basilea

Champion for patients: Overcoming barriers in the treatment of fungal and bacterial infections

Full-year results 2024 Webcast presentation February 18, 2025

States States

David Veitch

Chief Executive Officer

Introduction



Disclaimer

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.

Full-year 2024 – Key achievements

COMMERCIAL

- 20% increase of Cresemba global in-market sales to USD 533 million*
- 30% increase in Cresemba and Zevtera related revenue

FINANCIALS

- Tripled operating profit
- **Five-fold** increase in operating cashflow

- **Strong** cash position and net cash at year-end
- Secured significant non-dilutive funding from BARDA and CARB-X

PORTFOLIO

- **Zevtera:** FDA approval and US partnering
- Cresemba: pediatric approval EMA
- Fosmanogepix: initiated phase 3 program
- LptA inhibitor BAL2420: acquisition of preclinical antibiotics program

*MAT Q3/2024 vs. Q3/2023; MAT: Moving annual total; Source: IQVIA Analytics Link, September 2024

Innovative anti-infective pipeline

| Products / Product candidates / Indications | Preclinical | Phase 1 | Phase 2 | Phase 3 | Market | |
|---|-------------|---------|---------|---------|--------|--------------------|
| ANTIFUNGALS | | | | | | |
| Cresemba [®] isavuconazole | | | | | | |
| Invasive aspergillosis and mucormycosis (US, EU and several other countries) ¹ | | | | | | |
| Aspergillosis, (including invasive aspergillosis and chronic pulmonary aspergillosis), mucormycosis and cryptococcosis (Japan) | | | | | | |
| Fosmanogepix | | | | | | |
| Candidemia / invasive candidiasis (including Candida auris) | | | | | | |
| Invasive mold infections (including invasive aspergillosis, fusariosis, <i>Scedosporium</i> and <i>Lomentospora</i> , mucormycosis and other rare mold infections) | | | | | | |
| BAL2062 | | | _ | | | |
| Invasive aspergillosis | | | | | | |
| ANTIBACTERIALS | | | | | | |
| Zevtera [®] ceftobiprole | | | | | | |
| Hospital- and community-acquired bacterial pneumonia (HABP, CABP) (major European and several other countries) | | | | | | |
| Staphylococcus aureus bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) (United States) | | | | | | |
| BAL2420 (LptA inhibitor) | | | | | | |
| Severe Enterobacteriaceae infections | | | | | | |
| | | | | | | |
| Internal research | | | | | | |
| Focus for in-licensing and acquisitions | | | | | | |
| | | | | | [| Acquired/in-licens |
| ¹ The registration status and approved indications may vary from country to country. | | | | | ······ | since October 20 |

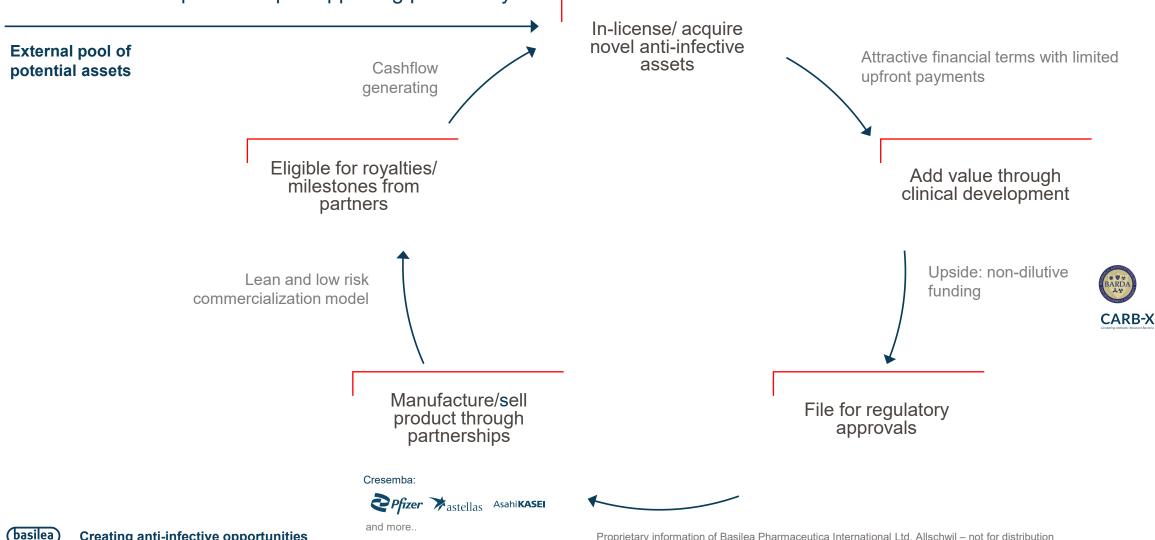
Adesh Kaul Chief Financial Officer

Commercial & financial update



Business model

Unique capabilities, limited acquisition and development costs, commercialization partnerships supporting profitability



Cresemba/Zevtera marketed countries



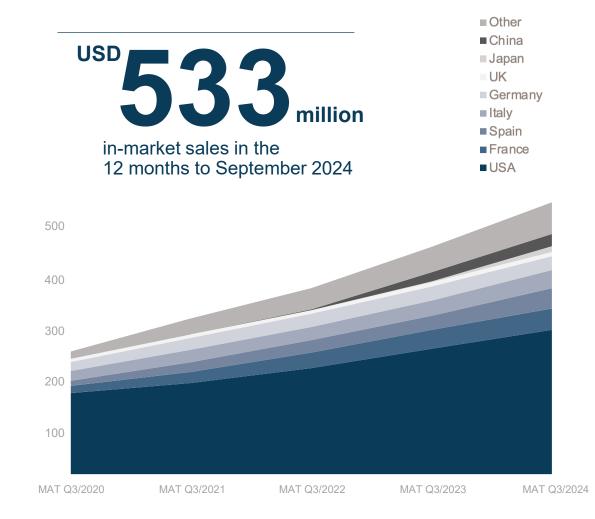
Cresemba® Global commercial partnerships

| United States | Astellas |
|-------------------------------|-----------------------|
| Canada | |
| Latin America | U Knight |
| Europe (excluding Nordics) | P fizer |
| Nordics | UNIMEDIC [®] |
| MENA Region | hikma. |
| Asia-Pacific and China | P fizer |
| Japan | Asahi KASEI |



countries

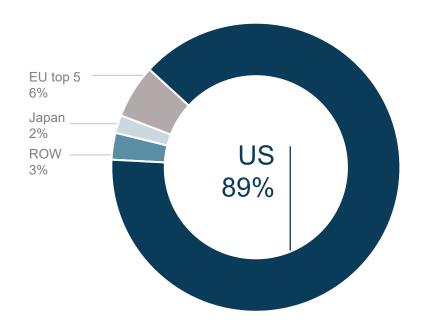
In-market sales



MAT: Moving annual total; Source: IQVIA Analytics Link, September 2024 Proprietary information of Basilea Pharmaceutica International Ltd, Allschwil – not for distribution

Hospital anti-MRSA antibiotics – US being the most important commercial opportunity

Daptomycin sales by region (2015, before LOE)



Zevtera — Strategy for accessing the US market

- Commercialization through partner:
 INNOVIVA Specialty Therapeutics⁻
- Preparing for commercial launch mid-2025
 - Launch material manufactured
 - Field force training in preparation
- Qualified Infectious Disease Product (QIDP) designation extends US market exclusivity to 10 years from approval

MRSA: Methicillin-resistant *Staphylococcus aureus*; LOE: Loss of exclusivity; ROW: Rest Of World; MAT: Moving annual total; Source: IQVIA Analytics Link, September 2024

Non-dilutive R&D funding

BARDA Other Transaction Agreement (OTA)¹

- Flexible contracting mechanism
- Initial commitment of USD 29 million for development of antifungals fosmanogepix and BAL2062
- Potential total funding of up to ~USD 268 million
- Reimbursement of about 60% of the total development cost

CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator)

- Funding agreement for LptA inhibitor antibiotic program²
- Initial funding of up to USD 0.9 million awarded until candidate nomination
- Additional funding of up to USD 7.3 million until first-in-human clinical studies for drug candidate BAL2420

¹ OTA number 75A50124C00033

² Agreement number 75A50122C00028 and WT224842



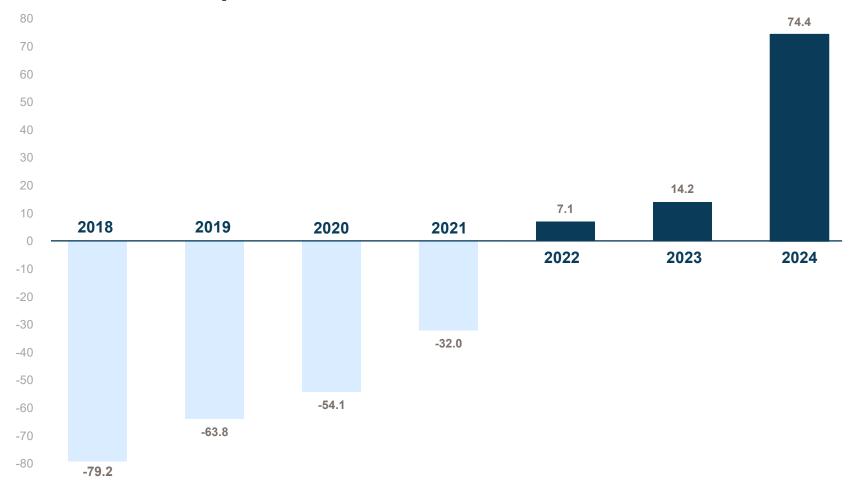
Strong financial results FY 2024 – Significant increase in revenue and profit

| in CHF million | FY 2023 | FY 2024 | Guidance FY 2024 |
|---|---------|---------|------------------|
| Cresemba and Zevtera related revenue | 150.3 | 194.9 | 190 |
| of which royalty income | 78.9 | 96.7 | |
| of which milestone and upfront payments | 33.5 | 40.4 | |
| Other revenue | 7.4 | 13.7 | 13 |
| Total revenue | 157.6 | 208.5 | 203 |
| Cost of products sold | 26.8 | 38.7 | |
| Operating expenses | 111.7 | 108.6 | |
| Operating profit | 19.2 | 61.2 | 43 |
| Net profit | 10.5 | 77.6 | 60 |
| Net financial debt / Net cash (as of December 31, 2024/2023) | -46.6 | 28.6 | |

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

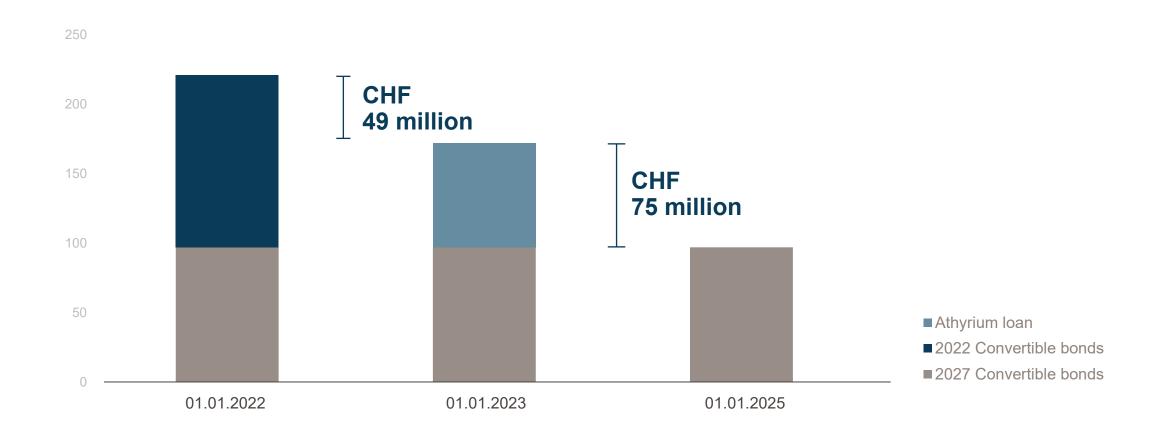
(basilea) Creating anti-infective opportunities

Significant increase in cash flows from operating activities (in CHF million)



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

CHF 124 million reduction of debt level 2022 – 2025



FY 2025 financial guidance – Significantly growing royalty income, maintaining high operating profit while increasing R&D investments

| in CHF million | FY 2025 (guidance) | FY 2024 (actuals) |
|--|-----------------------|----------------------|
| Cresemba and Zevtera related revenue of which royalty income | ~190 ~110 | 194.9 96.7 |
| Total revenue | ~220 | 208.5 |
| Research and development expenses | ~88 | 77.1 |
| Operating profit | ~62 | 61.2 |

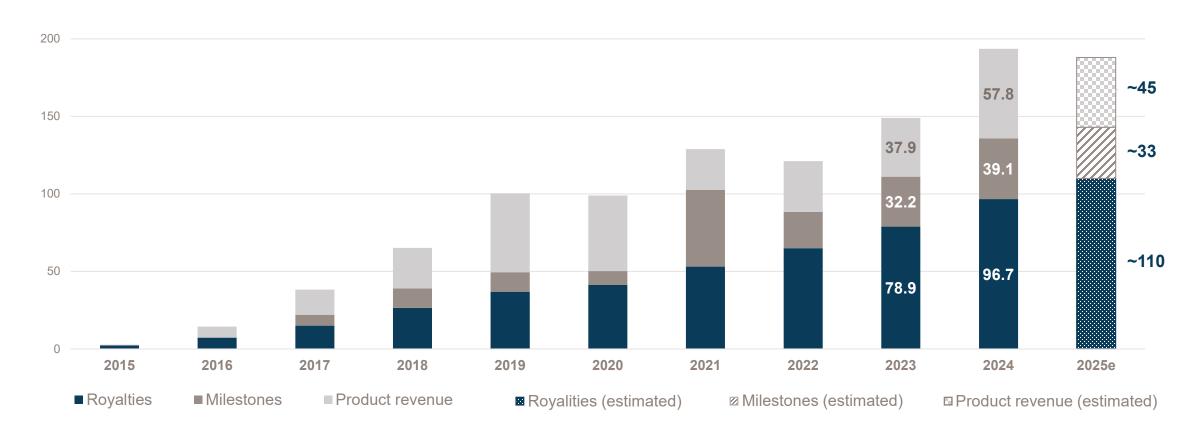
Note: Consistent rounding was applied



Cresemba and Zevtera related revenue – Continued double-digit growth in royalty income, reflecting strong in-market demand

250

in CHF million



Marc Engelhardt Chief Medical Officer

Portfolio update



Fosmanogepix – Our next leading product

PLACE IN THERAPY

For patients with difficult-to-treat infections across a wide range of yeast and mold infections, including those caused by resistant pathogens

KEY ATTRIBUTES

- New Mode of Action (Gwt-1 inhibitor)
- Broad-spectrum
- Active against MDR molds and yeasts

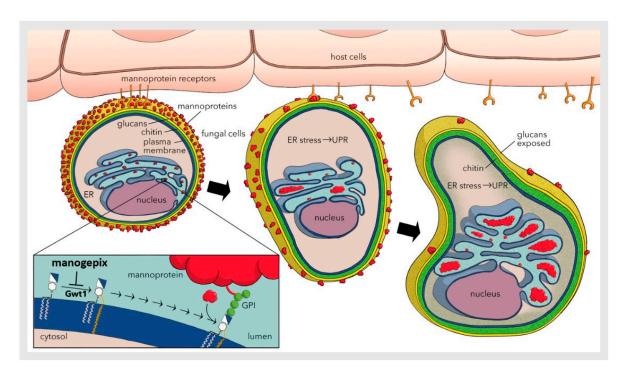
- Wide tissue distribution, incl. CNS
- Relatively low CYP inhibition
- IV and oral

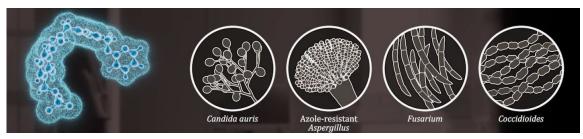
STATUS & NEXT STEPS

Ongoing phase 3 study in *Candida* infections (since H2 2024) Preparing for initiation of second phase 3 study in mold infections (Q2 2025)

Fosmanogepix – Mannoprotein Anchoring Pathway Inhibitor

- Manogepix acts on the Gwt1 enzyme and disrupts the anchoring of membrane and cell wall proteins
- Effects of Gwt1 inhibition include:
 - Decrease fungal pathogenicity
 - Reduce fungal cell viability
 - Promote cell death
 - Reduction in biofilm formation
 - Clear fungal infections





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



Fosmanogepix – Potent broad-spectrum activity

| | Fosmanogepix | lbrexafungerp | Olorofim | Rezafungin | |
|-------------------|---|---------------|----------|------------|-------------------|
| | IV and Oral | Oral | Oral | IV | |
| Fungal pathogens | | | | | |
| Candida spp. | | | | | |
| Aspergillus spp. | | | | | |
| Mucorales | • | | | | |
| Fusarium spp. | | | • | | |
| Scedosporium spp. | | - | | | |
| Lomentospora spp. | | - | | | Potent activity |
| Cryptococcus spp. | | | | | |
| Endemic molds | | | | | Variable activity |
| Other rare molds | $\bullet \bullet \bullet \bullet \bullet \bullet$ | | | | No activity |
| Other rare yeasts | | | | | Unknown |

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

Fosmanogepix – 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
- Study ongoing

Invasive mold infections (IMI)

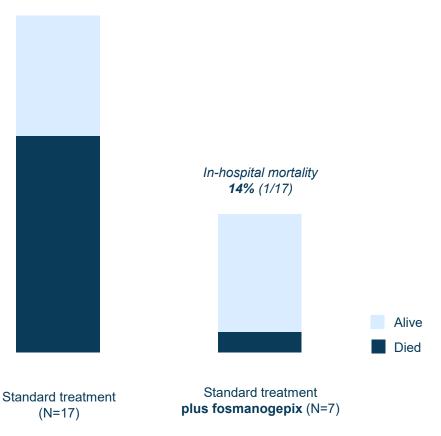


- Randomized, open-label study including non-controlled salvage treatment arm
 - Approximately 200 patients
- Cohorts of invasive mold disease including IMI caused by:
 - Aspergillus spp.
 - Fusarium spp.
 - Scedosporium spp.
 - Lomentospora prolificans
 - Mucorales, or
 - Other molds (salvage)
- Fosmanogepix IV or oral vs best available therapy
- Endpoints include survival and overall response
- Expected study start in Q2 2025

QIDP and Fast Track designations by the FDA for invasive candidiasis, invasive aspergillosis, scedosporiosis, fusariosis, mucormycosis, cryptococcosis, and coccidioidomycosis

Fosmanogepix saving lives – Expanded access experience

- For patients with serious and/or life-threatening IFIs and no other available treatment option
- More than 230 cases in more than 10 countries
- Cases with invasive fusariosis, aspergillosis,
 Candida infections and infections caused by other rare molds or endemic fungi
- Increasing number of cases following the *Fusarium* meningitis outbreak in US/Mexico (June 2023)
 - 24 patients from the US were diagnosed with fungal meningitis caused by *Fusarium* spp. due to iatrogenic contamination during peridural anesthesia
 - The addition of fosmanogepix led to favorable clinical outcomes in patients previously declining on approved antifungals



Smith DJ, Open Forum Infect Dis. 2023 Nov 27;10(Suppl 2):ofad500.2463 Strong N, N Engl J Med. 2024; 390: 522-529 Smith DJ, Infect Dis Clin North Am. 2025;39:23-40 Basilea, data on file

In-hospital mortality 65% (11/17)

NCT06433128 CDC = Centers for Disease Control and Prevention



BAL2062 – For the treatment of invasive aspergillosis

PLACE IN THERAPY

First-line IV treatment of invasive aspergillosis (incl. azole-resistant) with the potential to deliver superior efficacy to standard-of-care

KEY ATTRIBUTES

- New mode of action
- Potential for superior efficacy ٠
- No cross-resistance
- Rapidly fungicidal

- No renal toxicity
- No DDIs expected •

STATUS & NEXT STEPS

- Preclinical profiling studies ongoing
- Preparation of the phase 2 program in 2025 to start the study in 2026

Tonabacase – For staphylococcal infections

PLACE IN THERAPY

Adjunct therapy to standard-of-care antibiotics in complicated staphylococcal infections, including infective endocarditis

STATUS

- Acquired evaluation license in October 2023
- Preclinical profiling completed: Decided not to pursue further development
- Continue to look at novel modalities that could provide superior outcomes in Gram-positive bacterial infections

BAL2420 (LptA inhibitor) – Next generation first-in-class antibacterial

PLACE IN THERAPY New treatment option for the most frequent Gram-negative pathogens causing bloodstream infections (Enterobacteriaceae), including carbapenem-resistant isolates

KEY ATTRIBUTES New mode of action

Highly potent

•

- Bactericidal
- No cross-resistance to other antibiotic classes

STATUS & NEXT STEPS

- Acquisition of LptA inhibitor program in January 2024
- Nomination of BAL2420 as drug candidate
- Progressing towards first-in-human clinical study in mid-2026

David Veitch

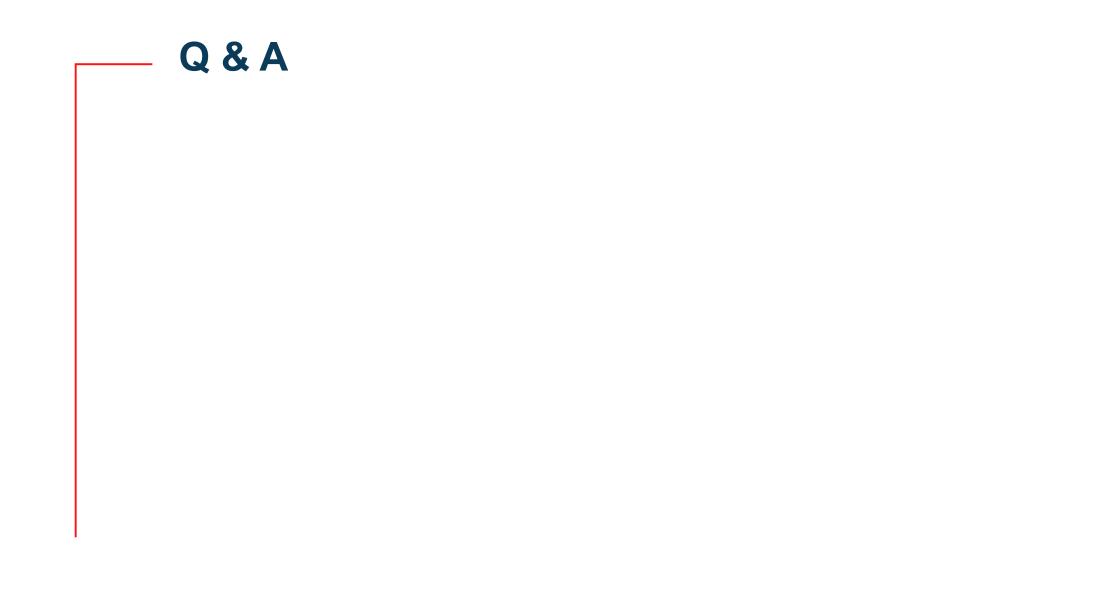
Chief Executive Officer

Outlook



Key value drivers 2025

- Increasing Cresemba & Zevtera revenue
 - US launch of Zevtera
- Advancement of preclinical and clinical anti-infective assets
 - Start of second phase 3 study with fosmanogepix (mold infections)
- In-licensing and acquisition of additional anti-infective assets
- Continue to access non-dilutive R&D funding for anti-infectives portfolio



Thank you



| - | ABSSSI: | Acute bacterial skin and skin structure infections |
|---|----------|---|
| - | BARDA: | Biomedical Advanced Research and Development Authority |
| - | CABP: | Community-acquired bacterial pneumonia |
| - | CARB-X | Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator |
| - | CNS: | Central Nervous System |
| - | CYP: | Cytochrome P |
| - | DDI: | Drug-drug interaction |
| - | EMA: | European Medicines Agency |
| - | FDA: | US Food and Drug Administration |
| - | Gwt-1: | GPI-anchored wall transfer protein 1 |
| - | HABP: | Hospital-acquired bacterial pneumonia |
| - | IMI: | Invasive mold infections |
| - | IV: | Intravenous |
| - | MRSA: | Methicillin-resistant Staphylococcus aureus |
| - | MDR: | Multidrug resistance |
| - | QIDP: | Qualified Infectious Disease Product |
| _ | SAB: | Staphylococcus aureus bacteremia |
| - | US GAAP: | United States Generally Accepted Accounting Principles |



Creating anti-infective opportunitites

Hegenheimermattweg 167b 4123 Allschwil Switzerland

info@basilea.com www.basilea.com

All rights reserved. © Basilea Pharmaceutica International Ltd, Allschwil