

# Basilea Pharmaceutica

EU paediatric approval triggers CHF10m milestone

Regulatory and milestone update

Pharma and biotech

28 August 2024

**Price** CHF44.6

**Market cap** CHF540m

US\$1.17/CHF

Net debt at 30 June 2024 CHF26.2m

Shares in issue (excluding 1.12m treasury shares) 12.1m

Free float 90%

Code BSLN

Primary exchange SIX

Secondary exchange N/A

## Share price performance



## Business description

Basilea Pharmaceutica is focused on treating infectious diseases. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). In late 2023, it expanded its clinical pipeline to include two antifungals, Phase III-ready, novel broad-spectrum antifungal treatment fosmanogepix (two Phase III trials to start in 2024) and Phase II asset BAL2062, and one antibiotic, tonabacase. In January 2024, Basilea acquired the preclinical LptA inhibitor antibiotics programme from Spexis.

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Basilea has announced yet another milestone following the European Commission (EC) approval for Cresemba's use in the paediatric population (in invasive aspergillosis (IA) or mucormycosis (IM)). The approval extends the market exclusivity of Cresemba by two years to October 2027, which triggered a CHF10m milestone payment from Pfizer, its European license partner. The EU nod follows the December 2023 approval in the US in the same indications, making Cresemba the first azole to be approved for children across the two key regions (it has been approved for adults since 2015). Cresemba reported strong in-market sales in H124, and the second half of the year is expected to be milestone rich with another CHF25–30m in payments expected, based on management guidance.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHFc)	DPS (CHFc)	P/E (x)	Yield (%)
12/22	147.8	12.3	104.1	0.0	42.9	N/A
12/23	157.6	10.8	89.7	0.0	49.7	N/A
12/24e	196.0	31.9	350.6	0.0	12.7	N/A
12/25e	201.6	34.1	282.4	0.0	15.8	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Cresemba (Basilea's lead asset) is the best-selling antifungal in the US (for invasive fungal infections) with a market share of c 40% among best-in-class antifungals (17% market share globally). The drug recorded in-market sales of US\$489m in the 12 months ended March 2024 (+24% y-o-y), driving a 16.6% growth in royalty income in H124 and a [guidance upgrade](#) for FY24. The recent paediatric approval follows that in the US in [December 2023](#), making Cresemba the first azole to be approved across key regions for this underserved population. The regulatory green light extends Cresemba's market exclusivity in the EU by two years to October 2027 (September 2027 in the US) and triggered a CHF10m milestone payment from Pfizer, its European license partner. Based on management guidance, we expect another CHF25–30m in milestone payments before year-end, primarily on achieving certain sales-related thresholds.

The approval was built on the results from two paediatric studies, including a Phase II open-label, non-randomised, multicentre study evaluating the safety, efficacy and pharmacokinetics of Cresemba for the treatment of IA or IM in patients aged between one and 17 ([NCT03816176](#)). A total of 31 patients with IA or IM were treated with Cresemba until successful outcome or for a maximum of 84 days (for IA) and 180 days (for IM). Patients were dosed (either IV or oral) at 10mg/kg every eight hours on the first two days and once daily thereafter. The primary endpoints were number of participants with treatment-emergent adverse events (until 30 days after the last dose) and percentage of participants with all-cause mortality through day 42. The study had an overall response rate of 54.8%. All-cause mortality through day 42 was 6.5% and 9.7% through day 84, although none were considered treatment related. Invasive fungal infections can be life threatening and primarily affect immunocompromised patients, with a study suggesting an IA (the most common invasive mould infection) incidence of [0.4%](#) of all hospitalised immunosuppressed children (particularly those with organ transplant and malignancies). IA and IM are extremely aggressive conditions, with a historical mortality rate of [c 53–85% \(in IA\)](#) in hospitalised children with cancer.

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