Creating anti-infective opportunities

David Veitch, CEO
Adesh Kaul, CFO

ZKB Swiss Equity Conference 2024

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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

Business model

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

External pool of potential assets

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

BARDA

CARB-X

File for regulatory approvals

Identify commercial partner

Manufacture/sell product through partnerships

Cresemba:

Pfizer astellas AsahiKASEI

and more..

Lean and low risk commercialization model: limited selling expenses and no significant CAPEX

Eligible for royalties/ milestones from partners

Cashflow generating

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

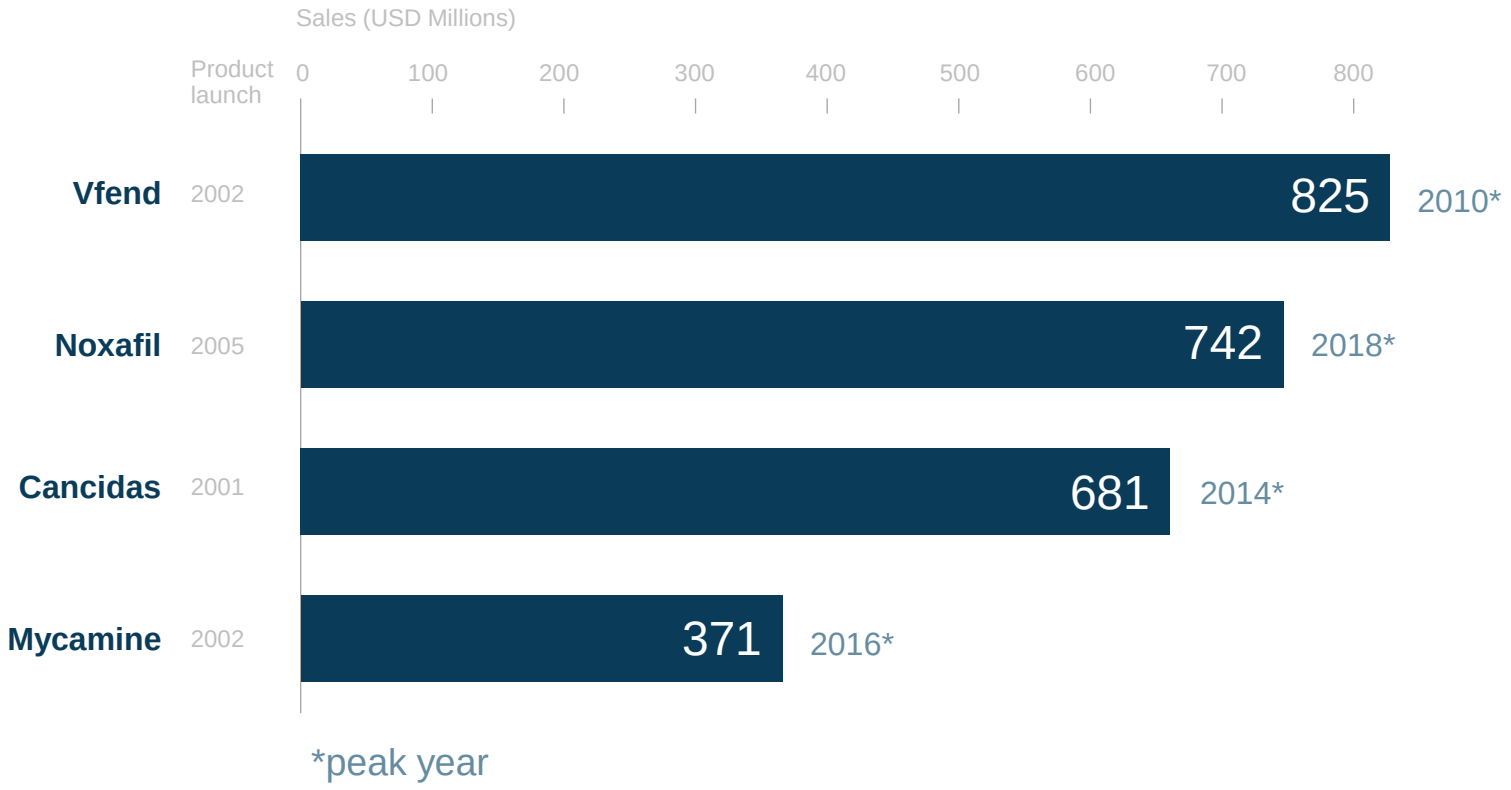
USD

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

Innovative anti-infective pipeline

[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 2024[1]
- 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

[1] OTA number 75A50124C00033 [2] Agreement number 75A50122C00028 and WT224842

Anti-infective pipeline

Antifungals

Cresemba®
Global commercial partnership

Marketed in

73

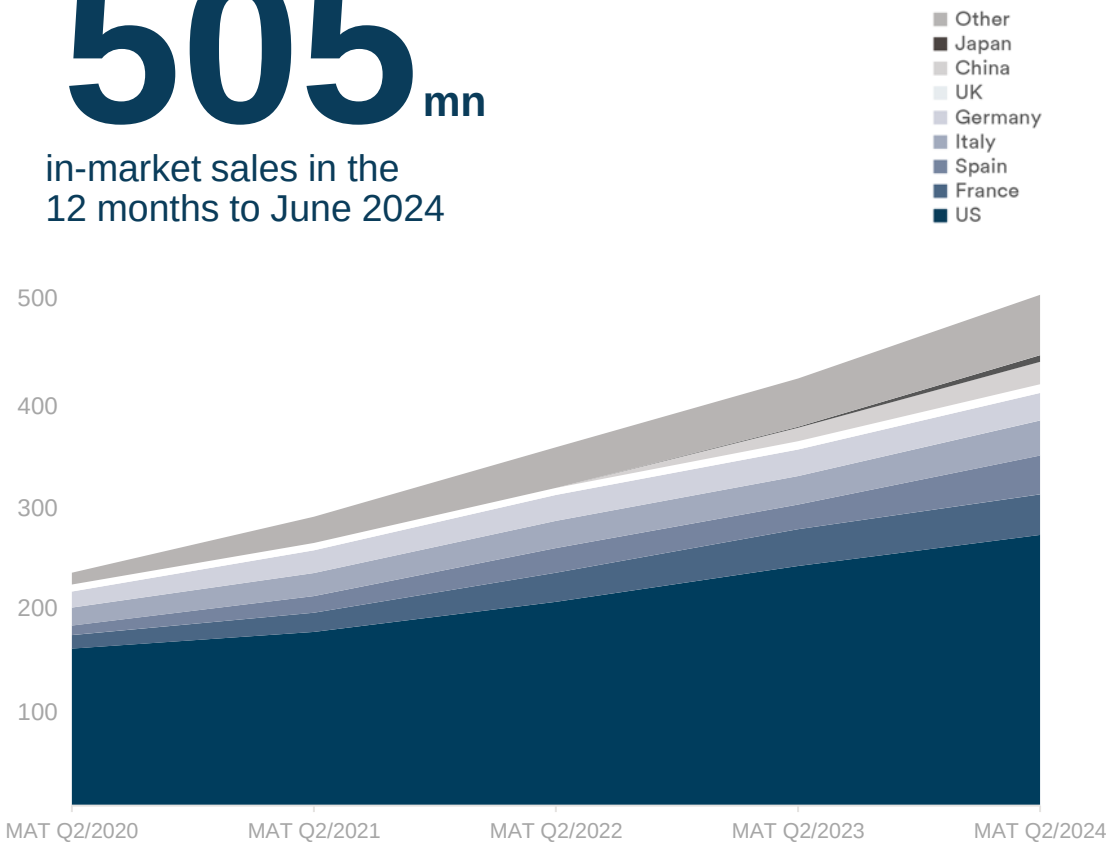
countries

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 505 mn

in-market sales in the 12 months to June 2024

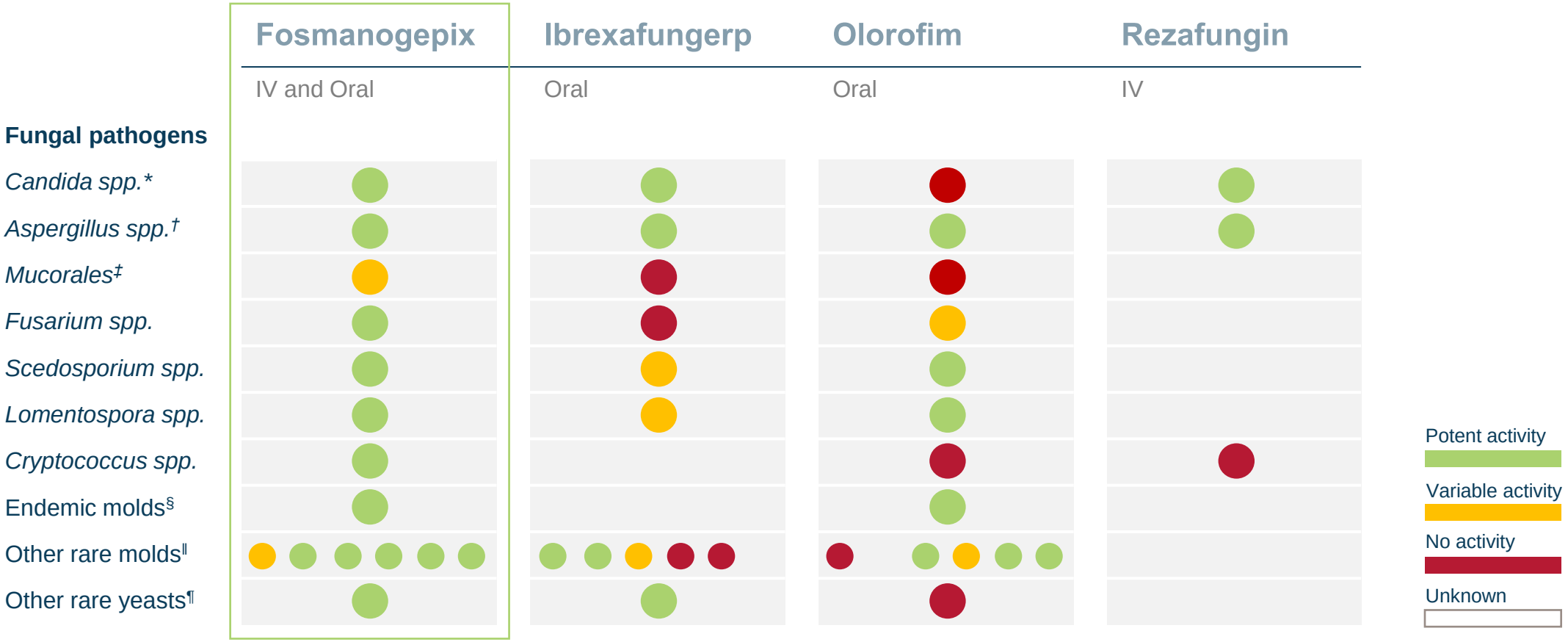


MAT: Moving annual total; Source: IQVIA Analytics Link, June 2024

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 – 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
- 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
- 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

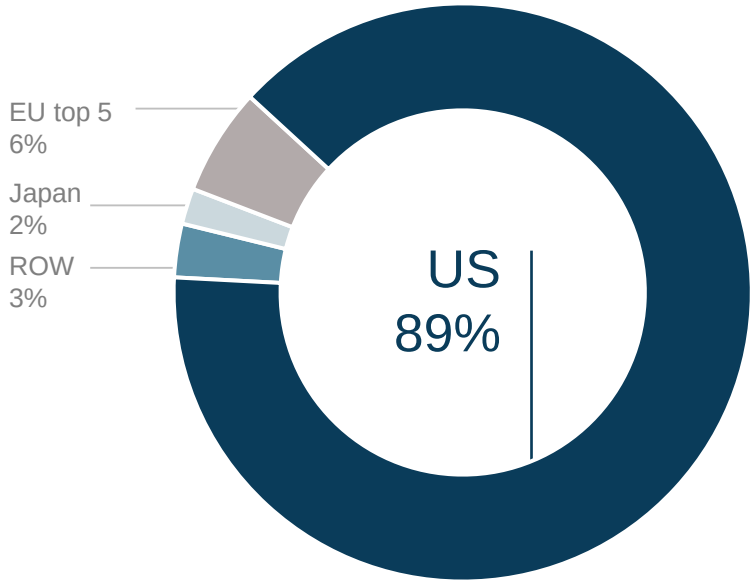
- Broad-spectrum hospital anti-MRSA cephalosporin (including Gram-negative bacteria)
  - Rapid bactericidal activity
  - Potential to replace antibiotic combinations
  - Efficacy demonstrated in phase 3 clinical studies in SAB, ABSSSI and pneumonia[1, 2, 3]
  - Low propensity for resistance development[1]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

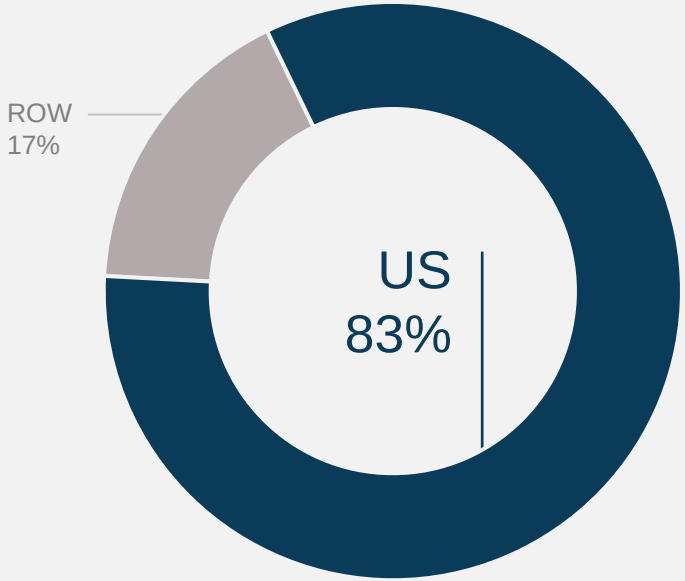
[1] Syed YY. Drugs. 2014;74:1523-1542 and Basilea data on file.
[2] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[3] Holland TL et al. N Engl J Med 2023;389:1390-1401.
[4] Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

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

Daptomycin sales by region
(2015, before LOE)



Ceftaroline sales by region
(MAT 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:

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)[4]
- 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
[4] Contract number HHSO100201600002C

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

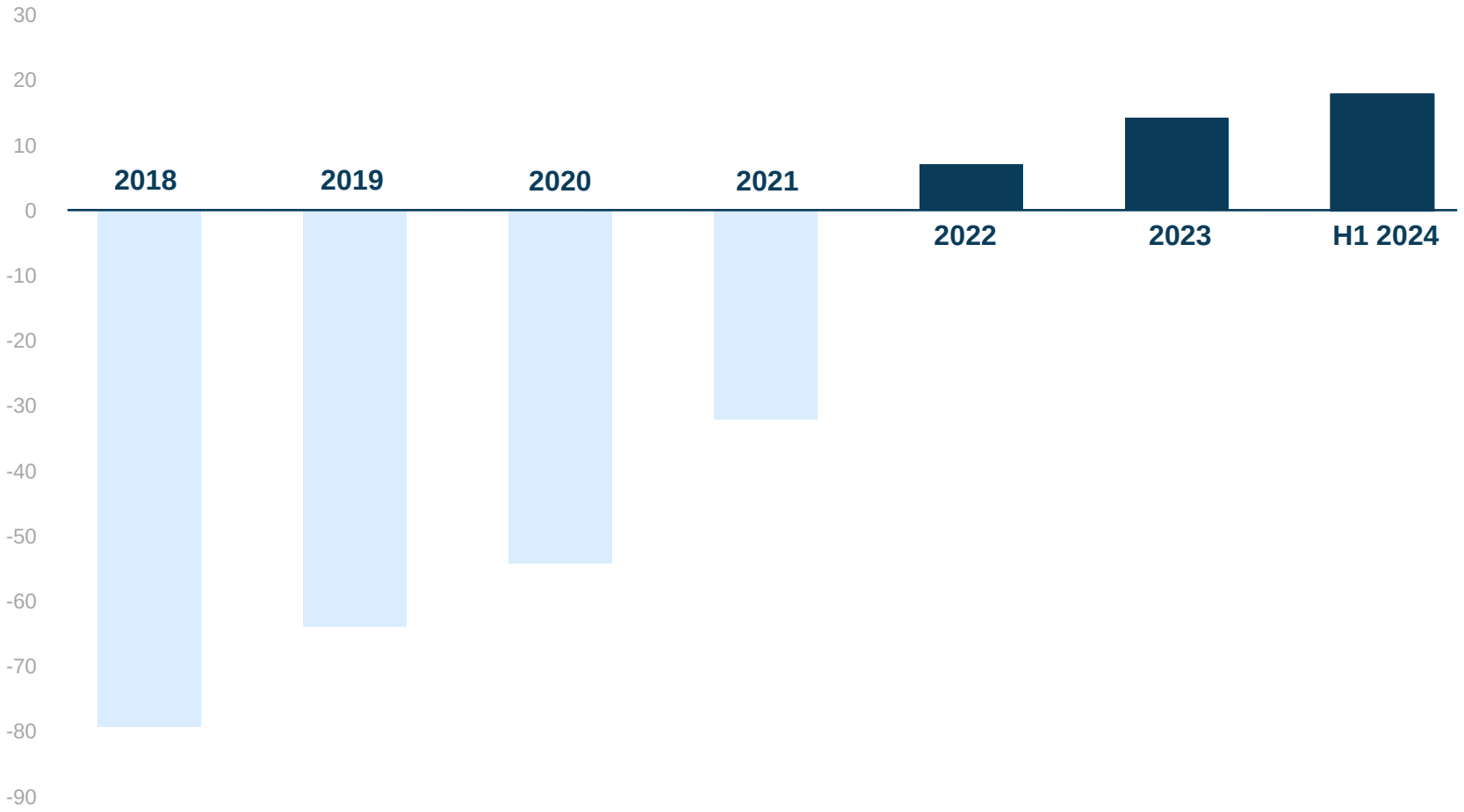
Financials & Outlook

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**

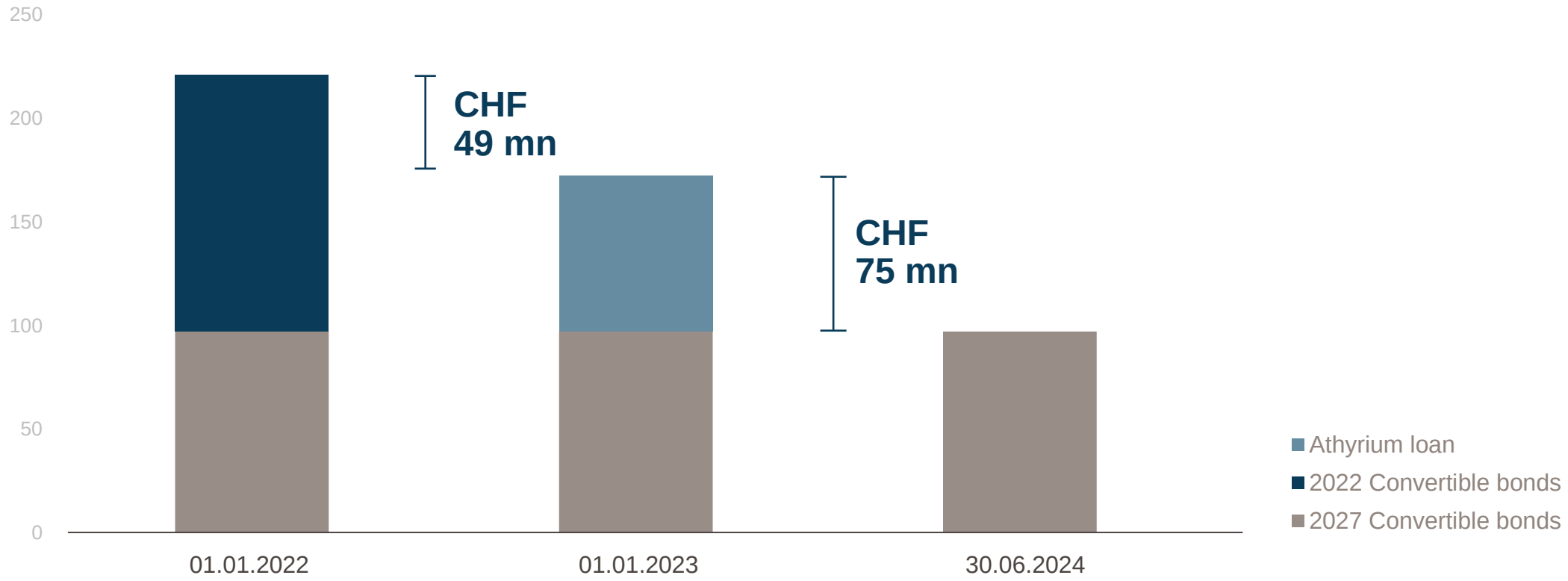
Note: Consolidated figures in conformity with US GAAP; rounding applied consistently

Cash flows from operating activities (in CHF mn)



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

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	~190	**~190**
of which royalty income	*78.9*	~92	***~92***
Total revenue	157.6	~196	**~203**
Cost of products sold	26.8	~40	**~40**
Operating expenses	111.6	~120	**~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
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

Non-dilutive R&D funding for anti-infectives portfolio

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Hegenheimermattweg 167b
4123 Allschwil
Switzerland

info@basilea.com
www.basilea.com