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Basilea Pharmaceutica

Clinical update

Advancing into Phase III in mould Infections

Healthcare

31 July 2025

Basilea Pharmaceutica has commenced the second Phase III study for fosmanogepix, a key step forward for its novel broad-spectrum antifungal candidate. The trial (FORWARD-IM) will evaluate the efficacy and safety of fosmanogepix in invasive, multi-drug-resistant mould infections against the standard of care (SoC) across two cohorts (n=220). In contrast to the ongoing placebo-controlled FAST-IC trial in invasive yeast infections, FORWARD-IM is an open-label study, raising the possibility of interim data readouts, ahead of top-line results expected in 2028. Fosmanogepix, a first-in-class agent with a novel mechanism of action, has demonstrated promising safety and efficacy across three completed Phase II studies and remains one of the broadest-spectrum antifungals in development. We maintain our valuation and estimates for Basilea following this milestone.

Year end	Revenue (CHFm)	EBITDA (CHFm)	PBT (CHFm)	EPS (CHF)	DPS (CHF)	EV/EBITDA (x)	P/E (x)
12/23	157.6	20.8	10.8	0.90	0.00	35.9	63.9
12/24	208.5	62.9	60.6	6.44	0.00	11.9	8.9
12/25e	219.4	63.4	63.1	4.70	0.00	11.8	12.2
12/26e	260.0	75.7	76.4	5.69	0.00	9.9	10.1

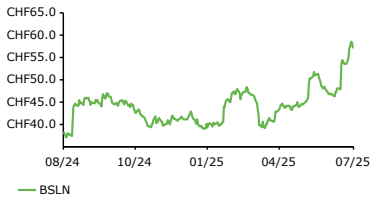
Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

The initiation of FORWARD-IM marks continued progress in Basilea's Phase III programme for fosmanogepix, following the FAST-IC trial in candidemia and/or invasive candidiasis launched in September 2024. FORWARD-IM will be an open-label study, enrolling 220 patients with invasive, multi-drug-resistant mould infections (eg *Aspergillus, Fusarium, Scedosporium* and *Mucorales*). Cohort 1 (n=160) will compare fosmanogepix to SoC (2:1 randomisation). A second, non-controlled salvage treatment arm (cohort 2) will enrol another 60 patients (with intolerance, resistance, lack of clinical response or treatment-associated toxicities to SoC) will be treated with fosmanogepix alone. The study will be conducted by PSI CRO, with top-line data expected in 2028. Given the open-label study design, we see the possibility of the company reporting interim data updates ahead of the top-line results. Fosmanogepix benefits from FDA fast track, orphan drug and qualified infectious disease product designations, supporting up to 12 years of US market exclusivity post-approval.

As Basilea's most advanced pipeline asset, fosmanogepix is of vital importance to the company and key to offsetting revenue erosion from Cresemba, which faces patent expiry in major markets by late 2027. Given the encouraging data to date from prior clinical studies as well as the drug's novel mechanism of action, broad spectrum of activity and strong safety profile, we remain optimistic on its regulatory and commercial potential (we forecast peak sales potential of $820m, with a 70% probability of success). Recent real-world data from an expanded access programme presented at ESCMID 2025 (response rate >70%; n=250) further support its potential in serious, drug-resistant fungal infections. If the Phase III trials are successful, we expect fosmanogepix to gradually offset the loss from Cresemba's forthcoming maturity, with full value realisation in the long term. Note that Pfizer holds the right of first negotiation for global rights, a catalyst we believe could materialise on positive late-stage data.

Price	**CHF57.30**
Market cap	**CHF775m**
	0.8CHF/$
Net cash/(debt) at 31 December 2024	CHF28.6m
Shares in issue	13.3m
Code	BSLN
Primary exchange	SWX
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, the Phase III novel broad-spectrum antifungal treatment fosmanogepix (first Phase III trial commenced in September 2024 and the second in July 2025) and Phase II asset BAL2062. In January 2024, Basilea acquired the preclinical LptA inhibitor antibiotics programme from Spexis and BAL2420 has recently been selected as the clinical candidate.

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