

Calvine Partners

Basilea Pharmaceutica

16 February 2021

Share Price	CHF 58
CP Fair Value	CHF 120

Market Cap (CHFm)	637
Cash (CHFm)	167
EV (CHFm)	720

Country	Switzerland
Code	BSLN
Exchange	SIX

Solid 2020, much more to come from the pipeline

The FY 2020 results at Basilea reflects a period of both financial and clinical progress. The financial contribution of the anti-infectives franchise and, in particular, the anti-fungal Cresemba through Astellas in the US and Pfizer, has allowed Basilea to invest in progressing its emerging oncology portfolio. Despite some Covid related issues, demand has been strong with non-deferred revenue of CHF78.2m (+13%) and we expect future success as demand continues and new geographies are added. Basilea is guiding to CHF108m-118m during 2021. At the same time the 5th generation antibiotic ceftobiprole is continuing its Phase 3 evaluation with the key bacteraemia (ERADICATE) study due to report in 2022. Success here would surely deliver a relevant partner in the US, which would provide additional funding through upfront and milestone payments. It is also important to remember that ceftobiprole has benefited from non-dilutive BARDA funding, which amounted to CHF13.2m in 2020.

Pipeline potential

Much of the recent focus at Basilea has involved securing the promise of the oncology portfolio and the FGFR inhibitor derazantinib. The FGFR class has been successfully validated elsewhere through the approvals of Balversa and Pemazyre in bladder and biliary cancer respectively. The key for Basilea in the competitively challenging environment is to identify appropriate positioning for derazantinib. While the clinical risk may have been reduced with the publication of the positive FIDES-01 monotherapy data in bile duct cancer (iCCA), clear differentiation from existing competition could come from a combination with the checkpoint inhibitor (CKI) Tecentriq (atezolizumab) in indications where CKI monotherapy has been sub-optimal. Of the approved FGFR inhibitors, derazantinib appears to have the sole ability to help reverse the immunosuppressive state found in many cancers thanks to its activity against the CSF-1/CSF1R axis. Basilea is seeking to capitalise on this activity with studies FIDES-02 in urothelial cancer and FIDES-03 in gastric cancer. The tumour checkpoint controller lisavanbulin has shown promising activity in glioblastoma and we look forward to the relevance of the biomarker EB1. Despite all this activity Basilea has managed to keep R&D spend relatively stable.



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So far so good with critical period ahead

Successful commercial execution through licensees and distributors has delivered a meaningful revenue stream for Basilea. The potential of the oncology pipeline is becoming clearer and in this respect, we look forward to the results of FIDES-02 and FIDES-03, with much to come over the next 12-18 months - not to mention the glioblastoma results for lisavanbulin. Success here should lead to greater investor appreciation and a significant valuation uplift.

Financial prudence evident

We expect sales growth to continue

Basilea's revenue has benefited from continued success of the anti-fungal Cresemba (isavuconazole) through licensees Astellas (US) and Pfizer (Europe, Israel and Asia/Pac), as well as distributors. We expect this growth to continue as new geographies are added and awareness of Cresemba's differentiated profile increases. These include an extended spectrum and a benign safety profile. It is worth remembering that growth is driven by an increasing number of immunocompromised patients. Also, there are few anti-fungals in development, and with only three classes available we see little prospect in significant competition in the medium term. In market sales of Cresemba to (12 months to end September) totalled approximately \$244m, representing year over year growth of 28%.

Long-term prospects for Zevtera should be significantly enhanced by ABSSSI and bacteraemia indications

Fleshing out the anti-infectives franchise is the 5th generation cephalosporin Zevtera (ceftobiprole). Current sales are impacted by the limited label (HAP excluding VAP) outside the US, although the long-term prospects should be boosted significantly by the potential addition of the ABSSSI and bacteraemia indications in the US. The outstanding (for approval) ERADICATE trial is due to complete enrolment at the end of 2021.

Cresemba will benefit from further geographic exposure

Combined (non-deferred) revenues for Cresemba and Zevtera amounted to CHF72.8m in 2020 representing growth of 13%. With new geographies expected, particularly for Cresemba, Basilea is confident that Cresemba will be available in 60 countries by end 2021 against the circa 50 countries currently represented. Important geographies include China, where the MAAs for invasive aspergillosis and mucormycosis have been accepted, and Japan where Cresemba has completed Phase 3 evaluation through partner Asaha Kasei.

Guidance for 2021 reflects more of the same

Basilea is guiding to non-deferred revenue contributions of CHF108-118m from a combination of Cresemba and Zevtera during FY 2021. This represents growth of 38%-51%. Total revenue guidance of CHF128m-138m for 2021 compares to our forecast of CHF132.8m, while the guidance for stable R&D and SG&A is also largely aligned with our expectations. With cash and investments of CHF110m-120m expected at end 2021, Basilea remains well capitalised to progress its pipeline ambitions.

Basilea has efficiently managed R&D spending

We remain encouraged by the in-market revenue growth of the commercially available products Cresemba (particularly) and Zevtera (currently with a limited label). Basilea has done well to contain its R&D expenditure at circa CHF100m despite the clear promise of derazantinib and the intensifying competitive environment. Ultimately, and dependent on the results of the combination studies FIDES-02 and FIDES-03, we would expect Basilea to be able to attract a suitable commercial partner, hopefully

with a requisite oncology franchise who can help fully capitalise on derazantinib's emerging clinical profile

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