Perspectives on ABX R&D and Finance Challenges for the Global Leaders Group

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

**PRIORIT 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 pharmps to exit
R&D Investors Have Lost ~US$4 Billion on ABX; Hurts small Biotechs access to capital

Bankruptcies and Closures

**Nabriva Therapeutics**
Launches Xenalta in 2019, announced closure in 2023

**Melinta Therapeutics**
$593 million invested into its program; declared bankruptcy in 2019

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

**Aradigm**
Declared bankruptcy in 2019 while pursuing regulatory approval of inhaled abx

Diminished Value and Exits

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

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

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

**Macrolide Pharmaceuticals**
Exited antibiotics work, rebranded, and focused on ribosome modulation agents
Venture Funding for Antibacterials Remains Stagnant

Source: Thomas, CFA, Wessel. BIO. 2022 FEB.
Small biotechs are responsible for 80% of antibacterials in the clinical pipeline.
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 de-duplicated. 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

“Invest in the clinical development of novel antibiotics to bridge them up to commercialization, providing an opportunity for governments to implement reimbursement reform and pull incentives that re-establish a sustainable market.”

We focus our investments on clinical-stage 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, 3rd 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 is 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