



Advancing a New Class of Antibiotics to Phase 3 Trials

Targeting WHO/CDC “Priority Pathogens”
While addressing Antimicrobial Resistance (AMR)



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Executive Summary

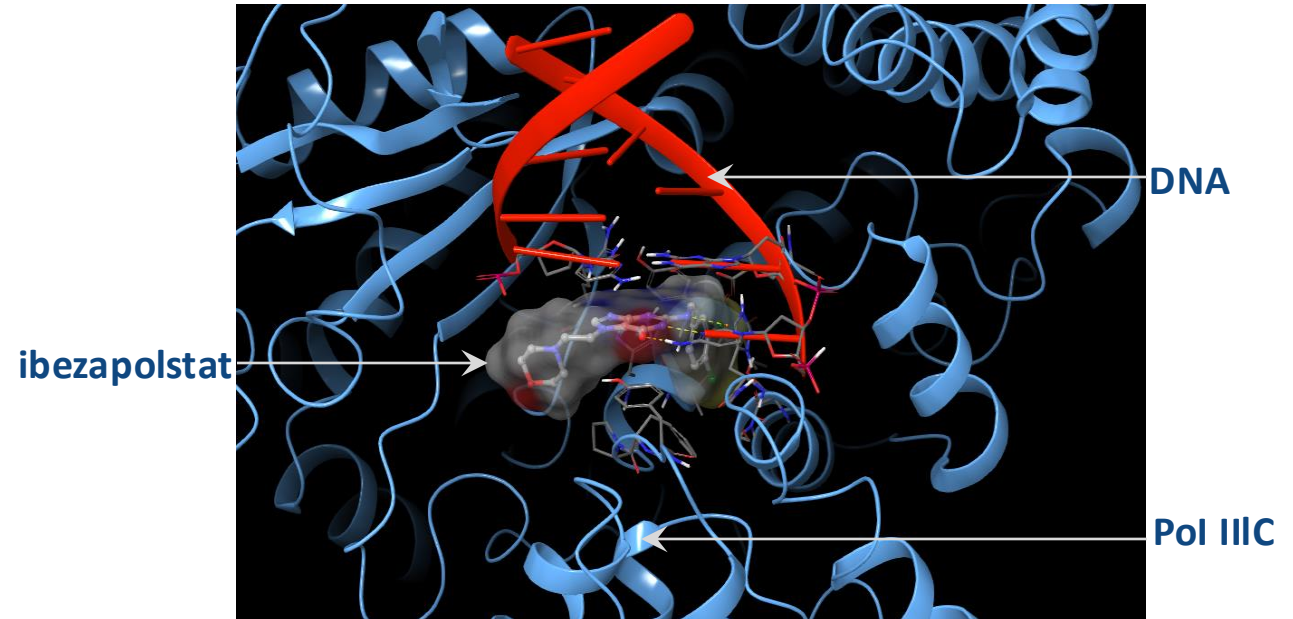


- **Corporate.** Acurx Pharmaceuticals, Inc. (Nasdaq: ACXP) incorporated in July 2017, acquired its lead antibiotic (AB) program to treat *C. difficile* Infection (CDI) in February 2018 (ibezapolstat or IBZ)
- **Novel Mechanism of Action (MOA):** Targets the polymerase III C enzyme, a previously unexploited scientific target now clinically validated through Phase 2b clinical trials in patients with CDI. ACX-375C (pre-clinical program) has same MOA and targets other CDC priority pathogens including MRSA, VRE, PRSP and anthrax
- **Unmet Medical Need.** Urgent need for new AB's for CDI, per CDC. Standards of Care (vancomycin/fidaxomicin) have high reinfection rates (20-40%) and AMR (antimicrobial resistance) is increasingly problematic for these old AB's
- **IBZ: Phase 3 Ready:** IBZ demonstrated 96% cure rate in Ph2 with no recurrence at 30 and 90 day follow-up. FDA & EMA both agreed to identical international Ph3 clinical trial design and regulatory pathway to NDA and MAA
- **Pilot Study vs. Standards of Care:** To enhance our Phase 3 program, evaluate IBZ in patients with multiple recurrences of CDI and resistant to standards of care (vancomycin/fidaxomicin). N=20, Open-Label, to start enrollment 1Q2026
- **CMC:** Commercial supply made in U.S.; Low cost of goods. Pricing Flexibility.; “Made In America” policy initiated 2H 2024
- **Cash On Hand:** \$6.1 mm

Mechanism of Action



- Ibezapolstat kills *C. difficile* bacteria by blocking the pol IIIC enzyme thereby not allowing DNA replication of the bacterial cell¹
- Same MOA for ACX-375C series of compounds
- Meets four criteria of innovation:
New chemical class, new target, new MOA, no cross-resistance²



¹ Wei-Chu Xu, et al., Bioorganic & Medicinal Chemistry <https://doi.org/10.1016/j.bmc.2019.06.017>; ² Theurezbacher, Innovation Criteria, WHO, 2017

Unmet Medical Need



No new antibiotics in clinical development showing improvement in either IC or SCC

		<i>C. difficile</i> Infection – mITT population		
Product		% Initial Cure	% without recurrence	% Sustained Clinical Cure*
Marketed (Ph3 Results US/CAN) ¹	vancomycin (n=309)	86	75	61
	fidaxomicin (n=287)	88	85	73
In Development (Ph2 Results) ²	vancomycin (n=33)	70	61	42
	ridinilazole (n=36)	78	86	67
In Development Ph3 Results**	vancomycin (n=375)	92	83	71
	ridinilazole (n= 370)	87	92	73
In Development (Ph2 PPP results) ³	ibezapolstat (n=26)	96%	100%	100%
	Vancomycin (n=14)	100%	86%	86%

¹ Louie et al, Fidaxomicin vs Vancomycin, Phase 3 study, NEJM, Feb 2011; ² Vickers et al, Efficacy and Safety of Ridinilazole Compared with Vancomycin for treatment of *C. difficile* Infection; Ph2 Randomized, Double-blind, Active-controlled, Non-inferiority Study; Lancet, July 2017; ³ Ibezapolstat Phase 2a, CID 2022 and Ph2b data on File Acurx.* Calculated percent of patients with Initial Cure who SCC. **IDWeek2022

Antibiotics: Global Standard to Treat CDI



Antibiotics

- Existing standards of care first-line and first recurrence treatment with established marketed antibiotics (vancomycin, fidaxomicin) recommended by IDSA¹
- Currently marketed antibiotics achieve relatively high initial cure rate but cause dysbiosis; leads to high reinfection rates (20-40%) and AMR is an expanding public health problem
- CDC: Significant unmet need remains for antibiotics that can meaningfully reduce recurrence
- **IBZ: Fast bactericidal effect demonstrated in trials / low incidence of recurrence -- restoring healthy microbiome - position ibezapolstat for first-line treatment if approved**

Live Biotherapeutic Products (LBPs)/Fecal Microbiota Transplant (FMT)

- Two LBP treatments approved (U.S. Only) for recurrent CDI (rCDI) (VOWSTTM; Oral) and Rebiotix®; Rectal) ; Can only be used after front-line antibiotic
- Safety & impact on microbiome are concerns
- Warnings & Precautions: manufactured from human fecal matter; may carry a risk of transmitting infectious agents
- High cost and inability to use as first-line treatment limit commercial traction

Vaccines

- None work /none approved to date; Pfizer failed (2022) and Sanofi failed (2017);
- No new vaccine trials in CDI currently ongoing

¹Clinical Practice Guidelines for *Clostridium difficile* in Adults and Children: 2017 Update by the Infectious Diseases Society of IDSA and SHEA

²Johnson,et al: Sustained Clinical Response as an Endpoint in Treatment Trials of *Clostridium difficile*-Associated Diarrhea, *Antimicrobial Agents and Chemotherapy*, August 2012

R&D Pipeline



Program	Target Pathogen	Discovery	Pre-Clinical	Ph 1	Ph 2	Ph 3
Ibezapolstat	<i>C. Difficile</i>					
ACX-375C QIDP/Fast Track Eligible	Gram-positive Infections					
Anthrax QIDP/Fast Track Eligible	Multiple product candidates; Gram-positive infections					



IBEZAPOLSTAT R&D

- * Open-Label Pilot Study (n=20) to evaluate IBZ in patients with multiple recurrences of CDI and resistant to standards of care (vancomycin/fidaxomicin). **1Q26 - 4Q2026**
- * University of Houston laboratory study (humanized mouse model); to address the critical need to identify microbiome changes in stool samples obtained from patients with multiple CDI recurrences after exposure to IBZ or FDX and assess treatment response based on FDX susceptibility. **3Q2025**

ACX-375C

- * Grant applications for ACX-375C (submitted/to-be-submitted and pursued over 6 months)
- * Scientific publications/presentation of Acurx DNA pol IIIC inhibitors and IBZ data

CORPORATE/FINANCE INITIATIVES

- * Continue multi-step approach to strategic financing
- * Continue Public and Private Partnership and Licensing Initiatives

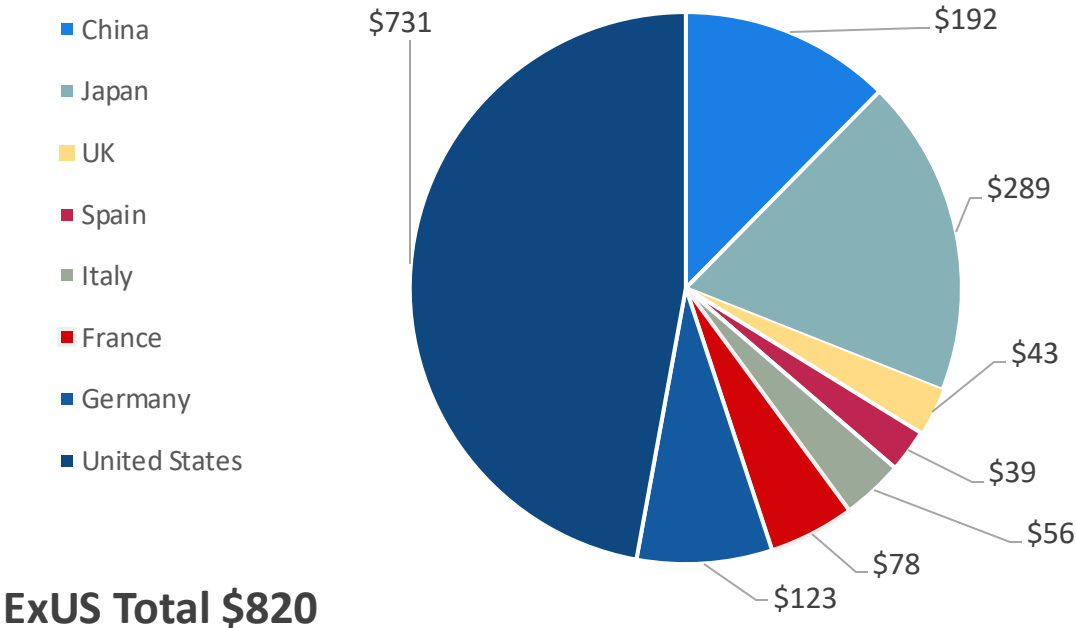
C. difficile Infection: Large Growing Market



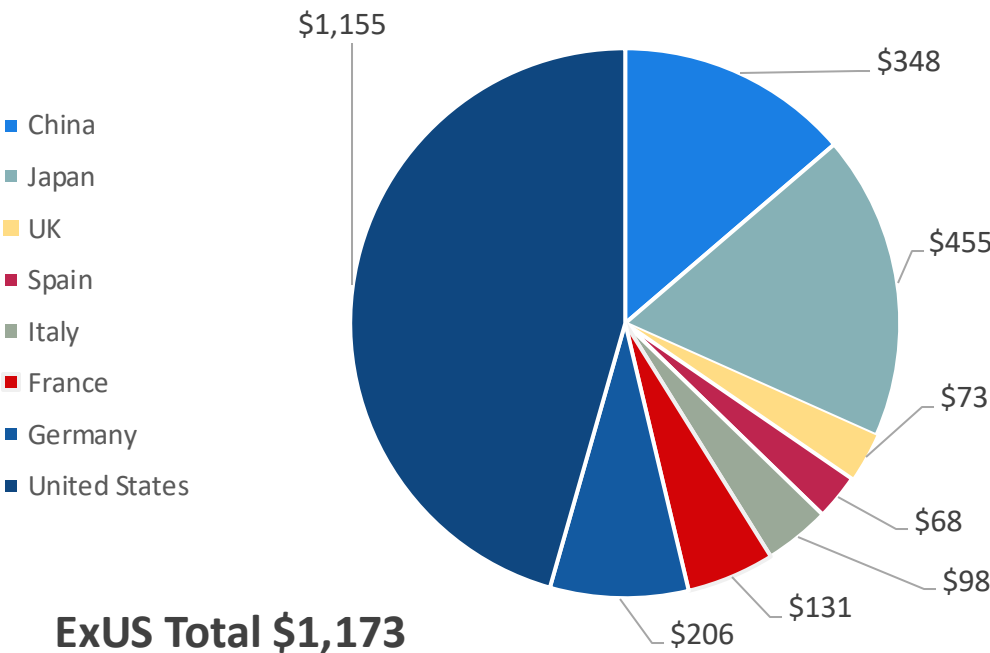
Global Market

Current and Forecast (2023-2032)

2023 TOTAL \$1.5bil



2032 TOTAL \$2.3bil



Ibezapolstat positioned to become first-line treatment for CDI if approved

Ibezapolstat: Phase 2 Success



EOT (End of Treatment)

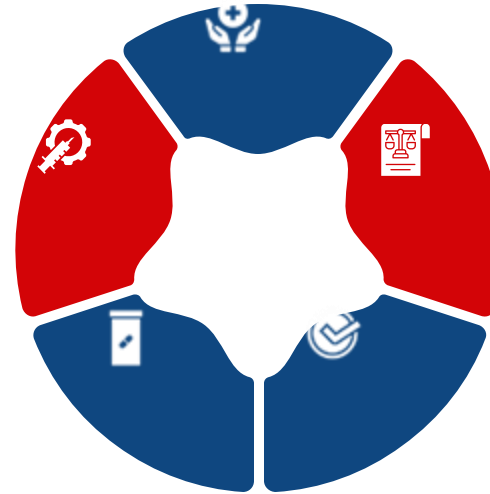
25/26 (96%) of evaluable patients were cured at EOT (10 of 10 in Ph2a and 15 of 16 in Ph2b). Well tolerated. No drug related SAE's

SCC (Sustained Clinical Cures)

All 15 ibezapolstat-treated patients in Phase 2b who achieved Clinical Cure (CC) at end of treatment (EOT) remained free of CDI recurrence 30 days after EOT, for a Sustained Clinical Cure (SCC) rate of 100%

ECC (Extended Clinical Cures)

100% (5 of 5) of ibezapolstat-treated patients experienced no recurrence of infection



Regulatory/Patent Exclusivity

Rolling 10 years regulatory exclusivity from FDA approval (QIDP and NCE); similar regulatory exclusivity in EU and internationally; Patents expire September 2030

Clinical Validation

Ph 2 efficacy results* provide clinical validation of a new class of antibiotics to treat other gram-positive bacterial infections

In Phase 2b, Ibezapolstat outperformed vancomycin showing eradication of fecal *C. difficile* at Day 3 of treatment in 15 of 16 treated patients (94%), versus vancomycin which had eradication of *C. difficile* in 10 of 14 treated patients (71%)

Ibezapolstat microbiome head-to-head showed IBZ beat vancomycin at preservation and regrowth of key gut microbiota essential to avoid recurrent CDI

Ibezapolstat Preserves & Enhances the Microbiome

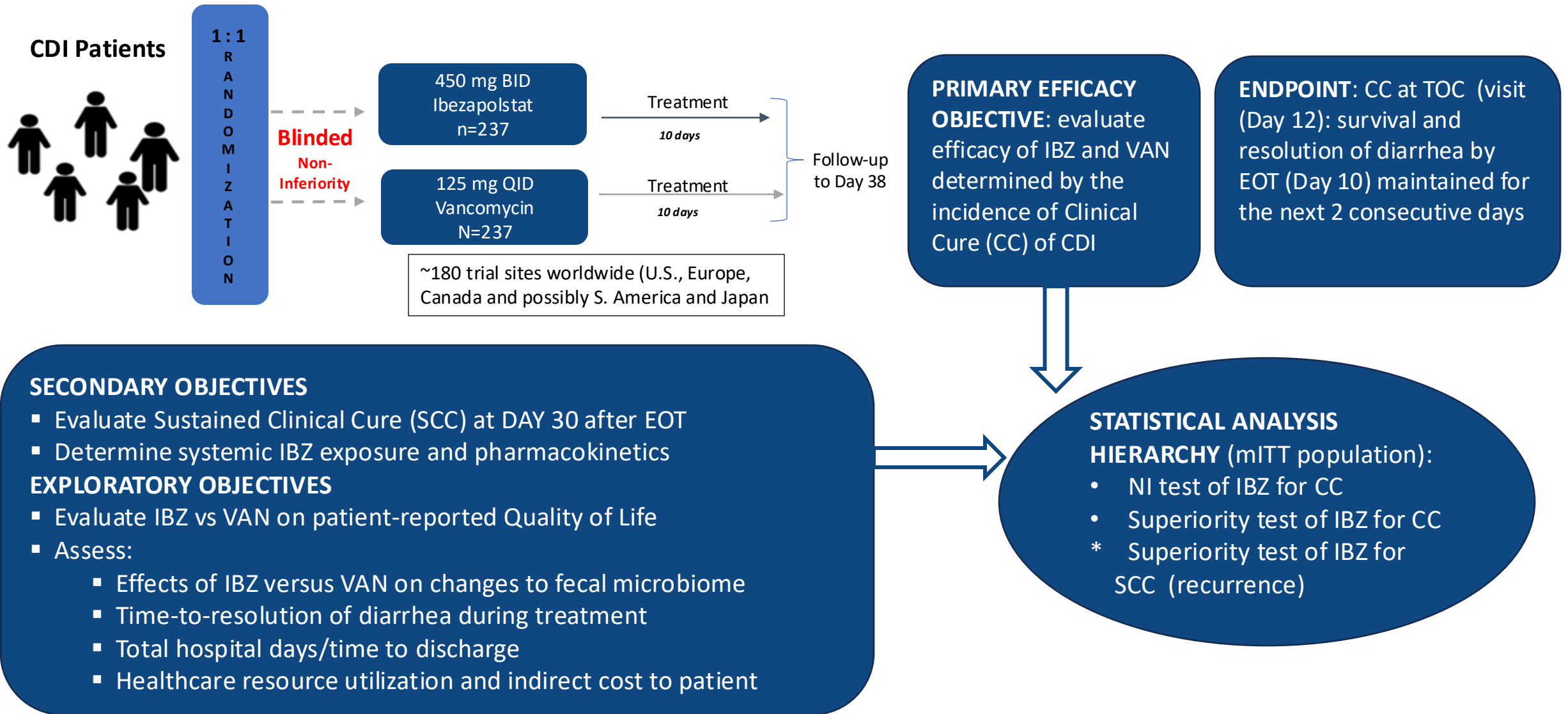


Ibezapolstat restores the microbiome by enhancing Actinobacteria in the microbiome while suppressing regrowth of Proteobacteria; reducing the likelihood of recurrence¹

PHYLUM	ANTIBIOTIC ACTIVITY	
	ibezapolstat	vancomycin (oral)
Actinobacteria	No	Yes
Bacteroidetes	No	Yes
Firmicutes	Selective	Yes
Fusobacteria	No	No
Proteobacteria	No	No

¹ Garey, Late-Breaker Presentation, Ibezapolstat Clinical Update, 8th Annual International C.diff. Virtual Conference, Nov 18, 2020

FDA / EMA Approved Phase 3 Trial Design*



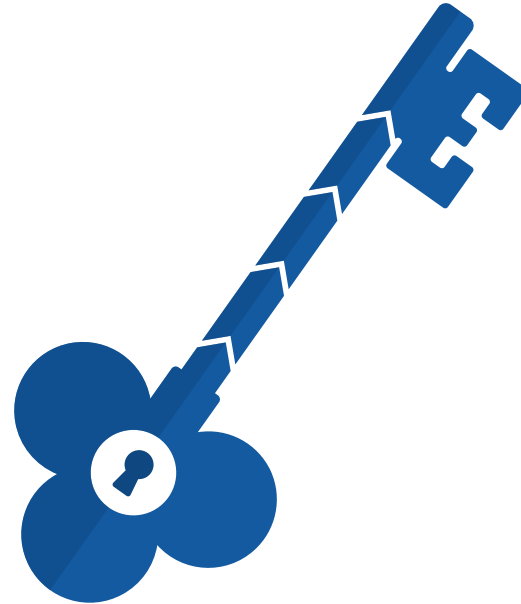
*Two clinical trials required for registration per FDA Guidance (Oct 2022); IBZ-ASPIRE-1 will be followed by IBZ-ASPIRE-2 planned to start 6 to 9 months after start of first trial

Key IBZ Factors For Potential Phase 3 Success



Nonclinical

- Bactericidal potency vs *C. difficile*
- Effective against MDR strains including vanco resistant and FDX resistant strains
- Does not trigger sporulation or toxin release
- Reduced flagellar movement
- Active in biofilms
- Preserves and restores microbiome unlike MET, VAN and FDX
- Differentiating IBZ Gut Microbiome Effects vs MET, VAN, FDX



Clinical

- Clinical Cure Rate 96% (25 of 26 patients) in Ph2 trials
- Sustained Clinical Cure Rate of 100% 30 days after EOT (15 of 15)
- Extended Clinical Care Rate 100% (5 of 5 patients)
- High human fecal concentrations (>1000x MIC)
- Rapid eradication of *C. difficile* (by Day 3) in CDI patients
- Favorable microbiome effects by day 3 while on treatment
- Favorable effect on bile acids
- No drug related SAEs



Second DNA Pol IIIC Inhibitor ACX-375C – Targets MRSA and *B. anthracis* (anthrax)

- Oral and I.V. formulation targets treatment of *Staphylococcus*, *Streptococcus* and *Enterococcal* infections, including vancomycin-resistant enterococcus (VRE), Methicillin-resistant staph (MRSA) and other resistant G+ bacterial infections; WHO/CDC Priority Pathogen List¹
- Demonstrated potency against *B. anthracis* (including CIPRO-resistant strains)

1

In hospitalized patients, MRSA accounted for 52% of all infections, almost twice as many as MDR Gram-negative infections²

2

VRE hospital infections exceeded carbapenem-resistant (CR) *Acinetobacter*, MDR *Pseudomonas aeruginosa* and CR Enterobacteriaceae infections combined²

3

Existing classes of antibiotics unable to reliably treat CDC-designated serious threat level priority pathogens such as *B. anthracis* (classified as a Category A agent, the highest potential for use as a bioweapon and poses severe military and public health threat when released deliberately)

1. CDC Antibiotic Resistance Threats in the U.S., 2019, Atlanta, U.S. Department of Health and Human Services, CDC, Nov. 2019

2. Jernigan, et al., Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012–2017, *N Engl J Med* 382:1309-19; (2020)



Potential Clinical Indications: (QIDP/Fast Track eligible); ABSSSI (MRSA + other G+)

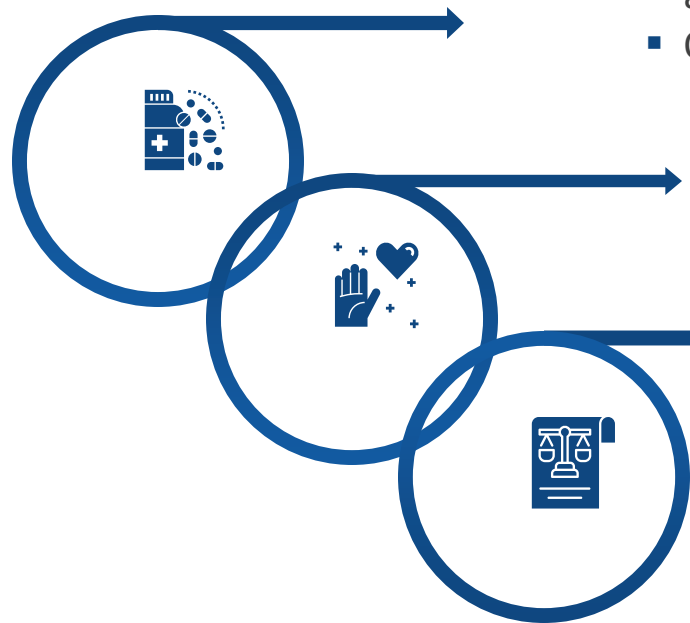
- Follow-on: community-acquired bacterial pneumonia, hospital and/or ventilator-associated bacterial pneumonia; bacteremia with or w/o infectious endocarditis, bone/joint infections and diabetic foot infections
- Oral antibiotic for treatment of inhalation anthrax

Unmet Medical Need

Antibiotic resistance to currently used antibiotics; including daptomycin and linezolid-resistant bacteria^{1,2}; bacterial resistance has emerged to all currently available antibiotics to combat potential bioweapons of mass destruction such as anthrax

IP and Regulatory

- To date, Acurx has obtained three U.S. patents, one Israeli patent and one Japanese patent, in each case, which cover the ACX-375C program, relating to DNA Polymerase III C Inhibitors, with other country-level filings in process; expire December 2039.
- QIDP, Fast Track and NCE eligible (potential 10 years of market exclusivity).



Experienced Senior Executive Management



David P. Luci, CPA, Esq

Co-Founder & CEO

Former CEO of Dipexium Pharmaceuticals (Nasdaq: DPRX), Abeona Therapeutics (Nasdaq: ABEO), MacroChem (OTC BB: MACM), and Bioenvision (Nasdaq: BIVN). Sold all 3 public companies he co-founded or joined in early stage. Orchestrated several in and out-licensing transactions prior to dispositions. M&A and corporate finance attorney (Paul Hastings NY) and CPA with Ernst & Young NY)



Robert J. DeLuccia

Co-Founder & Executive Chairman

Former Chairman of Dipexium Pharmaceuticals (Nasdaq: DPRX); Former President Sanofi U.S. and Pfizer, Sr. Executive; Former CEO Immunomedics (Nasdaq: IMMU) and MacroChem Corporation (OTC BB: MACM); Former Lead Director BOD, IBEX Pharmaceuticals (IBT-TSX)



Robert G. Shawah

Co-Founder & CFO

Former Chief Accounting Officer of Dipexium Pharmaceuticals (Nasdaq: DPRX); Former Vice President of Baldwin Pearson & Co., a commercial real estate firm



Bob DeLuccia, Co-founder & Executive Chairman (see prior slide)

Michael Silverman, MD, FACP: Acurx Medical Director

>35 years' experience clinical research/product development; KPMG Health Care Consulting; Biopure Corp, Sandoz, Sterling-Winthrop (Kodak-Sanofi) and clinical practice of medicine

Larry Mortin, PhD, Acurx Director, Pharmacology

>25 years' experience advancing new compounds into clinical testing; designing/optimizing efficacy screens/animal models, PK/PD drivers, mechanism of action, and dose optimization; 13 years leading Cubist In Vivo Pharmacology Group

Jeff Alder, PhD, Clinical Research and Development

>30 years' experience infectious disease research and clinical development; Abbott, Bayer, Cubist Pharmaceuticals, Scriptgen, 6 anti-infective drugs approved, NIH reviewer and chairperson.

Deepa Deshpande, PhD, RAC; Acurx Director, Regulatory Affairs

>25 years' experience in pharmaceutical drug development and regulatory affairs including as CEO of Universal Regulatory Affairs. Advisor for >100 pharmaceutical/biotechnology companies in US, EU, UK, Asia, on global development programs (IND/CTA, NDA, MAA, NADA filings and health authority negotiations)

Les Johnson, Acurx Manufacturing Director

>30 years' experience in manufacture of products for advanced therapeutics, biologics, pharmaceuticals and devices; Clear Path Development, Salamandra, Celsis, Cambrex, Biosynexus, Baxter Bioscience, Protein Polymer Technologies, Bayer Biologics, Cetus/Codon/Berlex

Judith Steenbergen, PhD, Director of Microbiology

>20 years' experience medical affairs and clinical development; Cubist, Paratek

Xiang Yu, PhD, Pre-Clinical Development Director (Medicinal Chemistry)

>27 years' industry experience advancing new compounds from discovery to clinical development; Accellient Partners, Ironwood Pharmaceuticals, Epix Pharmaceuticals, Cubist

Scientific / Corporate Advisors



SCIENTIFIC

Jack H. Dean, Ph.D., Former Director, Worldwide Pre-Clinical Research at Sanofi; Research Professor, Univ of Arizona (Pharmacology & Toxicology)

Richard Ellison, MD, Professor of Medicine, UMass Medical School (Microbiology)

Kevin Garey, PharmD*, Professor, University of Houston College of Pharmacy (Microbiology & Microbiome)

Mark Goldberger, MD, MPH, Former Director Office of Antimicrobial Products, U.S. Food and Drug Administration

Ellie Goldstein, MD, Clinical Professor of Medicine, UCLA (Infectious Disease)

Stuart Johnson, MD*, Professor of Medicine, Loyola University (Infectious Disease)

Ciaran Kelly, MD*, Professor of Medicine, Harvard Medical School (Gastroenterology)

CORPORATE

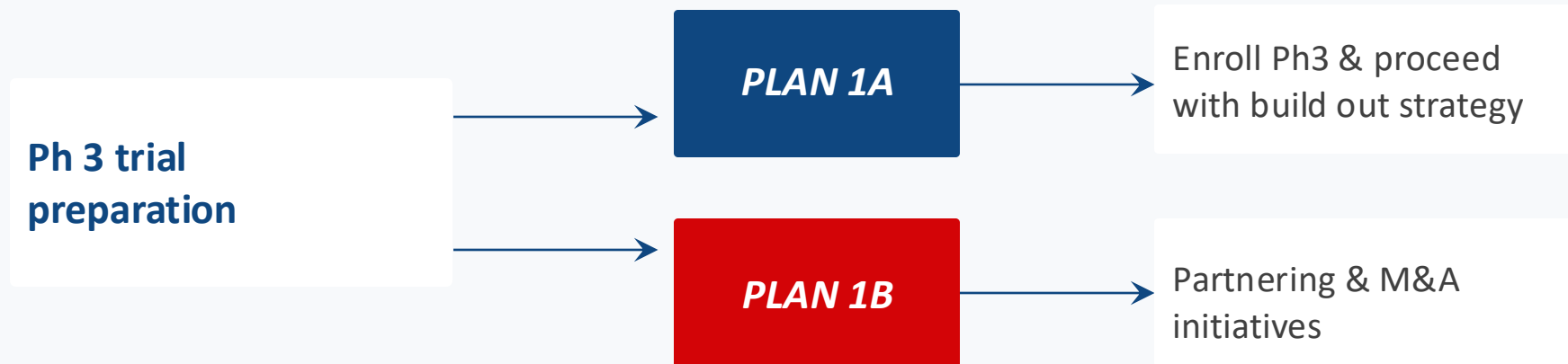
Fred Hassan, Director, Warburg Pincus; Previously Chairman & CEO of Schering-Plough and of Pharmacia, prior EVP of American Home Products (Wyeth) and CEO of Sandoz US Pharmaceuticals; Board of Directors of Precigen (formerly Intrexon) and Time Warner, Bausch & Lomb and Amgen

**Co-authors of Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). April 2018*

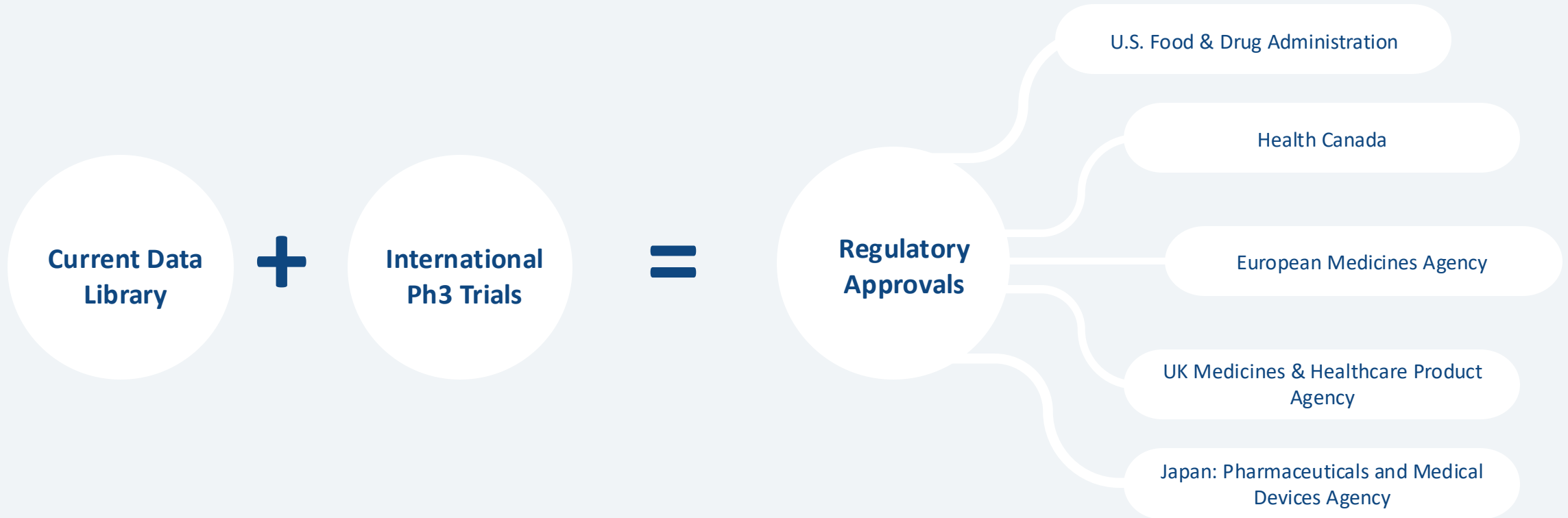


OBJECTIVE

In parallel with Ph3 trial preparation, explore strategic alternatives



Proposed Pathway To Commercialization





- **Jack H. Dean, Ph.D.**, Former Director, Worldwide Pre-Clinical Research at Sanofi; Research Professor, Univ of Arizona (Pharmacology & Toxicology)
- **James Donohue**, Vice President of Charles River Associates (Nasdaq: CRAI)
- **Thomas Harrison**, Chairman Emeritus of the Diversified Agency Services (“DAS”) division of Omicron Group Inc. (NYSE:OMC). Previous Chairman and Chief Executive Officer of Omicron Group Inc.
- **Carl Sailer**, VP Global Account Lead for Syneos Health (Nasdaq:SYNH). Previous VP of Sales and Marketing for Emisphere Technologies
- **Joseph C. Scodari**, Chairman of the Board of Directors of Optinose (Nasdaq:OPTN). Previous Worldwide Chairman, Pharmaceuticals Group, of Johnson & Johnson, and member of Executive Committee
- **Bob DeLuccia and David Luci** – see “Management”

Capitalization Summary



Cap Table as of 06/30/25

Common Shares Outstanding	1,470,352
Warrants (WAEP: \$65.60)	306,812
Stock Options (WAEP: \$101.00)	194,000
Fully Diluted Shares Outstanding	1,971,164

Balance Sheet as of 06/30/25 (\$mm)

Cash & Cash Equivalents	\$6.1
Total Assets	\$6.2
Total Debt	\$0
Total Liabilities	\$2.6
Shareholders' Equity	\$3.6



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Targeting WHO/CDC “Priority Pathogens”
While addressing Antimicrobial Resistance (AMR)