

**Enabling Breakthroughts in Antimicrobials** 

Perspectives on ABX R&D and Finance Challenges for the Global Leaders Group 2/8/23



# The Current Pipeline is Fragile and Insufficient to Meet the Global Challenge of AMR

### **PRIORITY PATHOGENS**



WHO: 12 priority bacterial pathogens



**CDC: 21 priority pathogens** 



WHO: 19 priority fungal pathogens

### **PIPELINE SNAPSHOT**

45 traditional abx in clinical development; 27 target priority pathogens

Only 12 antibacterial agents in Phase 3 testing, with little clinically differentiation among them

Antifungals > 20 yrs since new class introduced

### **R&D CHALLENGES**

13% success rate for novel NCEs; only 3 novel target drug programs transitioned at Phase III form 2010-2020

Time and money: >10 yrs and US\$1 billion for new abx

Novartis, Sanofi, Bristol Myers, Allergan among pharmas to exit

# R&D Investors Have Lost ~US\$4 Billion on ABX; Hurts small Biotechs access to capital

## **Bankruptcies and Closures**



Launches Xenalta in 2019, announced closure in 2023



\$593 million invested into its program; declared bankruptcy in 2019



~\$670 million expended to earn approval of plazomicin in 2018; bankrupt in 2019



Declared bankruptcy in 2019 while pursuing regulatory approval of inhaled abx

## **Diminished Value and Exits**



\$1.8 billion valuation in 2015 after approval of Xerav; acquired in 2020 for \$43 million



Cut workforce by 75% in 2022 and entered exclusive licensing deal with GSK



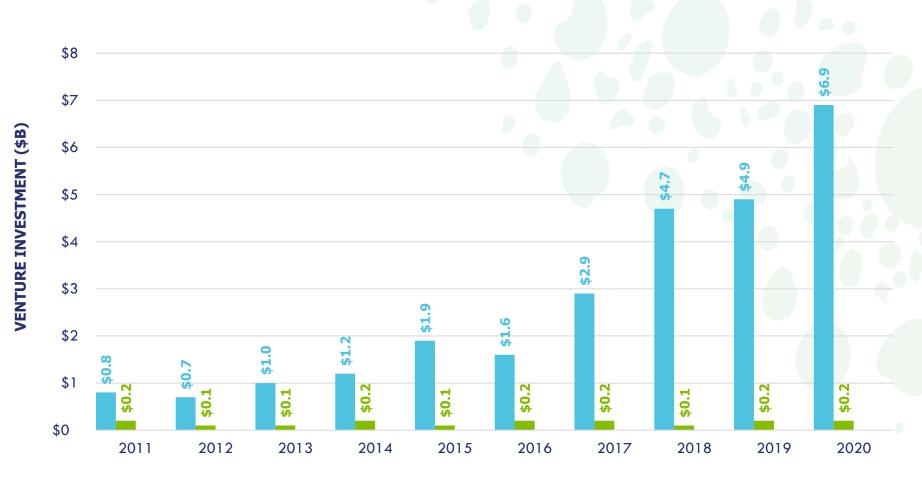
Shelved a promising antibiotics program due to investor sentiment and focused on autoimmune diseases



Exited antibiotics work, rebranded, and focused on ribosome modulation agents

# **Venture Funding for Antibacterials Remains Stagnant**



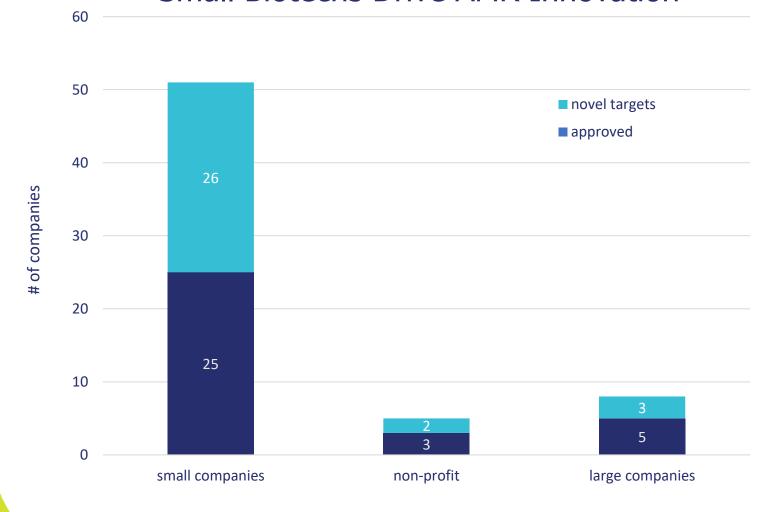


Source: Thomas, CFA, Wessel. BIO. 2022 FEB.

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# Small biotechs are responsible for 80% of antibacterials in the clinical pipeline

## Small Biotechs Drive AMR Innovation



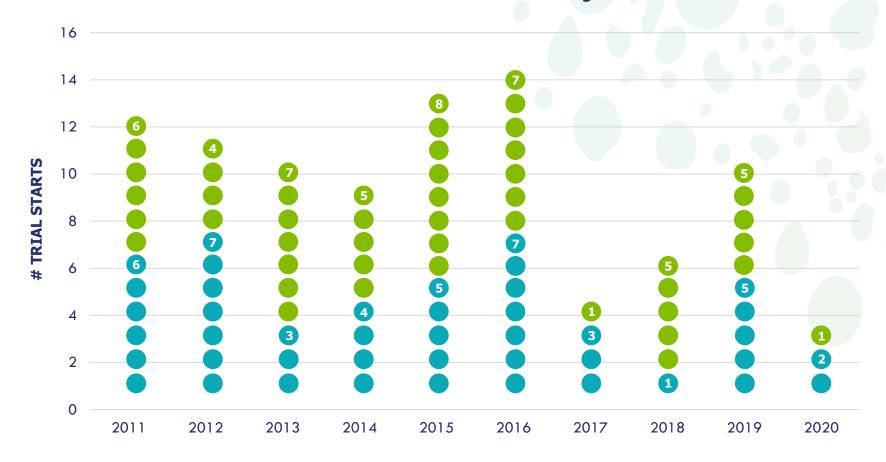
# Paucity of R&D Harms Patients and Creates Innovation Deficit

#### **2011-2022 Clinical Trial Starts for Antibacterial Drug Intervention Trials**





 Clinical trial starts for antibacterial NCEs, 2011-2020. TrialTrove data accessed October 2021. Trials were individually assessed for NCE intervention trials only and trial Phase cohorts deduplicated. A total of 92 NCE intervention trials were initiated during this time period, with 43 for NCEs with novel targets.



Source: Thomas, CFA, Wessel. BIO. 2022 FEB.

## Our investments bridge the gap in antibiotic R&D and provide time for necessary policy reforms that ensure market rewards and re-establish innovation ecosystem

development of novel antibiotics to bridge them up to commercialization, providing an opportunity for governments to implement reimbursement reform and pull incentives that reestablish a sustainable market





We focus our investments on clinicalstage biotechs with the goal of enabling the launch of two to four new antimicrobials by 2030



We advocate for polices to change how society values these lifesaving drugs in order to re-establish a sustainable ecosystem of investment and innovation

# **Strengthening the Pipeline Through Strategic Investment**



**Acinetobacter baumannii** carbapenem resistant



**Pseudomonas aeruginosa** carbapenem resistant



**Enterobacteriaceae** carbapenem resistant 3<sup>rd</sup> gen. cephalosporin resistant



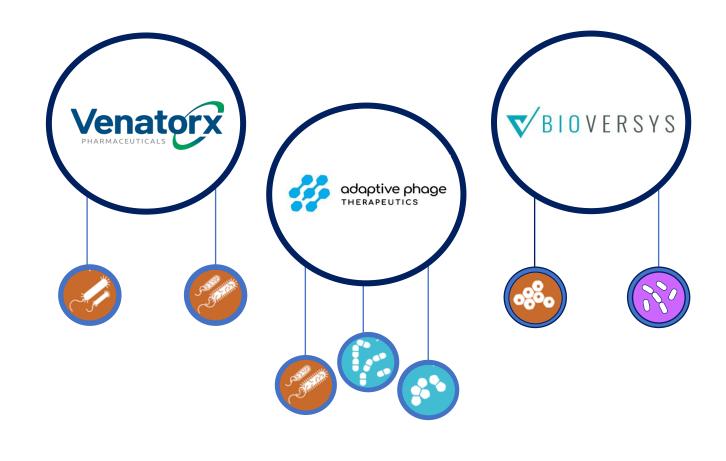
**Enterococcus faecium** vancomycin resistant



**Staphylococcus aureus** vancomycin resistant methicillin resistant



**Mycobacterium tuberculosis** multidrug resistant



# Market reform is Essential to Returning Private Investor Capital to AMR Innovation

The Antimicrobial market us unique and a critical public health good

The market failure has led to bankruptcies of innovative biotechnology companies

Private capital is refractory to investing in AMR innovation

Human capital to drive AMR innovation is at risk

Pull incentives to reward successful innovation delivering high-value new antimicrobials is essential to return capital investment

