



**Focused on
Growth and Innovation**

Full-year results 2022

Webcast presentation

February 14, 2023



David Veitch

Chief Executive Officer

Introduction



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This communication, including the accompanying oral presentation, contains certain forward-looking statements, including, without limitation, statements containing the words “believes”, “anticipates”, “expects”, “supposes”, “considers”, and words of similar import, or which can be identified as discussions of strategy, plans or intentions. Such forward-looking statements are based on the current expectations and belief of company management, and are subject to numerous risks and uncertainties, which may cause the actual results, financial condition, performance, or achievements of Basilea, or the industry, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: the uncertainty of pre-clinical and clinical trials of potential products, limited supplies, future capital needs and the uncertainty of additional funding, compliance with ongoing regulatory obligations and the need for regulatory approval of the company’s operations and potential products, dependence on licenses, patents, and proprietary technology as well as key suppliers and other third parties, including in preclinical and clinical trials, acceptance of Basilea’s products by the market in the event that they obtain regulatory approval, competition from other biotechnology, chemical, and pharmaceutical companies, attraction and retention of skilled employees and dependence on key personnel, and dependence on partners for commercialization of products, limited manufacturing resources, management’s discretion as to the use of proceeds, risks of product liability and limitations on insurance, uncertainties relating to public health care policies, adverse changes in governmental rules and fiscal policies, changes in foreign currency and other factors referenced in this communication. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements. Basilea disclaims any obligation to update any such forward-looking statements to reflect future events or developments, except as required by applicable law.

FY 2022 – Key achievements

CORPORATE

- Successful implementation of new strategy

FINANCIAL RESULTS

- 22.4% y-o-y increase of royalty income
- Operating profit of CHF 18.5 mn
- Net profit of CHF 12.1 mn

CRESEMBA

- 19% y-o-y increase of global in-market sales to > USD 363 mn*
- Launched in 63 countries
- Completed pediatric program

TRANSITION YEAR

- CHF 15 mn revenue from oncology asset transactions:
 - PARG to Nodus Oncology
 - CLK to Redona Therapeutics**
 - TTK/PLK1 (BAL0891) to SillaJen

BALANCE SHEET

- Repayment of the 2022 convertible bonds
- Debt level reduced without diluting shareholders

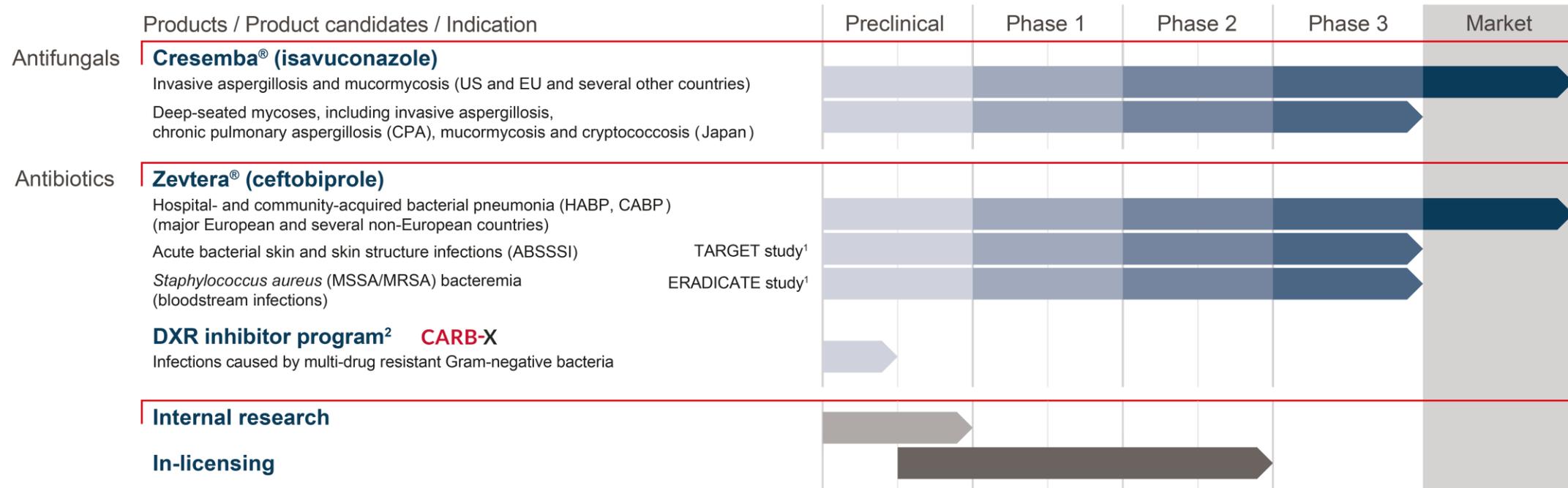
ZEVTERA

- Positive topline results for phase 3 ERADICATE study
- Pre-NDA meeting with FDA

*MAT Q3/2022 vs. Q3/2021; MAT: Moving annual total; Source: IQVIA Analytics Link, September 2022

** formerly: Twentyeight-Seven Therapeutics

Potential for sustainable growth and value creation based on commercialized brands and innovative pipeline



¹ Studies to support US NDA. Phase 3 program is funded in part with federal funds from the US Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA).

² CARB-X's funding for this project is sponsored by Cooperative Agreement Number IDSEP160030 from ASPR/BARDA and by awards from Wellcome Trust and Germany's Federal Ministry of Education and Research.

The content is solely the responsibility of the authors and does not necessarily represent the official views of CARB-X or any of its funders.

Adesh Kaul

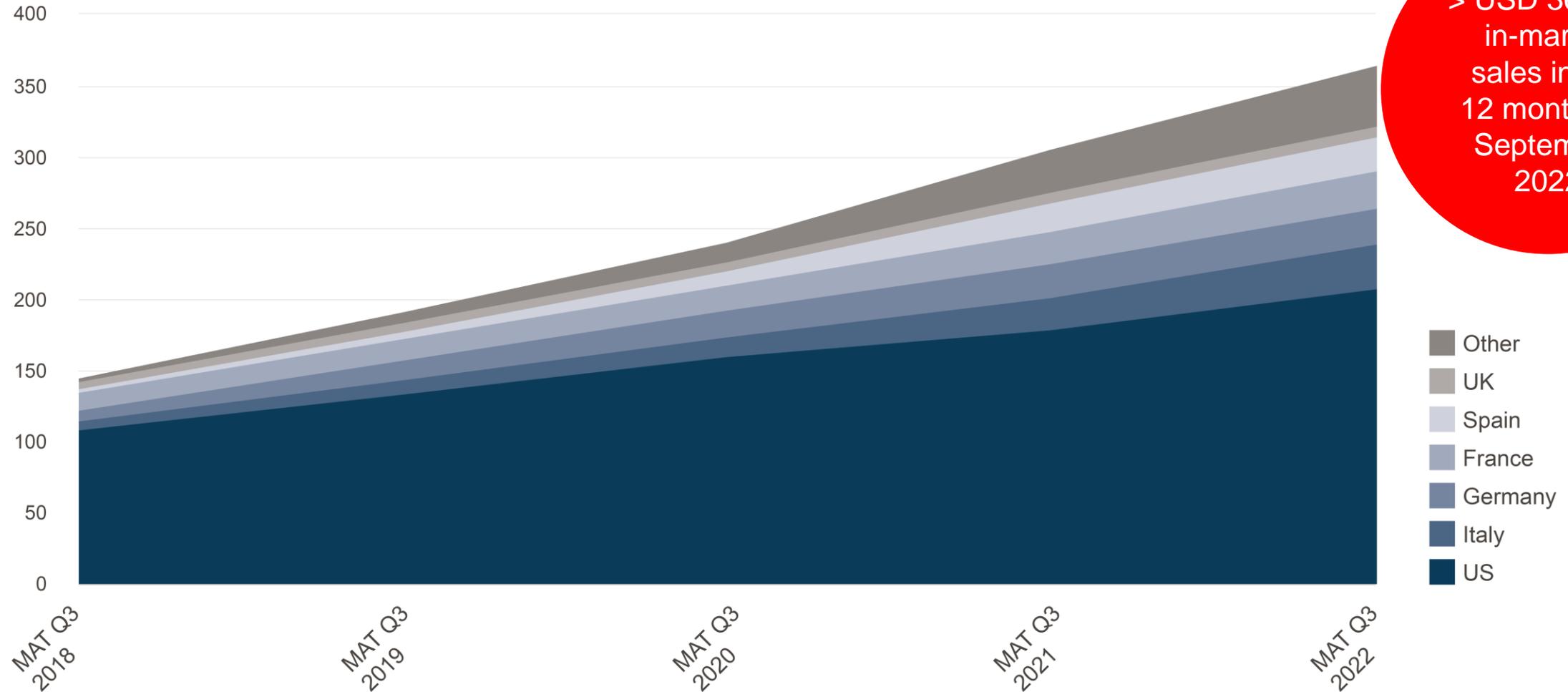
Chief Financial Officer

Commercial & financial update



Cresemba continues strong in-market sales uptake

Sales in USD mn



> USD 363 mn
in-market
sales in the
12 months to
September
2022

MAT: Moving annual total; Source: IQVIA Analytics Link, September 2022



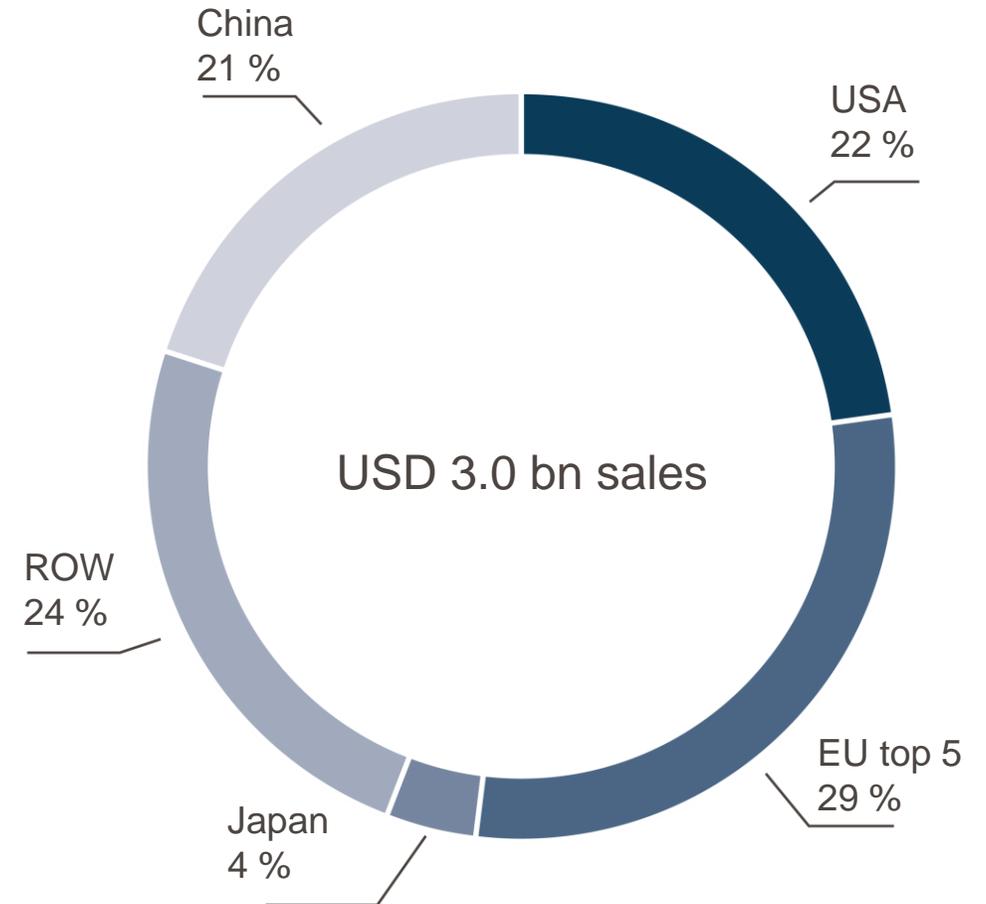
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Significant growth potential for Cresemba

- USD 3.0 bn sales of best-in-class antifungals* (MAT Q3 2022)
- Incremental growth from additional markets representing more than 25% of global potential
 - Launch in Japan coming soon
 - Listed on China's National Reimbursement Drug List (NRDL) for the i.v. treatment
 - Additional country launches

* Best-in-class antifungals: Cresemba (isavuconazole), posaconazole, voriconazole, AmBisome, anidulafungin, caspofungin, micafungin



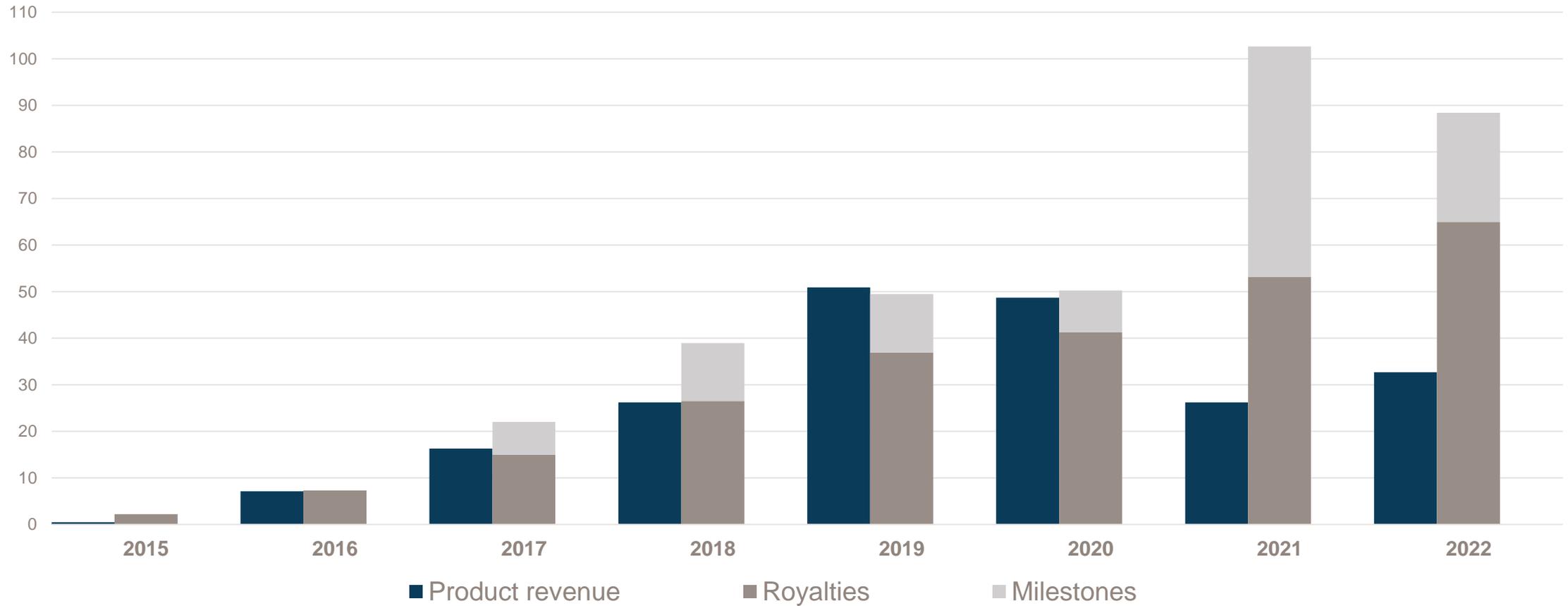
MAT: Moving annual total; Source: IQVIA Analytics Link, September 2022

Exceeded guidance – Strong financial results 2022

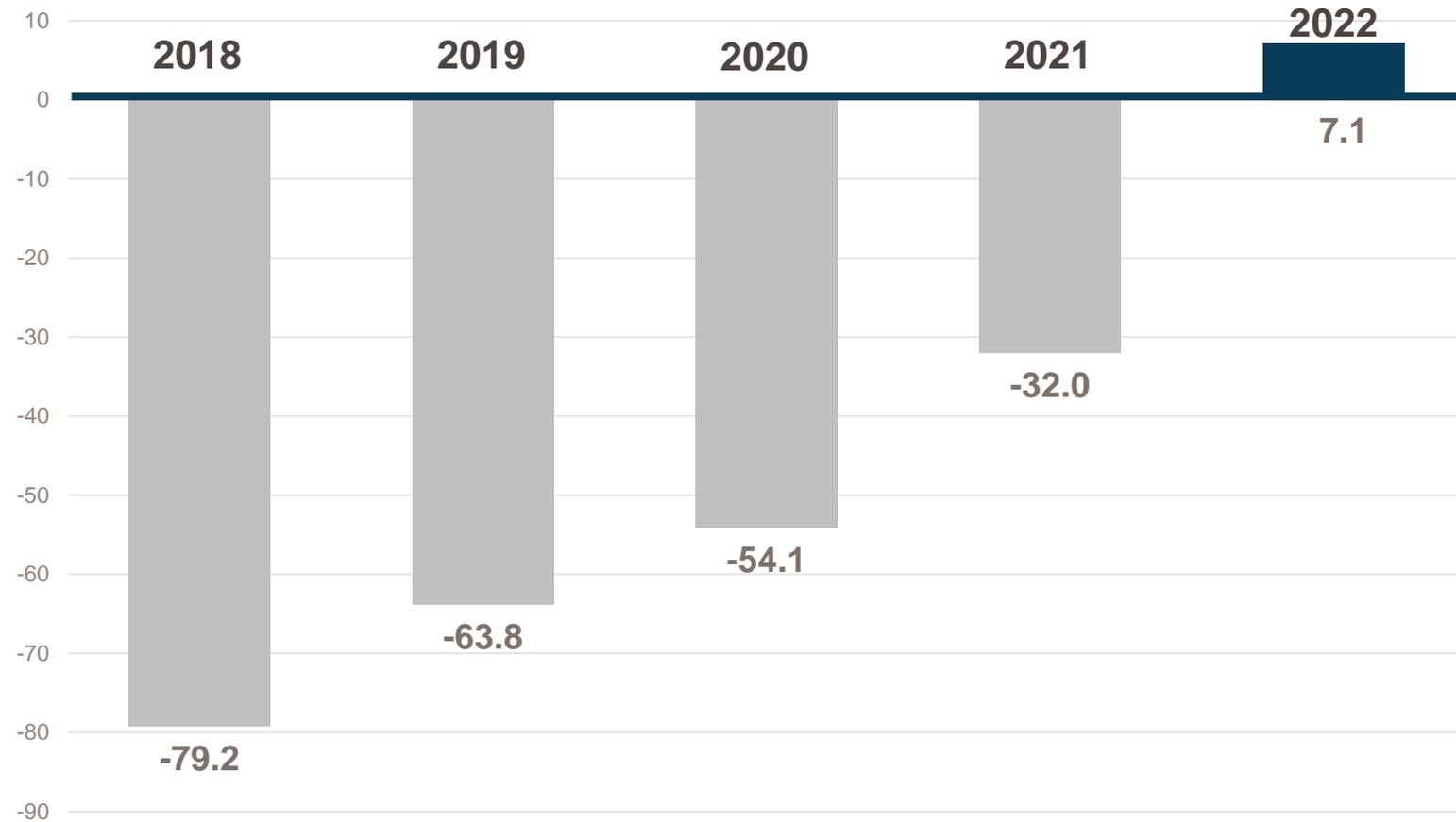
In CHF mn	FY 2022 (actual)	FY 2022 (guidance)
Cresemba & Zevtera related revenue	122.3	98 – 104
Royalty income	65.0	~59
Total revenue	147.8	116 – 122
Cost of products sold	24.6	21 – 24
Operating expenses	104.6	~110
Operating profit/(loss)	18.5	(10 – 15)

Note: Consistent rounding was applied.

Cresemba and Zevtera revenue breakdown (in CHF mn)

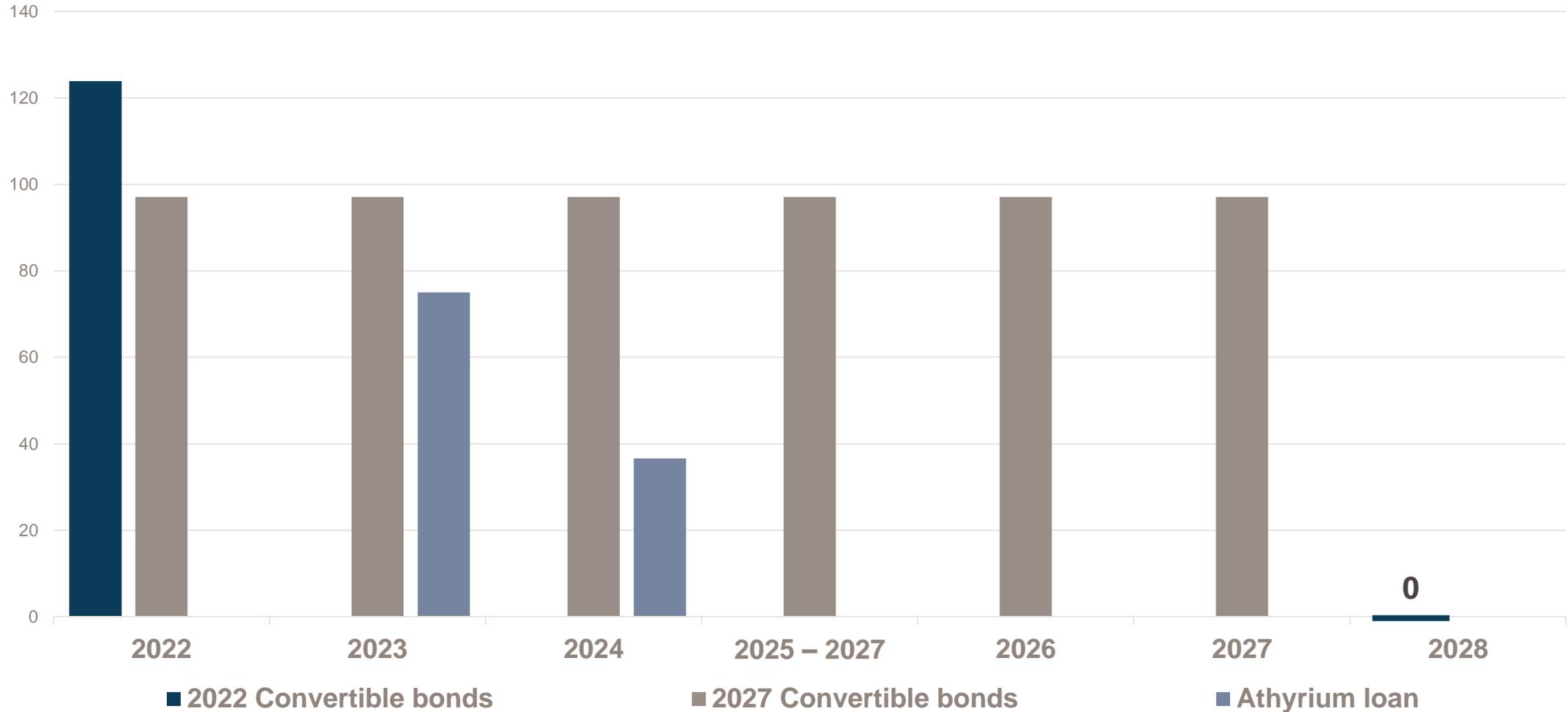


Cash flows from operating activities (in CHF mn)



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

2023 guidance – Continued growth in Cresemba & Zevtera related revenue and significant increase in profitability*

In CHF mn	FY 2023e (guidance)	FY 2022
Cresemba & Zevtera related revenue	145 – 148	122.3
Royalty income	~74	65.0
Total revenue	155 – 158	147.8
Cost of products sold Operating expenses	25 – 28 ~80	24.6 104.6
Operating profit	45 – 50	18.5
Net profit	36 – 41	12.1

*Excluding the impact of in-licensing activities

Marc Engelhardt

Chief Medical Officer

Portfolio update



Antifungal

Cresemba® (isavuconazole)

Invasive mold infections



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
- FDA/EMA submission to propose pediatric labelling and request extension of exclusivity is planned in H2 2023
- Pediatric label approval is expected in H2 2024 in order to gain the exclusivity extension in both territories

Antibacterial

Zevtera[®] (ceftobiprole)

Severe bacterial infections



basilea

 **Zevtera[®] 500 mg**

powder for concentrate for solution for infusion.
Ceftobiprole (as ceftobiprole medocaril sodium).

*Each vial contains 500 mg of ceftobiprole,
equivalent to 666.6 mg of ceftobiprole medocaril sodium.*

For intravenous use after reconstitution and dilution.
Read the package leaflet before use.

10 vials

Ceftobiprole opportunity

- Broad-spectrum hospital anti-MRSA cephalosporin (including Gram-negative bacteria)
 - Rapid bactericidal activity
 - Potential to replace antibiotic combinations
 - Efficacy demonstrated in phase 3 clinical program in SAB, ABSSSI and pneumonia^{1, 2, 3}
 - Low propensity for resistance development¹
 - Safety profile consistent with the cephalosporin class safety profile, demonstrated in both adult and pediatric patients^{1, 2, 3, 4}
- Marketed in selected countries in Europe, Latin America, the MENA-region and Canada

Approved in major European countries & several non-European countries for both hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated pneumonia (VAP), and community-acquired bacterial pneumonia (CABP). Not approved in the US

MENA: Middle East and North Africa

¹ Syed YY. *Drugs*. 2014;74:1523-1542 and Basilea data on file.

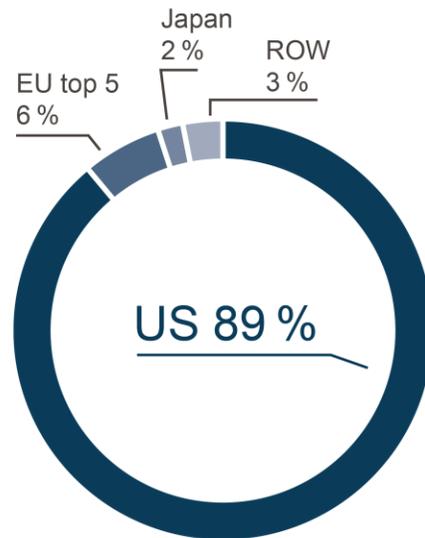
² Overcash JS et al. *Clin Infect Dis*. 2021;73:e1507-e1517.

³ Holland TL et al., *Open Forum Infect. Dis*. 2022, 9: (S931–S932).

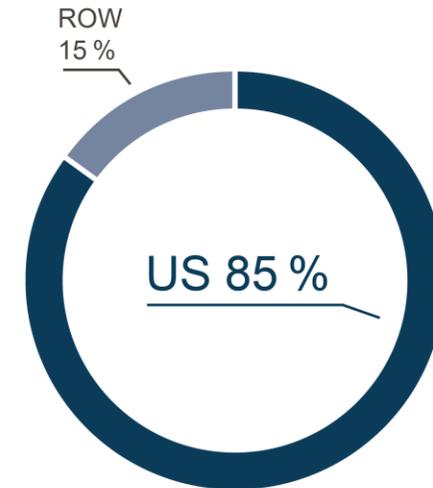
⁴ Rubino CM et al. *Pediatr Infect Dis J*. 2021;40:997-1003.

The hospital anti-MRSA antibiotic market — A USD 2.7 bn market* with the US being the most important region

Daptomycin sales by region
(2015, before LOE)



Ceftaroline sales by region
(MAT Q3 2022)



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

MRSA: Methicillin-resistant *Staphylococcus aureus*; LOE: Loss of exclusivity; ROW: Rest Of World; MAT: Moving annual total; Source: IQVIA Analytics Link, September 2022

Ceftobiprole — Strategy for accessing the US market

- Planned US NDA submission in March/April:
 - Two cross-supportive phase 3 studies under FDA Special Protocol Assessment (SPA)
 1. Acute bacterial skin and skin structure Infections (ABSSSI)¹
 2. *Staphylococcus aureus* bacteremia (SAB)²
- Previously completed phase 3 study in community-acquired bacterial pneumonia (CABP) as a third indication³
- Phase 3 program largely funded by BARDA (~70% total program costs; up to USD ~136 mn)
- Qualified Infectious Disease Product (QIDP) designation extends US market exclusivity to 10 years from approval
- Commercialization planned through partnership
 - Partnership to be secured prior to the regulatory decision



¹ Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

² Holland TL et al., Open Forum Infect. Dis. 2022, 9: (S931–S932).

³ Nicholson SC et al. International Journal of Antimicrobial Agents 2012 (39), 240-246.

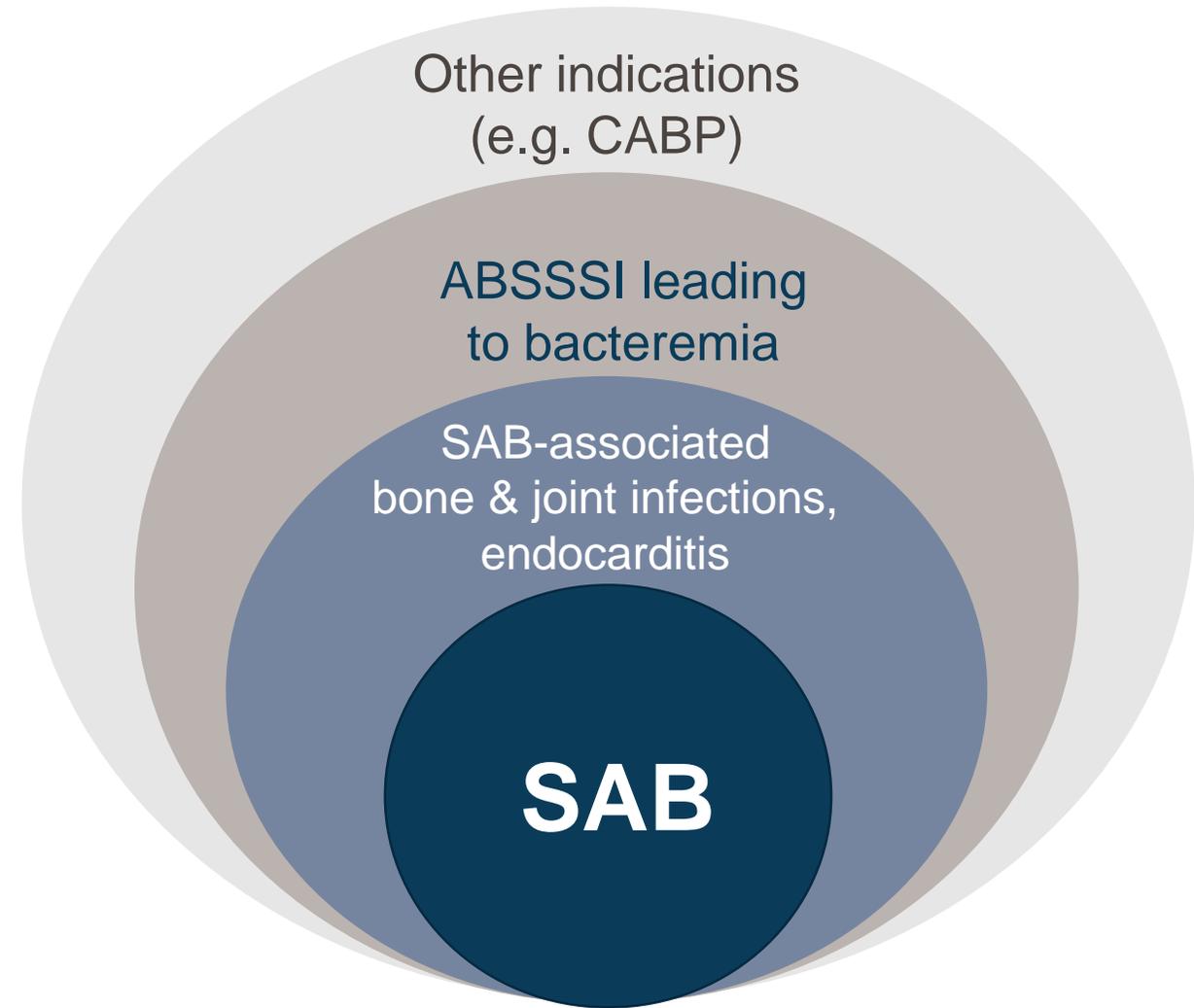
Ceftobiprole — Place in therapy

- 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 renal safety profile
 - The low propensity for resistance development

Focused launch in area of highest unmet medical with expansion opportunities

Patient potential in the United States

- *Staphylococcus aureus* bacteremia (SAB): 130,000 cases
- Acute bacterial skin and skin structure Infections (ABSSSI): 600,000 cases
- Community-acquired bacterial pneumonia (CABP): 800,000 cases



David Veitch

Chief Executive Officer

Outlook



Key milestones

Product	H2 2022	H1 2023	H2 2023
Ceftobiprole (Zevtera)		US NDA submission (March/April)	Regulatory decision in the US (November/December)
			Executing US partnership
Isavuconazole (Cresemba)	Marketing approval in Japan ✓	Launch in Japan	
	Launched in 63 countries ✓		Pediatric submission

Increasing Cresemba & Zevtera revenue

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

Advancement of preclinical anti-infective assets



Q & A



Thank you

Glossary

- ABSSSI: **A**cute **b**acterial **s**kin and **s**kin **s**tructure **i**nfections
- BARDA: **B**iomedical **A**dvanced **R**esearch and **D**evelopment **A**uthority
- CABP: **C**ommunity-acquired **b**acterial **p**neumonia
- CARB-X: **C**ombating **A**ntibiotic-**R**esistant **B**acteria **B**iopharmaceutical **A**ccelerator
- EMA: **E**uropean **M**edicines **A**gency
- HABP: **H**ospital-acquired **b**acterial **p**neumonia
- i.v.: **I**ntravenous
- MSSA: **M**ethicillin-susceptible *Staphylococcus aureus*
- MRSA: **M**ethicillin-resistant *Staphylococcus aureus*
- NDA: **N**ew **D**rug **A**pplication
- QIDP: **Q**ualified **I**nfectious **D**isease **P**roduct
- SAB: *Staphylococcus aureus* **b**acteremia
- SPA: **S**pecial **P**rotocol **A**ssessment
- US GAAP: **U**nited **S**tates **G**enerally **A**ccepted **A**ccounting **P**riniples
- VAP: **V**entilator-associated **p**neumonia



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**Hegenheimermattweg 167b
4123 Allschwil
Switzerland**

**info@basilea.com
www.basilea.com**

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