

Introducing Basilea and the executive management team

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











CEO

2014

2000

CFO

2009

POLYPHOR

ADESH KAUL

Genedata Solutions in silico

MARC ENGELHARDT MD, PH.D CMO

2010

U NOVARTIS

BRACCO

GERRIT HAUCK PH.D. CTO

2018

SANOFI

LAURENZ KELLENBERGER PH.D. CSO

2000

UNIVERSITY OF CAMBRIDGE



"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[®] and Zevtera[®]



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

Creating anti-infective opportunities

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



CARB-X
Constading Antitivetic-Resistant Bacteria

File for regulatory approvals

Identify commercial partner



and more.

Healthcare systems are spending > USD 20bn for hospital antifungals and antibiotics

GLOBAL SYSTEMIC HOSPITAL ANTIFUNGALS MARKET 2023

The **hospital antifungal** market is valued at

USD



GLOBAL SYSTEMIC HOSPITAL ANTIBIOTICS MARKET 2023

The **hospital antibiotics** market is valued at

USD



Source: The Lancet Infectious Diseases, Global incidence and mortality of severe fungal disease, https://doi.org/10.1016/S1473-3099(23)00692-8

Source: The Lancet, Global mortality associated with 33 bacterial pathogens in 2019: a systematic analysis for the Global Burden of Disease Study 2019, https://doi.org/10.1016/S0140-6736(22)02185-7

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)

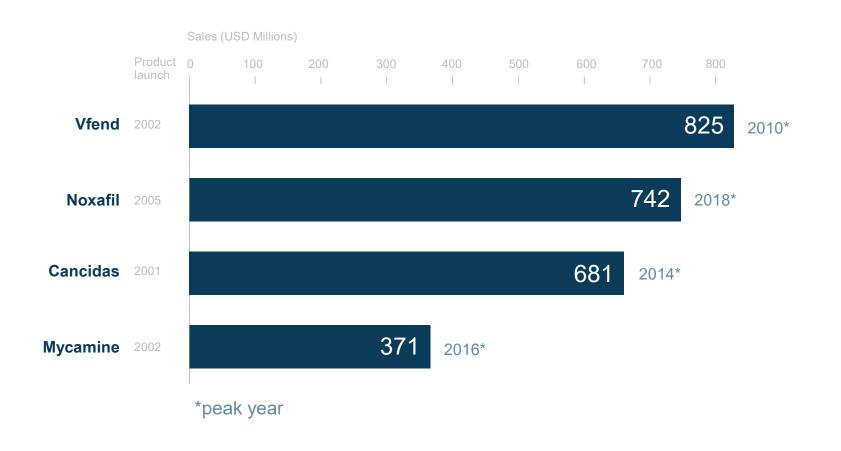


Increased use of immunosuppressive therapies (e.g. for organ or stem cell transplants, cancer therapies, biologic agents)



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

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



- 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 approximately USD 500 mn 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

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)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, Scedoporium and Lomentospora, 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) (US)					
Tonabacase					
Severe staphylococcal infections					
LptA inhibitor					
Severe Enterobacteriaceae infections					
Internal research					
Focus for in-licensing and acquisitions					

¹ The registration status and approved indications may vary from country to country.



Non-dilutive R&D funding

BARDA Other Transaction Agreement (OTA)

- Entered into in September 2024¹
- Flexible contracting mechanism to foster innovation, promote collaboration and enable faster development timelines
- 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 costs for the development of designated first-in-class antifungals and antibacterials in Basilea's portfolio over the term of the agreement (12 years)
- BARDA and Basilea can jointly decide to move drug candidates into and out of the portfolio

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

- Funding agreement since April 2024 for LptA inhibitor program (antibiotic)²
- Initial funding of up to USD 0.9 million supports the work until candidate nomination
- Potential additional funding to continue preclinical and early clinical development of the antibiotics program if the project achieves certain milestones



Creating anti-infective opportunities

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 partnership

astellas **United States** AVIR Latin America **UKnight ₽**Pfizer (excluding Nordics)

UNIMEDIC°

hikma.

Asahi **KASE**

Asia-Pacific **₽**Pfizer and China

Canada

Europe

Nordics

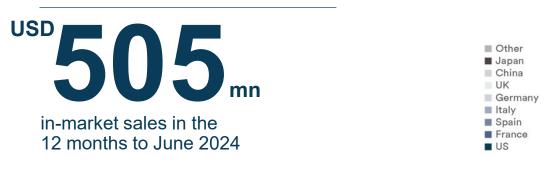
MENA

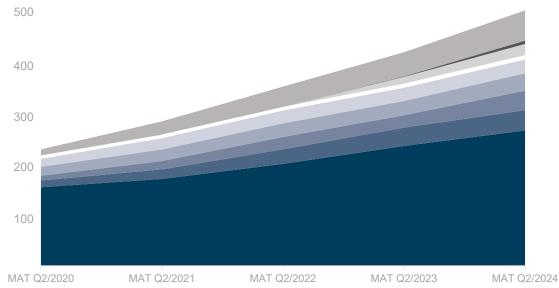
Region

Japan

Marketed in countries

In-market sales



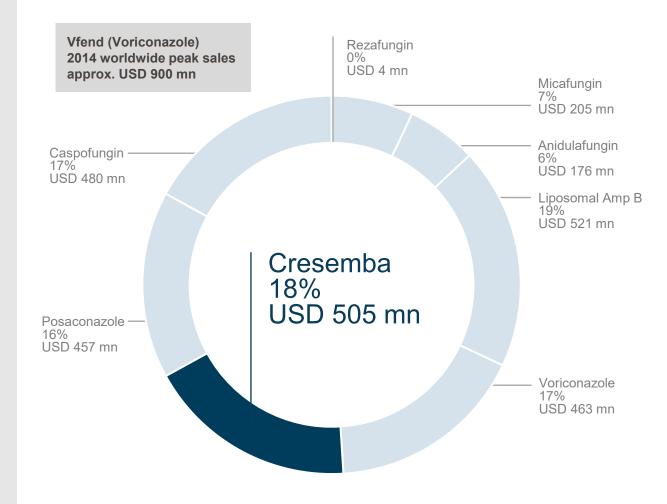


Global sales of best-inclass antifungals* by product

USD 2.8 bn sales (MAT Q2 2024)

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

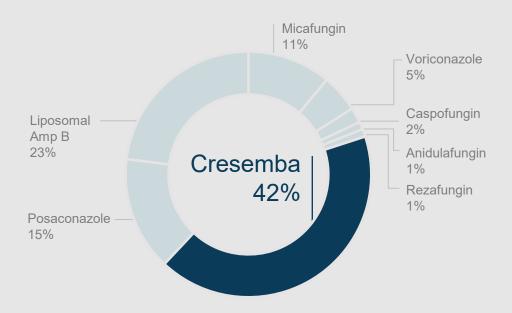
- Pediatric label extension in US granted in December 2023; market exclusivity extended to September 2027
- Pediatric label extension in EU granted in August 2024; market exclusivity extended to October 2027



^{*} Best-in-class antifungals: Cresemba (isavuconazole), posaconazole, voriconazole, Liposomal Amp B, anidulafungin, caspofungin, micafungin, rezafungin



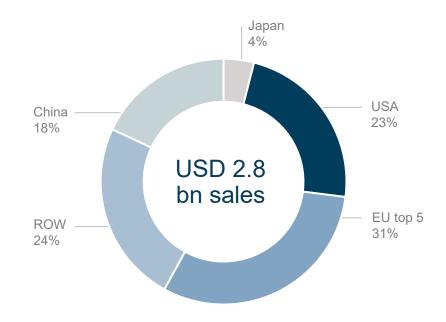
Cresemba – the market leader in the US in terms of value



Consistently increased market share among best-in-class antifungals* since launch to 42% by June 2024**

(basilea)

Significant global growth potential



- USD 2.8 bn sales of best-in-class antifungals* (MAT Q2 2024)**
- Recently launched in Japan and China, representing 22% of global potential

^{*} Best-in-class antifungals: Cresemba (isavuconazole), posaconazole, voriconazole, Liposomal Amp B, anidulafungin, caspofungin, micafungin, rezafungin

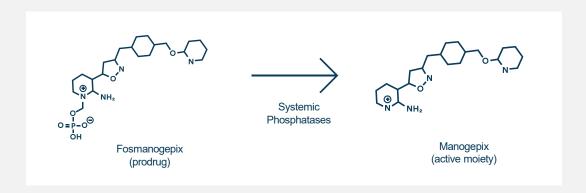
^{**}Market share based on MAT Q2 2024, in-market sales reported as moving annual total (MAT) in US dollar;

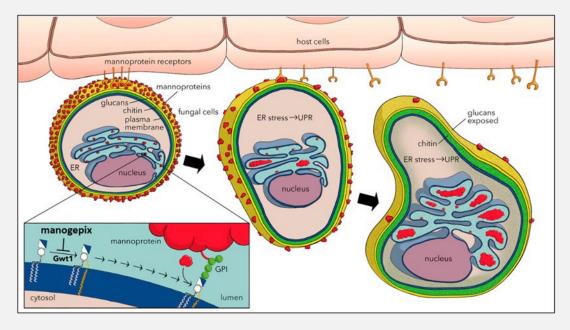
Fosmanogepix – Our next potential key product and mid-term value driver

- 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
- Potential to become our next leading commercial product and mid-term value driver
- Asset acquired from Pfizer, which maintains the right of first negotiation for commercialization

Fosmanogepix – 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 azoleresistant phenotypes
- IV and oral availability enables treatment in both inpatient and outpatient settings
- US FDA fast track status, QIDP and orphan drug designations





(basilea)

Fosmanogepix – Addressing high unmet medical needs

- Fast track status by the US FDA for invasive candidiasis, invasive aspergillosis, scedosporiosis, fusariosis, mucormycosis, cryptococcosis, and coccidioidomycosis
- Addressing emerging resistance issues in yeast infections including Candida auris and azole resistant Aspergillus spp.
- Potent activity against mold infections including difficult-to-treat Fusarium and Scedosporium spp.
- Wide tissue distribution enabling treatment of disseminated infections including CNS
- Favorable drug-drug interaction profile
- In-vivo synergism with liposomal amphotericin B and echinocandins may provide utility for the most difficult-to-treat infections



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



Fosmanogepix – Potent broad-spectrum activity

Fungal pathogens		
Candida spp.*		
Aspergillus spp.†		
Mucorales [‡]		
Fusarium spp.		
Scedosporium spp.		
Lomentospora spp.		
Cryptococcus spp.		
Endemic molds§		
Other rare molds		
Other rare yeasts¶		

Fosmanogepix	Ibrexafungerp	Olorofim	Rezafungin
IV and Oral	Oral	Oral	IV

^{*} 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



[†] 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*.

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
- Protocol and initial Health Authority approvals obtained
- Study initiated September 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 around year-end 2024

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

- Synergy with other antifungals
- Potential for superior efficacy
- No DDIs expected

NEXT STEPS

Preclinical profiling studies ongoing. Start clinical phase 2 program in 2025

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^{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
- US FDA approval in April 2024

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).





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

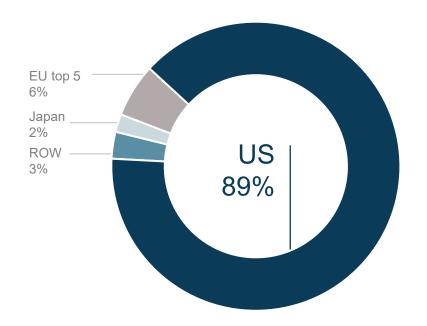
² Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

³ Holland TL et al. N Engl J Med 2023;389:1390-1401.

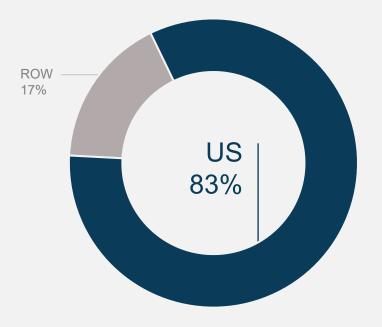
⁴ Rubino CM et al. Pediatr Infect Dis J. 2021:40:997-1003.

Hospital anti-MRSA antibiotics; US being the most important commercial region

Daptomycin sales by region (2015, before LOE)



Ceftaroline sales by region (MAT Q2 2024)



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

Zevtera — Strategy for accessing the US market

FDA approved three indications April 3, 2024:

- Staphylococcus aureus bacteremia (SAB)¹, including right-sided endocarditis
- Acute bacterial skin and skin structure infections (ABSSSI)²
- Community-acquired bacterial pneumonia (CABP, adult and pediatric)³



- 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)⁴
- Qualified Infectious Disease Product (QIDP) designation extends US market exclusivity to 10 years from approval
- Commercialization planned through partnership
 - Partnering negotiations ongoing



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

⁴ Contract number HHSO100201600002C

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

Tonabacase – For superior outcomes in staphylococcal infections

PLACE IN THERAPY

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

KEY ATTRIBUTES

- New mode of action
- Highly potent

- Rapidly bactericidal
- Active in biofilms
- Low risk of resistance development

NEXT STEPS

Preclinical profiling studies ongoing. Decision on definitive licensing option (around year-end 2024)

LptA inhibitors – Next generation first-in-class antibacterials

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

NEXT STEPS

Start first-in-human studies in 2026



Financials & Outlook



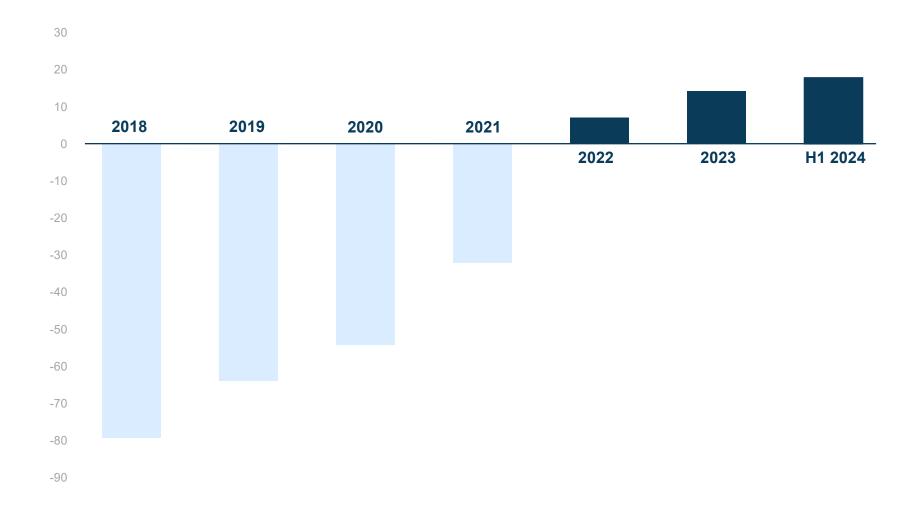
Strong financial results H1 2024 – Cresemba royalty growth, sustained profits and positive cash flow

In CHF million	H1 2024	H1 2023	2023
Cresemba and Zevtera related revenue of which royalty income of which milestone payments	73.3 42.8 2.9	80.5 36.7 30.6	150.3 78.9 32.2
Total revenue	76.3	84.9	157.6
Cost of products sold Operating expenses	18.1 48.9	10.0 38.0	26.8 111.6
Operating result	9.3	36.9	19.2
Net profit	20.7	31.8	10.5
Net financial debt (as of June 30, 2024/2023 and December 31, 2023)	26.2	38.1	46.6

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



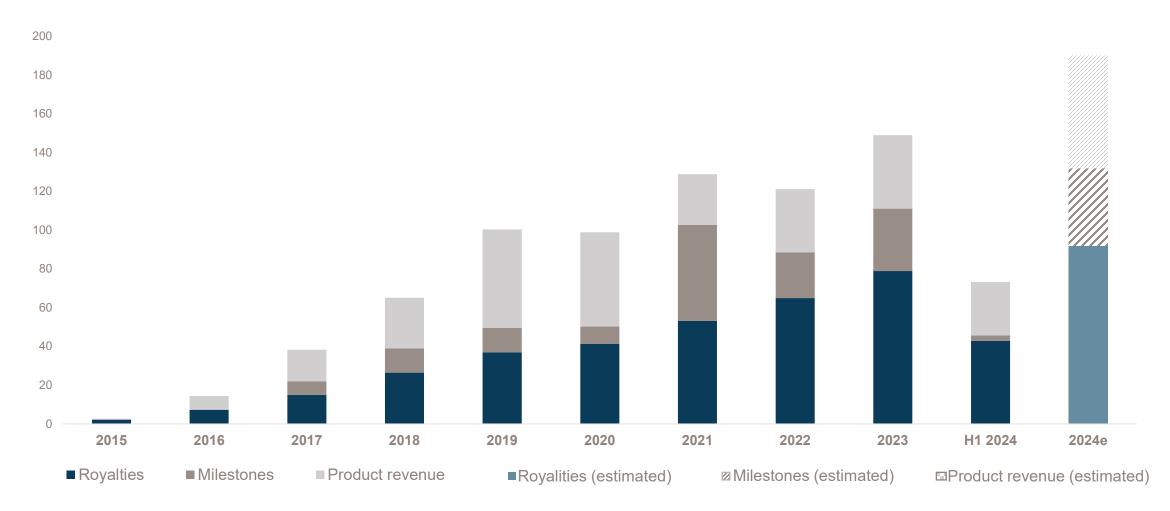
Cash flows from operating activities (in CHF mn)



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

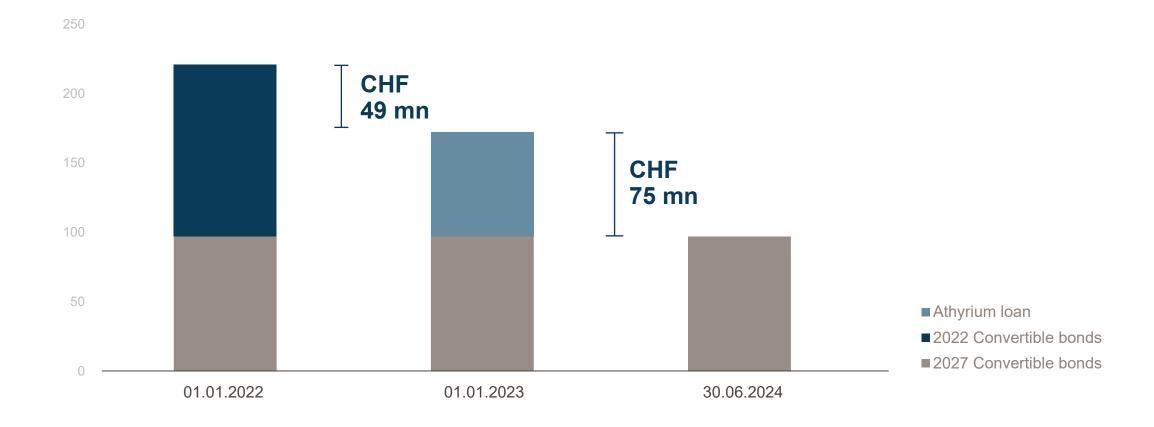


Continued strong growth in Cresemba and Zevtera related revenue (in CHF mn)





CHF 124 mn reduction of debt level 2022 - H1 2024



Note: Figures in CHF mn



Increased FY 2024 financial guidance

In CHF million	FY 2023	FY 2024 (previous guidance)	FY 2024 (current guidance)
Cresemba and Zevtera related revenue of which royalty income	150.3 78.9	~190 ~92	~190 ~92
Total revenue	157.6	~196	~203
Cost of products sold Operating expenses	26.8 111.6	~40 ~120	~40 ~120
Operating result	19.2	~36	~43
Net profit	10.5	~42	~60

Note: Consistent rounding was applied.

Key milestones

	Product	H1 2024	H2 2024		
	Coftobiovalo (Zautava)	✓ US FDA approval	US FDA approval		
Antibacterials	Ceftobiprole (Zevtera)		Executing US partnership		
	Tonabacase		Decide on definitive licensing option (around year-end)		
Antifungals	Isavuconazole (Cresemba)	EMA/CHMP positive opinion on pediatric indication	EC decision on pediatric indication		
			Initiate phase 3 study in candidemia / invasive candidiasis		
	Fosmanogepix		Initiate phase 3 study in mold infections (around year-end)		
Increasing Cre	semba & Zevtera revenue				
In-licensing and acquisition of anti-infectives					
Advancement of preclinical and clinical anti-infective assets					
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.



Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations

Basilea Pharmaceutica International Ltd, Allschwil Hegenheimermattweg 167b 4123 Allschwil | Switzerland

Phone +41 61 606 1102

E-mail investor relations@basilea.com

Glossary

ABSSSI: Acute bacterial skin and skin structure infections

BARDA: Biomedical Advanced Research and Development Authority

CABP: Community-acquired bacterial pneumonia

CNS Central Nervous System

CARB-X: Combating Antibiotic-Resistant Bacteria Biopharmaceutical

Accelerator

EC: European Commisson

EMA: European Medicines Agency

FDA: US Food and Drug Administration

HABP: Hospital-acquired bacterial pneumonia

IMI: Invasive mold infections

– IV: Intravenous

– MSSA: Methicillin-susceptible Staphylococcus aureus

MRSA: Methicillin-resistant Staphylococcus aureus

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

Hegenheimermattweg 167b 4123 Allschwil Switzerland

info@basilea.com www.basilea.com

All rights reserved.

© 2024 Basilea Pharmaceutica International Ltd, Allschwil