Advancing a New Class of Antibiotics to Phase 3 Trials

Targeting “Priority Pathogens”

March 2025

Disclosure

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Executive Summary

Corporate (Nasdaq: ACXP)

Acquired ibezapolstat (IBZ); lead antibiotic for *C. difficile* Infection (CDI); Feb 2018

Novel Mechanism of Action

- Pipeline (2) of DNA polymerase IIIC inhibitors
- Previously unexploited, now clinically validated bacterial target
- IBZ potential first-line treatment for CDI; microbiome-restorative potential; FDA Fast-Track Designation
- ACX-375 targets all known gram-positive bacterial infections (Including MRSA, VRE, PRSP and *B. anthracis*)

Unmet Medical Need

IBZ: CDC classifies CDI as **urgent threat** requiring new antibiotics; 2 of 3 current anti-CDI antibiotics have recurrent infection of 20% to 40% and antibiotic resistance[1] necessitating development of new antibiotics to treat CDI
ACX375: Existing classes of antibiotics unable to reliably treat CDC-**serious threat** designated priority pathogens (*B. anthracis* (anthrax), MRSA, VRE, DRSP; New classes of antibiotics needed to combat potential bioweapons of mass destruction (anthrax) since bacterial resistance has emerged to all current antibiotics.

IBZ: Phase 3 Ready

- Ibezapolstat demonstrated overall 96% cure rate in Ph2 trials (2a and 2b) at EOT; with no recurrence at 30day followup
- Successful FDA End of Ph2 meeting, April 2024; CMC confirmed
- Both FDA and EMA agreed to regulatory pathway for Ph3 and for NDA and MAA submission for the EU

ACX375: Lead Optimization

- Demonstrated oral bioavailability (>50%), potency against *B. anthracis* (anthrax); efficacy in murine models against priority gram-positive pathogens. Normal gut microbiome bacteria spared with no cross resistance to any existing antibiotic class; FDA Fast-Track Designation eligible

CMC

Capsules, made in U.S.; robust with low COGS targeted at $300 or less for full course of treatment

Cash On Hand

~$3.7 mm cash at 12/31/24

[1]Anne J. Gonzales-Luna, University of Houston College of Pharmacy, ECCMID 2023, Scientific Poster, April 6-20m 2023

Unmet Medical Need

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

	Product	*C. difficile* Infection – mITT population		
		% 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. **IDWeek 2022

Antibiotics: Global Standard to Treat CDI

Antibiotics

- Existing standard of care first-line and first recurrence treatment with established marketed antibiotics (vancomycin, fidaxomicin) recommended by IDSA[1]
- Currently marketed antibiotics achieve relatively high initial cure rate but leave high burden of C. *difficile* in the gut. This, together with a pronounced detrimental effect on the gut microbiome, leads to recurrence in approximately 20%-40%[2] of CDI patients after therapy ends
- Significant unmet need remains for antibiotics that can meaningfully reduce recurrence
- **Fast bactericidal effect noted in trials / low incidence of recurrence -- positions ibezapolstat for first-line treatment if approved**

Antibodies

- Generally, only administered in combination with antibiotic
- Only 1 approved
- Safety issues; Mild success
- **High costs and inability to use as a first-line treatment have limited commercial traction**

FMT / Microbiologics

- Two treatments approved for recurrent CDI (VOWST and Rebiotix)
- Safety & impact on microbiome are concerns; recommended only for patients with multiple recurrences of CDI who failed appropriate antibiotic treatments; **FDA box warning in labelling**
- **High costs and inability to use as first-line treatment have limited commercial appeal**

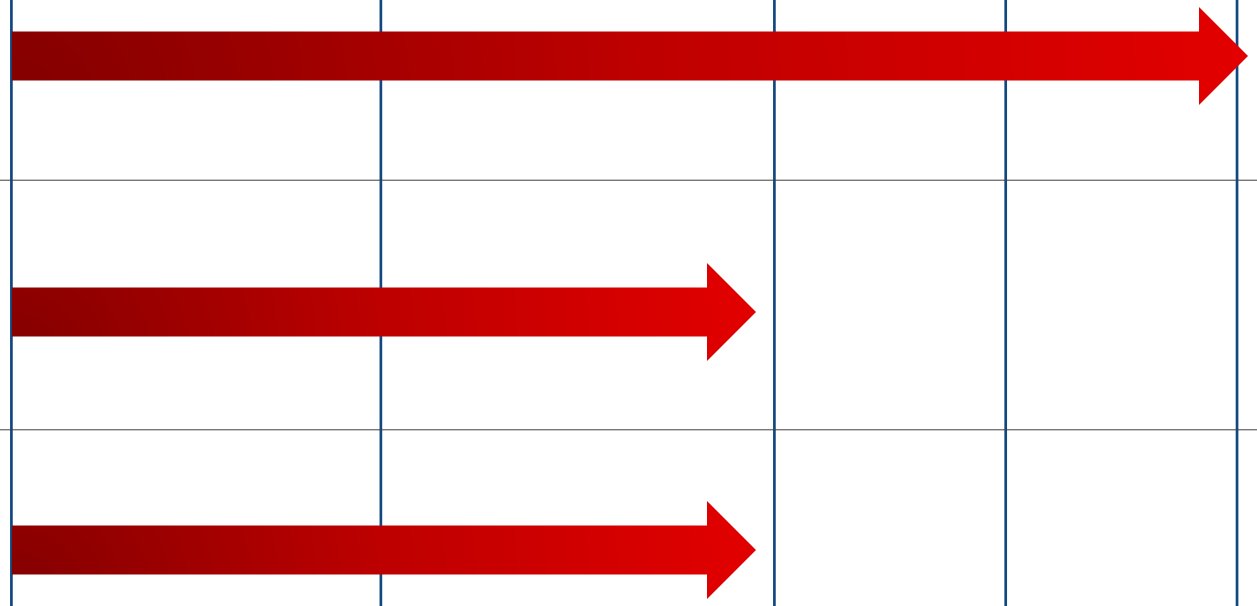
Vaccines

- Pfizer vaccine failed in Ph3 (March 2022)
- Sanofi vaccine failed in 2017
- None approved; publicly available data all negative
- Large numbers of patients required for trials

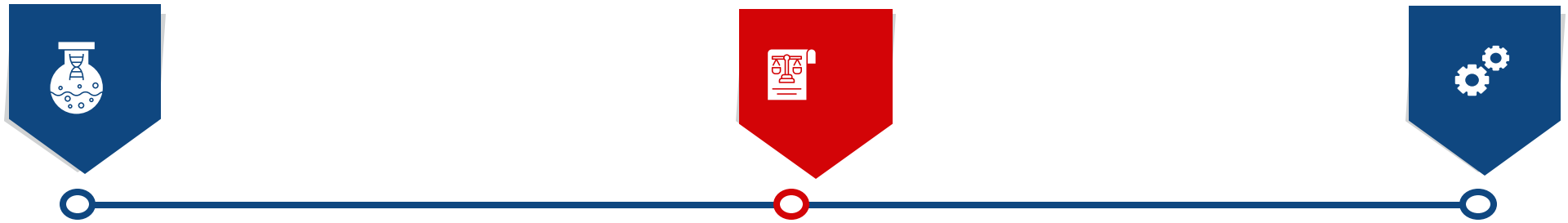
[1]Clinical Practice Guidelines for *Clostridium difficile* in Adults and Children: 2017 Update by the Infectious Diseases Society of IDSA and SHEA
[2]Johnson, et al: Sustained Clinical Response as an Endpoint in Treatment Trials of *Clostridium difficile-Associated Diarrhea, Antimicrobial Agents and Chemotherapy, August 2012*

R&D Pipeline

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



Upcoming Milestones



Clinical
Lead AB treating CDI - recently completed Ph2b trial ✓

- **Dec '23**: Sustained Clinical Cure Data (30 days after EOT)
- **Jan '24:** Extended Clinical Cure Data (94 days out)
- **Jan '24**: Microbiome head-to-head comparison to standard of vancomycin

Clinical, Regulatory
WW Strategy

- **Q2 '24:** FDA Meeting – finalize Ph3 mandate
- **2H '24:** Launch international strategy for commercialization in EU, UK, Japan & CDN
- **4Q '24:** FDA/EMA agreement for Ph 3 ready and pathway for NDA and MAA
- **1H '25:** File for FDA QIDP Designation for ACX-375
- **Q4'25:** Enroll first patient in Ph3 trial
- **Q4'25:** Commence IND-enabling preclinical tox studies for ACX-375 for MRSA
- **Q4'25:** Parallel anthrax development w/ACX375

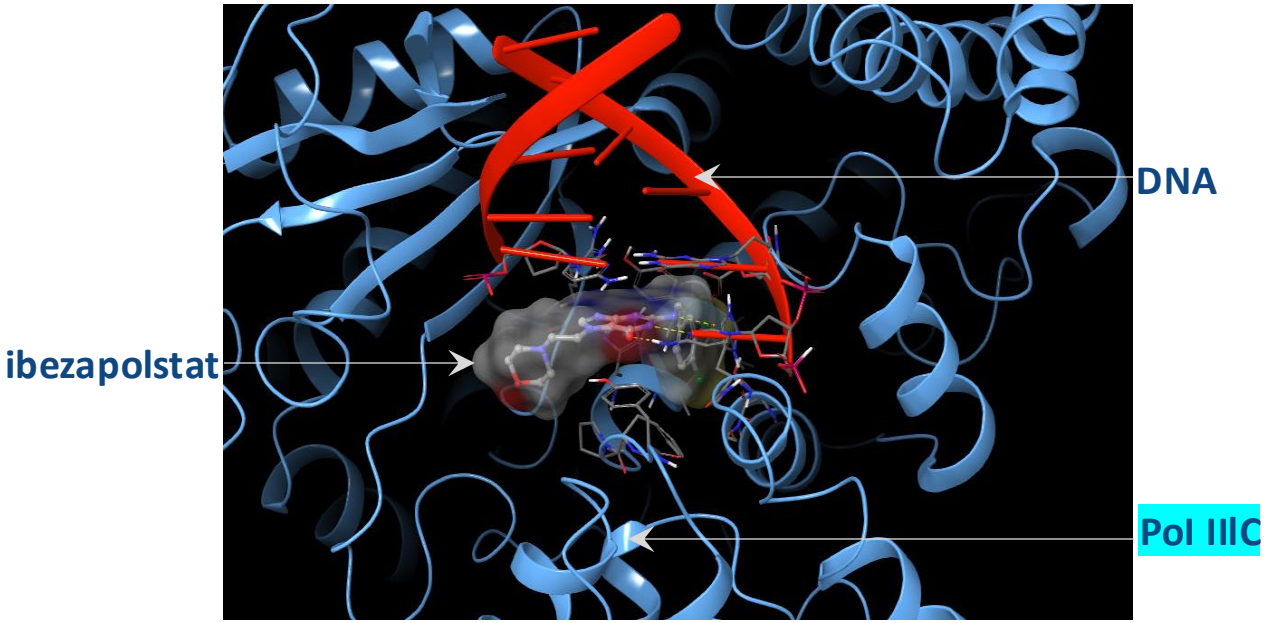
Manufacturing, IP, other

- **Q3 '24: IBZ** scaled up to 10 kg (x2) batches of API; pilot batches for IBZ Ph3 CTM
- **Q3 '24:** USPTO grants new patent for use of IBZ to treat CDI and restore the microbiome
- **Q4 '24**: Anthrax (preclinical)
- **Q1 '25**: CDI Microbiome-restorative potential (In silico model)
- **Q1 '25:** CDI-Differentiating IBZ Gut Microbiome Effects vs VAN, FDX
- **Q1 '25:** JPO grants new patent for DNA Pol IIIC Inhibitors

Mechanism of Action

Ibezapolstat kills *C. difficile* bacteria by blocking the pol IIIC enzyme thereby not allowing DNA replication of the bacterial cell.[1]

Same MOA applies to the ACX-375C series of compounds



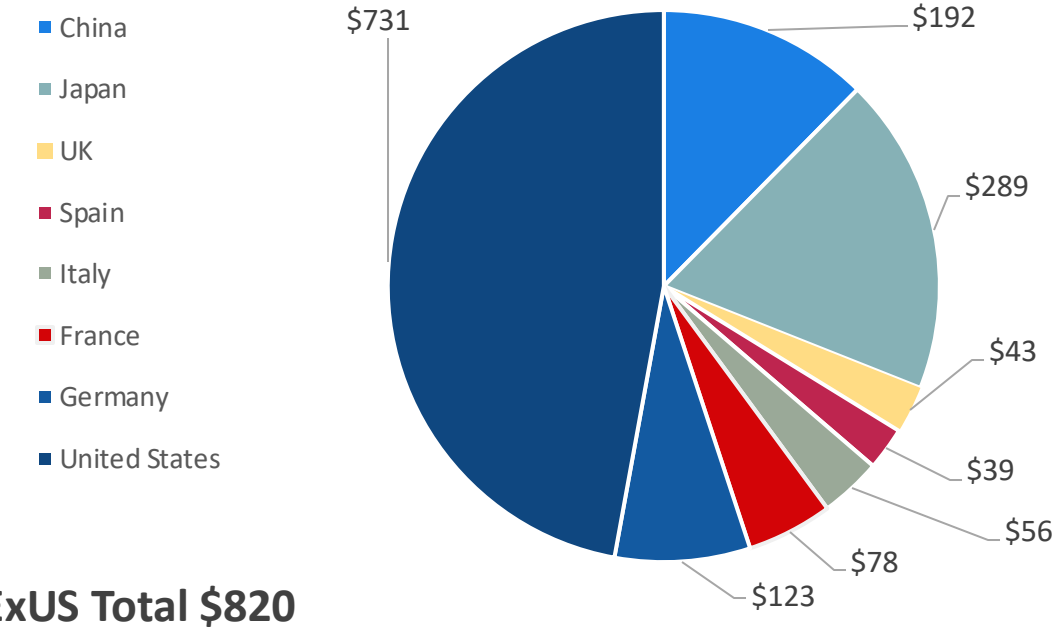
1. Wei-Chu Xu, et al., Bioorganic & Medicinal Chemistry https://doi.org/10.1016/j.bmc.2019.06.017,

C. difficile Infection: Large Growing Market

Global Market

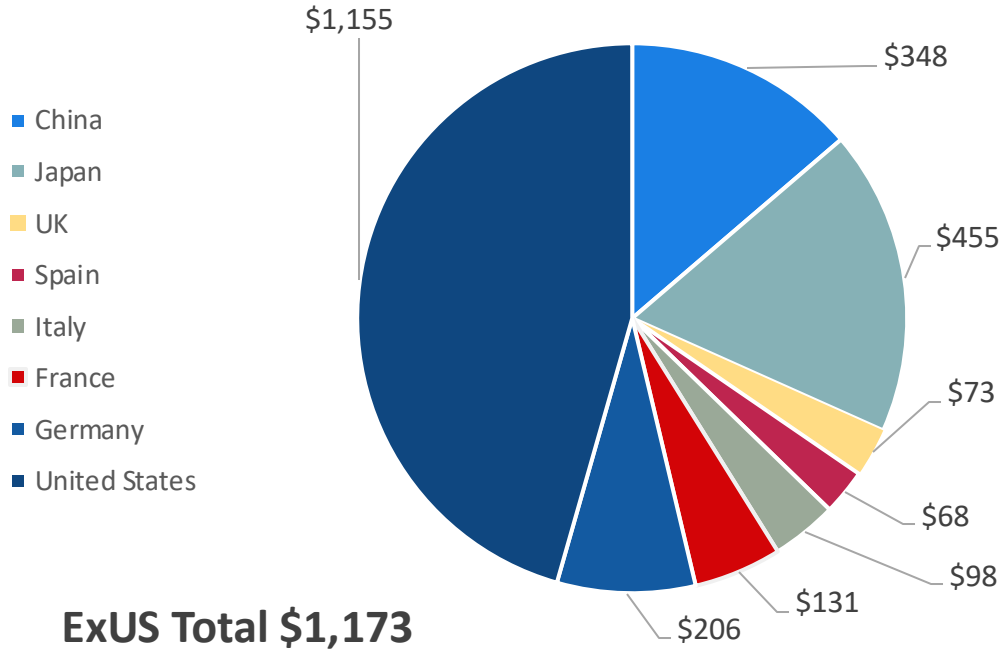
Current and Forecast (2023-2032)

2023 TOTAL $1.5bil



ExUS Total $820

2032 TOTAL $2.3bil



ExUS Total $1,173

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

* *Clostridium* Difficile Infection (CDI) -Market Outlook, Epidemiology, Competitive landscape, and Market Forecast; 2022 to 2032; Thelansis, June 2023

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 gram-positive bacterial infections

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 recurrence[1]

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

Ibezapolstat Clinical Trial Designs for CDI

Segment 2A Open-Label

- Phase 2 dose (450 mg BID)
- n = 10
- 6 sites (US)

After first 10 patients completed treatment, Trial Oversight Committee assessed ibezapolstat safety profile relative to treatment outcomes and recommended early termination of Ph2A

Segment 2B Double-Blind Active-Controlled

ibezapolstat 450 mg BID (n = 16), 10 days

vancomycin (n = 14), 125mg QID, 10 days

28 sites (US); observed aggregate blinded data discontinued the Ph 2b due to success; trial performed as anticipated for ibezapolstat and VAN control with high rates of clinical cure observed across the trial without any emerging safety concerns

Ibezapolstat for Oral Treatment of *C. difficile* Infection

An International Phase 3 Double-Blind Vancomycin-Controlled Trial (IBZ-ASPIRE-1 and IBZ-ASPIRE-2) at up to 150trial sites

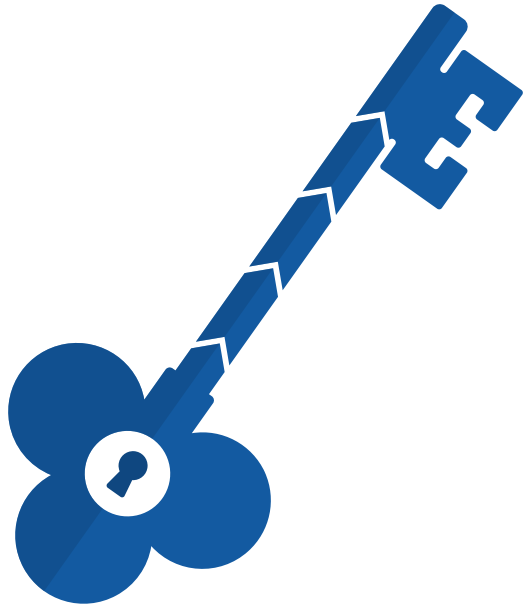
Ph3 (US and Ex-US) 450 patients

Ph 3 (US and Ex-US) 450 patients

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

ACX-375C Highlights

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 List[1]
- 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 infections[2]

2

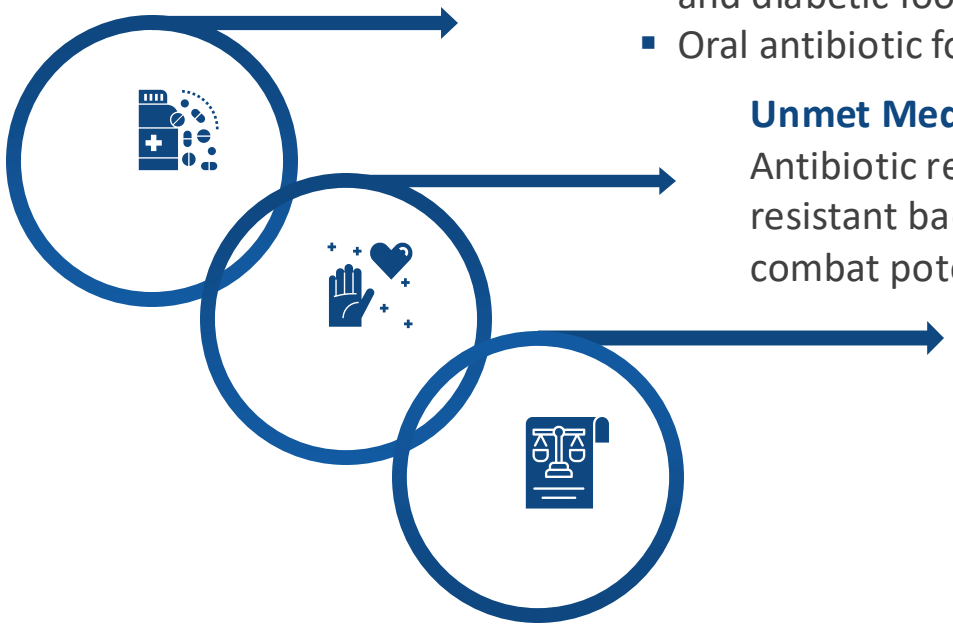
VRE hospital infections exceeded carbapenem-resistant (CR) Acinetobacter, MDR *Pseudomonas aeruginosa* and CR Enterobacteriaceae infections combined[2]

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)

ACX-375C Highlights



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 inhilation anthrax

Unmet Medical Need

Antibiotic resistance to currently used antibiotics; including daptomycin and linezolid-resistant bacteria[1,2]; bacterial resistance has emerged to all current available antibiotics to combat potential bioweapons of mass destruction such as anthrax[3] (need to add reference)

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 IIIC Inhibitors, with other country-level filings in process; expire December 2039.
- QIDP, Fast Track and NCE eligible (potential 10 years of market exclusivity).

1. Jernigan, et al., Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012–2017, *N Engl J Med* 382:1309-19; (2020)
2. Wei-Chu Xu, et al., Bioorganic & Medicinal Chemistry https://doi.org/10.1016/j.bmc.2019.06.017

Capitalization Summary

Cap Table as of 09/30/24	
Common Shares Outstanding	16,770,378
Warrants (WAEP: $3.28)	6,136,245
Stock Options (WAEP: $5.05)	3,880,000
Fully Diluted Shares Outstanding	**26,786,623**

Balance Sheet as of 09/30/24 ($mm)	
Cash & Cash Equivalents	$3.7
Total Assets	$3.8
Total Debt	$0
Total Liabilities	$3.2
Shareholders' Equity	**$2.7**

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

CPA, Co-Founder & CFO

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

Management Product Development Team

Bob DeLuccia, Co-founder & Executive Chairman

>50 years experience in pharmaceutical industry: product development, Regulatory Affairs, manufacturing, sales and marketing ,including 4 antibiotics with global pharma/ biopharma companies. Former Senior Executive at Pfizer; President, Sanofi U.S. Pharma, and CEO or Chairman of 3 publicly traded biopharmaceutical companies

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. President and CEO of Universal Regulatory Affairs consulting firm. 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 (cell therapies), biologics, pharmaceuticals and devices; Clear Path Developmenlest, 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

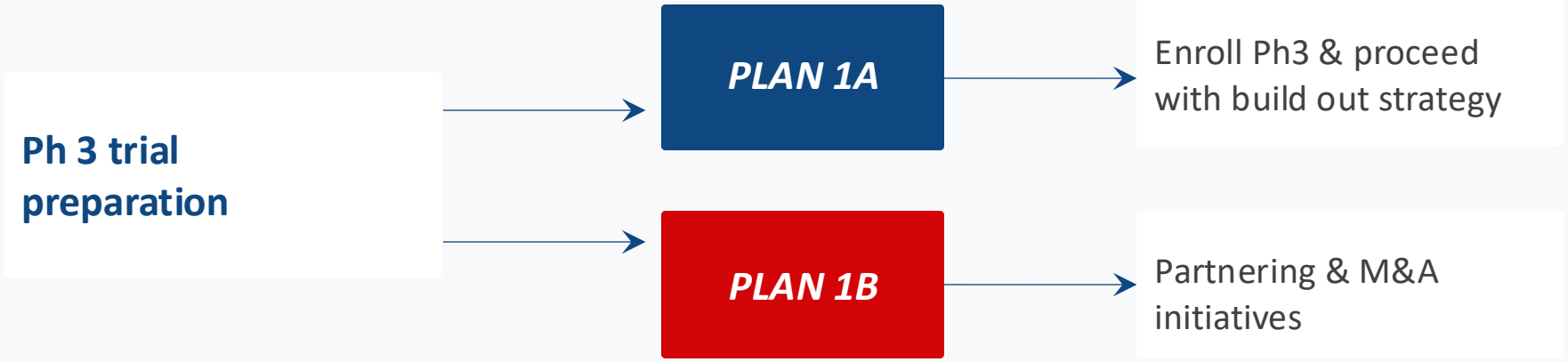
- **Fred Hassan,** Director, Warburg Pincus; Previously Chairman & CEO of Schering-Plough and of Pharmacia, prior EVP of American Home Products (Wyeth) and CEO of Sandoz US Pharmaceuticals; Board of Directors of Precigen (formerly Intrexon) and Time Warner, Bausch & Lomb and Amgen

**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*

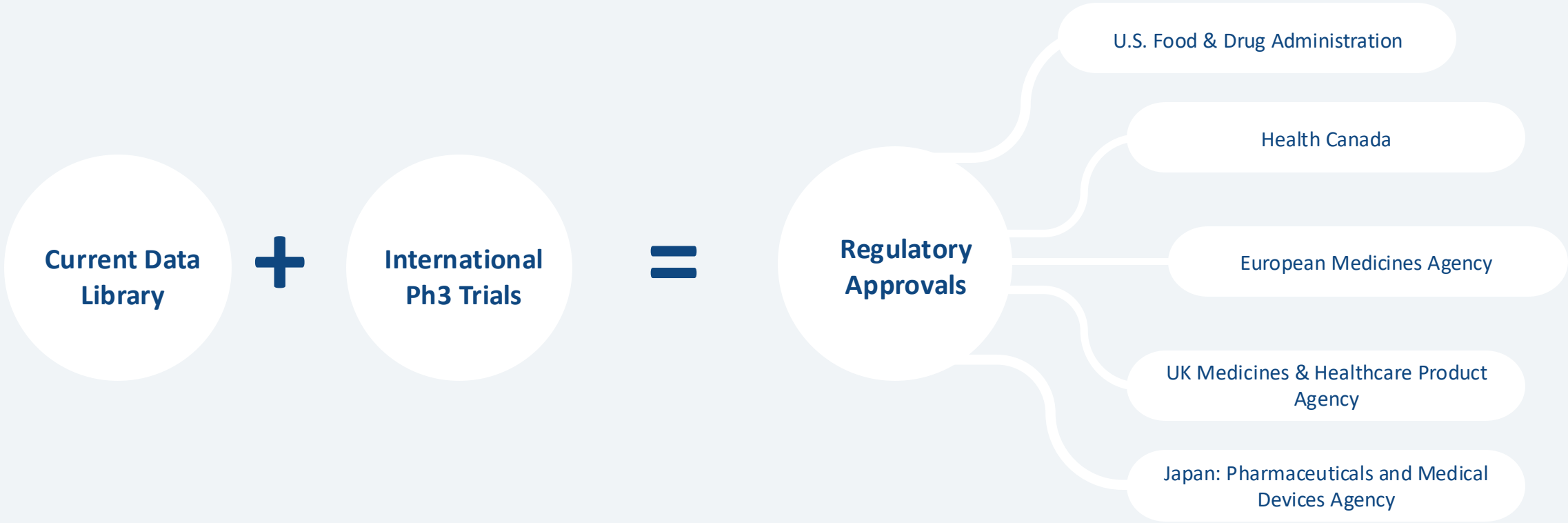
Strategic Alternatives

OBJECTIVE

In parallel with Ph3 trial preparation, explore strategic alternatives



Proposed Pathway To Commercialization



Recent M&A / Licensing Transactions

June 2023

Shionogi buys Qpex Pharma, an early-stage developer of beta lactamase inhibitor for drug resistant gram-negative bacterial infections. Deal terms - $100 million upfront and up to $40 million in downstream milestones. ***Lead antibiotic candidate was in Ph1b***.

March 2023

Sebela Pharmaceuticals acquires Destiny Pharmaceuticals, developer of a microbiome therapeutic to treat patients with recurrent C diff, in a structured deal valued at up to $570 million plus tiered double-digit royalties.

May 2022

Innoviva buys Entasis, in a deal valued at $113 mm for an antibiotic which succeeded in Phase 3 trials and was ready to apply for FDA approval. Clinical indication is quite small patient numbers – **Acinetobacter baumannii**. Deal was 50% premium over closing price day prior to announcement.

October 2021

Novartis' Sandoz acquires cephalosporin business from GSK acquiring revenue streams of $140 million per year. Deal terms not announced but Sandoz confirmed antibiotics are the centerpiece of their product pipeline.

November 2020

Tillotts Pharma buys fidaxomicin rights in EU, Middle East and Africa from Astellas Pharma AG for **$125 mm**. 2023 sales in Europe alone were **$120 million** primarily as last-line therapy.

Board of Directors (Independent)

- **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

**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*

Major Stockholders

INVESTOR	SHARES OWNED
Vanguard Group Inc.	528,350
Prospect Financial Services LLC	329,000
Geode Capital Management, LLC	146,500
Morgan Stanley	106,200
Insiders Total (per most-recent SEC filing)	6,285,770
Total Issued and Outstanding Shares	19,572,511

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Targeting “Priority Pathogens”

March 2025