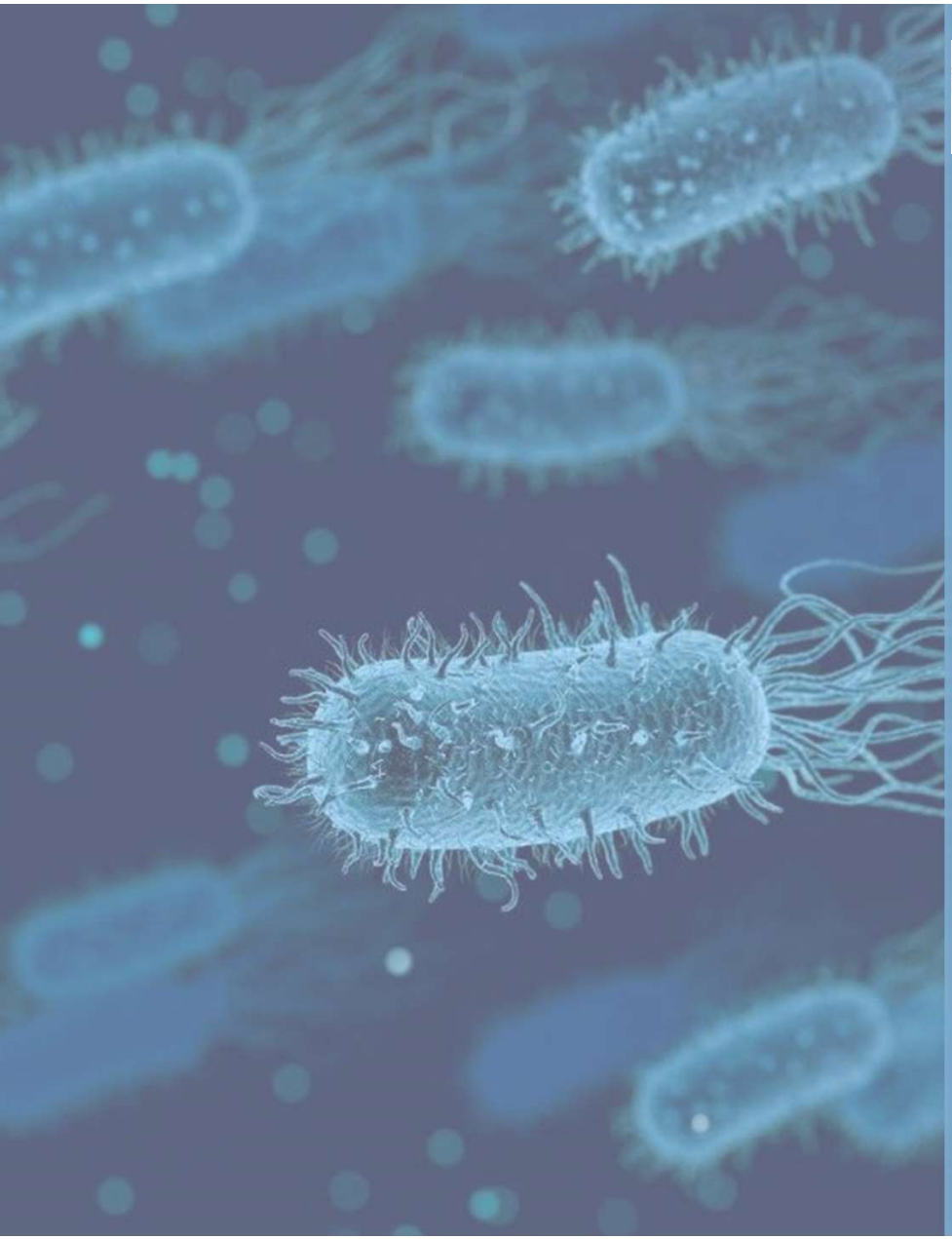

Improving the economic environment of AMR R&D

October 16, 2023

World Health Summit

Dr. Marc Gitzinger CEO BioVersys, President of BEAM Alliance

The AMR Innovation Landscape

SMEs hold the portfolio...

Preclinical
79%

171 out of 217 preclinical products

Clinical
73%

59 out of 80 clinical products

*: 2021 WHO report on antibacterial pipeline
https://www.who.int/publications/i/item/9789240047655

... but may soon disappear

Source: 

Products will be lost

Talents will move to other therapeutic field

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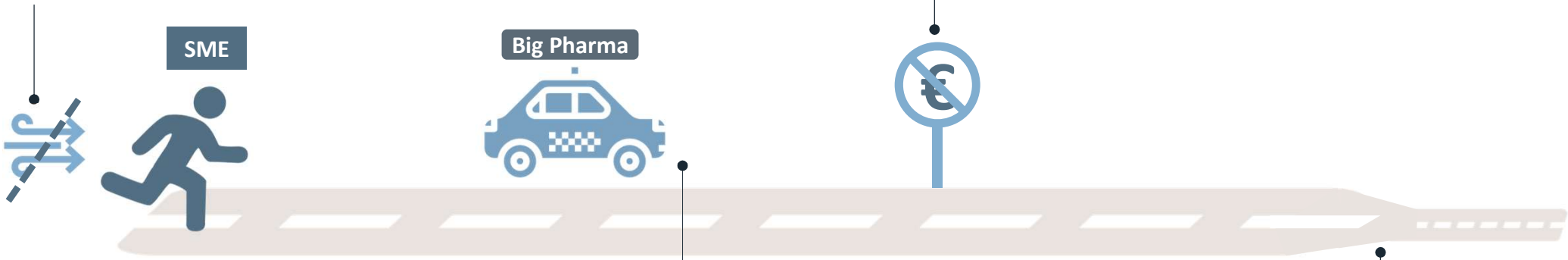
SMEs are Struggling to Advance their Assets

4 Public funding does not reach SMEs sufficiently and effectively

Heavy reliance on private investors

1 Generic-focused market and short treatment time

Low pricing and possible misuse



Partnering opportunities with Big Pharma for late-stage development are rare **3**

Lack of financial resources & skills

Stewardship policies lead to low volume of sales **2**

Revenues do not recoup R&D costs

➔ SMEs must go far beyond their core business and eventually fail (bankrupt) as the revenues never allow to recoup R&D investments, private investors are deserting the field, like big pharma

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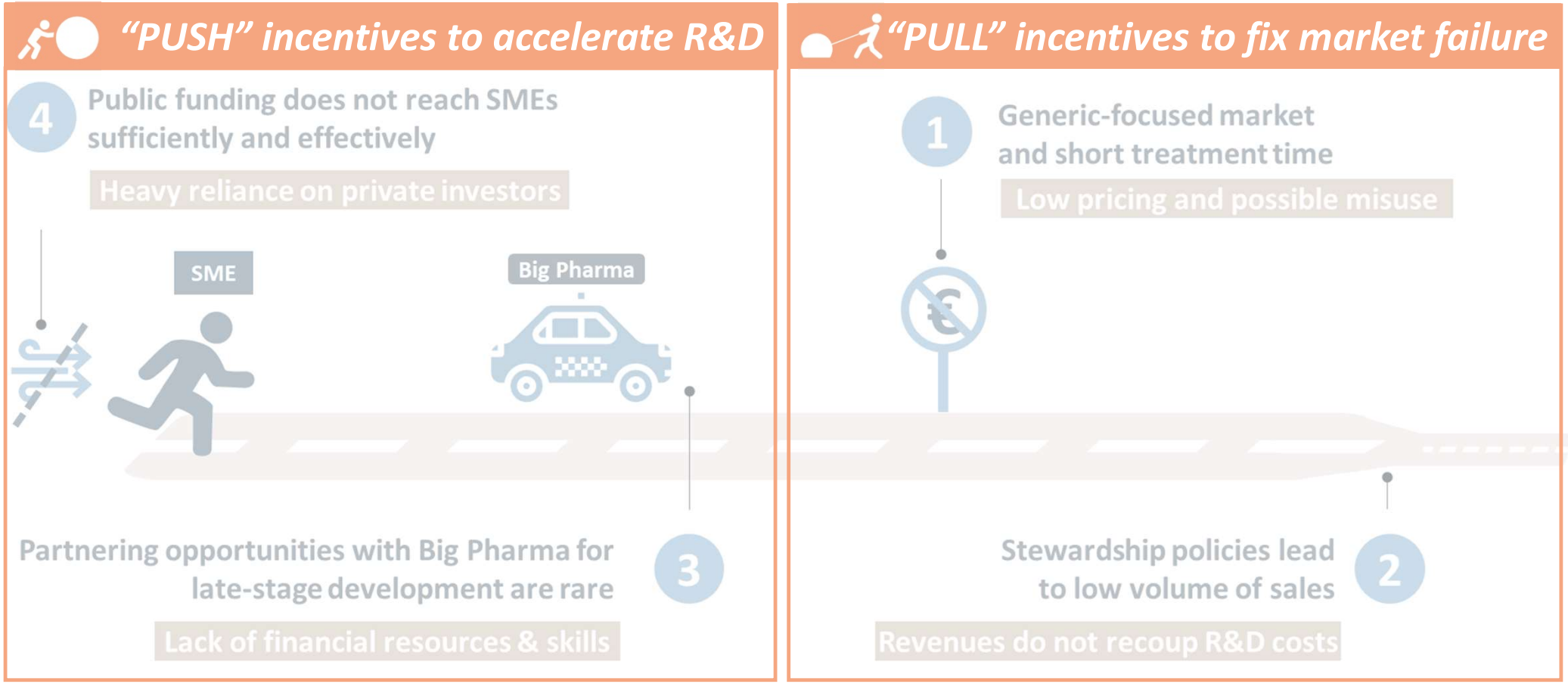
Incentives are Required to Support the Ecosystem



➔ **PUSH incentives are needed to de-risk R&D steps, but they can't fix the problem alone: PULL incentives (probably a mix of measures) are urgently needed to save the portfolio and their developers**

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PUSH funding helps but makes no miracle

- PUSH support is limited

CARB-X
Combating Antibiotic-Resistant Bacteria

AMR ACTION FUND

- Even successful support up to market uptake led to failure

ACHAOGEN

ZEMDRI™
(plazomicin) Injection

Achaogen spent 15 years and a billion dollars to win FDA approval for Zemdri
They received $124 million from BARDA (+ CARB-X, etc.)

PUSH without PULL is just buying time

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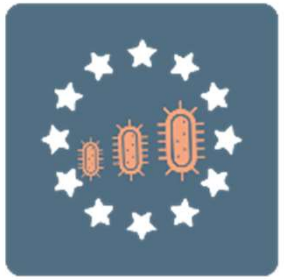
Witnessing the evolution of the ecosystem

The overall maturity of European SMEs (and the corresponding pipeline) is decreasing

Meanwhile

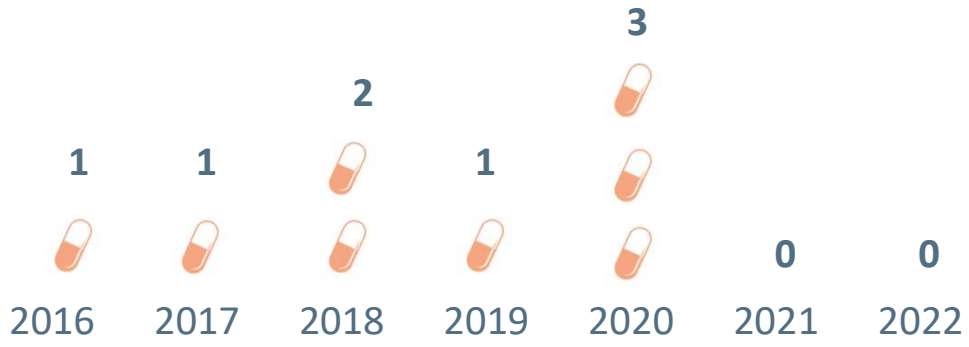
AMR is increasing in Europe



+ 20%

From 2016 to 2019, the annual number of cases of AMR infections and attributable deaths increased by 20%, reaching 865,000 and 39,000 respectively
See ECDC Report (here): Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020 (2022)

New drug approvals for the EU market remain rare



See Outterson et al (here): Patient Access in 14 High-Income Countries to New Antibacterials Approved by the US Food and Drug Administration, European Medicines Agency, Japanese Pharmaceuticals and Medical Devices Agency, or Health Canada, 2010-2020 (2021)

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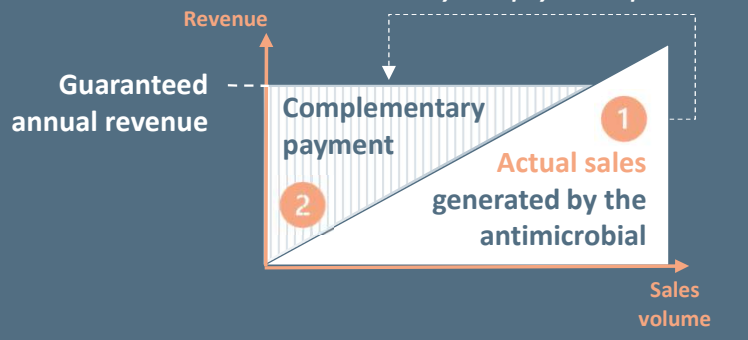
Two main options for a PULL incentive

Subscription contract

If the sales of the antimicrobial is below an agreed threshold, the health system pays a compensation



Relevant for a single-country mechanism, but uncertain at EU27 level

Transferable Exclusivity Extension

If the TEE is sold to another company, the sale allows the innovator to be rewarded

If the TEE is used by the innovator company for another product of its portfolio, the revenue generated by the recipient drug rewards the development of the new antimicrobial

Effective even within the European Union

How to change the AMR economic environment in Europe?

#1 Time plays against us

We need a simple, pan-EU solution, readily implementable

#2 Size matters

Required income
$2-3 billion

X

EU fair share
29-39%

=

+/- €0.6-1.2 billion*
Reward per new antimicrobial in the EU

#3 Strength in numbers

Pan-EU TEE
to reward innovation

+

National subscription
to ensure access

=

A hybrid model
to meet all needs

* *By way of comparison: i) the PASTEUR Act in the USE envisions rewards ranging from $0.75 to 3 billion and ii) AMR costs about €1.1 billion to the health care systems of EU/EEA countries*

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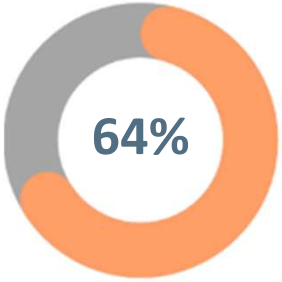
PULL Incentives are Not a Cost, but An Investment

New antimicrobials support modern medicine for a long time



106/164 approved direct-acting NCE antibiotics are still active

The global benefits of a significant PULL incentive are astonishing!

G7	Total Cost (Discounted)	Lives Saved	DALYs Saved	Value of DALYs Saved	Benefit: Cost Ratio
10-Year	$11.7 bn	518,000	19.5 million	310.6 billion	27:1
30-Year	$38.9 bn	9,933,000	374.5 million	4,874.2 billion	125:1

G7 Investments in New Antibiotics Would Pay Off Big—For Everyone

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BEAM Cy page

https://beam-alliance.eu

THANK YOU FOR YOUR INTEREST

BIOVERSYS

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DIVERSIFIED, INNOVATIVE AND DE-RISKED PIPELINE

Next-generation antimicrobial drugs, two proprietary platforms

Program	Indication	R&D/Preclinical	Phase 1	Phase 2	Phase 3	Expected Key Catalyst	Commercial Rights	FDA QIDP Designation
BV100 *Novel MoA* *Rifabutin IV form.* ***Ansamycin platform***	Hospital infections *Acinetobacter baumannii* (VABP/HABP & BSI)					Phase 2 data read-outs: Q3 2023 – Q1 2024		✓
Alpibectir *New Antibiotic Class* *Eto-potentiator* ***TRIC platform***	Tuberculosis: • Multi-drug resistant • TB-Meningitis					End of Phase 2a: Q2 2024	GSK Option[1]	✓
BV200 *Anti-virulence* ***TRIC platform***	Atopic dermatitis *Staphylococcus aureus* Innosuisse					IND Filing: 2025		
BV500 ***Ansamycin platform***	CF and COPD: Non-tuberculous mycobacteria infection					IND Filing: H1 2025		
BV Discovery	Targets undisclosed							

Source: Company information. Note: Data as of June 30, 2023; 1. For Alpibectir, GSK has an option to in-license commercial rights.
VABP: Ventilator Associated Bacterial Pneumonia; HABP: Hospital Acquired Bacterial Pneumonia; BSI: Blood Stream Infections; Eto: Ethionamide; FDA QIDP: FDA Qualified Infectious Disease Product Designation: 5 years additional market exclusivity (until 2044 for BV100) and the possibility of fast-track approval; MoA: Mechanism of Action; IND: Investigational New Drug. CF: Cystic Fibrosis; COPD: Chronic Obstructive Pulmonary Disease