Creating anti-infective opportunities

"Patients are at the heart of what we do"

INVESTOR PRESENTATION

September 03, 2024

Introducing Basilea and the executive management team

- Founded in 2000 as a spin off from Roche
- Profitable Swiss commercial-stage 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

	DAVID VEITCH CEO	**ADESH KAUL** CFO	**MARC ENGELHARDT MD, PH.D** CMO	**GERRIT HAUCK PH.D.** CTO	**LAURENZ KELLENBERGER PH.D.** CSO
JOINED	2014	2009	2010	2018	2000
PREVIOUS ROLES	Bristol-Myers Squibb SmithKline Beecham	POLYPHOR Genedata	NOVARTIS BRACCO	SANOFI	UNIVERSITY OF CAMBRIDGE Roche

"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®

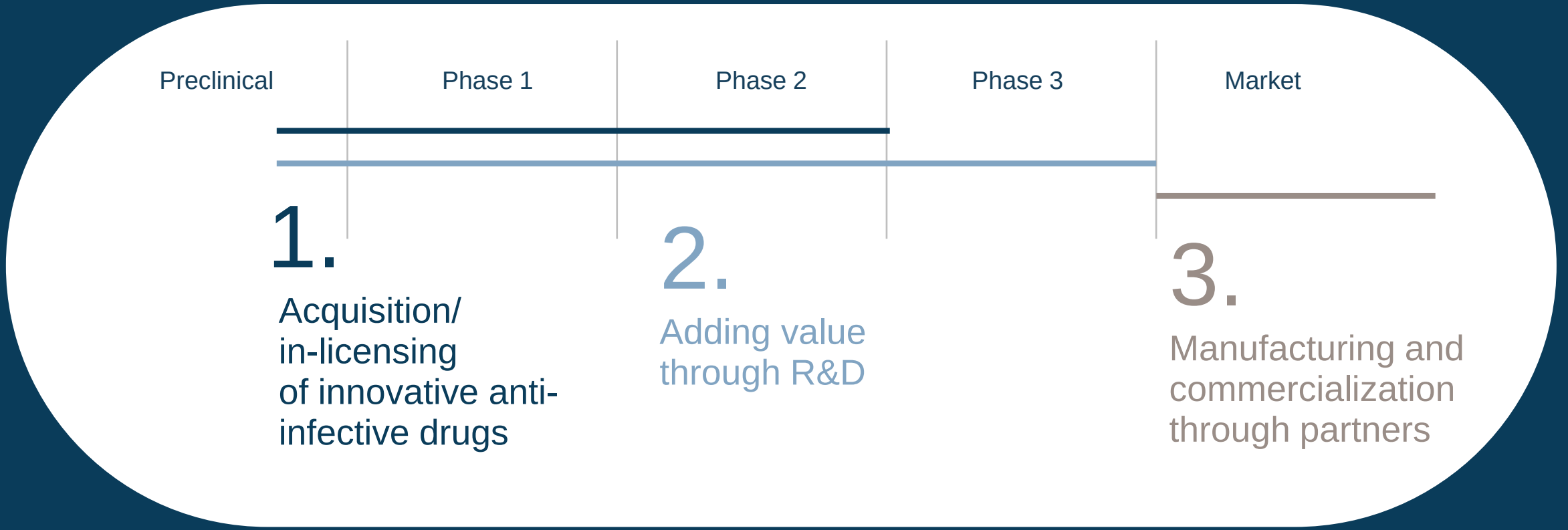
Manifestations of severe infections

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

Key success factors of our business model

- ✓ **Identify market opportunities in anti-infectives**
  - Focus on areas with meaningful market opportunity
  - Focus on high priority diseases/pathogens
- ✓ **Extend portfolio with the right external assets**
  - Focus on development stages that enable value creation through Basilea's proven R&D capabilities
  - Structure in-licensing and acquisitions to appropriately reflect the risk-return profile of a project over its lifetime
- ✓ **Make portfolio decisions based on long-term value creation potential of assets**
  - Select and prioritize assets through the scientific and commercial lens
  - Accept the development risk for the commercial gain
- ✓ **Optimize investment needs and capital allocation along the entire value chain**
  - Maintain a lean cost structure by commercializing and manufacturing through specialized external partners
  - Stop projects that no longer offer a compelling long-term risk-return profile
  - Gain access to non-dilutive funding opportunities (financial incentives) available in the anti-infectives area

Our business model covers the entire pharmaceutical value chain



Established strong partnerships

Commercialization
through partnerships with global, regional and local specialized pharmaceutical partners

LICENSE PARTNERS

Pfizer · astellas · AsahiKASEI · CR Gosun

DISTRIBUTION PARTNERS

ADVANZ PHARMA · hikma. · Knight · UNIMEDIC PHARMA · AVIR PHARMA · LANCET

Offsetting R&D expenses
through accessing non-dilutive funding

CARB-X Combating Antibiotic-Resistant Bacteria · BARDA Biomedical Advanced Research and Development Authority

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

4.4

billion

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

GLOBAL SYSTEMIC HOSPITAL ANTIBIOTICS MARKET 2023

The **hospital antibiotics** market is valued at

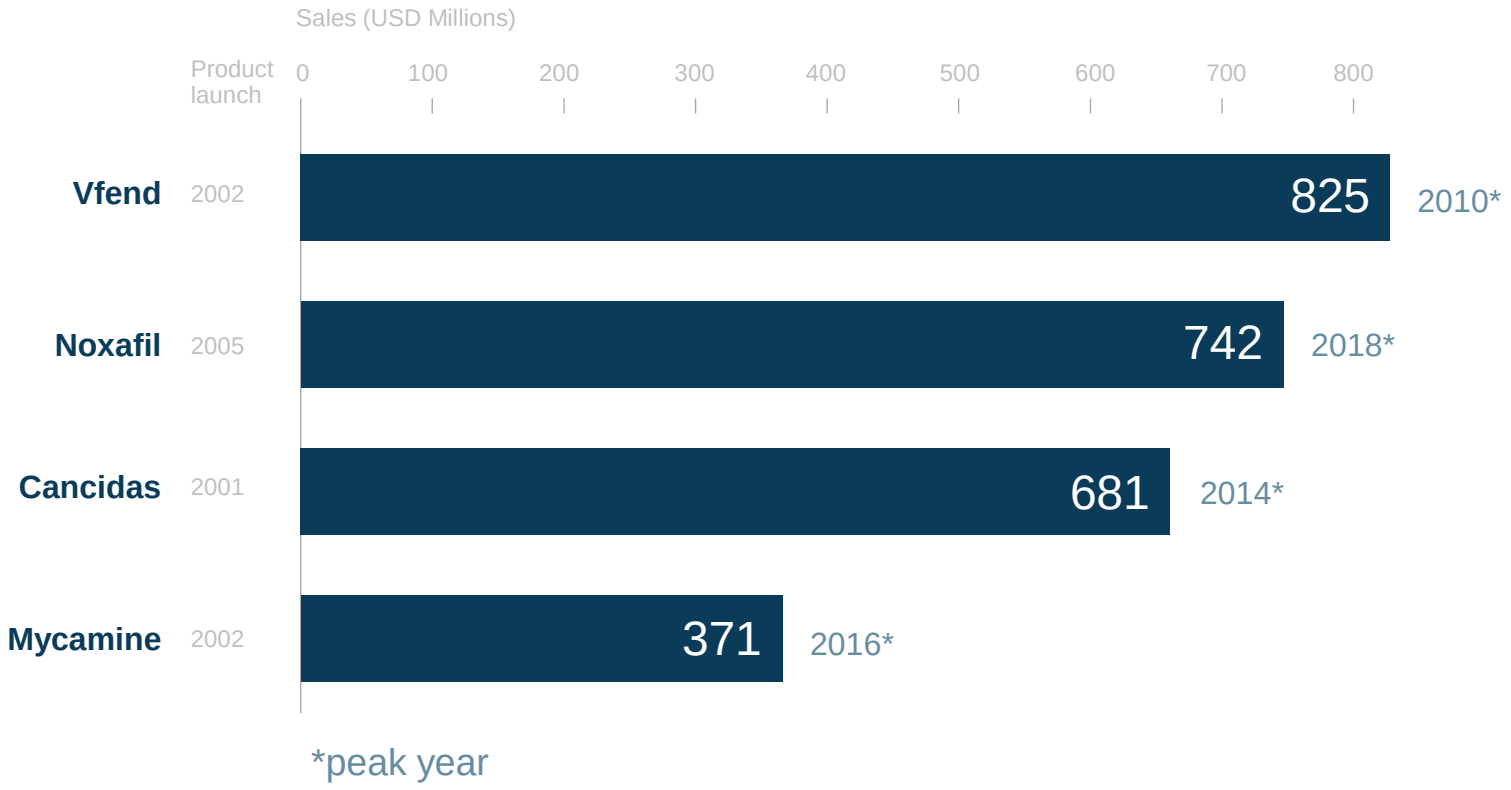
USD

17.8

billion

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

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

Merck & Co., Inc., Commission File No. 1-6571, page 43
Astellas Pharma Inc., IFRS, Financial results for the fiscal year 2017 (FY2017), page 6

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

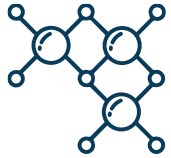
Aging population (e.g. elderly individuals more prone to infections)

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

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

Visualised 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

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

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

Marketed in

73

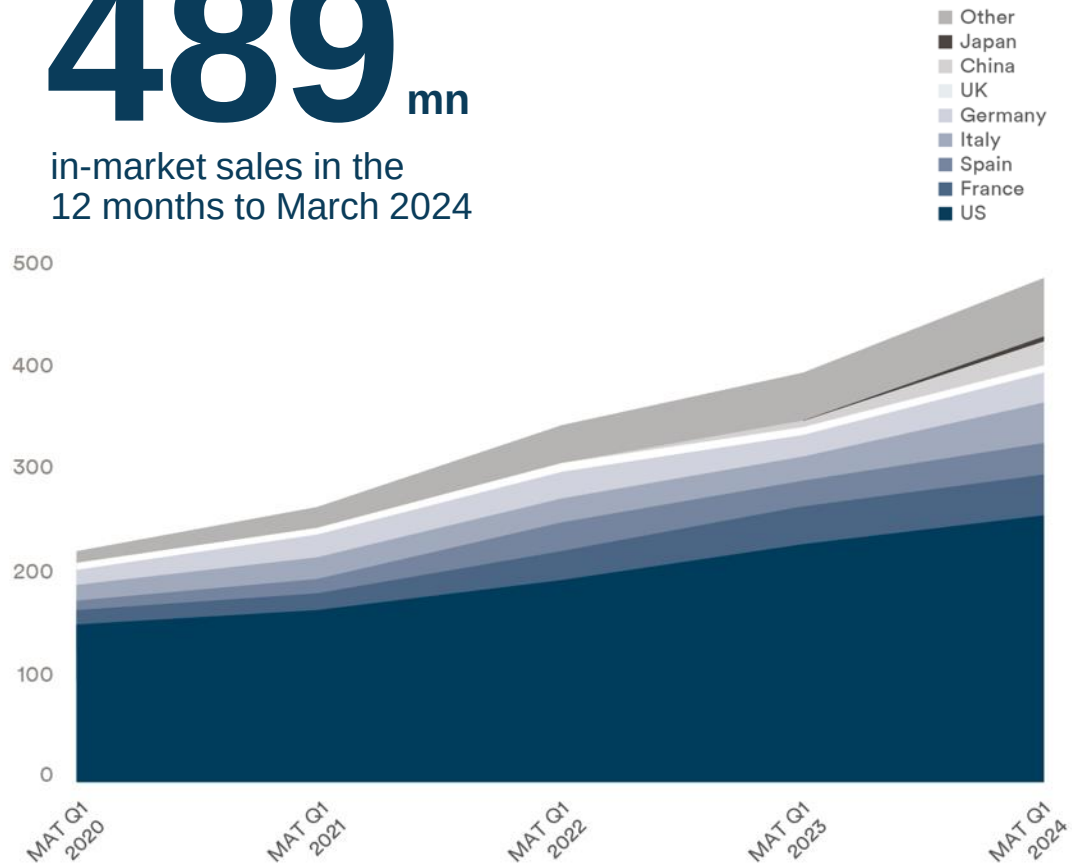
countries

United States	astellas
Canada	AVIR PHARMA
Latin America	Knight
Europe (excluding Nordics)	Pfizer
Nordics	UNIMEDIC PHARMA
MENA Region	hikma.
Asia-Pacific and China	Pfizer
Japan	AsahiKASEI

In-market sales

USD **489** mn

in-market sales in the 12 months to March 2024



MAT: Moving annual total; Source: IQVIA Analytics Link, March 2024

Global sales of best-in-class antifungals* by product

USD 2.9 bn sales (MAT Q1 2024)

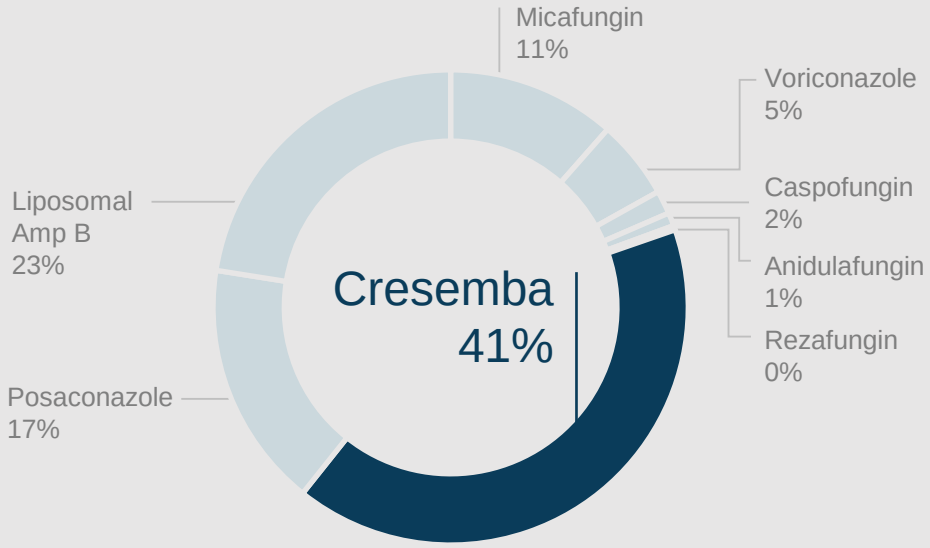
Significant potential to increase Cresemba® (isavuconazole) global market share

- 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

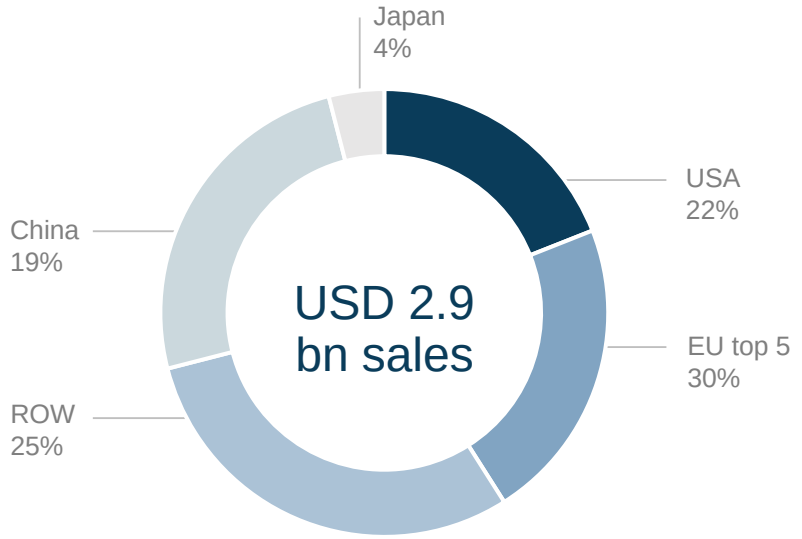
MAT: Moving annual total; Source: IQVIA Analytics Link, March 2024, rounding consistently applied

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



– Consistently increased market share among best-in-class antifungals* since launch to 41% by March 2024**

Significant global growth potential



– USD 2.9 bn sales of best-in-class antifungals* (MAT Q1 2024)

– Recently launched in Japan and China, representing 23% of global potential

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

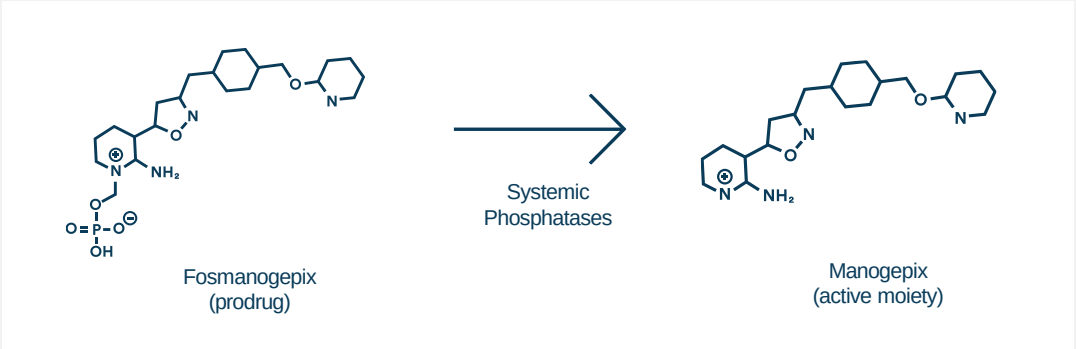
**Market share based on MAT Q1 2024, in-market sales reported as moving annual total (MAT) in US dollar; rounding consistently applied. Source: IQVIA Analytics Link, March 2024

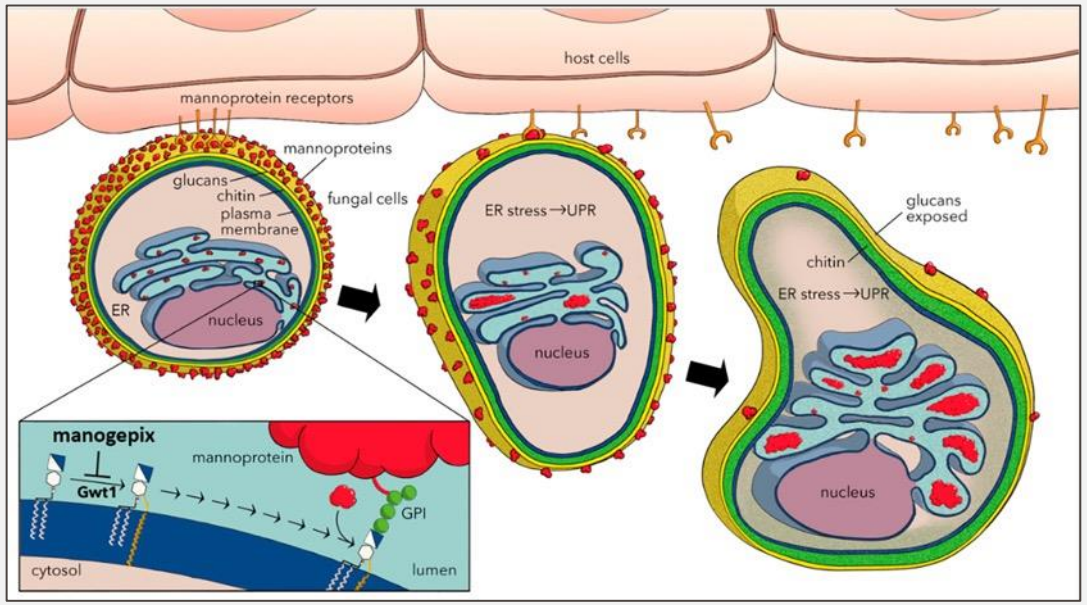
Fosmanogepix – Our next potential key product and mid-term value driver

- 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 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.

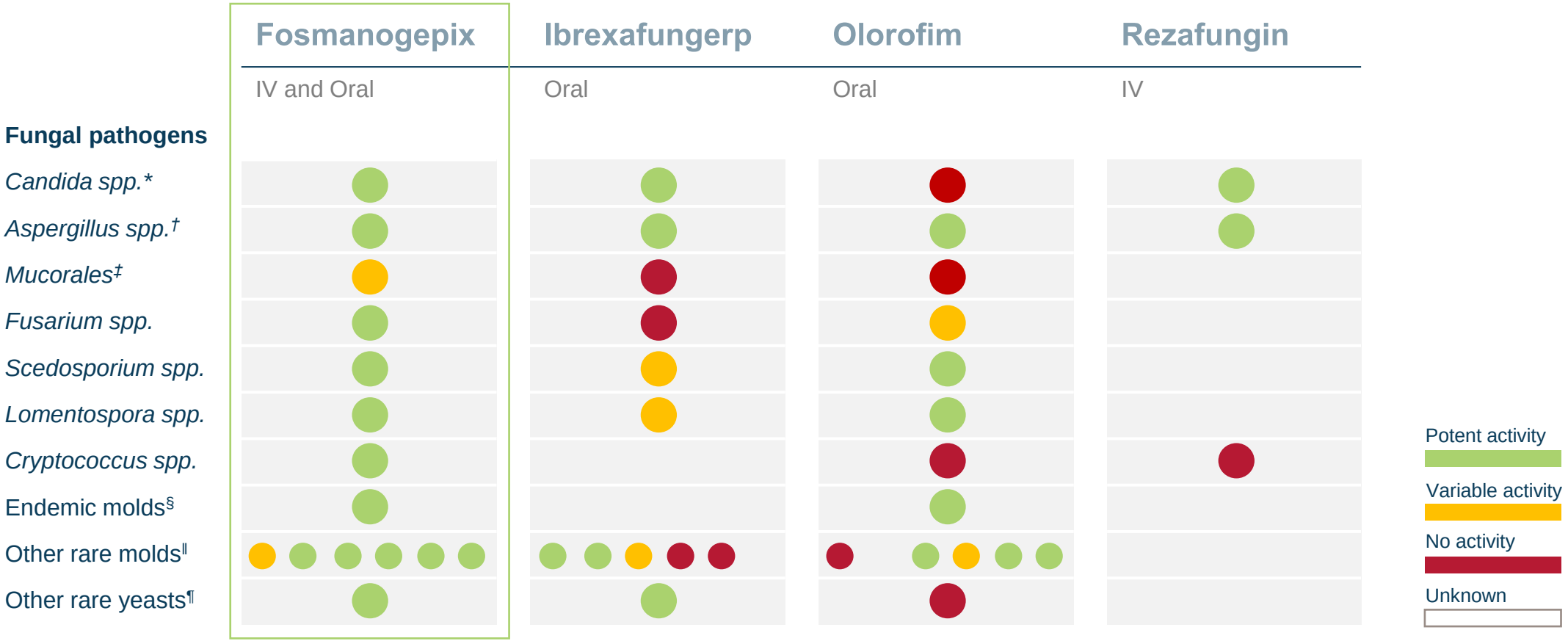
Shaw KJ, Ibrahim AS. J Fungi (Basel). 2020; 6:239

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.
Winston DJ, Young PA, Schlamm HT, Schiller GJ. Clin Infect Dis. 2023:ciad309.
Gebremariam T, Gu Y, Alkhazraji S, et al. Antimicrob Agents Chemother. 2022;66:e0038022.

Fosmanogepix – Potent broad-spectrum activity



* 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.

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
- Expected study start H2 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

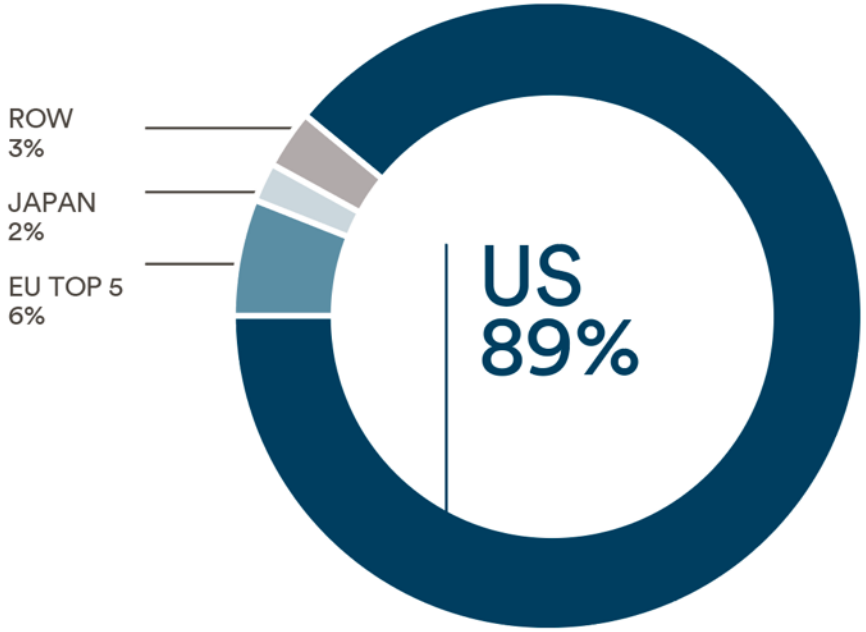
- Broad-spectrum hospital anti-MRSA cephalosporin (including Gram-negative bacteria)
  - Rapid bactericidal activity
  - Potential to replace antibiotic combinations
  - Efficacy demonstrated in phase 3 clinical studies in SAB, ABSSSI and pneumonia[1, 2, 3]
  - Low propensity for resistance development[1]
  - 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).

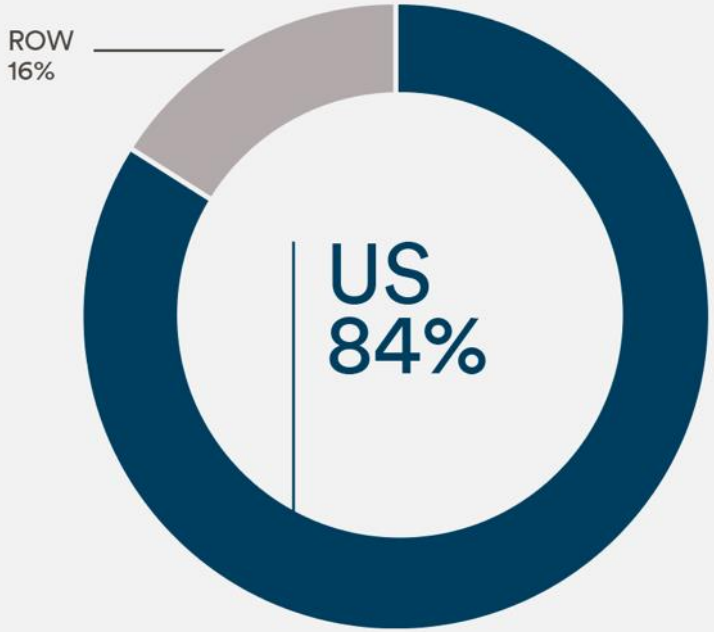
[1] Syed YY. Drugs. 2014;74:1523-1542 and Basilea data on file.
[2] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[3] Holland TL et al. N Engl J Med 2023;389:1390-1401.
[4] Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

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

Daptomycin sales by region
(2015, before LOE)



Ceftaroline sales by region
(MAT Q1 2024)



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

Zevtera — Strategy for accessing the US market

FDA approved three indications April 3, 2024:

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

ERADICATE SAB Study

TARGET ABSSSI Study

- 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
  - Partnering negotiations ongoing

BARDA — Biomedical Advanced Research and Development Authority

[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.

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

basilea

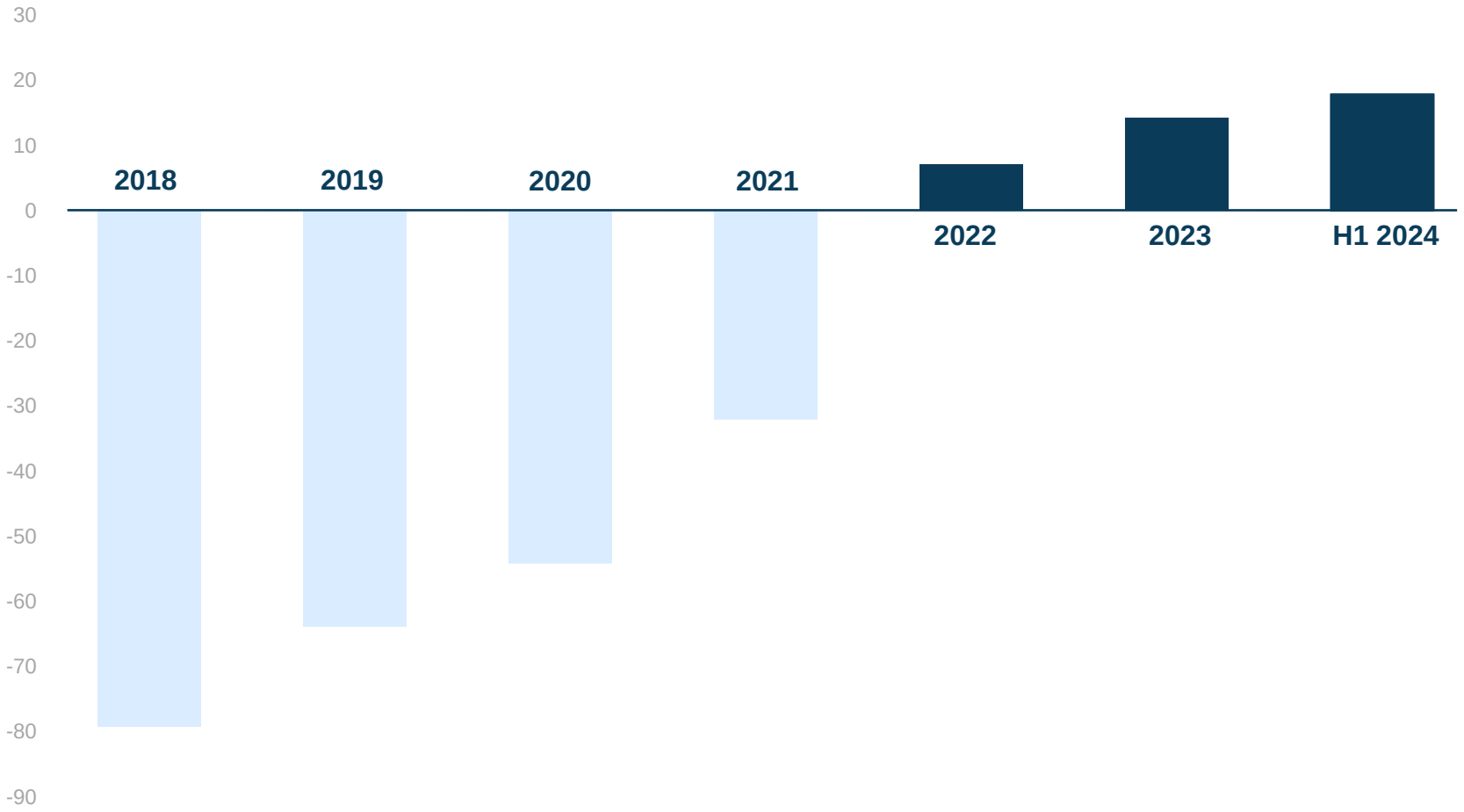
Financials & Outlook

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	**73.3**	80.5	**150.3**
of which royalty income	**42.8**	36.7	**78.9**
of which milestone payments	**2.9**	30.6	**32.2**
Total revenue	**76.3**	84.9	**157.6**
Cost of products sold	**18.1**	10.0	**26.8**
Operating expenses	**48.9**	38.0	**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**

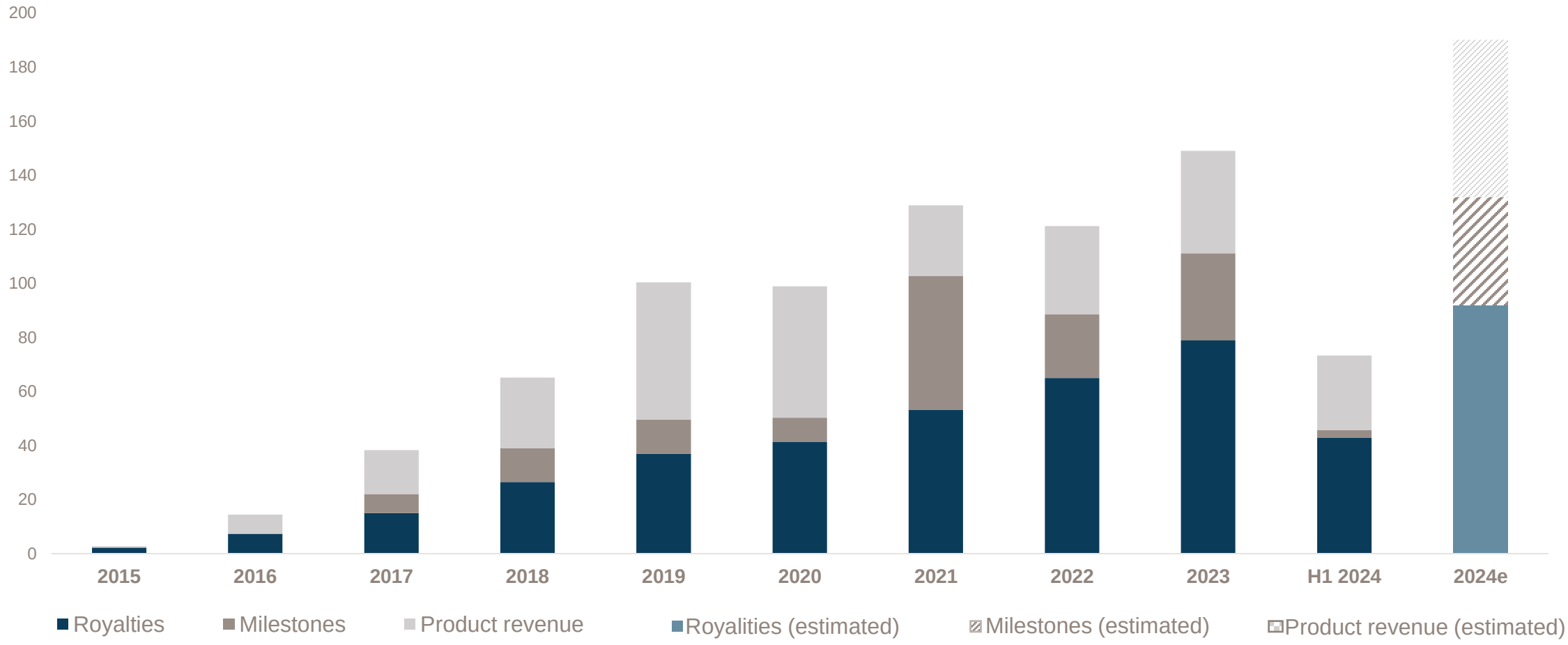
Note: Consolidated figures in conformity with US GAAP; rounding applied consistently

Cash flows from operating activities (in CHF mn)

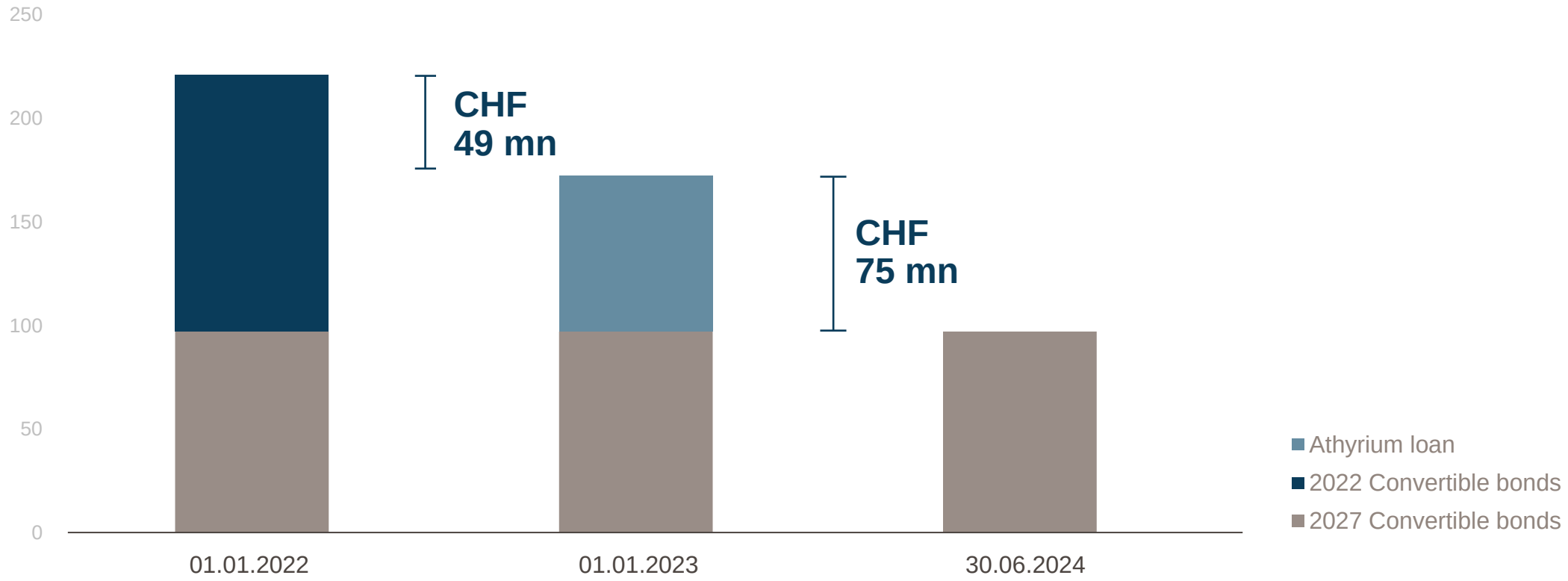


Note: Consolidated figures in conformity with US GAAP; rounding applied consistently

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	150.3	~180	**~190**
of which royalty income	*78.9*	*~89*	***~92***
Total revenue	157.6	~183	**~196**
Cost of products sold	26.8	~33	**~40**
Operating expenses	111.6	~120	**~120**
Operating result	19.2	~30	**~36**
Net profit	10.5	~25	**~42**

Note: Consistent rounding was applied.

Key milestones

	Product	H1 2024	H2 2024
Antibacterials	Ceftobiprole (Zevtera)	✓ US FDA approval	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
	Fosmanogepix		Initiate phase 3 study in candidemia / invasive candidiasis Initiate phase 3 study in mold infections (around year-end)

Increasing Cresemba & Zevtera revenue

In-licensing and acquisition of anti-infectives

Advancement of preclinical and clinical anti-infective assets

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.

Peer Nils Schröder, PhD

Head of Corporate Communications
& Investor Relations

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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
- CNS **C**entral **N**ervous **S**ystem
- CARB-X: **C**ombating **A**ntibiotic-**R**esistant **B**acteria Biopharmaceutical **Accelerator**
- EC: **E**uropean **C**ommisson
- 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
- IV: **I**ntra**v**enous
- MSSA: **M**ethicillin-**s**usceptible ***S**taphylococcus **a**ureus*
- MRSA: **M**ethicillin-**r**esistant ***S**taphylococcus **a**ureus*
- 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
- VAP: **V**entilator-**a**ssociated **p**neumonia

Creating anti-infective opportunities

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