Creating anti-infective opportunities

Full-year results 2023

Webcast presentation

February 13, 2024

David Veitch

Chief Executive Officer

Introduction

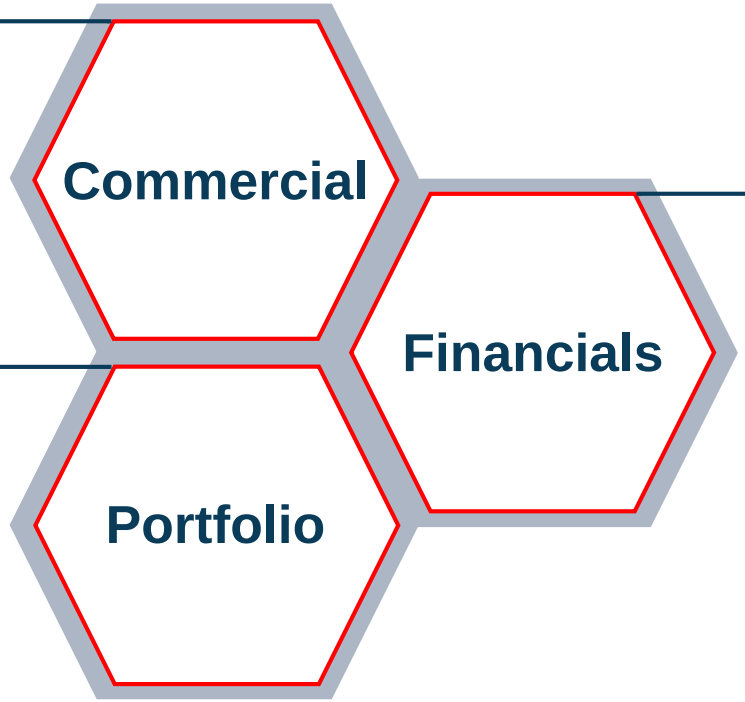
Disclaimer and forward-looking statements

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 2023 – Key achievements

22% y-o-y increase of global Cresemba in-market sales to USD 445 mn*

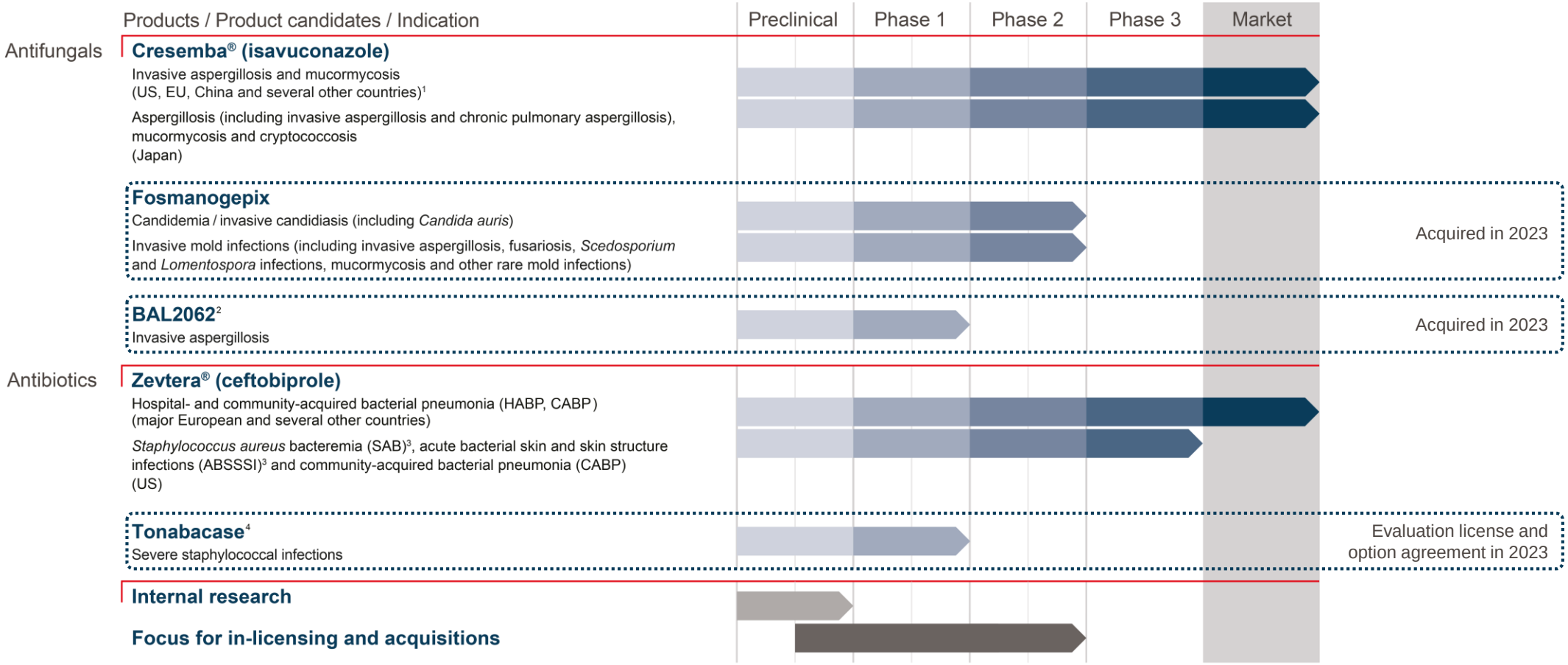
Acquisition of fosmanogepix, BAL2062, evaluation license for tonabacase



- **Cresemba & Zevtera** related revenue CHF 150.3 mn
- **Operating profit** of CHF 19.2 mn

*MAT Q3/2023 vs. Q3/2022; MAT: Moving annual total; Source: IQVIA Analytics Link, September 2023

Innovative anti-infective pipeline



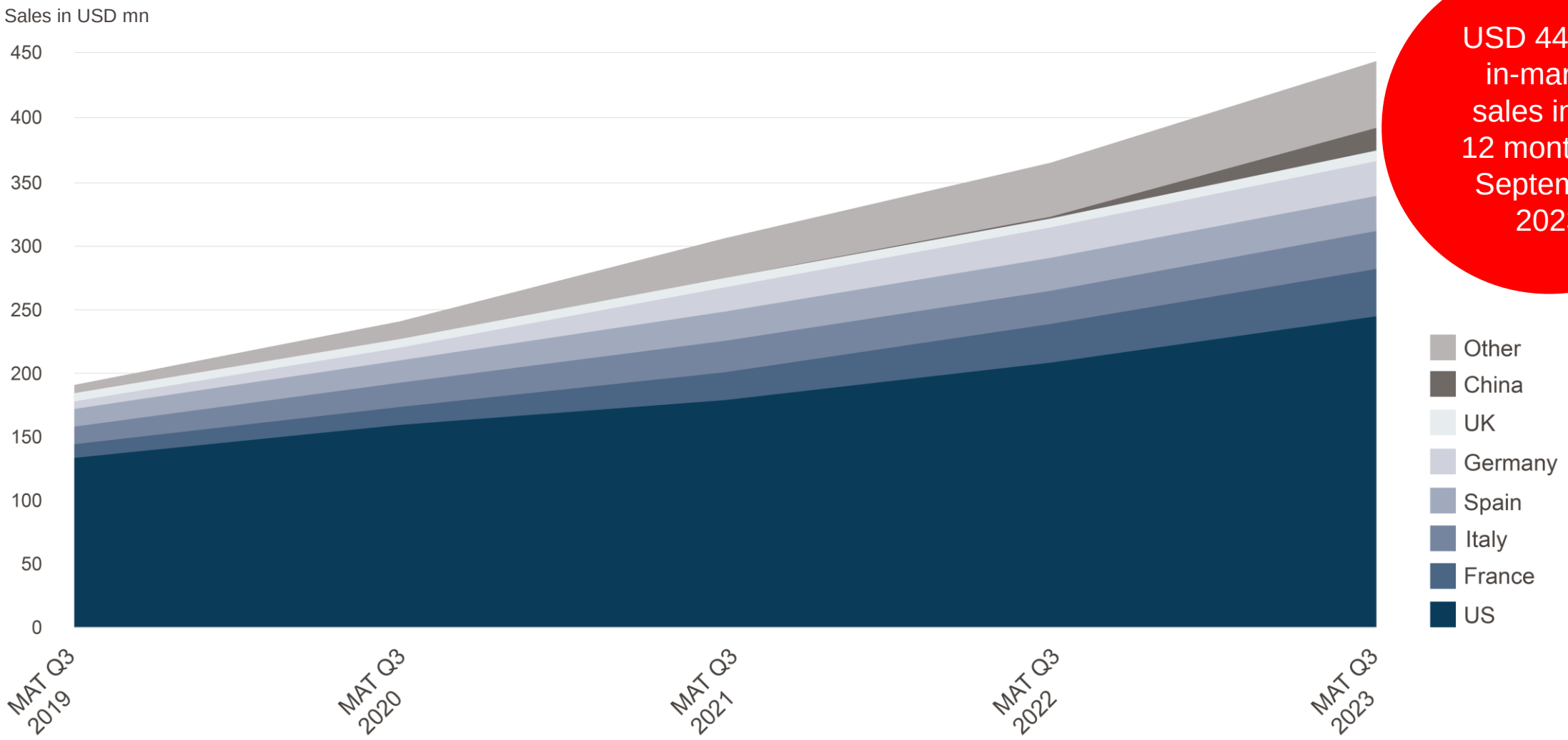
1 The registration status and approved indications may vary from country to country.
2 Formerly GR-2397
3 Phase 3 program was funded in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA).
4 Exclusive option to in-license upon completion of preclinical profiling

Adesh Kaul

Chief Financial Officer

Commercial & financial update

Cresemba continues strong in-market sales uptake



USD 445 mn in-market sales in the 12 months to September 2023

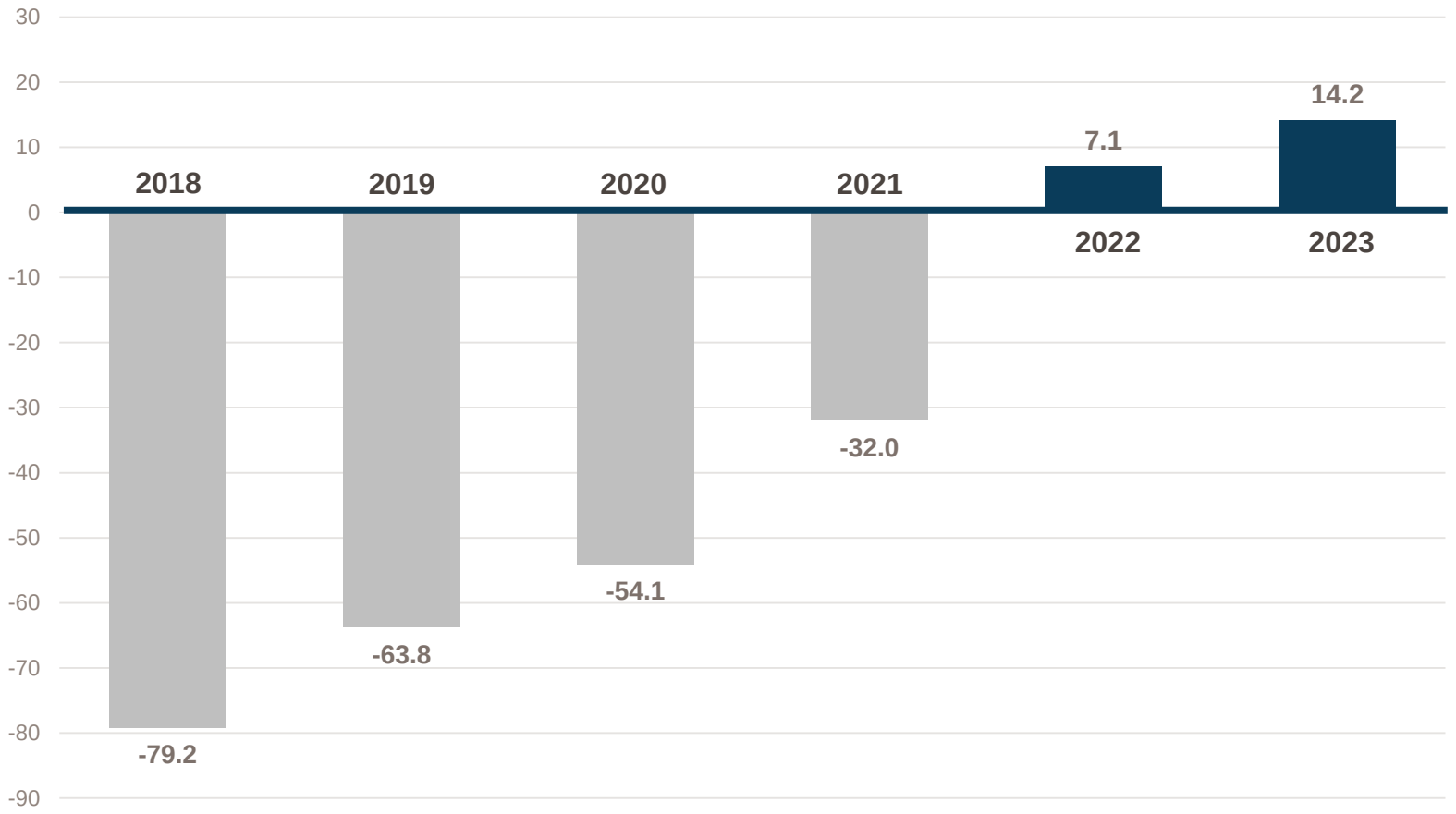
MAT: Moving annual total; Source: IQVIA Analytics Link, September 2023

Strong FY23 results with revenue at the upper end of guidance and operating and net profit above guidance

In CHF mn	FY 2023	FY 2023 (guidance)	FY 2022
Cresemba and Zevtera related revenue	150.3	147 – 150	122.3
of which royalty income	78.9	~76	65.0
Total revenue	157.6	154 – 157	147.8
Cost of products sold	26.8	~27	24.6
Operating expenses	111.6	~115	104.6
Operating profit	19.2	11 – 15	18.5
Net profit	10.5	2 – 6	12.1

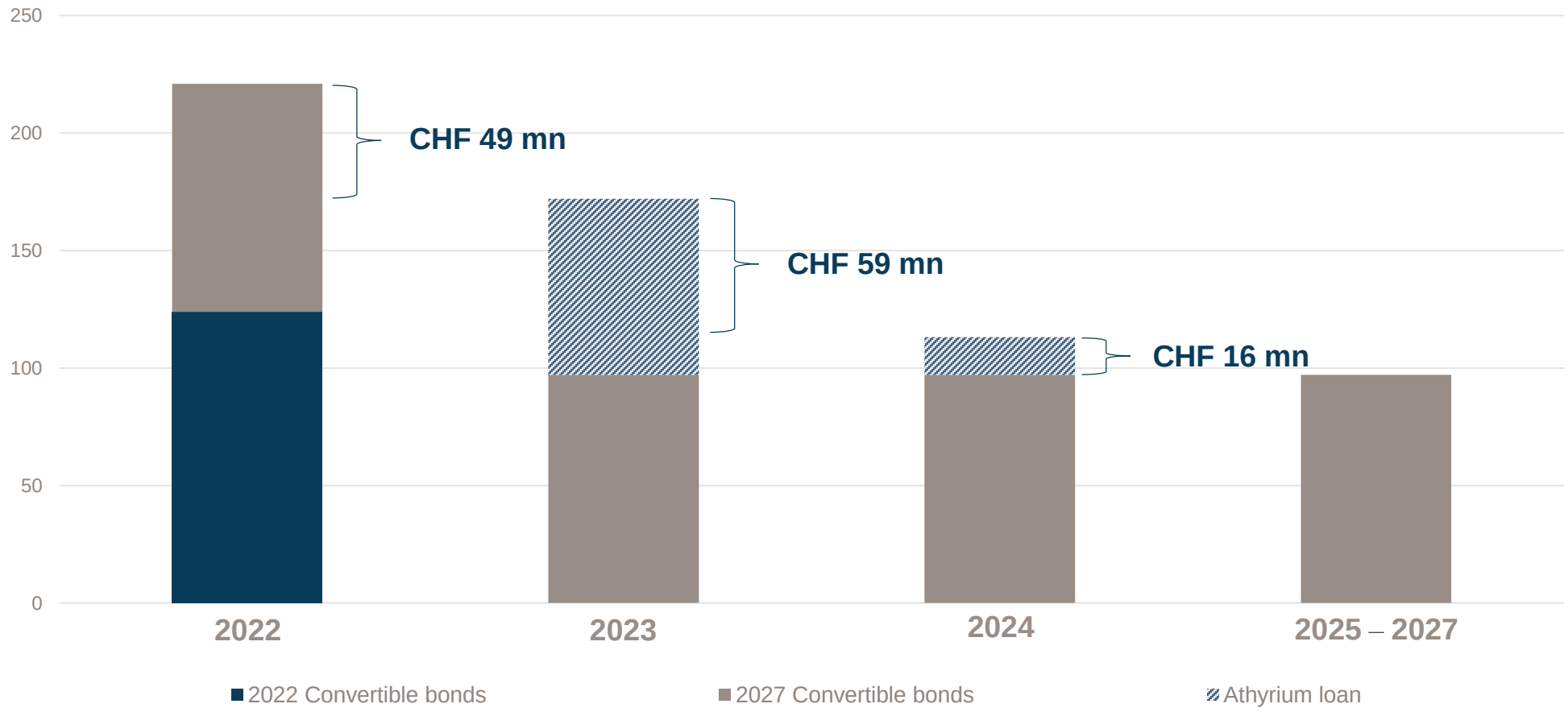
Note: Consistent rounding was applied.

Cash flows from operating activities (in CHF mn)



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

CHF 124 mn non-dilutive debt level reduction 2022-2024



Note: Figures (in CHF mn) as of the beginning of the fiscal year; rounding applied consistently

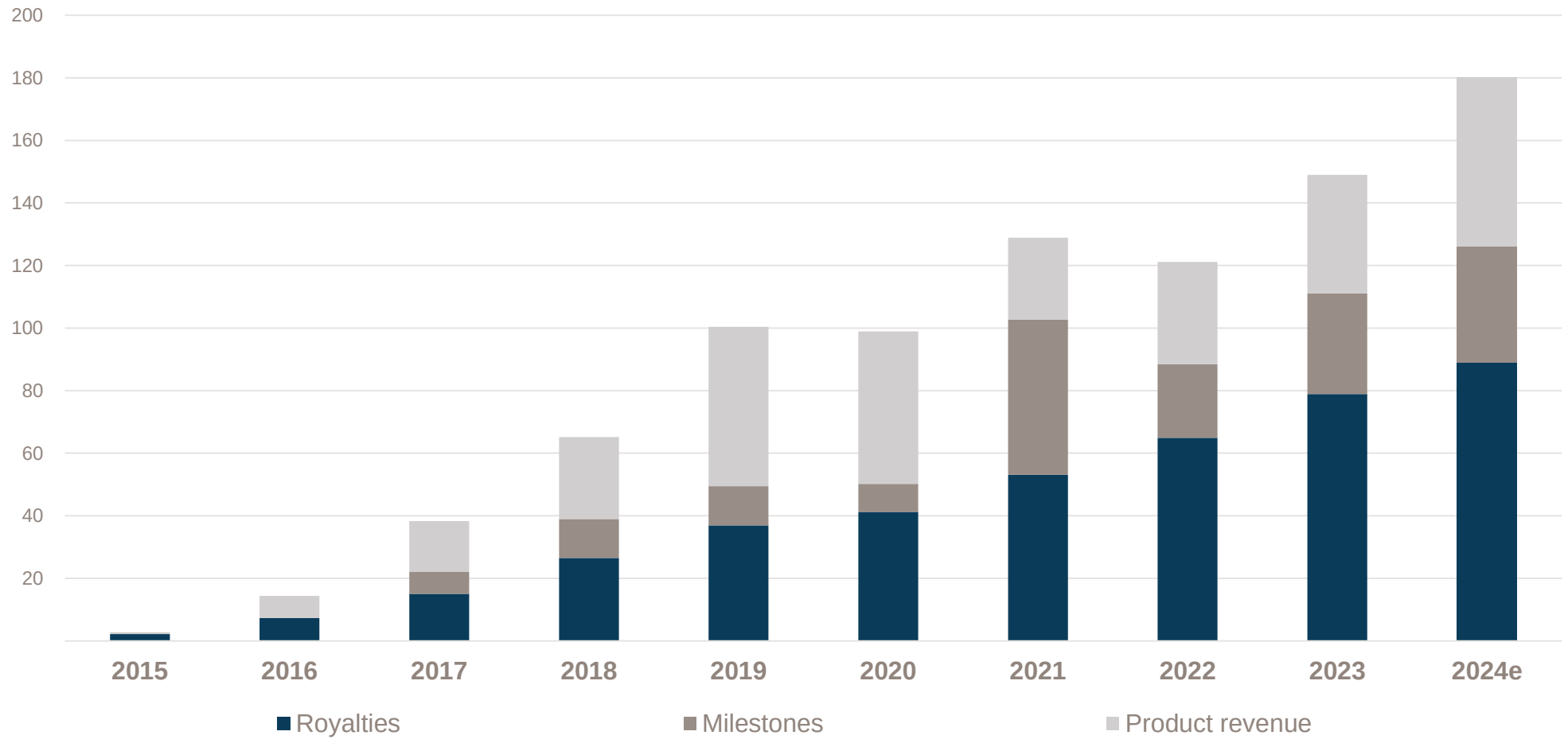
2024 Guidance – 20% increase in Cresemba and Zevtera-related revenue and more than doubling of net profit

In CHF mn	FY 2024 guidance*	FY 2023
Cresemba and Zevtera related revenue	~180	150.3
of which royalty income	~89	78.9
Total revenue	~183	157.6
Cost of products sold	~33	26.8
Operating expenses	~120	111.6
Operating profit	~30	19.2
Net profit	~25	10.5

* Excluding the impact of in-licensing and acquisitions

Note: Consistent rounding was applied.

Cresemba and Zevtera-related revenue breakdown (in CHF mn)



Marc Engelhardt

Chief Medical Officer

Portfolio update

Antibacterial

Zevtera® (ceftobiprole)

Severe bacterial infections

Ceftobiprole — Strategy for accessing the US market

- FDA accepted NDA submission for three indications:
  1. *Staphylococcus aureus* bacteremia (SAB)[1]
  2. Acute bacterial skin and skin structure infections (ABSSSI)[2]

  3. Previously completed phase 3 study in community-acquired bacterial pneumonia (CABP) as a third indication[3]

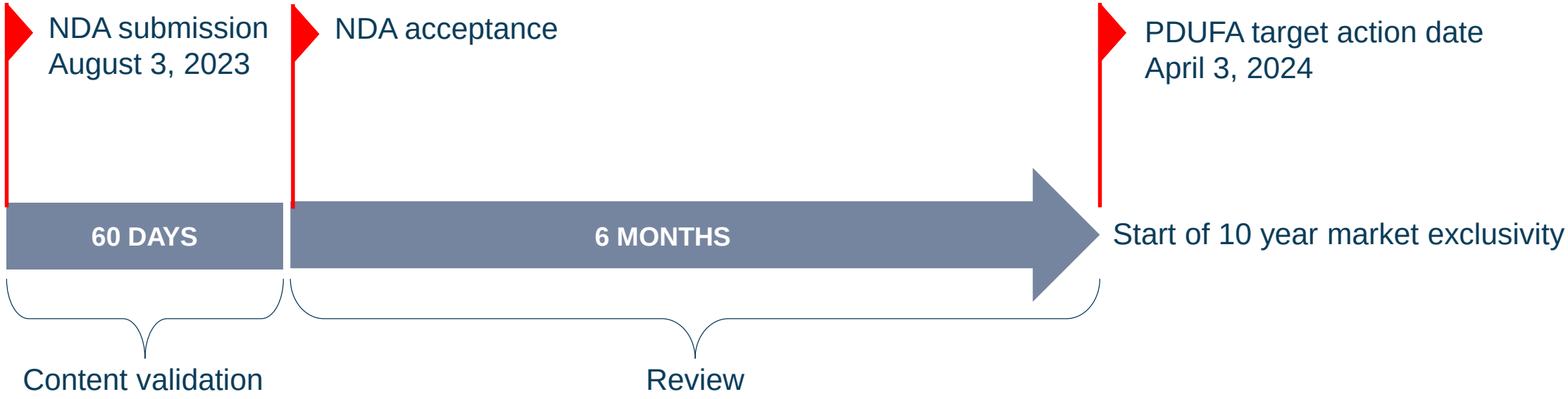
- PDUFA target action date April 3, 2024
- Phase 3 program largely funded by BARDA (~USD 112 million, or approximately 75 percent of the costs related to the SAB and ABSSSI phase 3 studies, regulatory activities and non-clinical work)
- Qualified Infectious Disease Product (QIDP) designation extends US market exclusivity to 10 years from approval
- Commercialization planned through partnership
  - Partnership expected prior to regulatory decision

[1] Holland TL et al. N Engl J Med 2023;389:1390-1401.
[2] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[3] Nicholson SC et al. International Journal of Antimicrobial Agents 2012 (39), 240-246.

Ceftobiprole — 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

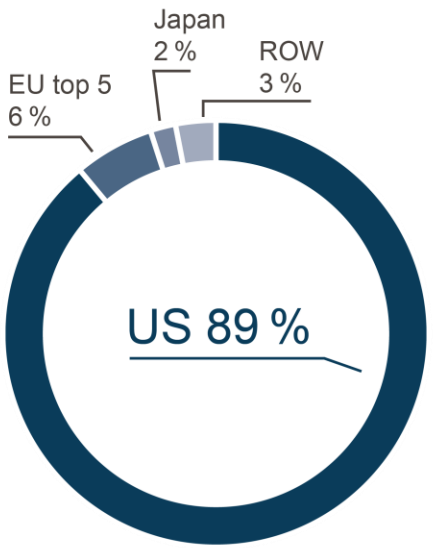


Ceftobiprole — Place in therapy

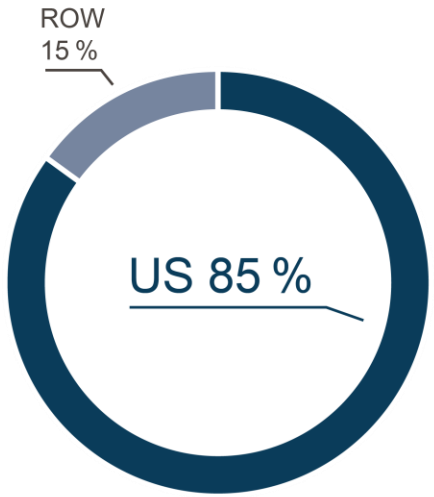
- Excellent treatment option in difficult-to-treat patients presenting to the hospital with severe infections, especially when the clinician suspects involvement of Gram-positive pathogens including *Staphylococcus aureus*
- Single agent first-line bactericidal broad-spectrum therapy with proven efficacy 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 2.4 bn market* with the US being the most important region

Daptomycin sales by region (2015, before LOE)



Ceftaroline sales by region (MAT Q3 2023)



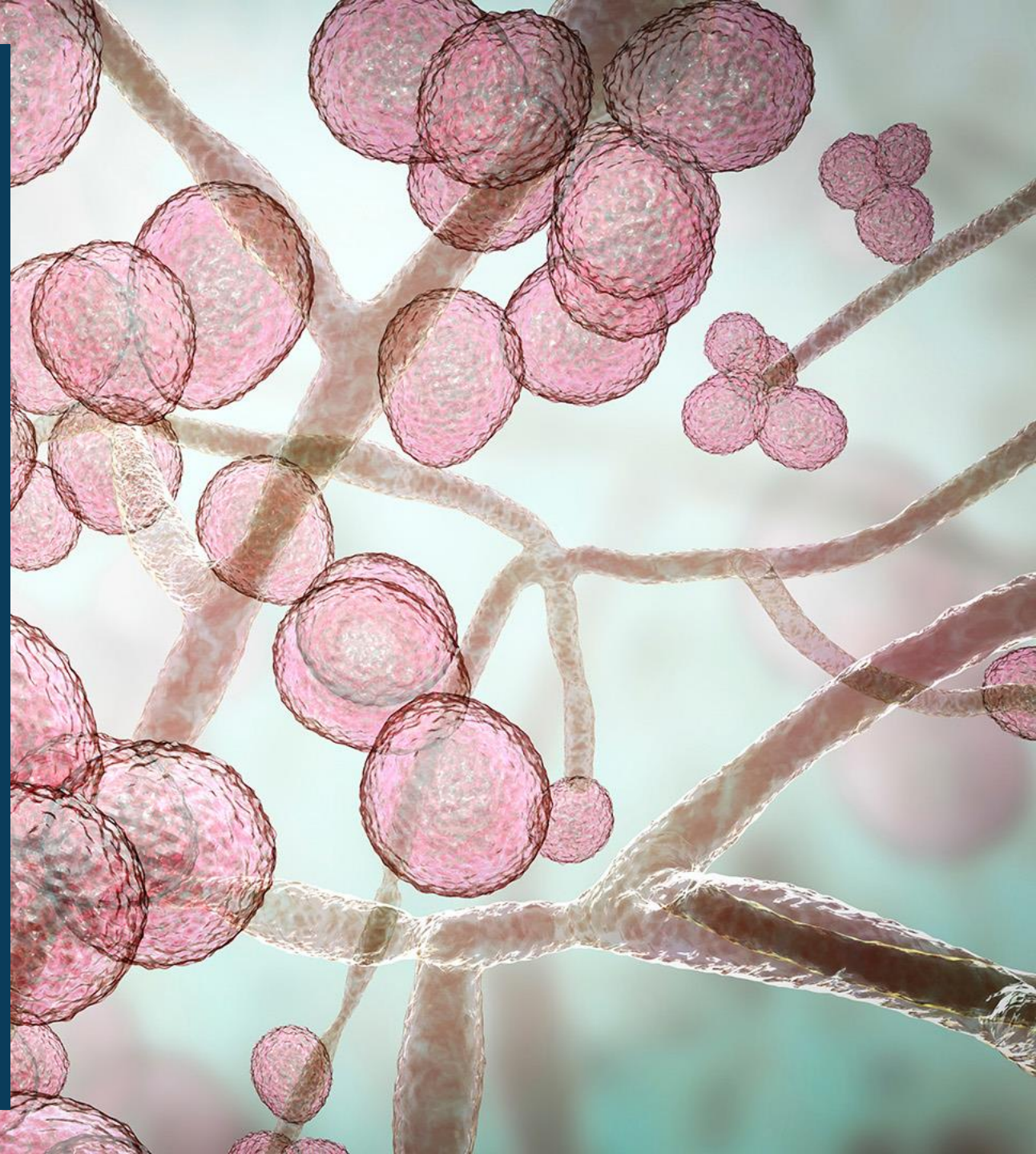
* Vancomycin, linezolid, teicoplanin, daptomycin, tigecycline, telavancin, ceftaroline, dalbavancin, ceftobiprole, oritavancin and tedizolid (daptomycin and tigecycline are partial sales in the US in IQVIA data)

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

Antifungal

Fosmanogepix

Invasive yeast and mold infections

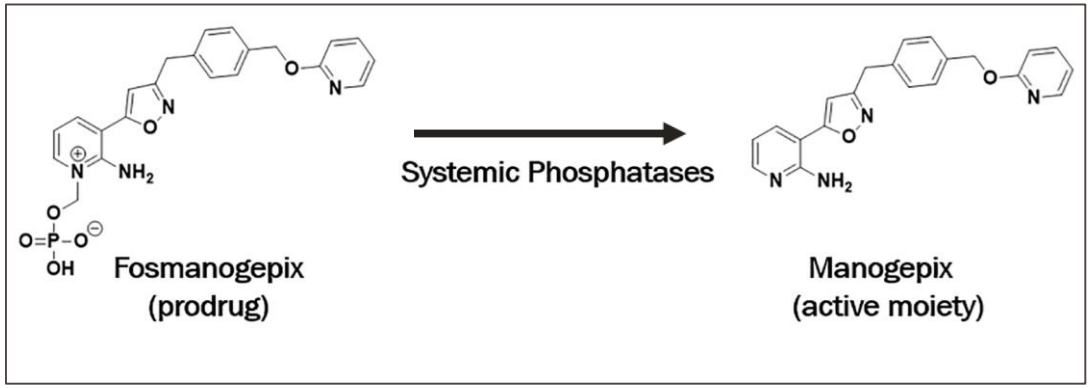


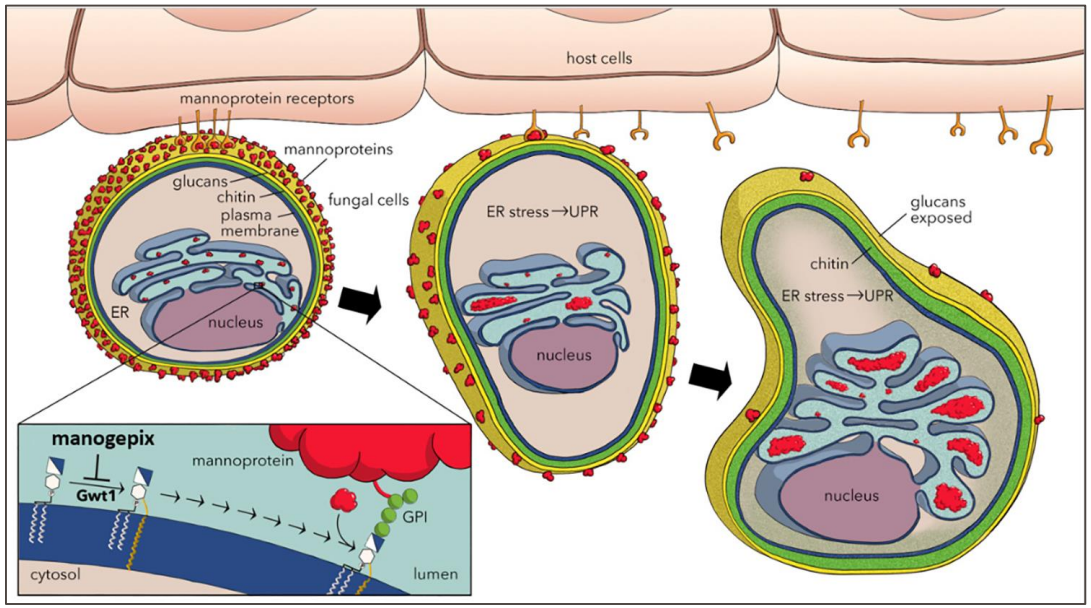
Fosmanogepix – A highly attractive antifungal asset

- First-in-class, intravenous and oral antifungal with a novel mechanism of action
- Broad spectrum antifungal activity against yeasts, molds and dimorphic fungi, including *Candida auris*, azole-resistant *Aspergillus* spp. and *Fusarium* spp.
- Three successfully completed phase 2 studies for the treatment of
  - Candidemia, including *Candida auris*
  - Mold infections
- Phase-3-ready for yeast and mold infections with first phase 3 study in candidemia / invasive candidiasis expected to start mid-2024
- Potential to become our next lead commercial product and mid-term value driver
- Asset acquired from Pfizer, which maintains the right of first negotiation for commercialization

Overview

- Fosmanogepix is the prodrug of manogepix
- Novel mechanism of action
- Inhibition of the protein Gwt1 impedes the production of cell wall mannoproteins, causing cell wall fragility, fungal cell death and decreased potential for biofilm formation
- Potent broad-spectrum activity against resistant yeasts, molds and dimorphic fungi, including azole-resistant phenotypes
- IV and oral availability enables treatment in both inpatient and outpatient settings
- US FDA fast track status, QIDP and orphan drug designations

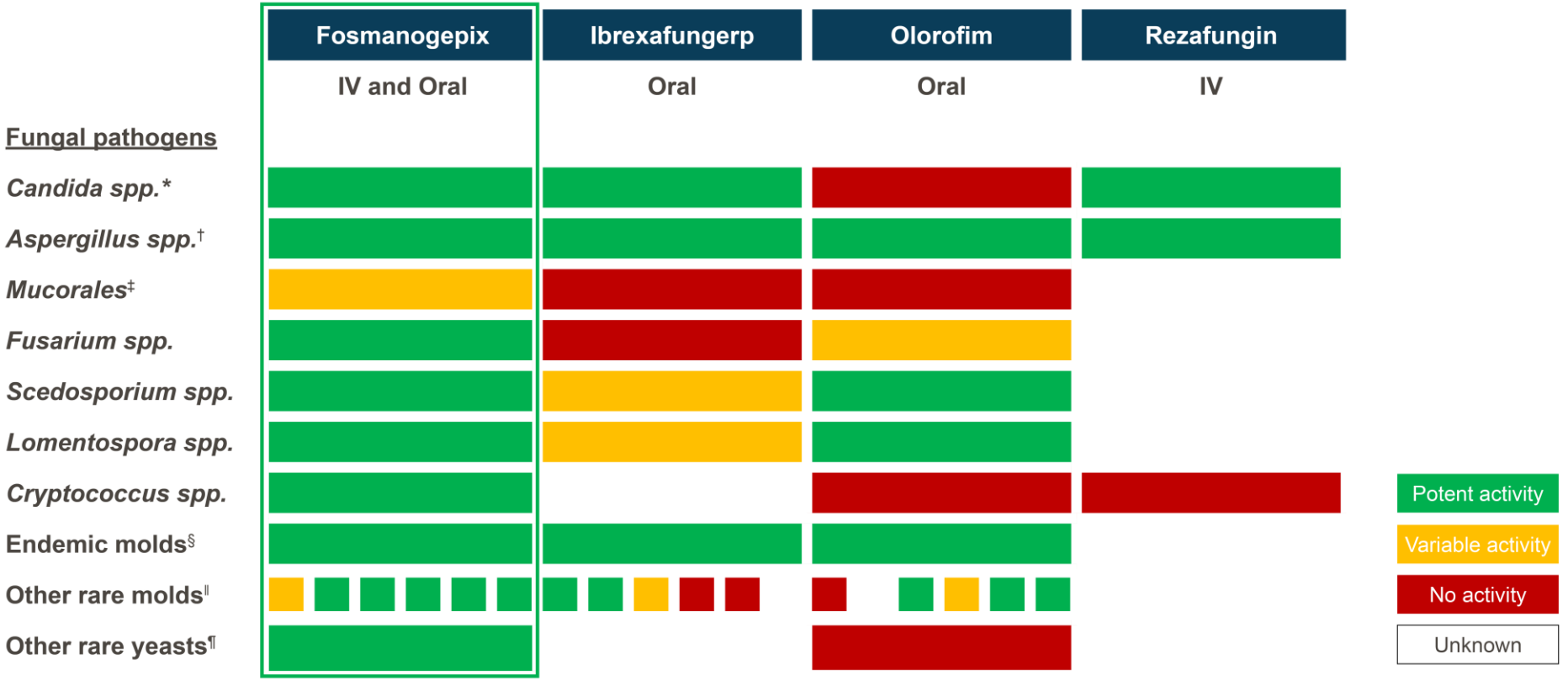




Friedman DZP, Schwartz IS. Infect Dis Clin North Am. 2023;37:593-616.

Shaw KJ, Ibrahim AS. J Fungi (Basel). 2020; 6:239

Addressing high unmet medical needs



* including *C. albicans*, *C. auris*, *C. dubliniensis*, *C. glabrata*, *C. krusei*, *C. lusitaniae*, *C.parapsilosis*, *C. tropicalis*. Fosmanogepix not active against *C. krusei*.
† including *A. calidoustus*, *A. fumigatus* (including azole-resistant), *A. flavus*, *A. lentulus*, *A. nidulans*, *A. niger, A. terreus*, *A. tubingensis*.
‡ including *Cunninghamella spp.*, *Lichtheimia spp.*, *Mucor spp.*, *Rhizopus spp*.
§ including *Blastomyces dermatitidis*, *Coccidioides immitis*, *Histoplasma capsulatum*.
‖ including *Alternaria alternata*, *Cladosporium spp*. *Paecilomyces variotii*, *Purpureocillium lilacinum*, *Scopulariosis spp.*, *Rasamsonia spp*.
¶ including *Trichosporon asahii*, *Exophiala dermatitidis*, *Malassezia furfur*.

Adapted from Hoenigl M, Sprute R, Egger M, et al. Drugs. 2021;81:1703-1729.

Planned global phase 3 program

Candidemia / Invasive candidiasis

- Randomized, double-blind, non-inferiority study
  - Approximately 450 patients
- Fosmanogepix IV (oral step-down fosmanogepix) vs caspofungin IV (oral step-down to fluconazole)
- Primary endpoints
  - FDA: Survival at 30 days
  - EMA: Overall response at end-of-study treatment
- Protocol and initial Health Authority approvals obtained
- Expected study start mid-2024

Invasive mold infections (IMI)

- Randomized, open-label study including non-controlled salvage treatment arm
  - Approximately 200 patients
- Cohorts of invasive mold disease including IMI caused by:
  - *Aspergillus* spp.
  - *Fusarium* spp.
  - *Scedosporium* spp.
  - *Lomentospora prolificans*
  - Mucorales fungi, or
  - Other multi-drug resistant molds
- Fosmanogepix IV or oral vs best available therapy
- Endpoints include survival and overall response
- Expected study start end-2024

Antifungal

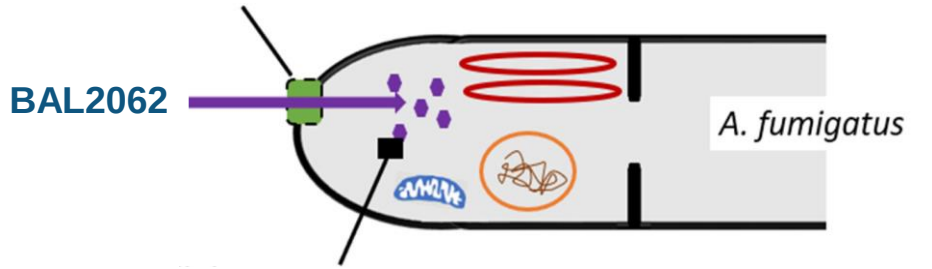
BAL2062

Invasive *Aspergillus* infections

BAL2062 – A first-in-class rapidly fungicidal antifungal

- First-in class antifungal with novel mechanism of action for intravenous administration
- Clinical safety and tolerability demonstrated in phase 1 study[1]
- Potential for enhanced clinical efficacy addressing unmet medical needs in invasive aspergillosis and other invasive fungal infections[2]
- QIDP, Orphan Drug and Fast Track designations granted from the FDA for invasive aspergillosis
- Phase 2 start planned in 2025 based on results from additional preclinical profiling studies
- Positioning as first-line treatment for invasive aspergillosis (IA)

BAL2062 – a siderophore antifungal agent



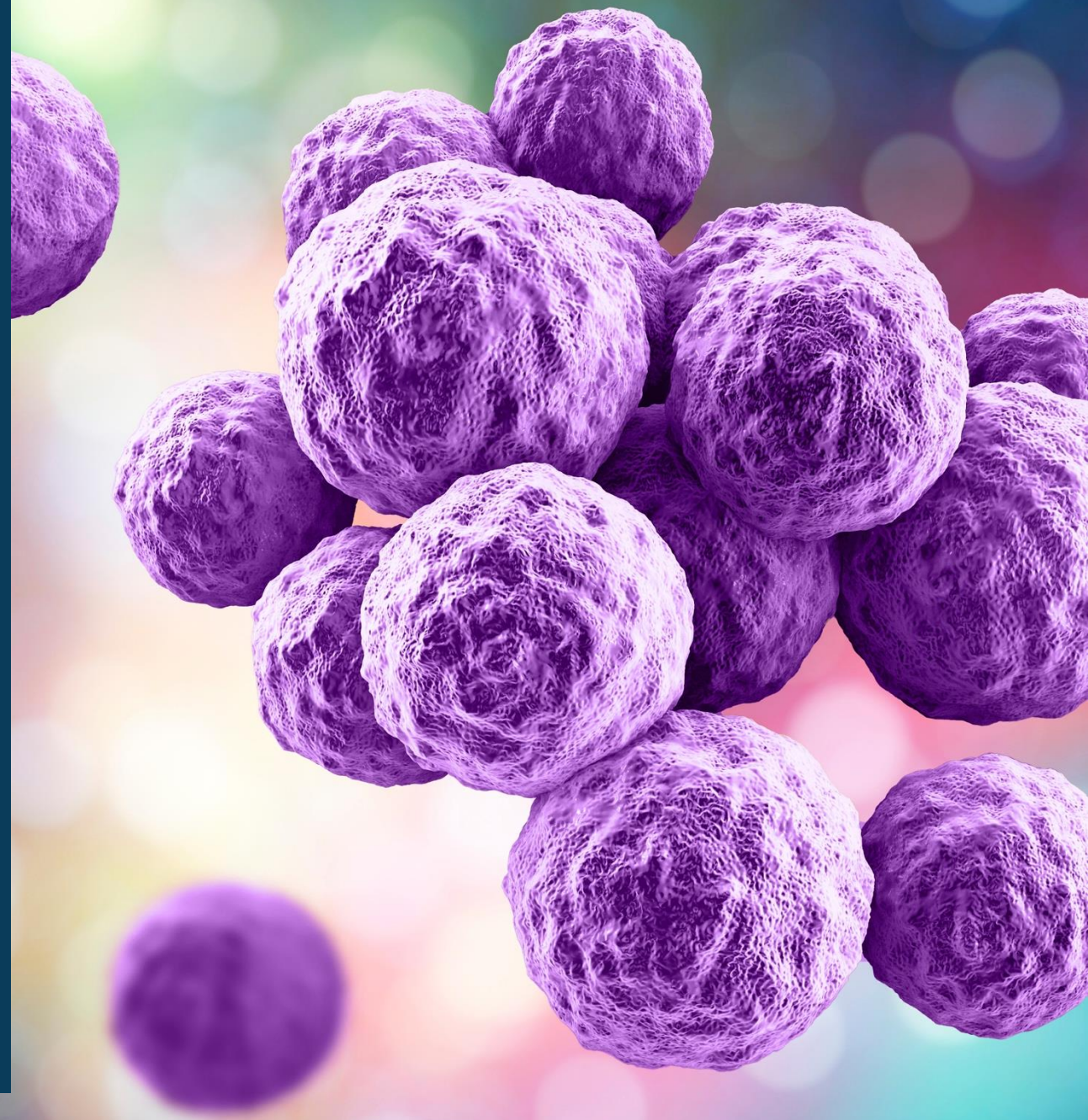
Adapted from Shaw KJ., 2022

[1] Mammen MP, Armas D, Hughes FH, et al. Antimicrob Agents Chemother. 2019;63:e00969-19.
[2] Shaw KJ. J Fungi (Basel). 2022; 8:909.

Antibacterial

Tonabacase

Severe staphylococcal infections



Tonabacase – A potent bactericidal endolysin for severe staphylococcal infections

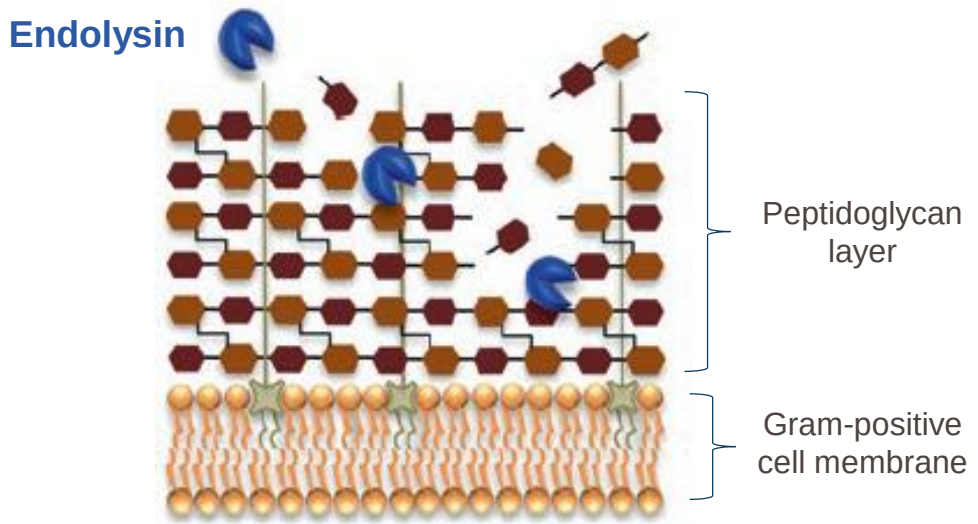
Profile

- Potent in-vitro activity: rapid bactericidal activity, biofilm degradation, superior biofilm activity to exebacase[1]
- Tonabacase can be dosed multiple times which may significantly increase exposure

Development plan

- Conducting preclinical profiling, including PK/PD, which is anticipated to complete by end-2024
- If the preclinical profiling is positive, Basilea can exercise its option to in-license tonabacase
- After in-licensing, phase 2 could start in H2 2025
  - Clinical program: Focus on the high unmet medical need in staphylococcal infections

Schematic representation of endolysin effects on Gram-positive bacteria



Reference: Dams D and Briers Y, 2019[2]

[1] Data on file

[2] Dams D, Briers Y Adv Exp Med Biol. 2019:1148:233-253

David Veitch

Chief Executive Officer

Outlook

Key milestones

	Product	H1 2024	H2 2024	2025
Antifungals	**Isavuconazole (Cresemba)**	Decision on EU pediatric extension		
	Fosmanogepix	Initiate phase 3 study in candidemia / invasive candidiasis (mid-2024)	Initiate phase 3 study in mold infections (around year-end)	
	BAL2062			Initiate phase 2 program
Antibacterials	**Ceftobiprole (Zevtera)**	Regulatory decision in the US (PDUFA target action date April 3)		
		Executing US partnership (prior to PDUFA target action date)		
	Tonabacase		Decide on definitive licensing option	Initiate phase 2 program

Increasing Cresemba & Zevtera revenue

In-licensing and acquisition of anti-infectives

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-**a**cquired **b**acterial **p**neumonia
- EMA: **E**uropean **M**edicines **A**gency
- FDA: US **F**ood and **D**rug **A**dministration
- HABP: **H**ospital-**a**cquired **b**acterial **p**neumonia
- IMI: **I**nvasive **m**old **i**nfections
- MSSA: **M**ethicillin-**s**usceptible ***S**taphylococcus **a**ureus*
- MRSA: **M**ethicillin-**r**esistant ***S**taphylococcus **a**ureus*
- NDA: **N**ew **D**rug **A**pplication
- PK: **P**harmacokinetics
- PD: **P**harmacodynamics
- QIDP: **Q**ualified **I**nfectious **D**isease **P**roduct
- SAB: ***S**taphylococcus **a**ureus* **b**acteremia
- US GAAP: **U**nited **S**tates **G**enerally **A**ccepted **A**ccounting **P**rinciples

Creating anti-infective opportunities

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