

# Creating anti-infective opportunities

"Patients are at the heart of what we do"

INVESTOR PRESENTATION

March 25, 2025



### Introducing Basilea and the executive management team

- Founded in 2000 as a spin off from Roche
- Profitable Swiss commercialstage biopharmaceutical company
- About 160 employees
- Headquarters in Allschwil, Switzerland, in the Basel area life sciences hub
- Listed on the SIX Swiss Stock Exchange, Ticker: BSLN.SW





2014







**ADESH KAUL** CFO

2009







MARC ENGELHARDT MD, PH.D CMO

2010







**GERRIT HAUCK** PH.D. CTO

2018





**LAURENZ KELLENBERGER** PH.D. CSO

2000





"Our experienced team brings deep expertise across Basilea's entire value chain."

# Our focus is on identifying and generating commercial opportunities in the anti-infectives area

- We are focused on developing treatments for severe bacterial and fungal diseases
- Unmet medical needs:
  - Therapies with limited spectrum of activity
  - Growing resistance
  - Lack of oral dosing forms
  - Toxicities
- We strive to create sustainable value with meaningful benefits for patients and healthcare systems, generating long-term returns for investors and our partners
- Currently two revenue generating hospital anti-infective brands:
   Cresemba<sup>®</sup> and Zevtera<sup>®</sup>



#### Manifestations of severe infections

Candida spp. Bloodstream, abdominal,

osteoarticular, cardiac, ocular,

CNS, pulmonary

Aspergillus spp. Pulmonary, sinuorbital, CNS,

cardiac, cutaneous,

abdominal

Fusarium spp. Bloodstream, cutaneous,

sinuorbital, ocular, CNS,

pulmonary

Mucorales fungi Pulmonary, sinuorbital, CNS,

renal, cutaneous, abdominal

**Staphylococci** Bloodstream, cutaneous,

cardiac, abdominal,

osteoarticular, pulmonary

Enterobacteriaceae Bloodstream, urinary,

pulmonary, cutaneous, abdominal, osteoarticular

### **Business model**

Unique capabilities, limited acquisition and development costs,

commercialization partnerships supporting profitability

**External pool of** Cashflow potential assets generating Eligible for royalties/ milestones from partners Lean and low risk commercialization model: limited selling expenses and no significant CAPEX Manufacture/sell product through partnerships Cresemba: Pfizer \*\* astellas AsahiKASEI

and more..

In-license/acquire novel anti-infective assets

e.g. fosmanogepix

Attractive financial terms with limited upfront payments due to the competitive situation in the anti-infectives space

Add value through clinical development

Upside: non-dilutive funds/support from governments and non-profit organizations



File for regulatory

approvals

Identify commercial partner



# Healthcare systems are spending > USD 20 billion for systemic antifungals and antibiotics

GLOBAL SYSTEMIC ANTIFUNGALS MARKET 2023

GLOBAL SYSTEMIC HOSPITAL ANTIBIOTICS MARKET 2023





Source: IQVIA Analytics Link 2023

## Invasive fungal and severe bacterial infections are on the rise due to several factors



**Aging population** (e.g. elderly individuals more prone to infections)



Advances in **medical procedures** (e.g. medical devices like catheters **or other foreign body materials**)



Agriculture: widespread use of fungicides in agriculture



Climate change (e.g. growing incidence of fungal infections)



Growing population of immunocompromised individuals (e.g. patients with chronic conditions)

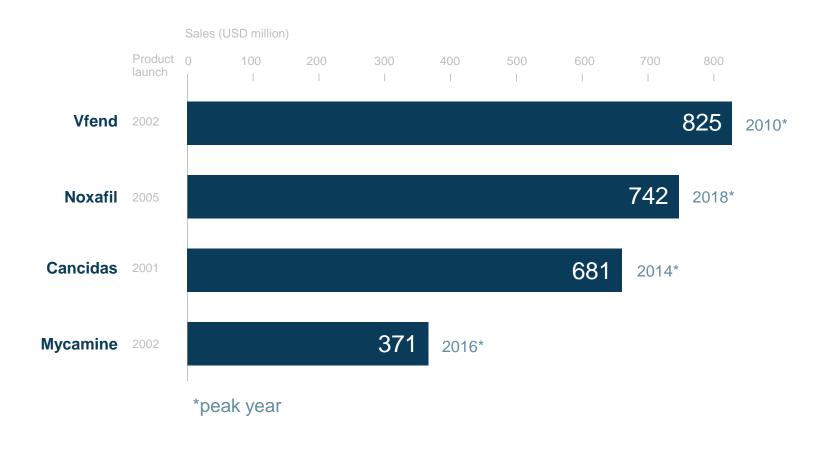


Increased use of immunosuppressive therapies (e.g. for organ or stem cell transplants, cancer therapies, biologic agents)



Increasing **resistance** against currently used antibiotics and antifungals

# Commercially successful hospital antifungals have achieved peak sales of ~ 600-900 USD million



- Sales of branded antifungals typically peak around the time of their loss of exclusivity (more than 10 years market opportunity)
- Basilea's Cresemba is already today achieving more than USD 500 million annual sales with continued strong double-digit year on year growth

Pfizer Inc., 2010 Financial Report, page 25 Merck & Co., Inc., Commission File No. 1-6571, page 124

Proprietary information of Basilea Pharmaceutica International Ltd, Allschwil - not for distribution

### CDC's antimicrobial resistance threats in the US

# Basilea's pipeline provides treatment options across all 3 threat levels

#### **Urgent Threats**

These germs are public health threats that require urgent and aggressive action:

Carbapenem-resistant

Acinetobacter

Candida auris

Clostridiodes difficile

Carbapenem-resistant **Enterobacteriaceae** 

Drug-resistant

Neisseria gonorrhoeae

#### **Serious Threats**

These germs are public health threats that require prompt and sustained action:

Drug-resistant

Campylobacter

Drug-resistant Candida

ESBL-producing

Enterobacteriaceae

Vancomycin-resistant **Enterococci** 

Multidrug-resistant

Pseudomonas aeruginosa

Drug-resistant

Nontyphoidal salmonella

Drug-resistant **Shigella** 

Methicillin-resistant

Staphylococcus aureus

Drug-resistant

Streptococcus pneumoniae

Drug-resistant

**Tuberculosis** 

#### Concerning Threats

These germs are public health threats that require careful monitoring and prevention action:

Erythromycin-resistant

Group A streptococcus

Clindamycin-resistant

Group B streptococcus

#### Watch list

Azole-resistant

Aspergillus fumigatus

Drug-resistant

Mycoplasma genitalium

Drug-resistant

Bordetella pertussis

Visualized based on CDC Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019. www.cdc.gov/DrugResistance/Biggest-Threats.html (electronic version)



# 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) <sup>1</sup>					
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					

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



### Non-dilutive R&D funding

#### BARDA Other Transaction Agreement (OTA)<sup>1</sup>

- 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 program<sup>2</sup>
- 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

<sup>&</sup>lt;sup>2</sup> Agreement number 75A50122C00028 and WT224842



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<sup>&</sup>lt;sup>1</sup> OTA number 75A50124C00033

Anti-infective pipeline

# Antifungals

# Cresemba — Differentiated by spectrum, safety and tolerability

- Broad spectrum of activity against molds, including emerging molds (Mucorales fungi)
- Consistent plasma levels
- Statistically fewer drug-related adverse events and treatment-emergent adverse events (liver, skin, eye) in invasive aspergillosis patients vs. voriconazole in SECURE phase 3 study
- Can be administered without restriction in patients with renal impairment

- Manageable drug-drug interaction profile
- Once daily maintenance dose, IV/oral treatment
- ECIL-6 guideline: Cresemba® recommended for the first-line treatment of invasive aspergillosis in leukemia and hematopoietic stem cell transplant patients. ECIL states that isavuconazole is as effective as voriconazole with a better safety profile.

# Cresemba® Global commercial partnerships

Marketed in

75
countries

United States	astellas
Canada	AVIR PHÁRMA
Latin America	<b>UKnight</b>
Europe (excluding Nordic	es) Pfizer
Nordics	UNIMEDIC*
MENA Region	hikma.
Asia-Pacific and China	<b>₹</b> Pfizer
 Japan	Asahi <b>KASE</b> I

# USD 562 million

In-market sales

in-market sales January to December 2024

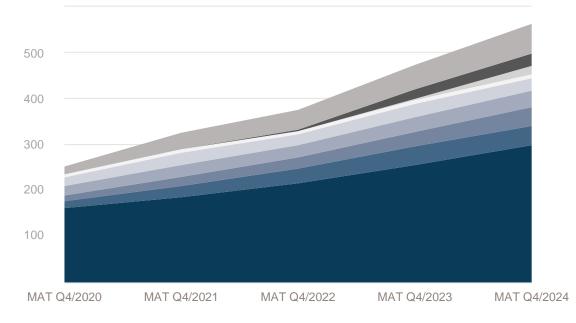


■ Germany

■ Italy

■Spain ■France

■USA

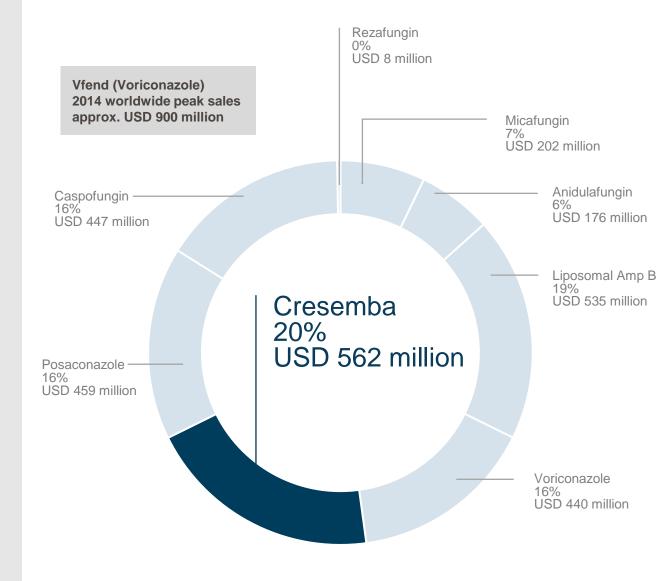


# Global sales of best-inclass antifungals\* by product

USD 2.8 billion sales (MAT Q4 2024)

Significant potential to increase Cresemba® (isavuconazole) global market share

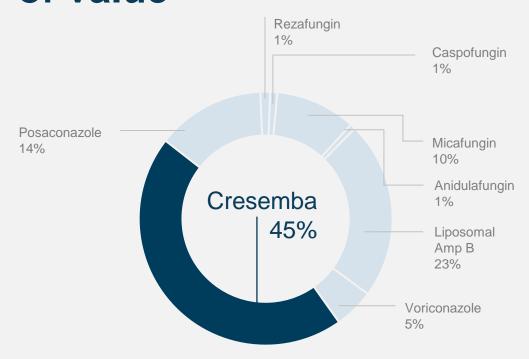
- Pediatric label extension in US granted in December 2023; market exclusivity extended to September 2027
- Pediatric label extension in EU granted in August 2024; market exclusivity extended to October 2027



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



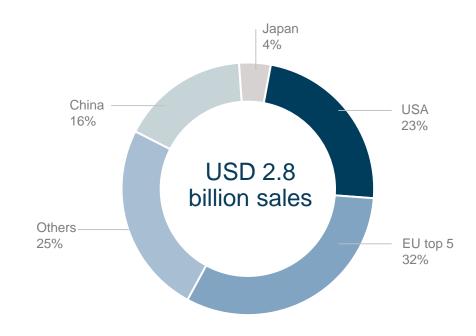
# Cresemba – the market leader in the US in terms of value



 Consistently increased market share among best-in-class antifungals\* since launch to 45% by December 2024\*\*

#### (basilea)

# Significant global growth potential



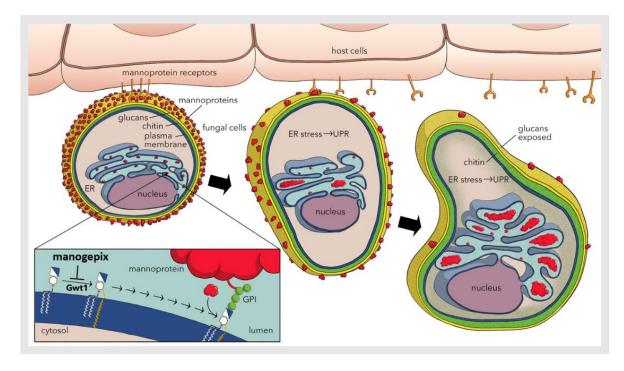
- USD 2.8 billion sales of best-in-class antifungals\* (MAT Q4 2024)\*\*
- Recently launched in Japan and China, representing 21% of global potential

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

<sup>\*\*</sup>Market share based on MAT Q4 2024, in-market sales reported as moving annual total (MAT) in US dollar; rounding consistently applied. Source: IQVIA Analytics Link, December 2024

## 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





## Fosmanogepix – Potent broad-spectrum activity

Fungal pathogens
Candida spp.*
Aspergillus spp.†
Mucorales <sup>‡</sup>
Fusarium spp.
Scedosporium spp.
Lomentospora spp.
Cryptococcus spp.
Endemic molds§
Other rare molds <sup>II</sup>
Other rare yeasts¶

Fosmanogepix	Ibrexafungerp	Olorofim	Rezafungin
IV and Oral	Oral	Oral	IV
•••••			

<sup>\*</sup> including C. albicans, C. auris, C. dubliniensis, C. glabrata, C. krusei, C. lusitaniae, C.parapsilosis, C. tropicalis. Fosmanogepix not active against C. krusei.

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

Potent activity

Variable activity

No activity

Unknown



<sup>†</sup> including A. calidoustus, A. fumigatus (including azole-resistant), A. flavus, A. lentulus, A. nidulans, A. niger, A. terreus, A. tubingensis.

<sup>‡</sup> including Cunninghamella spp., Lichtheimia spp., Mucor spp., Rhizopus spp.

<sup>§</sup> including Blastomyces dermatitidis, Coccidioides immitis, Histoplasma capsulatum.

including Alternaria alternata, Cladosporium spp. Paecilomyces variotii, Purpureocillium lilacinum, Scopulariosis spp., Rasamsonia spp.

<sup>¶</sup> including *Trichosporon asahii*, *Exophiala dermatitidis*, *Malassezia furfur*.

## 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

### 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
- No cross-resistance
- Rapidly fungicidal

- Potential for superior efficacy
- 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

Anti-infective pipeline

# **Antibacterials**

### **Zevtera®** — An introduction

- Broad-spectrum hospital anti-MRSA cephalosporin (including Gram-negative bacteria)
  - Rapid bactericidal activity
  - Potential to replace antibiotic combinations
  - Efficacy demonstrated in phase 3 clinical studies in SAB, ABSSSI and pneumonia<sup>1, 2, 3</sup>
  - Low propensity for resistance development<sup>1</sup>
  - Safety profile consistent with the cephalosporin class safety profile, demonstrated in both adult and pediatric patients<sup>1, 2, 3, 4</sup>
- Marketed in selected countries in Europe,
   Latin America, the MENA-region, Canada and
   China
- US launch expected mid-2025

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). Indicated in the US for the treatment of adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) (SAB), including right-sided infective endocarditis, and adult patients with acute bacterial skin and skin structure infections (ABSSSI) and for adult and pediatric patients (3 months to less than 18 months old) with community-acquired bacterial pneumonia (CABP).



<sup>&</sup>lt;sup>1</sup> Syed YY. Drugs. 2014;74:1523-1542 and Basilea data on file.

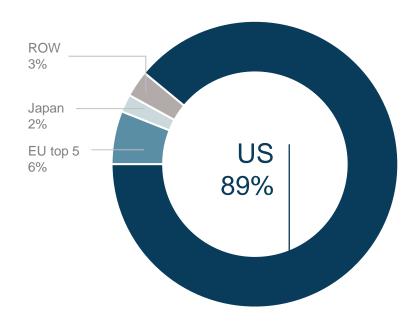
<sup>&</sup>lt;sup>2</sup> Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

<sup>&</sup>lt;sup>3</sup> Holland TL et al. N Engl J Med 2023;389:1390-1401

<sup>&</sup>lt;sup>4</sup> Rubino CM et al. Pediatr Infect Dis J. 2021:40:997-1003.

# 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:

INN()VIVA 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, December 2024



### **Zevtera** — 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

# 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

- Acquired LptA inhibitor program in January 2024
- Nominated BAL2420 as drug candidate
- Progressing towards first-in-human clinical study in mid-2026

# Financials & Outlook



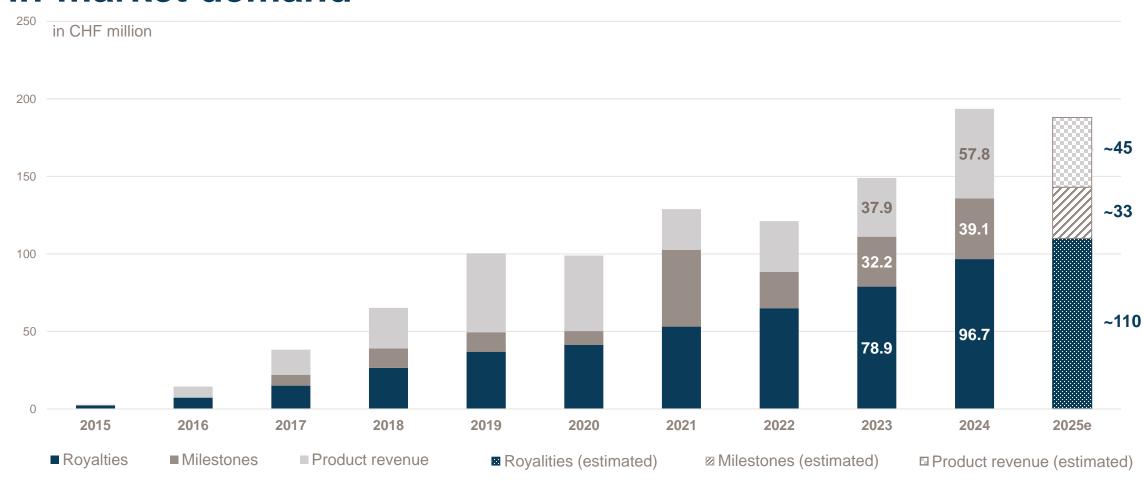
# Strong financial results FY 2024 – Significant increase in revenue and profit

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	

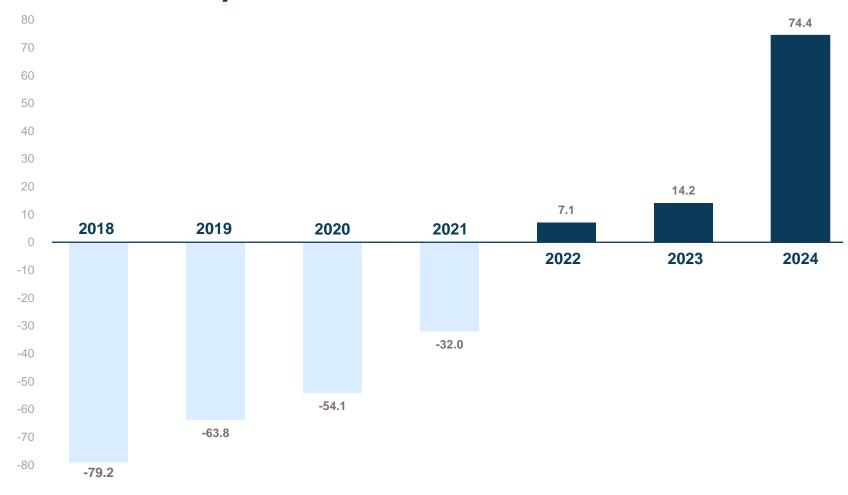
Note: Consolidated figures in conformity with US GAAP; rounding applied consistently



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



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

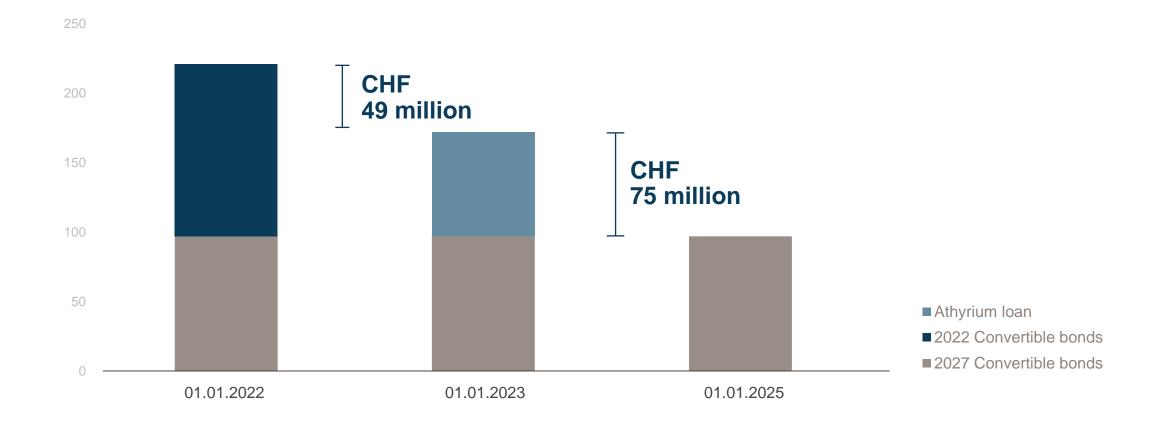


Note: Consolidated figures in conformity with US GAAP; rounding applied consistently



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### 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 <i>96.7</i>
Total revenue	~220	208.5
Research and development expenses	~88	77.1
Operating profit	~62	61.2

Note: Consistent rounding was applied.

## **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

### 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 forwardlooking statements. Basilea disclaims any obligation to update any such forward-looking statements to reflect future events or developments, except as required by applicable law.



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# Glossary

ABSSSI: Acute bacterial skin and skin structure infections

BARDA: Biomedical Advanced Research

and **D**evelopment **A**uthority

CABP: Community-acquired bacterial pneumonia

CARB-X: Combating Antibiotic-Resistant Bacteria

Biopharmaceutical **Accelerator** 

CNS Central Nervous System

CYP: Cytochrome P

DDI: Drug-drug interaction

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

MS-DRG: Medicare Severity Diagnosis-Related Group

- MSSA: **M**ethicillin-**s**usceptible **S**taphylococcus **a**ureus

QIDP: Qualified Infectious Disease Product

SAB: Staphylococcus aureus bacteremia

US GAAP: United States Generally Accepted

Accounting Principles

VAP: Ventilator-associated pneumonia



**Creating anti-infective opportunities** 

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