Basilea Pharmaceutica

Broadening Cresemba's Japanese opportunity

Clinical development update

Healthcare

14 September 2026

Basilea Pharmaceutica has announced that Japanese partner Asahi Kasei Therapeutics has initiated an open-label Phase II safety and pharmacokinetics study of Cresemba in paediatric patients at risk of invasive fungal infections. Cresemba has been approved for adults in Japan since December 2022 and for paediatric use in the US, Canada, Europe and China. While we expect the direct commercial opportunity from the paediatric population to be modest, we see greater relevance from a lifecycle-management perspective, potentially supporting a two-year extension of regulatory protection in Japan, to end-2032. We note that eligibility for such an extension remains to be confirmed. With the US and European franchises approaching maturity from Q427 and H228, respectively, maintaining growth and extending the commercial tail in markets such as Japan and China is becoming increasingly strategically relevant, and we see this as a positive incremental step in this direction.

Year end	Revenue (CHFm)	EBITDA (CHFm)	PBT (CHFm)	EPS (CHF)	P/E (x)	EV/EBITDA (x)
12/24	208.5	62.9	60.6	6.44	10.4	12.6
12/25	232.4	53.4	46.2	3.31	20.1	14.8

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

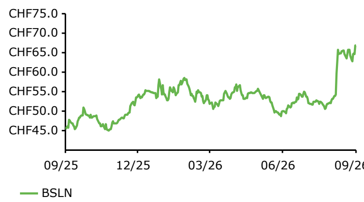
The Phase II study focuses on safety and pharmacokinetics rather than a controlled efficacy comparison. This is supported by the existing paediatric approvals in several major markets, which provide useful clinical precedent, although Japanese approval remains subject to successful completion of the local programme. Serious fungal infections such as invasive aspergillosis and mucormycosis can be particularly debilitating in immunocompromised children, including those with haematological malignancies or immunodeficiency disorders, while treatment options remain limited. We therefore see a credible medical rationale, although the relatively small paediatric population means that a material uplift to Japanese sales is unlikely.

The more interesting read-through, in our view, is the potential extension of regulatory protection. Japan generally provides an eight-year re-examination period for new active ingredients, with qualifying paediatric development potentially extending this by two years. Cresemba's December 2022 Japanese approval therefore implies protection to around December 2030, with potential extension to end-2032 if the programme meets the relevant requirements. Under the licensing agreement with Asahi Kasei, Basilea is eligible for double-digit tiered royalties and up to c CHF60m in regulatory and commercial milestones. It is currently unclear whether the study initiation triggers a milestone payment to Basilea.

Strategically, this potential extension matters as the geographic mix of Cresemba growth continues to evolve. The US and European franchises are expected to begin facing generic competition from Q427 and H228, respectively. Japan and the broader Asian franchise should therefore become increasingly important in supporting the product's longer-term royalty tail. We remind readers that Cresemba remains Basilea's key commercial asset, with global in-market sales of US$782m in the 12 months to March 2026, up 27% year-on-year, while H126 royalty income increased 10.9% to CHF57.8m.

Price	**CHF66.70**
Market cap	**CHF896m**
	US$1.25/CHF
Net cash/(debt) at 30 June 2026	CHF105.3m
Shares in issue	13.4m
Code	BSLN
Primary exchange	SWX
Secondary exchange	N/A

Share price performance



Business description

Basilea Pharmaceutica is focused on treating severe bacterial and fungal infections. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). It also has a broad development pipeline that includes two antifungals: Phase III novel broad-spectrum treatment fosmanogepix (two Phase III trials ongoing) and Phase II asset BAL2062; and two antibacterials: LptA inhibitor BAL2420 (Phase I) and Phase III-ready oral combination treatment CTB-LEDA.

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