

Basilea Pharmaceutica

2021 outlook

Derazantinib spearheads oncology portfolio

Basilea has successfully brought two anti-infective drugs to the market. Lead product Cresemba continues to benefit from ongoing launches by multiple partners including Astellas (US) and Pfizer (ex-US). Longer-term value creation is dependent on crystallising the mid-/late-stage oncology portfolio. Three ongoing Phase II trials (FIDES-01/02/03) will define lead R&D asset derazantinib's utility in intrahepatic cholangiocarcinoma (iCCA; bile duct cancer), urothelial cancer and gastric cancer. Lisavanbulin, a unique, internally developed asset, has progressed into a proof-of-concept Phase II biomarker-driven trial in recurrent glioblastoma (GBM) (interim results expected H221). Our forecast profitability in 2022 is dependent on the late-stage clinical development strategy for derazantinib and lisavanbulin. We value Basilea at CHF1.17bn or CHF99 per share.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHF)	DPS (CHF)	P/E (x)	Yield (%)
12/19	134.4	(22.3)	(2.08)	0.0	N/A	N/A
12/20	127.6	(29.6)	(2.89)	0.0	N/A	N/A
12/21e	135.1	(26.8)	(2.10)	0.0	N/A	N/A
12/22e	140.1	1.5	0.12	0.0	N/A	N/A

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

Anti-infectives portfolio near-term revenue driver

Basilea has given guidance for FY21, including CHF108–118m non-deferred revenue contributions from Cresemba and Zevtera, operating loss of CHF13–23m and year-end cash of CHF155–160m (excluding any effect from the repurchase of the outstanding convertible bond). Cresemba is key and FY20 'in market' sales are expected to exceed \$250m. Ex-US sales have triggered a \$10m milestone payment from Pfizer in Q121. For Zevtera, the US market is the critical value driver, the planned NDA submission in late 2022 rests on the outcome of the ongoing ERADICATE study in bloodstream infections; top-line data from this second study (required for registration) are expected in H122 and we forecast US launch in 2023.

Derazantinib hat-trick of FIDES clinical trials

Oncology is the next pillar of growth. Basilea is looking to maximise derazantinib's value by assessing its utility in multiple indications; its unique MOA (FGFR inhibitor plus CSF1R activity) and safety profile suggests it could enable synergies with other therapies. Although we forecast its first route to market in 2023 in iCCA, multiple datapoints expected in 2021/22 expected from FIDES-02 (urothelial cancer) and FIDES-03 (gastric cancer) will determine combination strategies (including PD-L1 inhibitor and VEGFR inhibitor) and its potential differentiation to the competition. We forecast peak sales of \$0.93bn across all three indications.

Valuation: rNPV of CHF1.17bn or CHF99 per share

Our valuation is CHF1.17bn or CHF99 per share, from CHF1.14bn or CHF106 per share. We have made minor adjustments to the model and increased the probability of success for lisavanbulin to 35% from 20%, and derazantinib to 50% from 40%, reflecting pipeline progression and encouraging data readouts. Our core underlying assumptions are unchanged. Our valuation reflects CHF77.9m net debt at 31 December 2020, excluding the gross CHF45.75m post-period capital raise.

Pharma & biotech

4 March 2021

Price **CHF46.1**
Market cap **CHF596m**

\$1.12/CHF

Net debt (CHFm) at 31 December 2020 (excluding net proceeds from sale of Chinese R&D subsidiary and capital raise) 77.9

Shares in issue (including 1.1m treasury shares) 12.9m

Free float 90%

Code BSLN

Primary exchange SIX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (13.3) (14.8) 4.9

Rel (local) (13.2) (18.2) (1.8)

52-week high/low CHF61.0 CHF32.1

Business description

Basilea is focused on oncology and infectious diseases. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). The oncology R&D pipeline consists of three assets including clinical-stage products lisavanbulin and derazantinib.

Next events

Derazantinib FIDES-01 cohort 2 interim data in iCCA H121

Derazantinib FIDES-02 interim data in urothelial cancer H121

Ceftobiprole Phase III ERADICATE top-line data for bacteraemia (SAB) H122

Analysts

Dr Susie Jana +44 (0)20 3077 5700

Dr John Priestner +44 (0)20 3077 5700

healthcare@edisongroup.com
[Edison profile page](#)

Basilea Pharmaceutica is a research client of Edison Investment Research Limited

Investment summary

In the near term, Cresemba (isavuconazole) is the major revenue driver for Basilea; the product is now available in 50 countries. Basilea expects global in-market sales to exceed \$250m in FY20, as the product benefits from multiple worldwide partnerships including Astellas in the United States and Pfizer in Europe. Sales of its fifth-generation cephalosporin antibiotic Zevtera (ceftobiprole) have been lacklustre, reflecting the hurdles for even innovative antibiotics, the product is available in Europe and multiple countries in RoW (excluding the United States) through partners. The US market is more receptive to novel antibiotics, so remains key to Zevtera's fortunes. Targeting resistant pathogens are important pursuits in antibiotic drug development, and Zevtera's ongoing Phase III ERADICATE study in *Staphylococcus aureus bacteraemia* (SAB) bloodstream infections could differentiate the product from standard of care (daptomycin and vancomycin for SAB involving MRSA and beta lactam inhibitors for MSSA). Completion of ERADICATE enrolment is still expected in H221 (COVID-19 has delayed patient recruitment by a quarter) and **top-line data are now expected in H122**, to enable the NDA submission in 2022 followed by potential launch in 2023.

Oncology the next significant value driver

Expectations for Basilea are rapidly focusing on longer-term value creation, which is dependent on the success of the mid-stage oncology pipeline that consists of in-licensed asset derazantinib (a fibroblast growth factor receptor, or FGFR, inhibitor) and in-house developed product lisavanbulin (microtubule-targeting tumour checkpoint controller). Derazantinib has been making good progress in its broad Phase II development programme across three oncology indications in the Phase I/II FIDES clinical trial programme; FIDES-01 in **iCCA**, FIDES-02 in **advanced urothelial cancer** and FIDES-03 in **advanced gastric cancer**. In 2020, a second FGFR inhibitor received accelerated FDA approval for use as monotherapy for late-stage cancers. Incyte's Pemazyre (pemigatinib) was approved in April 2020 for iCCA (FGFR2 fusion or rearrangements), adding to Janssen's Balversa (erdafitinib) approved for urothelial cancer (FGFR2/3 genetic alterations) in 2019. Interest in the area continues to expand and to provide a differentiated profile, we believe three things need to be addressed by novel FGFR inhibitors in development. First, broadening utility to encompass a wider range of genetic alterations in the FGFR gene, addressing larger patient populations instead of specific smaller subsets. Second, additional oncology indications (not limited to iCCA and UC). And third, combination with immune modulating agents or other rationale combinations (targeted therapies plus immunotherapies will likely become standard of care and in earlier lines of therapy); tolerability is key and combination strategies aid to mitigate to an extent the issue of acquired resistance to these agents as monotherapy. It is within this context that the breadth of data expected on derazantinib in 2021/22 is of importance.

Derazantinib multiple data readouts to define registration strategy

Multiple catalysts (Exhibit 1) including interim and top-line results from the entire FIDES clinical programme in bile duct cancer (iCCA), urothelial cancer and gastric cancer are expected throughout 2021 and 2022. Cumulatively, these data will address derazantinib's utility across the breadth of FGFR gene aberrations (FIDES-01 evaluates FGFR2 alterations, including fusions, amplifications and mutations), in combination with immunotherapy and targeted therapy (FIDES-02/03 with Tecentriq and FIDES-03 with Cyramza and paclitaxel), and efficacy in gastric cancer (there are no approved FGFR inhibitors and combination strategies). Amongst FGFR inhibitors, derazantinib's profile is unique as in addition to its ability to inhibit FGF receptor tyrosine kinase, it has activity against other receptor tyrosine kinases (inhibits the colony stimulating factor 1 receptor, CSF1R, and inhibits vascular endothelial growth factor receptor 2, VEGFR2, the primary VEGFR involved in vascular growth and function). Thus, its potential synergy with checkpoint inhibitors

(CPIs) is being examined; in combination with Roche's Tecentriq (atezolizumab) in urothelial cancer and gastric cancer, and in combination with Eli Lilly's VEGFR inhibitor Cymraza and paclitaxel (chemotherapy) in gastric cancer. Collectively, these data will enable Basilea to define an optimal registration and commercialisation strategy. Our forecasts reflect first launch in iCCA, the most advanced indication, in 2023. However, Basilea may elect to build up a considerable data package addressing the above points and ensuring derazantinib is truly differentiated to enable it to take a larger market share. This could delay filing by one to two years but could ensure value optimisation from this unique FGFR inhibitor.

Lisavanbulin: A unique, internally developed asset

Furthermore, as lisavanbulin has progressed to Phase II clinical development for GBM, we anticipate the interim data will define its utility in patients whose tumours tested positive for end-binding protein 1 (EB1), a potential response-predictive biomarker. GBM is the proof-of-concept indication (**interim results are expected in H221**) and we expect development in additional solid tumour indications as Basilea builds on its understanding of EB1 as a predictive marker, an area where the company is pioneering research. Furthermore, Basilea could choose to self-commercialise lisavanbulin, a wholly owned asset, in specific indications and select markets.

Financials: Profitability close but dependent on derazantinib strategy

Our forecast for Basilea to break-even in 2022 is based on an out-licensing deal for derazantinib in 2022 and a partner funding the registration phase trials. Basilea has yet to fully define its registrational and commercialisation strategy for the asset as this is largely dependent on the extent of the efficacy data across its three ongoing indications and whether its multiple mechanisms of action (MOA) can enable differentiation versus competitors in a rapidly evolving FGFR inhibition arena. Basilea has historically looked to partner its assets after positive Phase II data to gain the necessary financial resources to explore additional opportunities but could elect to conduct Phase III trials itself or extend to additional oncology indications. Basilea has expressed an interest in participating in a potential Phase III study to retain more of the ownership and potential economic benefit. This would increase R&D expenses and extend the time to break-even but could garner higher deal economics if it is able to demonstrate more advanced data that could be applicable over several indications. A short-term cash outlay would be easily justified if it ensures optimal placement (target disease, treatment line and combination) and a successful launch strategy to maximise long-term value from this potentially differentiated FGFR inhibitor.

Exhibit 1: Basilea 2021/22 catalysts

Cresemba® & Zevtera® — Increasing cash flows					
By the end of 2021, Cresemba to be on the market in 60 countries					
		H1 2021	H2 2021	H1 2022	H2 2022
Isavuconazole		✓ Complete patient enrolment in phase 3 study in Japan	Topline results from phase 3 study in Japan		
Ceftobiprole			Complete patient enrolment in SAB phase 3 study	Topline results from SAB phase 3 study	
Derazantinib	FIDES-01 (iCCA)	✓ Topline results (FGFR2 fusions)			
		Interim results (other FGFR2 gene aberrations)		Topline results (other FGFR2 gene aberrations)	
	FIDES-02 (urothelial cancer)	Interim results in derazantinib monotherapy	Interim results in combination therapy with atezolizumab		Topline results in combination therapy with atezolizumab
	FIDES-03 (gastric cancer)		Interim results in monotherapy and recommended phase 2 dose with ramucirumab/paclitaxel		Interim results in combination with ramucirumab/paclitaxel
Lisavanbulin			Interim results from phase 2 biomarker-driven glioblastoma study	Topline results from phase 2 biomarker-driven glioblastoma study	
			Recommended phase 2 dose in phase 1 study in newly-diagnosed glioblastoma in combination with radiotherapy		

Source: Basilea corporate presentation

Derazantinib unique MOA has the potential for differentiation

We believe derazantinib's key differentiation versus the most clinically advanced competition is its favourable safety and tolerability profile, combined with its unique mechanism of action that could potentially enable improved efficacy as a monotherapy and applicability to patients with a broader range of FGFR aberrations. These attributes also make it an ideal candidate for use in combination, particularly with immunotherapies, which could also provide differentiation. Multiple data readouts expected in 2021 and 2022 will determine its optimal positioning in a constantly evolving treatment landscape. Derazantinib is an oral kinase inhibitor that targets FGFR and CSF1R kinases. It is a selective and potent pan-FGFR inhibitor (FGFR1, FGFR2, FGFR3) anticipated to have efficacy in tumours that test positive for FGFR aberrations (identified through [FISH](#) or [NGS](#) testing of tumour biopsy samples). Deregulation of the FGF signalling axis has been implicated in oncogenesis, tumour progression and resistance to anticancer therapy across many solid tumours.

Beyond its ability to inhibit FGFRs, derazantinib inhibits CSF1R (in preclinical models at similar concentrations to those required for the inhibition of FGFR), which regulates immunosuppressive tumour-associated macrophages and restores T-cell activity. This makes cancer cells more susceptible to treatment and could provide additional synergies in combination with immune CPIs or small molecule drugs compared to commercially available FGFR inhibitors.

At [ENA 2020](#) in October, Basilea presented preclinical data supporting that derazantinib also inhibits VEGFR2 (the primary VEGFR involved in vascular growth and function and a common target of cancer drugs), leading to moderate antiangiogenic effects that may contribute to its antitumour properties. This is becoming increasingly important in an arena where immunomodulatory drugs (CPIs) and rational combinations thereof are being used in earlier lines of treatment across a range of cancers. We continue to forecast first launch in iCCA in 2023, followed by urothelial cancer and gastric cancer in 2024 and 2025, respectively. We will revisit these assumptions as we gain more insight on the registrational intent, as we expect this to be defined as the data crystallises during 2021/22.

Top-line data in iCCA establishes clinical proof of concept

Derazantinib's most advanced indication is for [iCCA](#) (bile duct cancer) and the potentially registrational Phase II [FIDES-01](#) study comprises two cohorts for patients with FGFR2 gene fusions (cohort one) and patients with FGFR2 gene mutations or amplifications (cohort two). Basilea recently reported [positive top-line data](#) from cohort one that established clinical proof of concept as monotherapy with potential read across to other cancers where FGFR2 aberrations are implicated. Although the data were not fully mature (12 out of 103 patients were still receiving treatment), efficacy was in line with competitor FGFR inhibitors (20.4% objective response rate, ORR, 72.8% disease control rate and 6.6 months median progression-free survival, PFS) and that observed in previous studies. Treatment-related adverse events were manageable and there was a particularly low incidence of events commonly observed for FGFR inhibitors as a class (nail toxicity, retinal events, hand-foot syndrome and stomatitis).

Enrolment into cohort two (FGFR2 gene mutations or amplifications) of FIDES-01 is ongoing (estimated enrolment of 43 patients), **interim results are expected in H121**, and **top-line data are expected in H122**. Although a smaller patient population (~5% of iCCA patients), this cohort is particularly important as approved FGFR inhibitors are limited to use in patients with FGFR fusions in iCCA. In October, at [ESMO MAP 2020](#), Basilea presented a pooled analysis for derazantinib in 23 iCCA patients with FGFR2 mutations and amplifications (from [ArQule's Phase I/II study, FIDES-01 cohort two](#) and the [expanded access programme](#)). Derazantinib demonstrated promising PFS consistent with that observed in patients with FGFR2 gene fusions (7.2 months median PFS and 8.2 months median duration of treatment). The data were still maturing, with several patients

continuing to receiving treatment. Although we note the apparent limitations of a post hoc pooled analysis, the data are particularly encouraging given other FGFR inhibitors in advanced clinical development have only reported limited efficacy in these patients. This highlights the broad therapeutic potential of derazantinib in FGFR2-positive iCCA and could warrant approval with a wider prescribing label versus existing products. Derazantinib has been granted orphan drug designation by FDA and EMA for the iCCA indication, providing potential market exclusivity and pricing incentives.

FIDES-02 probes combination potential in urothelial cancer

In August 2019 Basilea initiated the multi-cohort Phase I/II [FIDES-02](#) study in patients with advanced [urothelial cancer](#). FIDES-02 is investigating derazantinib as a monotherapy and in combination with Tecentriq (Roche's PD-L1 targeting antibody, an immunotherapy) and will enrol c 300 patients with FGFR-driven disease (first line and above). Activating FGFR aberrations are frequently found in urothelial cancer tumours ([up to 32%](#)), from genetic mutations, rearrangements or amplifications that lead to overactivation of FGFRs and disease progression. The advent of CPIs has led to a paradigm shift in the treatment of many cancers and multiple PD-1/PD-L1 inhibitors are now approved for either first- or second-line treatment of urothelial cancer. Real-world data have revealed FGFR mutations are a predictive biomarker for worse outcomes with CPIs and a valid target for the next generation of cancer treatments. Its CSF1R activity is unique amongst FGFR inhibitors and could enable synergies with CPIs as it limits the production of immunosuppressive tumour-associated macrophages and restores T-cell activity, making cancer cells more susceptible to PD-1/PD-L1 inhibitors.

At [ASCO GU 2021](#) in February, Basilea presented data from the successfully completed Phase Ib dose-finding portion of the FIDES-02 study. The recommended Phase II dose (RP2D) for the combination of derazantinib and Tecentriq was established at the full standard doses for the single agents (300mg daily oral derazantinib plus 1,200mg Tecentriq administered by iv every three weeks), which were safely combined with no dose-limiting toxicities. Early efficacy signals were identified and several patients were still receiving treatment, including one patient with an FGFR2 gene fusion-positive tumour that reported a partial response and is ongoing after more than nine months. The Phase II portion of the study is still enrolling. Basilea will explore in two cohorts of the Phase II study a 30% higher dose of derazantinib (its established maximum-tolerated dose) as both a monotherapy and in combination with Tecentriq. This may provide additional benefits and strengthen the evidence for its differentiation versus other FGFR inhibitors from both a safety and efficacy perspective. **Interim results for the original dose monotherapy are expected in H121 with interim results for the combination expected in H221. Top-line results for the combination are expected in H222.** Prudent trial execution will be key to crystallising value from derazantinib, as the evolving landscape in FGFR drug discovery is becoming increasingly competitive in the urothelial cancer indication. We believe the combination with Tecentriq will be key as the [threshold of efficacy for a successful therapy continues to develop](#).

FIDES-03 in gastric cancer marks a hat-trick of studies

Basilea is also pursuing the development of derazantinib in [gastric cancer](#) due to its unique kinase profile, promising preclinical data (presented at [ESMO 2020](#)) and the high unmet medical need in this large patient population. In September 2020 Basilea initiated the multicohort Phase I/II [FIDES-03](#) study expected to enrol >250 patients with advanced gastric cancer and FGFR genetic aberrations. FIDES-03 is investigating derazantinib as a monotherapy, in combination with PD-L1 inhibitor Tecentriq and with Eli Lilly's Cyramza (ramucirumab) and paclitaxel as a second line and above treatment.

Cyramza is a VEGFR2 antibody (anti-angiogenic therapy) indicated for use as a single agent and in combination with targeted therapy and chemotherapy for a range of cancers including gastric, non-small cell lung cancer and colorectal cancer. While also indicated as a monotherapy, the combination of Cyramza and paclitaxel is an established second line standard of care in gastric cancer (based on the [Phase III RAINBOW study](#)), which is a large group of patients given the high rates of disease progression observed with this aggressive disease in the first line ([five-year survival rate <10%](#)).

Gastric cancer represents a potential first-in-class opportunity for derazantinib given current limited evidence for the activity of other FGFR inhibitors in this indication. Given the broad use of Cyramza and paclitaxel, we see this combination as the biggest opportunity for derazantinib which, given its unique kinase profile (FGFR, CSF1R and VEGFR2 inhibition), may complement the anti-angiogenic effects of Cyramza and help combat acquired treatment resistance by targeting multiple mechanisms. The combination with Tecentriq could enable use in the first-line setting as CPIs continue to see broad uptake in earlier lines of treatment (BMS's PD-1 inhibitor Opdivo (nivolumab) in combination with chemotherapy could be the first approved in the first-line setting in gastric cancer, [PDUFA date 25 May 2021](#)). Tecentriq is currently in a range of Phase I/II studies that include gastric cancer. **Interim results for the monotherapy and the RP2D of the combination with Cyramza and paclitaxel are expected in H221, with interim results for this combination expected in H222.**

Evolving competitive landscape update

Deregulation of the FGFR signalling axis has been implicated in oncogenesis, tumour progression and resistance to treatment across many solid tumours. Several FDA-approved tyrosine kinase inhibitors have now been identified as FGFR inhibitors: Stivarga (regorafenib, advanced CRC and drug-resistant GIST), Iclusig (ponatinib, drug-resistant CML and Philadelphia chromosome-positive ALL) and Votrient (pazopanib, renal carcinoma and sarcoma). However, these non-selective, multi-kinase inhibitors have demonstrated limited response in FGFR-mutated cancers, due to dose-limiting toxicities observed by blocking other kinase pathways (all three of the above treatments carry black box warnings) that stop them being used at a high enough dose to sufficiently inhibit FGFR.

To overcome the off-target effects of non-selective inhibitors, efforts have focused on developing selective FGFR inhibitors (pan-FGFR inhibitors). Selectivity to FGFR should enable higher drug doses, and thus better target and therapeutic coverage. In April 2019, the first selective pan-FGFR inhibitor, Janssen's Balversa (erdafitinib) was granted accelerated approval in urothelial cancer (second line and above with FGFR2/3 genetic alterations), on the basis of the Phase II [BLC2001](#) study (32.2% ORR, median duration of response 5.4 months). However, there were no responses to Balversa in the FGFR2 fusion patient population, although we note that the study only had a small number of these patients (n=6). Balversa is in clinical trials for other FGFR-driven cancers (lung, cholangiocarcinoma and gastric cancer) including a [tumour-agnostic Phase II study](#). Consensus currently forecasts that Balversa sales could reach \$499m by 2026 (source: EvaluatePharma).

In April 2020, the FDA granted accelerated approval for Incyte's Pemazyre (pemigatinib) for advanced cholangiocarcinoma with FGFR2 fusion or rearrangements based on Phase II data from the [FIGHT-202 study](#) (36% ORR, median duration of response 9.1 months, as per the [prescribing information](#)). Incyte has also initiated a [Phase III study](#) in the first-line setting as well as clinical trials in urothelial cancer in combination with PD-L1 inhibitor Keytruda ([FIGHT-205](#)). Incyte is also pursuing tumour-agnostic development in solid tumour expressing FGFR1–3 mutations or translocations ([FIGHT-207/208](#)). In FY20, Incyte reported \$26m sales of Pemazyre.

The competitive landscape is constantly developing and multiple FGFR inhibitors are progressing through clinical trials as monotherapy or in combination with other therapeutic classes. In December 2020, FDA granted priority review to BridgeBio's NDA for infigratinib (formerly BGI398) as a treatment for FGFR2 gene fusion-positive cholangiocarcinoma (PDUFA date 1 June 2021). A [Phase III](#) monotherapy study as an adjuvant in urothelial cancer is currently ongoing. Taiho Oncology's futibatinib (formerly TAS-120) is currently in a [Phase III study](#) as a first-line treatment for advanced cholangiocarcinoma (harbouring FGFR2 gene rearrangements) and two Phase II studies in advanced solid tumours with FGFR aberrations (including [cholangiocarcinoma](#), [urothelial cancer](#) and [gastric cancer](#)).

[Derazantinib's main differentiation](#) versus the most clinically advanced competition is fewer off-target side effects and thus improved tolerability (lower adverse events to date include central serous retinopathy, stomatitis, hand-foot syndrome and nail toxicities), which should translate to more amenable combination therapy. On-target side effects, especially high blood phosphorus, were high across the differing FGFR inhibitors, as expected for a class effect, but this is a manageable side effect. The next generation of isoform-selective FGFR inhibitors is still at the preclinical or early stage of clinical development and we will need to see clinical data on how the high selectivity for individual FGFRs affects the interplay between efficacy and toxicity. Competitors to look out for in the near term are Five Prime Therapeutics' FGFR2 selective mAb bezaritinib in [Phase II](#) in first-line gastric cancer in combination with chemotherapy and Relay Therapeutics' FGFR2 selective inhibitor RLY-4008 in [Phase I](#) in solid tumours (including iCCA and gastric cancer). Importantly, we do not think there will be a winner-takes-all in this class, as utilisation will be determined by a multitude of factors such as affinity for receptor subtype target (FGFR2 or FGFR3), genetic aberration (fusion, amplification, translocation) and the ability to combine with other therapies.

Lisavanbulin: Phase II study in GBM underway

Lisavanbulin (BAL101553), an internally developed microtubule-targeting tumour checkpoint controller, is a prodrug of BAL27862, a novel microtubule-destabilising drug (Exhibit 2), which induces tumour cell death through activation of a checkpoint important for tumour cell division. At present, there are no approved drugs that target the BAL27862 binding site. Lisavanbulin's profile includes its ability to cross the blood-brain barrier (confirmed in preclinical models) and potential flexible dosing (including daily oral dosing) schedule.

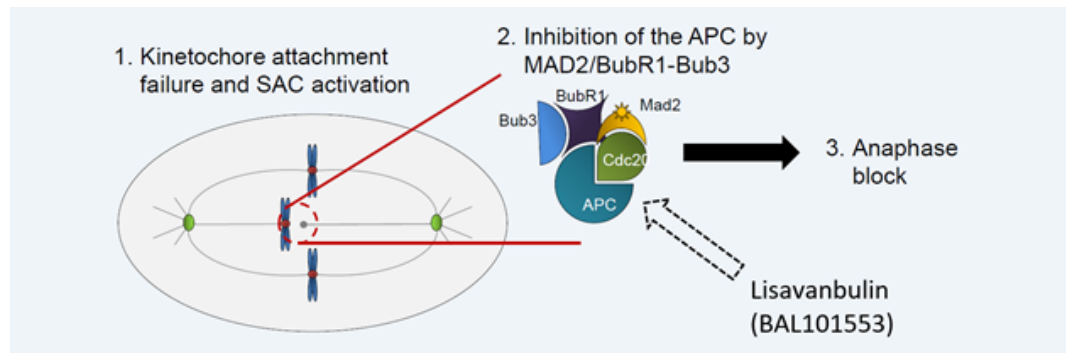
Following confirmed efficacy signals from the [Phase I study](#) (44% disease control rate at six months) in GBM patients ([presented at ESMO 2020](#)), including one patient with high EB1 positivity that achieved >80% tumour shrinkage and has been ongoing for more than two years, Basilea initiated a [Phase II](#) biomarker-driven study in patients with recurrent GBM. This study is utilising EB1 (end-binding protein 1) expression that appears to be a predictive biomarker for a response and is estimated to have a prevalence of 2–5% in GBM. GBM tissue is used to confirm EB1 status using a CE-marked immunohistochemistry assay (industry gold standard) specifically designed for this study. **Interim results are expected in H221, with top-line results in H122.** In parallel, lisavanbulin is also being explored in combination with radiotherapy in a Phase I study in newly diagnosed GBM following surgery (in collaboration with the Adult Brain Tumor Consortium). **Confirmation of the RP2D in this population is expected in H221.**

Further studies are likely to centre on Basilea's biomarker stratified approach to clinical oncology, with preclinical and clinical data suggesting that EB1 is a predictive biomarker for response. The Phase II in GBM is a proof-of-concept study for both lisavanbulin and the EB1 biomarker, and a positive result could have broad read across to cancers with a higher prevalence of the EB1 biomarker. Basilea expects to present its EB1 prevalence assessment in other cancers at a

scientific conference later this year, which will define the opportunity in other indications. This could potentially enable a tumour-agnostic approach targeting all EB1 positive tumours. The presence of cancer stem-like cells (CSLC) contributes to therapeutic resistance and invasiveness; overexpression of microtubule EB1 correlates with GBM progression and poor survival (EB1 is overexpressed in the CSLC line GBM6). Lisavanbulin inhibits the growth of GBM CSLCs.

GBM is the most common type of brain cancer in adults, representing 35–40% of malignant brain tumour (primary cancer origin) and is aggressive in nature (median survival 15–18 months, ~15% of patients survive for five years). In the US ~14,000 cases of GBM are diagnosed per year. Standard of care involves surgery to debulk the tumour, followed by radiotherapy plus chemotherapy with Temodar (temozolomide). There are currently limited treatment options for patients with GBM. Chemotherapy and radiotherapy are not curative and the average survival for these patients is ~15 months.

Exhibit 2: Lisavanbulin activates ‘spindle assembly checkpoint’, which promotes tumour cell death



Source: Basilea scientific presentation (ASCO 2017 – TPS2602). Note: SAC = spindle assembly checkpoint.

Commercial partnerships key to anti-infective portfolio

Basilea’s top line benefits from income generated by commercially available anti-infective products, Cresemba and Zevtera. Basilea has multiple licensing deals for both assets covering more than 100 countries globally (Exhibit 3 highlights the existing partnerships). So far, it has received more than \$260m in total upfront and milestone payments, and under the terms of existing agreements, it could receive a total of more than \$1.0bn in potential regulatory and sales milestones if the assets reach predetermined targets. Cresemba is the main growth component in the top line (Exhibit 4). In its guidance for FY21, Basilea expects CHF108–118m in Cresemba and Zevtera non-deferred revenues (which represent a mix of royalties on sales, product sales, contract revenues and milestones) and CHF2.5m in deferred revenues. For Zevtera, the US remains the significant value driver (potential launch in 2023), with filing dependent on the outcome of the ERADICATE study (SAB).

Exhibit 3: Cresemba and Zevtera partners/distribution agreements

Product	Partner/distributor*	Territory	Comments
Cresemba	Astellas	US	CHF75m upfront and up to CHF332m in regulatory and sales milestones plus tiered royalties starting in the mid-teens and ramping up to mid-20s on sales.
	Pfizer	Europe (over 40 countries excluding Nordics), Russia, Turkey, Israel. China and 16 Asia-Pacific countries	CHF70m and US\$3m upfront and up to US\$650m in regulatory and sales milestones plus mid-teens on sales royalties.
	Asahi Kasei Pharma	Japan	CHF7m upfront and up to CHF60m in regulatory and commercial milestone payments, plus double-digit tiered royalties.
Cresemba and Zevtera	Unimedica Pharma*	Nordic countries, including Sweden, Denmark, Norway and Finland	Upfront and sales milestone payments. Participate in sales through a transfer price.
	Grupo Biotoscana*	19 countries in Latin America, including Brazil, Mexico, Argentina and Colombia	CHF11m upfront, plus milestone payments. Participate in sales through a transfer price.
	Avir Pharma*	Canada	Upfront and sales milestone payments. Participate in sales through a transfer price.
	Hikma Pharmaceuticals*	MENA region	Upfront and sales milestone payments. Participate in sales through a transfer price. 2018 saw the approval of Cresemba in Jordan, the first country in the MENA region.
Zevtera	Correio Pharma*	Europe (excluding Nordics) and Israel	Upfront CHF5m and regulatory and commercial milestone payments. Participate in sales through a transfer price.
	Shenzhen China Resources Gosun Pharmaceutical	China	CHF3m execution payment, plus up to CHF145m in additional payments on achievement of regulatory and commercial milestones, plus double-digit tiered royalties.

Source: Edison Investment Research, Basilea Pharmaceutica. Note: *Distribution agreements where Basilea supplies product at a transfer price.

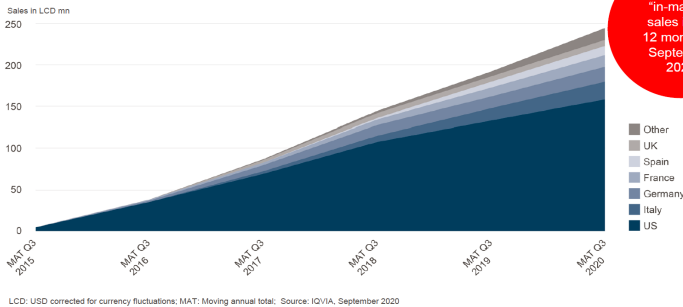
Cresemba continues impressive growth trajectory

Cresemba (isavuconazole) is a broad-spectrum antifungal for the treatment of severe, life-threatening fungal infections. It is available in the US and major European countries through regional partners including Astellas in the US and Pfizer in most of Europe. In-market sales for Cresemba amounted to c \$244m in the 12 months to end September 2020 (+28% vs the comparable period). Basilea expects global 'in-market' sales for FY20 will have exceeded \$250m. Exhibit 4 highlights the steady growth in sales in the US and the increasing contribution from the key EU5 markets. During 2020, Basilea received a CHF6m milestone from Pfizer related to commercial and regulatory milestone payments, and furthermore in January 2021 Cresemba sales in Pfizer commercialisation territories bypassed the level to trigger a [\\$10m sales milestone payment](#) (based on cumulative sales). Cresemba is now available in 50 countries. During 2020, it was launched in key Asia-Pacific markets and received approval in Russia, and by year-end, Basilea expects Cresemba to be available in more than 60 countries. We note that global sales of best-in-class antifungals were split c 25% US and c 75% RoW, highlighting the opportunity ex-US for Cresemba. At Q320, sales of the best-in-class anti-fungal drugs (Exhibit 5) totalled \$3.0bn (moving annual total, source: IQVIA), of which Cresemba had garnered an 8% market share.

China represents an interesting opportunity as it accounted for 18% of the global market for antifungals drugs, second only to the US, which represents 24% (source: IQVIA). The China regulatory body, the National Medical Products Administration (NMPA), has accepted the marketing authorisation application (MAA) for [mucormycosis \(August 2020\)](#) and [invasive aspergillosis \(November 2020\)](#) for review, such that a potential launch in 2022 is possible (we note that if an additional study is required these timelines would be delayed). Additionally, the partner for Japan, Asahi Kasei, has completed enrolment of the required Phase III trial needed to submit the Japanese MAA.

Exhibit 4: Cresemba sales in key launched markets

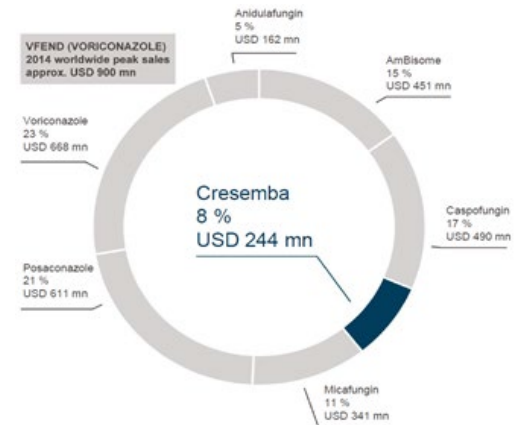
Cresemba continues strong in-market sales uptake



LCD: USD corrected for currency fluctuations. MAT: Moving annual total. Source: IQVIA, September 2020

Source: Basilea corporate presentation. Note: In-market sales for 12 months to 30 September 2020 c \$244m.

Exhibit 5: Cresemba US market share



Source: Basilea corporate presentation

Cresemba could offer advantages over standard treatments

Cresemba is recommended for the first-line treatment of invasive aspergillosis in leukaemia and hematopoietic stem cell transplant patients. The invasive fungal infection market remains an area of unmet medical need, driven by the rise of underlying predisposition conditions. It is estimated that globally there are more than [1.5 million fungal infection-related deaths per year](#). Cresemba has reported fewer statistically significant drug-related adverse events and treatment-emergent adverse events (liver, skin, eye) in invasive aspergillosis patients vs voriconazole in the [Phase III SECURE study](#). Given the safety advantages Cresemba offers over other treatments and its broad spectrum of activity (including mucormycosis), it is well suited to empiric use when the exact underlying cause of infection is unknown. Importantly, according to the [European Conference on Infections in Leukemia \(ECIL-6\) guidelines](#), isavuconazole is as effective as voriconazole, with a better safety profile. ECIL provides recommendations for therapeutic strategies for various types of infection in patients with hematologic malignancies or hematopoietic stem cell transplantation recipients. We believe these features differentiate Cresemba from the competition and assume that it is being directly positioned against both branded and generic drugs, for example Vfend and AmBisome. Cresemba has exclusivity through 2027 in the US, with potential paediatric exclusivity extension to 2027 (from 2025) in the EU.

Zevtera hits TARGET; next up ERADICATE

Zevtera/Mabelio (ceftobiprole) is a broad-spectrum antibiotic for the treatment of drug-resistant, Gram-positive infections, including methicillin-resistant Staphylococcus aureus (MRSA), and Gram-negative bacterial infections, including Pseudomonas. Zevtera's differentiation is through its potential utility in SAB bloodstream infections and related complications such as endocarditis. If approved, it will be the first beta lactam inhibitor to be approved in the US for MRSA and MSSA bacteraemia. Staphylococcus aureus infections can be resistant to methicillin or susceptible to it. Tests to identify the bacterial pathogen are dependent on cultivating blood cultures, which can take hours/days; in life-threatening cases, empiric use of broad-spectrum antibiotics with activity against MRSA is required. The product is available in major European countries (approved for both community- and hospital-acquired bacterial pneumonia) and some international markets through multiple partners. The major commercial opportunity for Zevtera resides in the US market (in part due to higher pricing, wider reimbursement and a higher incidence of MRSA infections); data from two Phase III clinical trials are required to form the regulatory submission to the FDA. [TARGET](#), one of two cross-supportive Phase III trials required for the US filing, has already reported data for ceftobiprole in the treatment of acute bacterial skin and skin structure infections (ABSSSI). The

product met primary and secondary efficacy endpoints including non-inferiority to standard-of-care vancomycin plus aztreonam in the intent-to-treat population. **Top-line data from the second Phase III study in SAB bloodstream infections (ERADICATE) are expected in H122.** Enrolment of this trial has been affected by one quarter due to the impact of COVID-19. During 2020, the FDA approved a protocol amendment to ERADICATE to expand the maximum treatment duration to six weeks (from four weeks), the relevance of which is that patients with more difficult-to-treat infections, such as osteomyelitis, epidural or brain abscesses can be included in the treatment. We note that approximately 70% of the anticipated costs for the Phase III programme (plus the potential trial in community-acquired pneumonia) are being funded by BARDA (a division of the US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response).

A US launch date of 2023 for ceftobiprole with a focus on SAB and ABSSSI is feasible based on a timely readout of ERADICATE, **now expected in H122.** We believe Basilea's strategy for out-licensing is optimal to derive value from the Zevtera US opportunity for shareholders. We forecast \$550m in peak sales for ceftobiprole, comprising US peak sales of \$317m in 2027, predicated on Basilea securing a US commercialisation partner. In China, partner CR Gosun received approval for Zevtera to treat community-acquired pneumonia and hospital-acquired pneumonia in November 2020 (triggering a **CHF3m milestone** to Basilea). We note that in China inclusion in the national reimbursement drug list (NRDL) will be important for widespread reimbursement. China represents the second most important market after the US. We will adjust our geographic peak sales split accordingly as launches continue and the first sales figures in the US and China crystallise.

We note that Novartis's generic division (Sandoz) recently acquired GSK's cephalosporin business for a **total value of \$500m**, highlighting the value that resides in antibiotics. The recent COVID-19 pandemic serves as a reminder that antimicrobial resistance continues to be a huge issue, and more needs to be done to tackle resistance through the development of novel classes and/or target resistant microbials. On that effort, 'push' and 'pull' incentives will be critical to aid pharmaceutical and biotech companies working in this arena. 'Push' incentives are aids in the funding of R&D, for example the BARDA funding received for Zevtera, while 'pull' incentives help to realise acceptable economic returns. In June 2020, **the AMR action fund** launched with the aim of bringing two to four novel antibiotics to market by 2030. AMR expects to invest more than \$1bn into a portfolio of companies to address the funding gap in antibiotic drug development. For 'pull' incentives, the UK government has launched **a pilot scheme**, a world first, to provide new antibiotics to the NHS by offering to pay pharmaceutical companies upfront at the start of their R&D efforts to incentivise work into novel classes and share the risk-reward given the unpredictability of future resistance rates by guaranteeing a fixed revenue which is not linked to volume utilisation. The hope is that more countries will follow suit (the US has recently submitted proposals under the PASTEUR Act), and lessons learnt through the acceleration of research in COVID-19 can be implemented for the development of novel antibiotics.

Sensitivities

Basilea is subject to the usual biotech and drug development risks, including clinical development delays or failures, regulatory risks, competitor successes, partnering setbacks, and financing and commercial risks. The key sensitivities for Basilea relate to successful commercialisation of both Cresemba and Zevtera in their respective approved territories, success of the Zevtera Phase III programme in the US and crystallising value from the oncology pipeline. For the earlier-stage pipeline, both clinical development and partnering risks remain. As research in the FGFR inhibitor space deepens, timely drug development and the broad clinical trial programme (including combinations) are critical to maximise the value of this asset.

Valuation

Our revised valuation is CHF1.17bn or CHF99/share versus CHF1.14bn or CHF106/share previously. We have increased the probability of success for lisavanbulin to 35% from 20%, as the Phase II trial is now underway and derazantinib to 50% from 40%, reflecting positive data readouts (FIDES-01 in iCCA) and the fact that all three FIDES trials are in Phase II. We have made minor adjustments to the model, but our core underlying assumptions remain unchanged. Our valuation is based on an NPV analysis for marketed products, a risk-adjusted NPV for the pipeline and net debt. We have rolled forward our DCF, updated for spot FX rates and reflect a net debt position of CHF77.9m at 31 December 2020 (Exhibit 6).

We forecast derazantinib peak sales of \$934m based on a pricing assumption of \$18,400 per month, six months' duration of treatment and EU pricing at 75% of US. Breakdown as follows:

- We forecast launch in iCCA in 2023 with \$147.0m peak sales across the US and EU5 (2028), which includes the original FGFR2 fusion cohort and the expanded patient cohort in FIDES-01 (FGFR2 amplification and mutation), based on 75% penetration in this highly unmet indication.
- We forecast launch in urothelial cancer in 2024, with \$481.8m peak sales across the US and EU5 (2030) covering all activating molecular FGFR1/2/3 aberrations (fusion, amplification and mutation), based on 10% peak penetration.
- We forecast launch in gastric cancer in 2025 with \$305.2m peak sales across the US and EU5 (2030) based on 30% peak penetration. We have assumed a target patient population with FGFR2 fusions, mutations and amplifications in line with iCCA. We note that the trial is expected to target patients with any FGFR aberrations initially and we will refine our forecasts as we get a deeper understanding of the exact FGFR aberrations that are oncogenic drivers in gastric cancer and are targeted by derazantinib. We note that unlike iCCA and UC, there is not much FGFR competition in this space, which could lead to a significant market share. In our risk-adjusted valuation of derazantinib, we reflect royalties paid on sales to ArQule plus sales and development milestones paid. Under the terms of the deal, ArQule will be eligible to receive single-digit to double-digit, tiered royalties on net sales, plus up to \$326m in regulatory and sales milestones. We anticipate that these milestones will be more heavily weighted to sales-related milestones for other indications (including solid tumours). We anticipate that small milestones will be payable (regulatory and sales) relating to the iCCA and urothelial cancer indications. Our valuation reflects a commercial partnering deal, based on a 20–35% tiered royalty rate, which is higher than our usual assumptions as we take into account the pay away to ArQule.

Exhibit 6: Basilea rNPV valuation

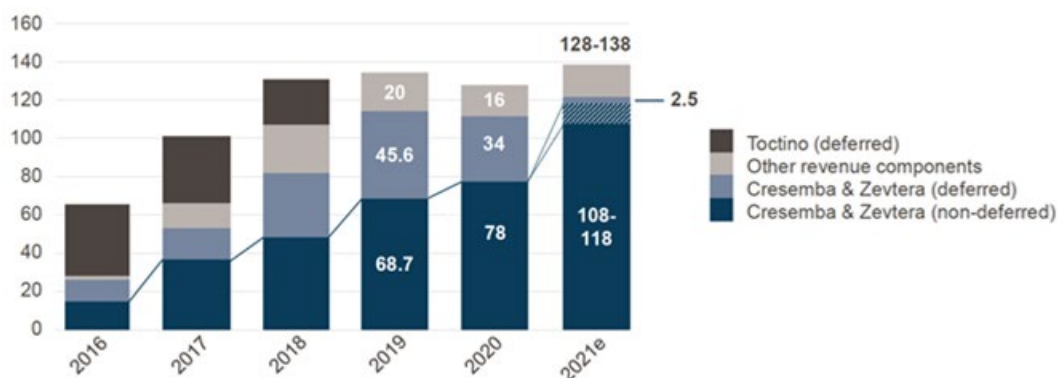
Product	Indication	Launch	Peak sales (\$m)	Value (CHFm)	Probability	rNPV (CHFm)	NPV/share (CHF)
Cresemba (isavuconazole)	Severe mould infections	2015 (US); 2016 (EU); 2018 (RoW); 2022 (Japan)	818	824.9	75–100%*	781.0	65.8
Zevtera/Mabelio (ceftobiprole)	Severe bacterial infections	2015 (EU); 2018 (RoW); 2023 (US)	550	237.3	75–100%**	194.5	16.4
Lisavanbulin	GBM	2023	500	228.7	35%	77.1	6.5
Derazantinib	iCCA, urothelial cancer and gastric cancer	2023 (iCCA); 2024 (urothelial); 2025 (gastric)	934	389.3	50%	194.7	16.4
Net debt at 31 December 2020				(77.9)	100%	(77.9)	(6.6)
Valuation				1,602.3		1,169.4	98.5

Source: Edison Investment Research. Note: Treasury shares are not included in the per-share valuation. *100% probability for the US and EU, 75% for RoW and Japan. **100% probability for the EU, 75% probability for China, RoW and the US.

Financials

Basilea reported total revenues of CHF127.6m in FY20 (FY19: CHF134.4m). The 5.1% decline is due to the expected decrease in the recognition of deferred revenues (CHF33.8m vs CHF45.6m in FY19) related to upfront, development and regulatory milestones received from partners in prior years. The reported revenue line to focus on is 'non-deferred revenue', which relates to income from Cresemba and Zevtera sales booked in the period. This increased by 13.8% to CHF78.2m in FY20 (vs CHF68.7m in FY19), mainly reflecting revenues related to Cresemba sales and, to a much smaller extent, Zevtera (sales are not split out). This trend of increase in non-deferred revenues is expected to continue in 2021, Exhibit 7. Post period end, Basilea received a \$10m milestone payment from Pfizer as Cresemba has passed pre-agreed cumulative sales in Pfizer distribution regions. In China, Basilea has divested its Chinese R&D subsidiary to US-based custom manufacturing organisation PHT international for a total purchase price of \$6.3m. The transaction is expected to close in Q221, leading to a \$2.5m payment in 2021 and an additional \$3.7m booked over the course of the next three years. We will update our financial forecasts accordingly once the transaction has completed.

Exhibit 7: Revenue breakdown



Source: Basilea corporate presentation

Total cost and operating expenses decreased slightly y-o-y to CHF150.9m from CHF151.6m, aiding a reduction in the net loss to CHF14.7m vs CHF22.4m previously, which reflects the one-time gain from the sale of the corporate HQ. Basilea reported gross cash (including financial investments) of CHF167.3m at 31 December 2020, as cash benefits from the property sale and convertible bond issuance was partly offset by the increase in working capital. In July 2020, Basilea optimised its debt maturity profile by the placement of CHF97.0m in a new convertible bond issue (maturity in 2027) and the repurchase of CHF47.1m in existing convertible debt (maturity in 2022). This transaction extended the maturity of c 25% of its mid-term debt to 2027 and yielded gross cash proceeds of c CHF50m. Basilea has stated that it has earmarked the majority of these funds to further reduce its mid-term debt in the future. Post period end, Basilea raised gross funds of CHF45.75m through the issue of 1.0m ordinary shares. The proceeds will be used to continue the development of its clinical and preclinical pipeline, as well as potentially in-licensing complementary businesses, products or assets.

Basilea has issued guidance for FY21 of CHF108–118m non-deferred Cresemba and Zevtera revenue, which included royalties and potential milestones from partners. While the cost of products is expected to increase to reflect higher product deliveries to partners, R&D and SG&A is expected to remain stable, and so the operating loss is expected at around CHF13–23m. We forecast stable product revenues from Cresemba and Zevtera in 2021 and that break-even is achievable in 2022, with sustainable profitability (at operating profit level) from 2023 – the major swing factors to this being the timing (and amount) of milestones received, the future development strategy for

derazantinib and potential timing of an out-licensing deal. Basilea remains well funded to key inflection points including Phase II data readouts for derazantinib. We expect Basilea to achieve a commercial partnering agreement for derazantinib in 2022 and so we do not forecast the material costs associated with commercialising the product globally. We will revisit these assumptions once the strategy surrounding derazantinib becomes clearer. Additionally, we do not include potential upfront or milestone payments from a potential partner, or the pay away to ArQule, in our financial forecasts given the uncertainty of the timing and amounts. Following the post-period capital raise, Basilea has increased FY21 guidance for year-end cash to CHF155–160m.

Exhibit 8: Financial guidance for FY21

CHFm	FY20	FY21 guidance	Edison forecasts 2021
Total revenue	127.6	128–138	135.1
Cresemba and Zevtera non-deferred revenue	78.2	108–118	114.3
Cresemba and Zevtera deferred revenue	33.8	2.5	2.5
Operating loss	8.2	13–23	18.6
Cash and investments*	167.3	155–160**	159.8

Source: Basilea corporate presentation. Note: *Cash, cash equivalents, restricted cash and investments, **Excluding any potential impact from a reduction of the outstanding convertible bonds but including the February 2021 capital raise.

Exhibit 9: Financial summary

Accounts: US GAAP, year-end: 31 December, CHF000s	2018	2019	2020	2021e	2022e
PROFIT & LOSS					
Total revenues	132,555	134,381	127,629	135,148	140,122
Product revenues (Cresemba and Zevtera)	105,900	114,461	112,032	116,800	139,809
Cost of sales	(20,299)	(18,868)	(24,054)	(27,319)	(22,696)
Gross profit	112,256	115,513	103,575	107,830	117,426
Research and development expenses (net)	(104,942)	(102,662)	(97,410)	(97,000)	(78,700)
SG&A costs	(31,409)	(30,051)	(29,422)	(29,442)	(29,813)
Other income/(expense)	0	0	0	0	0
Exceptionals and adjustments	0	0	15,035	0	0
EBITDA (reported)	(22,243)	(15,561)	(7,032)	(17,110)	10,520
Reported operating income	(24,095)	(17,200)	(8,222)	(18,613)	8,913
Operating margin %	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	(7,065)	(5,182)	(6,445)	(8,307)	(7,497)
Exceptionals and adjustments	0	0	0	0	0
Profit before tax (reported)	(31,160)	(22,382)	(14,667)	(26,919)	1,416
Profit before tax (normalised)	(31,060)	(22,282)	(29,602)	(26,801)	1,538
Income tax expense (includes exceptionals)	(192)	(40)	(55)	0	0
Net income (reported)	(31,352)	(22,422)	(14,722)	(26,919)	1,416
Net income (normalised)	(31,252)	(22,322)	(29,657)	(26,801)	1,538
Basic average number of shares, m	10.8	10.8	10.3	12.8	12.9
Basic EPS (CHF c)	(289.3)	(208.5)	(143.2)	(210.8)	11.0
Adjusted EPS (CHF c)	(288.4)	(207.5)	(288.5)	(209.9)	11.9
Dividend per share (CHF c)	0	0	0	0	0
BALANCE SHEET					
Tangible assets	6,424	5,162	2,627	3,242	3,757
Intangible assets	372	372	672	754	832
Long-term investments	0	30,000	0	0	0
Other non-current assets	217	1,073	2,967	2,967	2,967
Total non-current assets	7,013	36,607	6,266	6,963	7,556
Cash and equivalents	173,034	109,024	60,749	53,319	60,103
Short-term investments	50,000	20,000	101,023	101,023	101,023
Inventories	14,411	18,569	21,192	32,184	26,738
Trade and other receivables	3,757	6,242	8,710	11,108	11,517
Other current assets	33,536	31,025	31,854	31,854	31,854
Total current assets	274,738	184,860	223,528	229,487	231,235
Long-term liabilities	196,982	197,740	239,668	241,024	242,380
Deferred revenue	69,945	16,471	13,158	2,990	2,990
Non-current operating lease liabilities	0	548	896	896	896
Other non-current liabilities	14,827	24,174	27,957	27,957	27,957
Total non-current liabilities	281,754	238,933	281,679	272,867	274,223
Accounts payable	6,399	6,765	13,151	8,607	7,151
Deferred revenue	25,025	32,873	2,556	2,500	0
Current operating lease liabilities	0	352	1,752	1,752	1,752
Other current liabilities	35,260	35,504	32,702	32,702	32,702
Total current liabilities	66,684	75,494	50,161	45,561	41,605
Net assets	(66,687)	(92,960)	(102,046)	(81,978)	(77,037)
CASH FLOW STATEMENT					
Reported net income	(31,352)	(22,422)	(14,722)	(26,919)	1,416
Depreciation and amortisation	1,852	1,639	1,190	1,503	1,607
Share based payments	6,251	3,048	3,525	3,525	3,525
Other adjustments	758	758	(13,365)	1,356	1,356
Movements in working capital	(56,719)	(46,859)	(30,762)	(28,158)	1,080
Cash from operations (CFO)	(79,210)	(63,836)	(54,134)	(48,693)	8,985
Capex	(419)	(294)	(1,823)	(2,000)	(2,000)
Short-term investments	60,000	30,000	(51,023)	0	0
Long-term investments	0	(30,000)	0	0	0
Other investing activities	(190)	(110)	17,883	(200)	(200)
Cash used in investing activities (CFIA)	59,391	(404)	(34,963)	(2,200)	(2,200)
Net proceeds from issue of shares	0	0	0	43,463	0
Movements in debt	0	0	43,451	0	0
Other financing activities	(5,986)	1,309	1,616	0	0
Cash from financing activities (CFF)	(5,986)	1,309	45,067	43,463	0
Cash and equivalents at beginning of period	200,724	173,908	111,044	66,256	58,826
Increase/(decrease) in cash and equivalents	(25,805)	(62,931)	(44,030)	(7,430)	6,785
Effect of FX on cash and equivalents	(1,011)	67	(758)	0	0
Cash and equivalents at end of period	173,908	111,044	66,256	58,826	65,610
Net (debt)/cash	26,052	(68,716)	(77,896)	(86,682)	(81,254)

Source: Company accounts, Edison Investment Research

Contact details Grenzacherstrasse 487 PO Box 4005 Basel Switzerland +41 61 606 11 11 www.basilea.com	Revenue by geography N/A
Management team	
CEO: Mr David Veitch Mr Veitch has been CEO since April 2018. He joined Basilea in 2014 as chief commercial officer, having spent over 25 years in the pharmaceutical industry. Before Basilea, he was president of European operations at Savient Pharmaceuticals and spent 15 years at Bristol-Myers Squibb, including leading the commercial operations in Europe, the Middle East and Asia. Mr Veitch holds a BSc degree in biology.	CFO: Mr Adesh Kaul Mr Kaul has been CFO since April 2019. He joined Basilea in 2009 as head of business development and licensing, IR and head of public relations and corporate communications. He held the position of chief corporate development officer of Basilea from 2018. Mr Kaul holds master's degrees in economics and biochemistry from the University of Basel, and an executive MBA from the University of St Gallen.
CMO: Dr Marc Engelhardt Dr Engelhardt has been the chief medical officer since January 2018. He joined Basilea in 2010 as head of clinical research. In 2012, he was promoted to head of development. In this role, Dr Engelhardt led Basilea's clinical research and development group. Prior to joining Basilea, he served as global programme medical director at Novartis Pharma in Basel, before which he held various positions with increasing responsibility at Bracco-Altana, Konstanz, Germany and Bracco Diagnostics in Princeton, NJ, US. Dr Engelhardt holds a medical degree and a PhD from the University Frankfurt/Main, Germany and is board certified in internal medicine.	
Principal shareholders	
UBS RBC Investor & Treasury Services Norges Bank Vanguard Group	(%) 4.9 4.1 2.9 2.4

General disclaimer and copyright

This report has been commissioned by Basilea Pharmaceutica and prepared and issued by Edison, in consideration of a fee payable by Basilea Pharmaceutica. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out of or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2021 Edison Investment Research Limited (Edison).

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia