

Focused on Growth and Innovation

Half-year results 2023

**Webcast presentation** 

August 15, 2023



# **David Veitch**

Chief Executive Officer

Introduction



## Disclaimer and forward-looking statements

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## HY 2023 – Key achievements

Zevtera NDA submission in August 2023

Cresemba

- 14% y-o-y increase of global in-market sales to > USD 393 mn\*
- Launched in Japan

Financial Performance

- 57% y-o-y increase in Cresemba & Zevtera related revenue
- Operating profit of CHF 36.9 mn
- Net profit of CHF 31.9 mn

Financial strength

- Increase of mid-year cash position to CHF 112.9 mn
- Net financial debt reduction by CHF 22 mn to CHF 38.1 mn

\*MAT Q1/2023 vs. Q1/2022; MAT: Moving annual total; Source: IQVIA Analytics Link, March 2023



## Potential for sustainable growth and value creation

	Products / Product candidates / Indication	Preclinical	Phase 1	Phase 2	Phase 3	Market	Notes
Antifungals	Cresemba® (isavuconazole) Invasive aspergillosis and mucormycosis (US, EU, China and several other countries)¹ Aspergillosis (including invasive aspergillosis and chronic pulmonary aspergillosis), mucormycosis and cryptococcosis (Japan)					0	Launched in H1 2023
Antibiotics	Zevtera® (ceftobiprole)  Hospital- and community-acquired bacterial pneumonia (HABP, CABP) (major European and several other countries)  Staphylococcus aureus bacteremia (SAB)², acute bacterial skin and skin structure infections (ABSSSI)² and community-acquired bacterial pneumonia (CABP) (US)  DXR inhibitor program  Infections caused by multi-drug resistant Gram-negative bacteria  Internal research				0		Submitted New Drug Application (NDA) in August 2023
	In-licensing focus						

<sup>2</sup> Phase 3 program was funded in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA).



<sup>1</sup> The registration status and approved indications may vary from country to country.

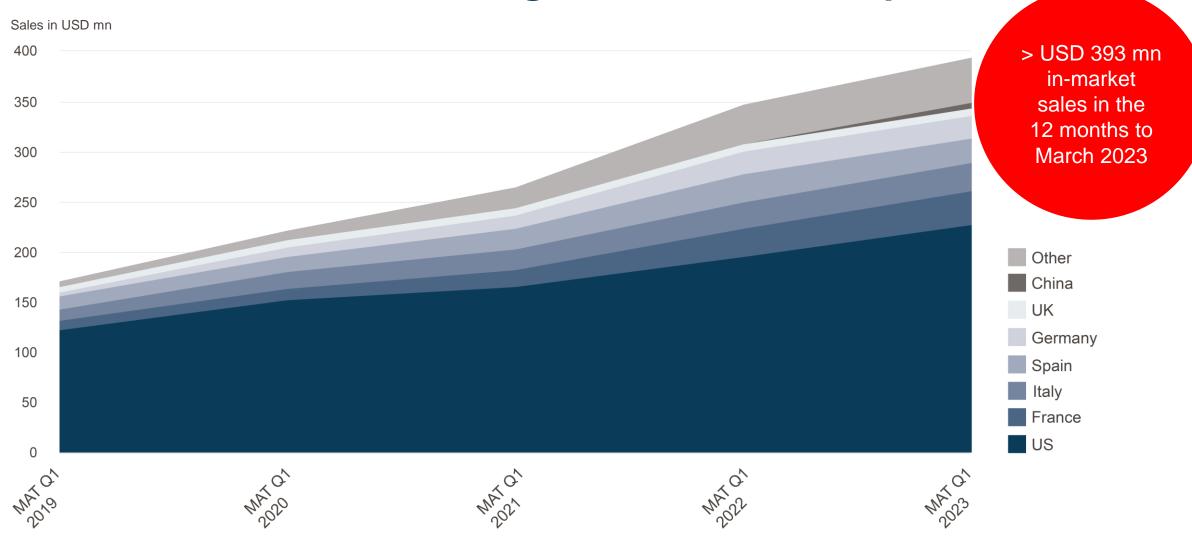
## **Adesh Kaul**

Chief Financial Officer

Commercial & financial update



Cresemba continues strong in-market sales uptake

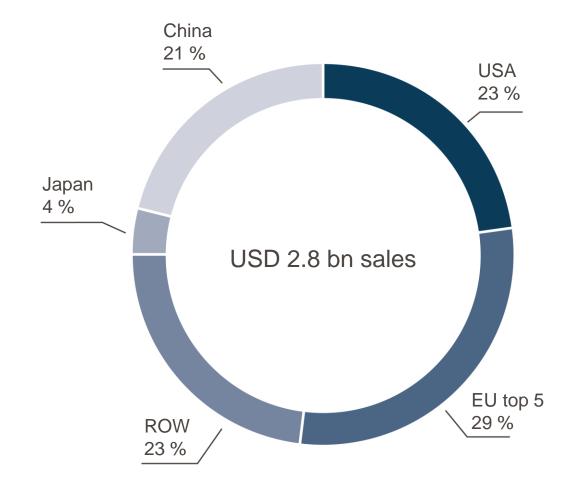


MAT: Moving annual total; Source: IQVIA Analytics Link, March 2023



# Significant growth potential for Cresemba

- USD 2.8 bn sales of best-in-class antifungals\*
   (MAT Q1 2023)
- Recently launched in Japan and China, representing 25% of global potential



<sup>\*</sup> Best-in-class antifungals: Cresemba (isavuconazole), posaconazole, voriconazole, AmBisome, anidulafungin, caspofungin, micafungin



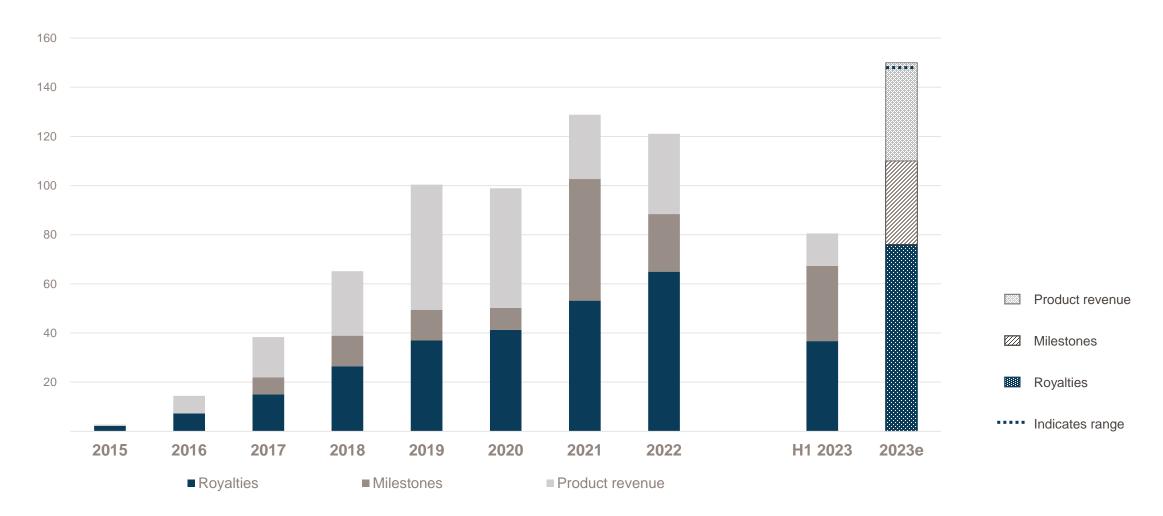
MAT: Moving annual total; Source: IQVIA Analytics Link, March 2023

# **Strong financial half-year results 2023**

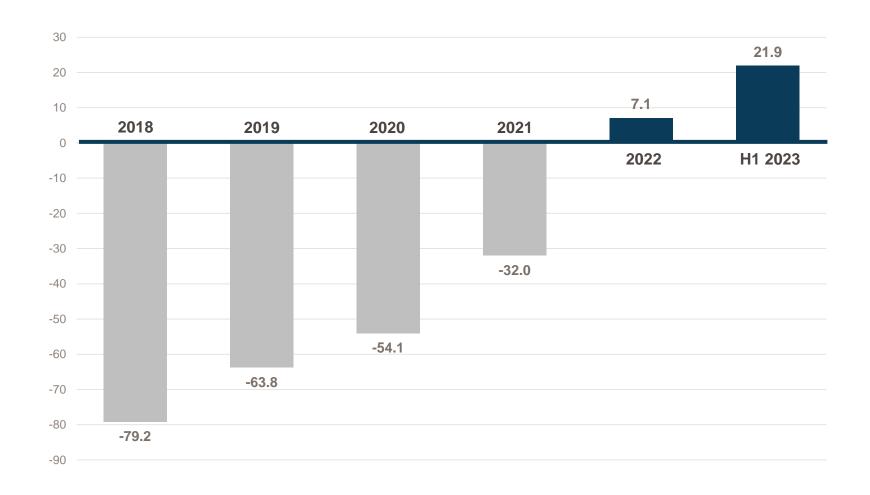
In CHF mn	H1 2023	H1 2022	
Cresemba & Zevtera related revenue	80.5	51.2	
Royalty income	36.7	28.9	
Total revenue	84.9	57.6	
Cost of products sold Operating expenses	10.0 38.0	14.9 52.8	
Operating profit/loss	36.9	(10.0)	
Net profit/loss	31.8	(12.2)	

Note: Consistent rounding was applied.

# Cresemba & Zevtera related revenue breakdown (in CHF mn)



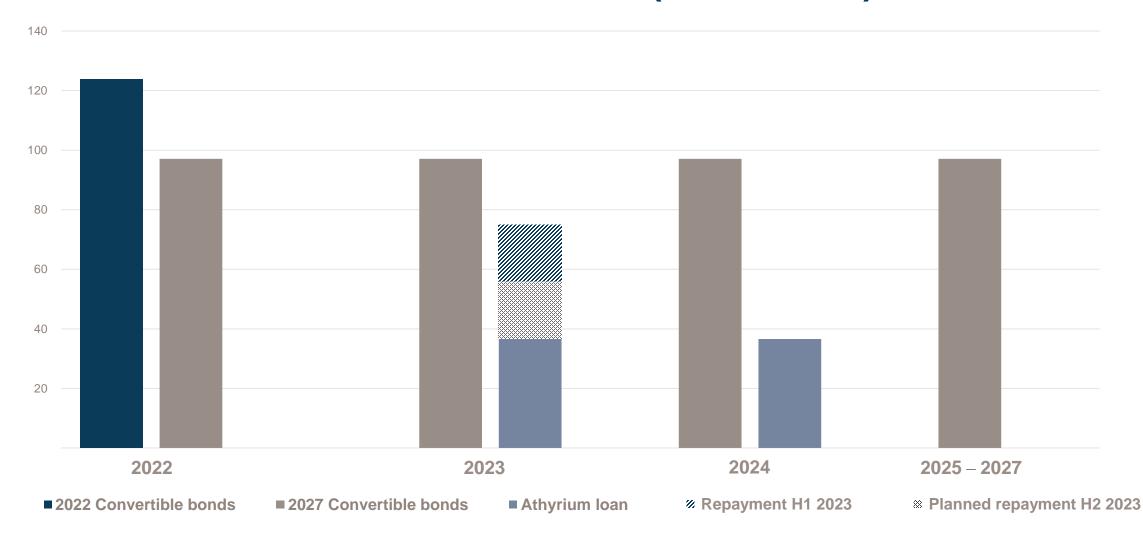
# Cash flows from operating activities (in CHF mn)



Note: Consolidated figures in conformity with US GAAP; rounding applied consistently



## Continued reduction of debt level (in CHF mn)



Note: Figures as of the beginning of the fiscal year; rounding applied consistently



# Increased revenue and profit guidance for FY 2023

In CHF mn	FY 2022	FY 2023* (previous guidance)	FY 2023* (new guidance)	
Cresemba & Zevtera related revenue	122.3	145 – 148	147 – 150	
Royalty income	65.0	~74	~76	
Total revenue	147.8	155 – 158	157 – 160	
Cost of products sold Operating expenses	24.6 104.6	25 <b>–</b> 28 ~80	25 <b>–</b> 27 ~80	
Operating profit	18.5	45 – 50	50 – 55	
Net profit	12.1	36 – 41	41 – 46	

<sup>\*</sup>Excluding the impact of in-licensing activities

Note: Consistent rounding was applied.



# Marc Engelhardt Chief Medical Officer

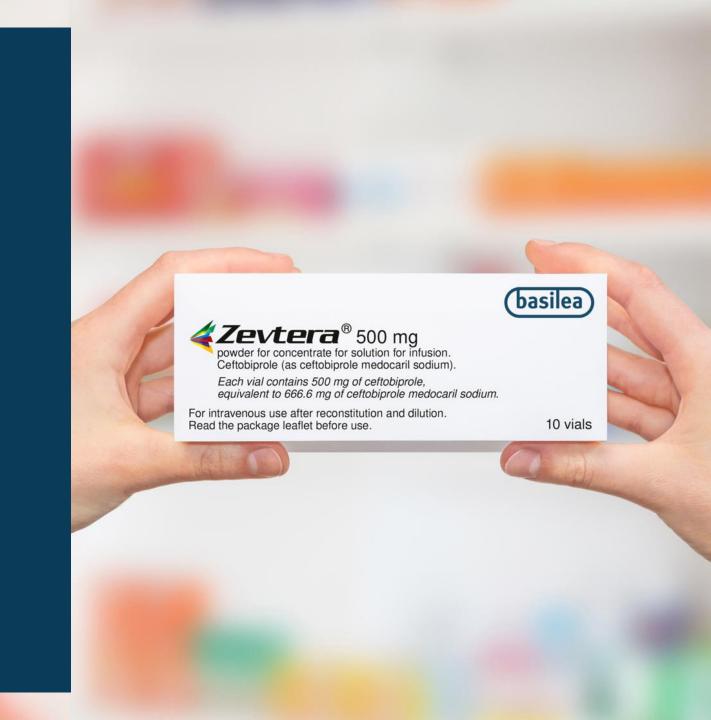
Portfolio update



**Antibacterial** 

# Zevtera® (ceftobiprole)

Severe bacterial infections

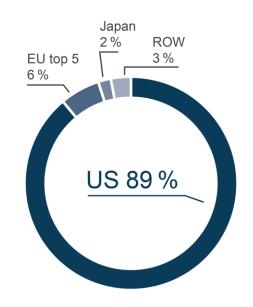


## Ceftobiprole — Place in therapy

- Excellent treatment option in difficult-to-treat patients presenting to the hospital with severe infections, especially
  when the clinician suspects involvement of Gram-positive pathogens including Staphylococcus aureus
- Single agent first-line bactericidal broad-spectrum therapy with proven efficacy in SAB, ABSSSI and CABP, enabling to treat these vulnerable patients effectively early in their disease to achieve recovery
- Ceftobiprole is differentiated versus competitors in various clinically important aspects, including:
  - The strong, bactericidal activity against MSSA and MRSA
  - A robust Gram-negative coverage
  - Efficacy demonstrated in pulmonary infections in phase 3 studies
  - The safety profile reflecting the cephalosporin class
  - The low propensity for resistance development

# The hospital anti-MRSA antibiotic market — A USD 2.6 bn market\* with the US being the most important region

Daptomycin sales by region (2015, before LOE)



Ceftaroline sales by region (MAT Q1 2023)



MRSA: Methicillin-resistant Staphylococcus aureus; LOE: Loss of exclusivity; ROW: Rest Of World; MAT: Moving annual total; Source: IQVIA Analytics Link, March 2023



<sup>\*</sup> Vancomycin, linezolid, teicoplanin, daptomycin, tigecycline, telavancin, ceftaroline, dalbavancin, ceftobiprole, oritavancin and tedizolid (daptomycin and tigecycline are partial sales in the US in IQVIA data)

# Ceftobiprole — Strategy for accessing the US market

- NDA submitted in August 2023 for three indications:
  - 1. Staphylococcus aureus bacteremia (SAB)<sup>1</sup>
  - 2. Acute bacterial skin and skin structure Infections (ABSSSI)<sup>2</sup>



3. Previously completed phase 3 study in community-acquired bacterial pneumonia (CABP) as a third indication<sup>3</sup>

- Phase 3 program largely funded by BARDA (~USD 112 million, or approximately 75 percent of the costs related to the SAB and ABSSSI phase 3 studies, regulatory activities and non-clinical work)
- Commercialization planned through partnership
  - Partnership to be secured prior to regulatory decision



<sup>&</sup>lt;sup>3</sup> Nicholson SC et al. International Journal of Antimicrobial Agents 2012 (39), 240-246.



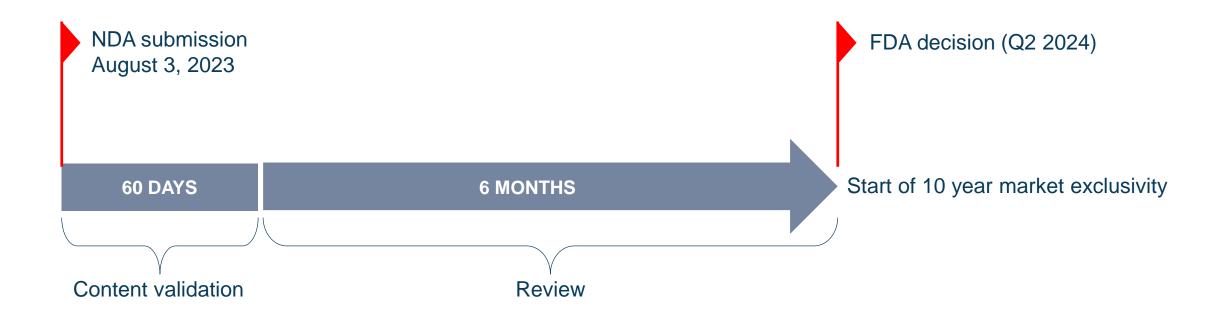
<sup>&</sup>lt;sup>1</sup> Holland TL et al., Open Forum Infect. Dis. 2022, 9: (S931–S932).

<sup>&</sup>lt;sup>2</sup> Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

# FDA's NDA review process for a Qualified Infectious Disease Product

Ceftobiprole was granted QIDP status for SAB, ABSSSI and CABP

QIDP status provides 6 month priority review and extends market exclusivity to 10 years



# Focused launch in area of highest unmet medical need with opportunities for broader utilization

#### Patient numbers in the United States

- Staphylococcus aureus bacteremia (SAB): 120,000 cases¹
- Acute bacterial skin and skin structure Infections (ABSSSI): >600,000 hospitalizations per year<sup>2</sup>
- Community-acquired bacterial pneumonia (CABP):
   >1,500,000 hospitalizations per year<sup>3</sup>

Other indications (e.g. CABP)

ABSSSI leading to bacteremia

SAB-associated bone & joint infections, endocarditis

SAB

- 1. Kourtis AP et al. MMWR Morb Mortal Wkly Rep. 2019;68:214-219.
- 2. Edelsberg J et al. Emerg Infect Dis. 2009;15:1516-8.
- 3. Ramirez JA et al. Clin Infect Dis. 2017;65:1806-1812.



# **Antifungal Cresemba**® (isavuconazole)

Invasive mold infections



hard capsules

#### Isavuconazole

#### Oral use.

Each hard capsule contains 100 mg isavuconazole (as 186.3 mg isavuconazonium sulfate)

14 hard capsules



EU/1/15/1036/002

## Cresemba pediatric development

- A pediatric development plan comprising 2 clinical studies was agreed with the FDA and the EMA
- Successful completion of the plan potentially results in 2 years additional market exclusivity in Europe and 6 months additional market exclusivity in the USA
- Clinical studies were undertaken in collaboration with Basilea's US partner Astellas and completed enrollment in August 2022
- Pediatric label extension in US/Europe is expected in 2023/2024, which would subsequently extend market exclusivity to Sep/Oct 2027

# **David Veitch**

Chief Executive Officer

Outlook



## **Key milestones**

Product	H1 2023	H2 2023	H1 2024
Ceftobiprole (Zevtera)		US NDA submission (August) 🗸	Regulatory decision in the US (Q2)
			Executing US partnership (before regulatory decision)
Isavuconazole (Cresemba)	Launched in Japan 🗸	Pediatric submission	

Increasing Cresemba & Zevtera revenue

In-licensing of anti-infectives (2023 and beyond)

Advancement of preclinical anti-infective assets

## In-licensing focus



#### Partner of choice in the anti-infectives space

- Strong and proven R&D capabilities to bring drugs from research to market
- ✓ Cost-effective business model
- ✓ Experience in accessing non-dilutive funding incentives
- ✓ Financial strength and strong cash flow generation from commercialized brands

#### Antifungals

- Novel mechanisms of action
- Addressing areas of highest unmet medical needs
- Gaining benefits through orphan drug pathways
- Novel formulations

#### Commonalities

- Addressing serious hospital infections with increasing medical need
- Innovative & differentiated assets with potential for successful commercialization
- In-licensing assets from late stage research through to end of phase 2

#### Antibacterials

- Traditional and non-traditional approaches
- Potential for demonstrating superiority
- Balance development risks to optimize market access/label



# Q&A

# Thank you



# Glossary

ABSSSI: Acute bacterial skin and skin structure infections

BARDA: Biomedical Advanced Research and Development Authority

CABP: Community-acquired bacterial pneumonia

EMA: European Medicines Agency

FDA: US Food and Drug Administration

HABP: Hospital-acquired bacterial pneumonia

MSSA: Methicillin-susceptible Staphylococcus aureus

MRSA: Methicillin-resistant Staphylococcus aureus

NDA: New Drug Application

QIDP: Qualified Infectious Disease Product

SAB: Staphylococcus aureus bacteremia

US GAAP: United States Generally Accepted Accounting Principles



#### **Focused on Growth and Innovation**

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