old, Hispanic male with myeloid blast crisis of CML

- Prior therapies consisted 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

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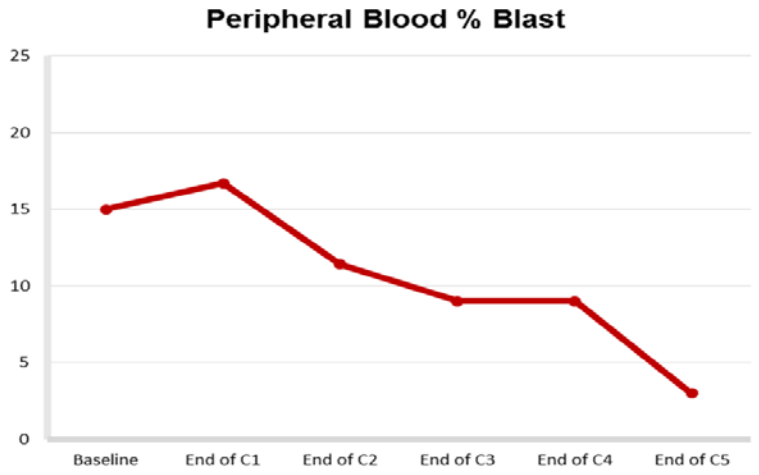
- **Extended Treatment: Patient 006**
- 54 year-old HIV+ male with AML transformed from Jak2 positive Polycythemia Vera
- 3 patients showed improvement and/or stable disease, received 5 treatment cycles over 5 months
- Patient 006 achieved stable disease and marked reduction in peripheral blasts



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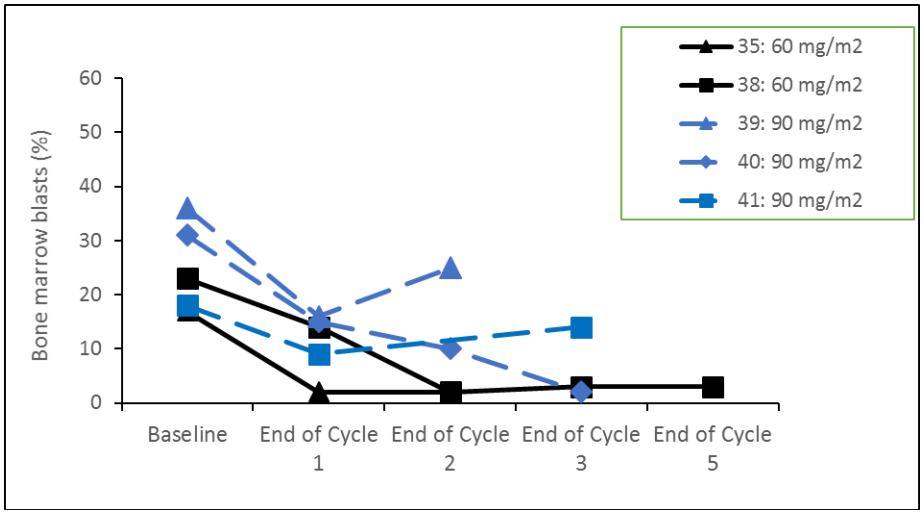
Safety Segment Phase II BP1001 + LDAC Combination Results



Relapsed/refractory AML patients
- 6 evaluable patients in 2 cohorts
- Average age 75

3 patients achieved *complete remission*
2 patients achieved *partial remission*

Pharmacokinetics indicate BP1001 has a 30 hr half life in plasma

No adverse effects attributed to BP1001 were observed. MTD was not reached.

CR = Complete remission PR = Partial remission PD = Progressive disease

Subject	BP1001 (mg/m^2)	BM Baseline	BM Nadir	Cycles completed	Response
35	60	17	2	1	CR
37	60	25	25	1	PD
38	60	23	2	5	CR
39	90	36	16	3	PR
40	90	31	10	3	CR
41	90	18	9	3	PR

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Results of Phase II Safety Segment Combination LDAC + BP1001

- Safety evaluation of combination low-dose cytarabine (LDAC) with BP1001 in refractory and relapsed patients
- Three (3) evaluable patients per cohort were treated twice a week for 4 weeks
- Cohort 7 and 8 received 60 mg/m^2 and 90 mg/m^2 of BP1001, respectively
  - Three patients achieved ***complete remission***
  - Two achieved ***partial remission***

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

Overall the drug combination is safe with very promising results in refractory/relapsed advanced patients

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Plans For Phase II Efficacy Trial for BP1001 AML Combination Therapy

- Safety segment of the Phase II trial completed, demonstrated no negative synergies using BP1001 together with frontline therapy (LDAC)
  - Phase II will have 54 patients with an interim analysis after 19 patients
  - If successful, the trial will be rolled into a pivotal trial for accelerated approval
  - Conducted at leading cancer centers in the U.S., including the MD Anderson Cancer Center
  - Primary endpoint for the study is the number of patients who achieve complete remission
- ❖ Phase II trial in CML starting in Q3 of 2016

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BP1001 Treatment Paradigm

- Frontline therapy for de novo AML patients who are induction therapy ineligible and unfit for a stem cell transplant
  - BP1001 combination with LDAC
  - Current response rate frontline therapy alone is 20%
  - BP1001 to improve response rates significantly
  - Reduce treatment related mortality

- Salvage therapy for relapsed and refractory AML patients who have failed two prior regimens
  - Safety segment trial of BP1001 combination with LDAC demonstrated complete or partial response in 5 of 6 elderly patients
  - Average patient age 75 years old

- Blast crisis and accelerated phase CML patients
  - BP1001 combination with frontline therapy
  - Current response rate frontline therapy alone is <30%
  - Average survival 9 months

Preclinical Pipeline

Validating DNAbilize™ with Key Opinion Leaders:

- Investigation of BP1001 in triple negative and inflammatory breast cancer and advanced ovarian cancer with The MD Anderson Cancer Center
- Investigation of clinical and preclinical targets for treatment of systemic lupus in collaboration with UT Southwestern Medical Center
- Investigation of clinical and preclinical targets in pancreatic cancer using a patient derived *ex vivo* tumor model developed by The MD Anderson Cancer Center
- Investigation of DNAbilize technology for systemic immunotherapy for glioblastoma in collaboration with Thomas Jefferson University

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Accomplishments and Upcoming Milestones

- Safety segment of the Phase II for AML completed
- Preparing to begin the safety segment of the Phase II clinical trial for CML
- Expanding development with new target drug candidates (lymphoma, pancreatic, brain)
- New drug indication outside of cancer
- 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
  - Demonstrated effectiveness of delivery technology (broad drug development, licensing implications)
  - Continued new manufacturing and target IP

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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 Cancer 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, MPH

Director, Clinical Operations

- More than 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

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

Focus

- Clinical team added to manage clinical trials and place new candidates into an IND, clinical trial
- Expanding preclinical research and manufacturing capabilities

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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 integral role in the Avastin™ program
- Former Senior Director of Medical and Regulatory Affairs at Seattle Genetics

Recruiting additional members

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IP and Financial Snapshot

Intellectual Property

- Original patents licensed from MD Anderson
- New composition and methods of use patents filed to cover DNAbilize technology, solely owned by Bio-Path

Financial Snapshot

- **Ticker:** NASDAQ: BPTH
- **Cash:** $6.5 million as of March 31, 2016
  - June 2016 $10 million registered direct offering extends cash runway through 2017
- **Market Cap:** Approximately $180 million
- **Burn rate:** $1 million
  - External programs: $1-1.5 million

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