EDISON

Basilea Pharmaceutica

Business outlook

2020 vision on derazantinib in iCCA

Pharma & biotech

Basilea Pharmaceutica is a revenue-generating biotech company that is on the cusp of breaking even (2021e) and sustainable profitability thereafter. It has successfully brought two anti-infective drugs to the market: Cresemba (severe mould infections) and Zevtera (bacterial infections). Combined revenue contributions (as reported by Basilea, both assets are commercialised through partners) are expected to exceed CHF105m in FY19. Longer-term value creation is also dependent on crystallising the mid/late-stage oncology portfolio. Basilea is investing for future growth; multiple datapoints on derazantinib are expected in 2020. If data from the registrational FIDES-01 are particularly positive, they could form the basis of an accelerated approval in iCCA. We value Basilea at CHF1.18bn.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHF)	DPS (CHF)	P/E (x)	Yield (%)
12/17	101.5	(18.9)	(1.78)	0.0	N/A	N/A
12/18	132.6	(31.0)	(2.89)	0.0	N/A	N/A
12/19e	132.9	(27.7)	(2.57)	0.0	N/A	N/A
12/20e	134.2	(23.8)	(2.21)	0.0	N/A	N/A

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

Cresemba benefiting from ongoing launches

Guidance for FY19 includes CHF105–110m revenue contributions from Cresemba and Zevtera. The majority of these are attributable to Cresemba, which is benefiting from ongoing launches (available in 40 countries) by multiple partners including Astellas (US) and Pfizer (ex US). In August, Basilea reported positive US Phase III TARGET data on Zevtera for the treatment of skin infections (ABSSSI). TARGET will form the basis of a US NDA submission, along with bacteraemia data from ERADICATE, which could differentiate Zevtera. The major commercial opportunity for Zevtera is in the US market (potential launch in 2023).

Derazantinib indications expanding

Derazantinib, a pan-FGFR (fibroblast growth factor receptor) inhibitor, could be the first of Basilea's oncology assets to market, which we forecast in 2023 (iCCA). Positive interim results in the FIDES-01 registrational Phase II study in bile duct cancer (iCCA) have been reported (full data expected H220). Basilea has initiated Phase I/II FIDES-02 in urothelial cancer (UC) in combination with immunotherapy (PD-L1) as it looks to maximise the value of derazantinib through broadening its utility in other indications and with combination approaches. We have upgraded our peak sales forecasts, broadened the iCCA indication and now include UC, which, given larger patient numbers, has a material impact on our estimates. We now forecast total derazantinib peak sales of $629m vs $59m.

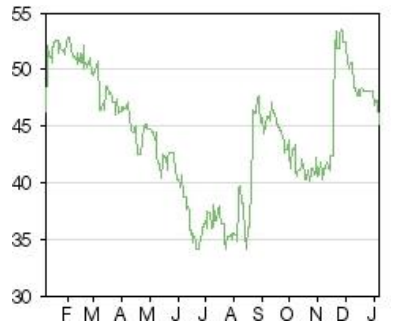
Valuation: rNPV of CHF1.18bn or CHF109/share

Our revised valuation is CHF1.18bn vs CHF1.08bn or CHF100/share previously. We have increased derazantinib peak sales in iCCA and include the urothelial cancer indication for the first time, leading to valuation uplift. Our valuation is based on an NPV analysis for marketed products, a risk-adjusted NPV for the pipeline and net debt of CHF19.5m at 30 June 2019.

7 January 2020

Price	**CHF45.12**
Market cap	**CHF536m**
	$1.03/CHF
Net debt (CHFm) at 30 June 2019	19.5
Shares in issue (including 1.1m treasury shares)	11.9m
Free float	91%
Code	BSLN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(10.9)	5.1	(1.6)
Rel (local)	(12.6)	(3.1)	(20.6)
52-week high/low	CHF54.2		CHF34.1

Business description

Basilea Pharmaceutica is focused on oncology and anti-infectives. Its marketed products are Cresemba (an antifungal) and Zevtera/Mabelio (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 top-line results from Phase II in iCCA (FGFR2 fusion cohort)	Mid-2020
Derazantinib interim data from first cohort in urothelial cancer	H220
Ceftobiprole Phase III ERADICATE top-line data for bacteraemia (SAB)	H221

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Investment summary

Basilea Pharmaceutica is a Switzerland-based biopharmaceutical company (spun out of Roche in 2000) with a focus on developing innovative anti-infective agents and oncology treatments that target drug resistance. Basilea has two approved hospital products, Cresemba and Zevtera; numerous commercial partnerships are in place for both assets (Exhibit 1). Basilea is one of a handful of revenue generating biotechnology companies in Europe; cash generated by the anti-infective portfolio has reduced reliance on capital markets for funding its R&D requirements. For FY19, management has guided to total revenues of CHF128–133m, of which CHF105–110m is expected from Cresemba and Zevtera. In contrast, operating expenses (ex COGS) have been running at around CHF135m pa in recent years. As Cresemba continues its growth trajectory and operating expenses stabilise around CH135m pa (according to our forecasts), we believe Basilea can break even in 2021 and we forecast sustainable profitability thereafter. Basilea's late-stage oncology pipeline (derazantinib for FGFR-driven solid tumours and lisavanbulin (BAL101553) for glioblastoma) is pivotal to future growth and long-term profitability. We expect steady newsflow from the cancer portfolio throughout 2020/21 to define the positioning of these novel drugs within the rapidly evolving space that is oncology.

Valuation: rNPV of CHF1.18bn or CHF109/share

We value Basilea at CHF1.18bn or CHF109/share (vs CHF1.08bn previously). The main impact on our valuation is an increase in our derazantinib peak sales in iCCA and inclusion of the urothelial cancer indication for the first time. Our other product peak sales assumptions remain unchanged. For 2020, we have reduced our total revenue forecast due to a decrease in expected deferred revenues recognised. Our NPV analysis is based on Cresemba (worldwide) and antibiotic Zevtera (ex-US), plus risk-adjusted contributions for Zevtera US, derazantinib and lisavanbulin (BAL101553). Our valuation is weighted to commercially available assets Cresemba and Zevtera. We include net debt of CHF19.5m at 30 June 2019, and have rolled forward our DCF and updated the US dollar/Swiss franc exchange rate.

Sensitivities: Commercialisation is key

The key sensitivities for Basilea relate to successful commercialisation (largely through respective partners) of both Cresemba and Zevtera (where approved), progress with the Phase III US Zevtera trials and crystallising value from the oncology pipeline. Success for Zevtera and Cresemba is largely in the hands of existing, or prospective, partners where we have limited visibility. For the oncology assets, key risks relate to drug development, and failure of one or more trials could lead to termination of the programme. Furthermore, combination strategies for derazantinib will be important for commercialisation as treatment paradigms in oncology move towards immunoncology treatments and targeted therapies for tumours expressing mutational burdens.

Financials: Break-even in 2021

We believe that Basilea's gross cash (including financial investments) of CHF178m at 30 June 2019 should be sufficient to fund operations beyond 2020, even excluding future potential deals for either Zevtera in the US or the oncology pipeline. The company has a convertible bond in issue, which is not due for conversion until end 2022. We forecast break-even at the operating profit level in 2021, and profitability thereafter will be driven by Cresemba- and Zevtera-related revenues. We expect operating expenses to stabilise in 2019–21, with some fluctuation in R&D (2019–21) as slightly lower Zevtera US Phase III clinical development costs offset progressing oncology pipeline costs in the near term. With SG&A costs remaining flat, we believe that profitability will be driven by significant operational leverage of the top line in 2022 and beyond.

Commercial partnerships key to anti-infective portfolio

Basilea's top line benefits from income generated by commercially available anti-infective products, Cresemba and Zevtera. It has multiple licensing deals for both assets (Exhibit 1 highlights the existing partnerships). We note that Basilea's FY19 total revenue guidance stands at CHF128–133m vs FY18 total revenue of CHF132.6m. Note that revenues in FY18 benefited from deferred revenue related to Toctino from Stiefel (CHF23.9m reported in 2018). We highlight that the main growth component in the top line, anti-fungal drug Cresemba, remains strong (Exhibit 2). In its guidance, Basilea believes an uplift of 28–34% in contributions from Cresemba and Zevtera (which represent a mix of royalties on sales, product sales, contract revenues and milestones) will translate to CHF105–110m in revenues in FY19. For Zevtera, the US remains the significant value driver (potential launch in 2023), with filing dependent on the outcome of the ERADICATE study (bacteraemia).

Basilea has multiple licensing deals in place for Cresemba and Zevtera. So far, it has received $252m in total upfront and milestone payments. Under the terms of existing agreements, it could receive a total of $1.1bn in potential regulatory and sales milestones if the assets reach predetermined targets.

Exhibit 1: Cresemba and Zevtera partners/distribution agreements

Product	Partner/distributor*	Territory	Comments
Cresemba (isavuconazole)	Astellas	US	CHF122m upfront and regulatory milestones received with up to CHF275m of sales milestones outstanding. Tiered royalty starting in the mid-teens and ramping up to mid-20s on sales.
	Pfizer (PFE)	Europe (over 40 countries excluding Nordics), Russia, Turkey, Israel. China and 16 Asia-Pacific countries	CHF73m upfront and up to US$638m in sales and regulatory milestones outstanding plus mid-teen on sales royalties.
	Asahi Kasei Pharma (AKP)	Japan	CHF7m upfront and up to CHF60m in regulatory and commercial milestone payments, plus double-digit tiered royalties.
Cresemba and Zevtera	Unimedic Pharma*	Nordic countries, including Sweden, Denmark, Norway and Finland	Upfront and sales milestone payments. Participate in sales through a transfer price.
	Grupo Biotoscana (GBT)*	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*	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 (ceftobiprole)	Correvio*	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

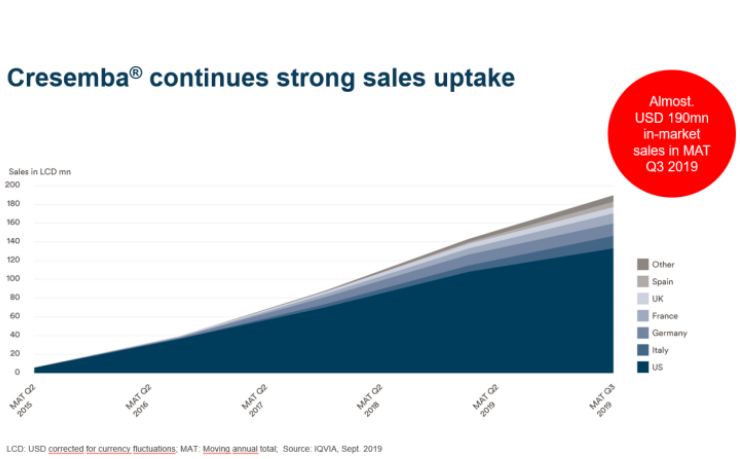
Cresemba (isavuconazole) is a broad-spectrum antifungal for the treatment of severe, life-threatening fungal infections. It is available in the US and major European countries through regional partners including Astellas in the US and Pfizer in most of Europe. In-market sales for Cresemba amounted to c $190m in the 12 months to end September 2019 (+32% vs the comparable period). Exhibit 2 highlights the steady growth in sales in the US and the increasing contribution from the key EU5 markets. By year-end, Basilea expects Cresemba to be available in 40 countries, and in more than 60 countries by end 2021. We note that before the loss of exclusivity, global sales of best-in-class antifungals were split c 25% US and c 75% RoW, highlighting the opportunity ex-US for Cresemba. At Q319, sales of the best-in-class anti-fungal

drugs (Exhibit 3) totalled €3bn (moving annual total, source IQVIA), of which Cresemba had garnered 6% market share (Exhibit 3).

Cresemba could offer advantages over standard treatments

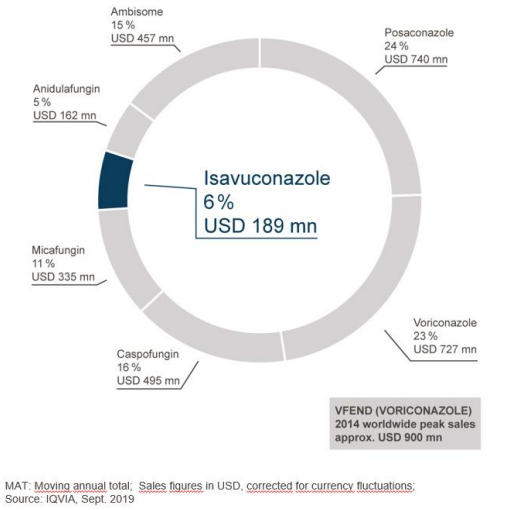
The invasive fungal infection market remains an area of unmet medical need, driven by the rise of underlying predisposition conditions (eg immunocompromised patients, cancer patients on an intensive chemotherapy regimen). Cresemba has reported fewer statistically significant drug-related adverse events and treatment-emergent adverse events (liver, skin, eye) in invasive aspergillosis patients vs voriconazole in the SECURE Phase III study. Cresemba can be administered in patients with renal impairment. 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. This is particularly important with severe, life-threatening, invasive fungal infections, where timely initiation of treatment is important and diagnosing the causative pathogen is not always straightforward. Cresemba has a broad spectrum of activity against moulds, including emerging moulds (Mucorales). Importantly, according to ECIL-6 guidelines Cresemba is recommended for the first-line treatment of invasive aspergillosis in leukaemia and hematopoietic stem cell transplant patients. Specifically, the European Conference on Infections in Leukaemia (ECIL) states that isavuconazole is as effective as voriconazole, with a better safety profile. The 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, eg Vfend and AmBisome.

Exhibit 2: Cresemba sales in key launched markets



Source: Basilea presentations. Note: In-market sales for 12 months to 30 September 2019 c $190m.

Exhibit 3: Cresemba US market share



Source: Basilea presentations

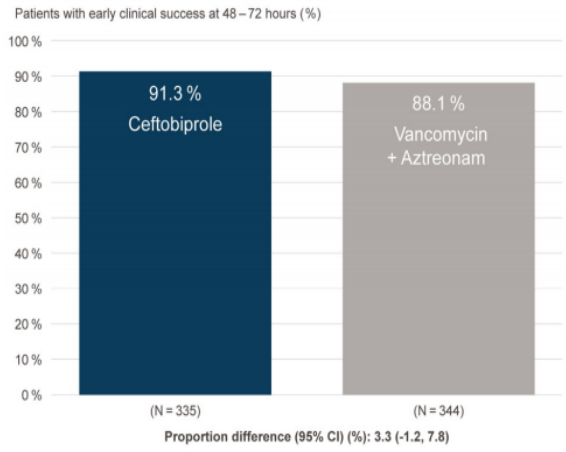
Zevtera hits TARGET; next up ERADICATE

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. The product is available in major European countries (approved for both community- and hospital-acquired bacterial pneumonia) and some international markets through multiple partners, and further roll-outs are expected (ex US) in 2020. In August, Basilea announced positive top-line data from the Phase III TARGET trial, which is evaluating 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. In the TARGET trial, which evaluated 679 patients, ceftobiprole met pre-specified primary efficacy of non-inferiority (with the pre-specified margin of 10%) to vancomycin plus aztreonam (91.3% vs 88.1%, see Exhibits 4 and 5). This means that ceftobiprole, if approved, could be utilised instead of vancomycin and a combination of vancomycin plus aztreonam. Ceftobiprole was well tolerated – drug-related adverse events in both treatment groups were nausea, diarrhoea and headache. Full data from this study will be presented at a forthcoming scientific conference. Data from the TARGET study could be used to support a post-marketing label extension outside the US. Furthermore, positive data could be leveraged in many approved countries, by detailing the data to the medical community.

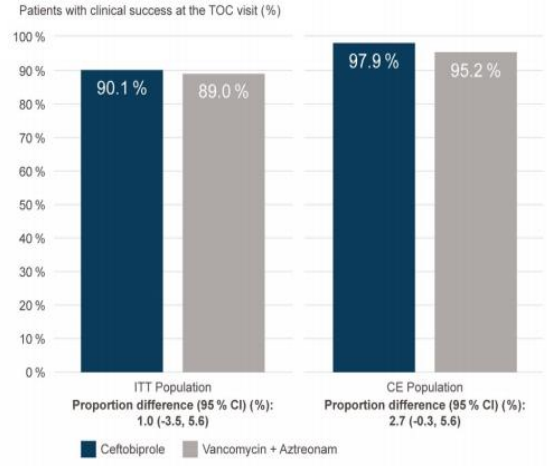
We believe the major commercial opportunity for Zevtera resides in the US market. TARGET is one of two cross-supportive Phase III trials required for the US filing. Top-line data from the second study in Staphylococcus aureus bacteraemia (SAB) bloodstream infections (ERADICATE) are expected in H221. Critically, funding for these trials (plus the potential trial in community-acquired pneumonia) is in place, with BARDA funding approximately 70% of the anticipated costs for the Phase III programme. BARDA is a division of the US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response. We note that Zevtera's Qualified Infectious Disease Product (QIDP) designation extends US market exclusivity to 10 years from approval.

Exhibit 4: Early clinical response at 48–72 hours after start of treatment (ITT population)



Source: Basilea presentations. Note: ITT = Intent-to-treat.

Exhibit 5: Investigator-assessed clinical success



Source: Basilea presentations

We note that in the US, Paratek launched its novel antibiotic Nuzyra (omadacycline) in February 2019. Nuzyra is the first once-a-day oral/IV treatment for community-acquired bacterial pneumonia (CABP) and ABSSSI to receive FDA approval in 20 years. Sales in the first eight weeks of launch were reported at $1.3m. According to Paratek corporate presentations, it estimates the potential opportunity for hospitalised ABSSSI (first-line treatment failure, resistance suspected) to be $1.2bn by 2028 and community ABSSSI to be $1.5bn in the US alone.

The competition is increasing in the treatment of infections such as skin and skin structures and urinary tract, as the newer antibiotics compete for the same patient subsets. Omadacycline is a novel aminomethylcycline antibiotic, derived from the tetracycline class to overcome tetracycline resistance (MRSA in ABSSSI infections). It belongs to the macrolide class of antibiotic drugs, compared to ceftobiprole, which is a beta lactam. Zevtera's differentiation is through its potential utility in SAB bloodstream infections and related complications such as endocarditis. It could also be the first beta lactam inhibitor to be approved 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. Nuzyra is not approved for use in staphylococcus aureus bacteraemia and, while its prescribing label details coverage of ABSSSI caused by MRSA, its CABP coverage covers MSSA and not MRSA.

We believe a US launch date of 2023 for ceftobiprole could be feasible, with a focus on SAB and ABSSSI. Paratek was aiming to expand its 40 reps at launch to 80 reps by year-end 2019, targeting 800 institutions. Given the costs associated with this, 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.

Derazantinib spearheads oncology portfolio

Basilea's oncology pipeline is spearheaded by its pan-FGFR inhibitor derazantinib, which was in-licensed from ArQule in April 2018. Since our note Oncology product portfolio to drive future growth was published in July 2018, significant developments have occurred in the FGFR field including FDA approval of the first pan-FGFR inhibitor (Janssens's Balversa for urothelial carcinoma) in April 2019, positive data from Incyte's pemigatinib in advanced cholangiocarcinoma, as well as positive interim data for derazantinib in patients with FGFR2 gene fusion iCCA (2L). Developments in the field serve as validation of FGFR as a target. However, this is a complex scientific space. We discuss how the challenges of developing low-toxicity, efficacious, reversible, specific inhibitors are being overcome, how the competitive landscape is unfolding, and derazantinib's potential positioning.

Derazantinib's dual mechanism of action

Derazantinib is an oral immunokinase inhibitor that targets FGFR1/2/3 and CSF1R kinases. It is a selective and potent pan-FGFR inhibitor (FGFR1, FGFR2, FGFR3 and, to a lesser degree, FGFR4) anticipated to have efficacy in tumours that test positive for FGFR fusion mutation biomarker. Inhibition of the FGFR receptors aims to prevent uncontrolled proliferation of the tumour cells. Deregulation of the fibroblast growth factor (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's ability – immunomodulation activity through CSF1R inhibition – could provide additional synergies in combination with a PD-(L)1 antibody or small molecule drug compared to other FGFR inhibitors in the clinic. This may be a critical differentiating factor in an arena where immunomodulatory drugs such as checkpoint inhibitors are being used in earlier lines of treatment.

Immune mediation could be synergistic to PD-(L)1 inhibitors

CSF1R has emerged as an attractive target in immunoncology. It is a cell-surface protein that acts as the receptor for the cytokine CSF1, which controls macrophage (a type of white blood cell) function. Inhibition of CSF1R limits the production of pro-tumour macrophages, which, among other functions, is believed to aid in angiogenesis, tumour cell invasion and evasion of the immune system. CSF1R activity is very novel and potentially important for PD-(L)1 combinations, as there may be synergy (both act by activating the immune system against the cancer). However, tolerability is key, as the promise of increased clinical activity is accompanied by the increased risk of side effects, which can lead to dose interruptions or the discontinuation of treatment. Derazantinib's tolerability and manageable side effect profile to date make it a suitable candidate for combination therapy approaches. While other FGFR inhibitors do exhibit activity against CSF1R, much higher concentrations are required for CSF1R therapeutic benefit, which could change the toxicity profile of these drugs.

Two clinical trials assessing derazantinib are currently ongoing: monotherapy in FGFR-driven intrahepatic cholangiocarcinoma (FIDES-01) and as monotherapy and in combination with Roche's PD-(L)1 inhibitor Tecentriq in UC (FIDES-02). Basilea's development strategy for achieving differentiation of derazantinib is to leverage its specific properties of low toxicity (which enables combination strategies) and exploit its affinity for colony-stimulating factor 1 receptor (CSF1R) kinase at therapeutic dosing levels (which could be synergistic with immune checkpoint inhibitors). In the near term, we expect Basilea to add maximum value to derazantinib by broadening its utility beyond iCCA and UC. We do not include other indications in our current forecasts, but expect additional trials to start in FGFR-driven solid tumours in 2020.

FIDES-01 promising interim data, top-line ICCA data expected in mid-2020

The Phase II study (FIDES-01) for derazantinib in FGFR2 gene fusion expressing intrahepatic cholangiocarcinoma (iCCA) reported promising interim data in January 2019. The interim analysis of the Phase II study, based on the subset of 29 patients (42 enrolled on the study) who had at least one post-baseline imaging assessment, showed an objective response rate of 21% and disease control rate (partial response or stable disease) of 83%. Safety and tolerability were confirmed as seen in previous studies. Top-line data from cohort 1 of FIDES-01 should be available in mid-2020; the trial is expected to enrol 100 patients. We note that if these data are particularly positive, they could form the basis of an accelerated approval in iCCA. We model a 2023 launch following a traditional development path including a Phase III trial, although this could prove conservative. In June 2019, Basilea expanded the FIDES-01 trial to include a second cohort to assess the activity of derazantinib in a broader range of iCCA FGFR2-driven tumours (specifically FGFR2 gene mutations or amplifications). Interim data from cohort 2 are expected in H220.

Cholangiocarcinoma is an uncommon and aggressive malignancy that arises from the epithelial cells of the biliary tract (a system of vessels that link up the gallbladder and liver to aid in the secretion of bile). iCCA, a form of biliary tract cancer, is the second most common primary malignancy of the liver representing 10–20% of all primary liver tumours. During the past 40 years, the US incidence of iCCA has risen to 2.1 per 100,000 in western countries (~6,500 cases per year in the US). However, the true incidence could be higher.

Around 10% of patients who present with early-stage disease may be cured by full liver resection. However, cholangiocarcinoma presents a major diagnostic and treatment challenge, with the majority of patients representing late-stage with surgically unresectable disease and survival prognosis of less than a year (based on palliative chemotherapy with gemcitabine and a platinum agent). While there are currently no approved targeted therapies for iCCA, the discovery of FGFR2 fusions in ~10–20% of patients could change the treatment paradigm for these patients. While small patient populations in iCCA are expected, there is an unmet need and thus the FDA and EMA have granted orphan drug designation. Orphan drug status can provide financial incentives such as market exclusivity (seven years from approval in the US, 12 years in the EU), reduced R&D costs (eg through tax credits and R&D grants) and substantial pricing incentives.

We have revised our assumptions in iCCA and now include the expanded patient cohort in FIDES-01 (FGFR2 application and mutation), while our previous numbers reflected iCCA patients with FGFR2 fusion. We now forecast that $147.0m peak sales across the US and Europe (2028) could be achieved in this indication alone (previously $59m) based on 75% penetration in this highly unmet indication

FIDES-02 expands use into urothelial cancer

Basilea has initiated a multi-cohort Phase I/II study in advanced urothelial cancer (FIDES-02), in which derazantinib will be investigated as monotherapy or in combination with Tecentriq (Roche's

PD-L1 targeting antibody, an immunotherapy) and will enrol up to c 300 patients with FGFR-driven disease (first line and above). With the momentum in cancer treatment algorithms shifting towards targeted therapies and immunoncology, we believe this is a comprehensive strategy for adding further value to derazantinib. Activating FGFR aberrations are found frequently in UC tumours (up to 32%), from genetic mutations, rearrangements or amplifications that lead to over-activation of FGFRs and disease progression.

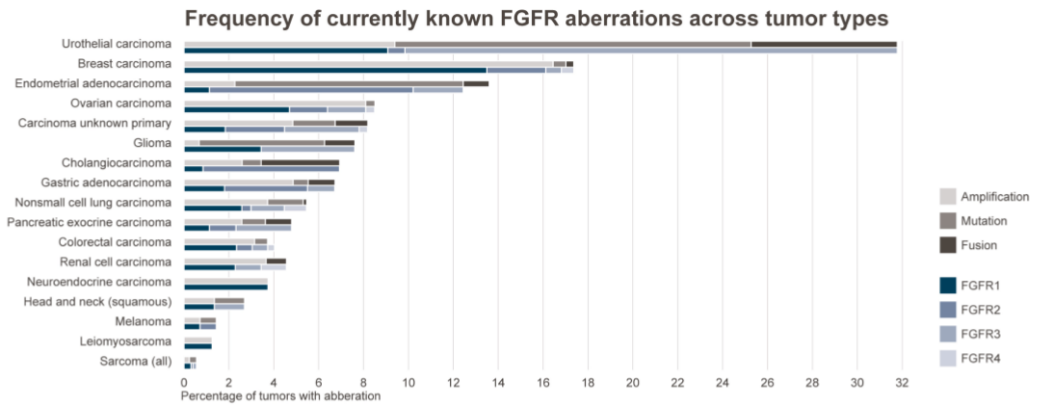
Bladder cancer is the ninth most common cancer in the world, with 430,000 new cases diagnosed in 2012. With annual mortality from bladder cancers across North America and Europe estimated at c 85,000, the opportunity is significant (source: GloboCan). Urothelial cancers account for 90% of all bladder cancers and 10–15% of kidney cancers (source: www.cancer.net). Cisplatin-based combination chemotherapy regimen is the first-line therapy for patients with metastatic urothelial cancer of the bladder and urinary tract who are cisplatin candidates; 50% of patients are not candidates for cisplatin due to comorbidities (impaired kidney function, heart failure, neuropathy). The advent of checkpoint inhibitor therapy with PD-1/PD-L1 inhibitor drugs – Bristol-Myers Squibb's Opdivo (nivolumab), Merck & Co's Keytruda (pembrolizumab), Roche's Tecentriq (atezolizumab), AstraZeneca's Imfinzi (durvalumab) and Merck KGaA/Pfizer's Bavencio (avelumab) approved for either first- or second-line treatment of UC has changed the treatment of these cancers. Given that FGFR is a mutagenic driver in UC, in April 2019 Janssen's FGFR inhibitor, Balversa (erdafitinib), became the first drug in the class to be approved by the US FDA for the treatment of UC (second line and above; FGFR2/3 +ve).

Interim data from the first patient cohort are expected in H220. Prudent trial execution will be key to crystallising value from derazantinib, as the emerging landscape in FGFR drug discovery is becoming increasingly competitive in the UC indication. Consensus currently forecasts that Balversa sales could reach $1.2bn by 2024 (source: EvaluatePharma). We now include forecasts for this indication for the first time and forecast peak sales in UC of $481.8m based on 15% peak penetration.

Multiple indications and combinations key to unlocking value

FGFR inhibitors have a role in the treatment armament for cancers in patients with FGFR genomic alterations. This is predicated on tumour mutational burden specifics and the complicated genetic changes in FGFR (multiple oncogenic driver alterations in the FGFR pathway including gene amplification, mutation, translocation and fusion) affect multiple tumour types, at low incidence rates. The use of molecular diagnostic tests for the identification of targeted mutations (DH1/2 mutations10 and FGFR2 fusions) has in part improved the ability to diagnose some of these tumours through next generation sequencing (NGS) and/or fluorescence in situ hybridization (FISH) testing. The key is marrying the FGFR inhibitor in development with the aberration it may work optimally against. For derazantinib, Basilea's initial patient target for the FIDES-01 trial was iCCA tumours with FGFR2 gene fusion, which was subsequently expanded to include FGFR2 gene mutations or amplifications.

Exhibit 6: Derazantinib potential beyond iCCA



Source: Basilea corporate presentations

Ongoing tumour analysis at both research and commercial levels is increasing working knowledge in the FGFR aberration space. Molecular profiling data of FGFR-driven cancer patients revealed that FGFR aberrations were found in 7.1% of cancers, with 66% of the aberrations being gene amplification, 26% mutations and 8% rearrangements. In this patient population (4,853 tumours were analysed by NGS, source: Helsten et al), the most common cancers affected were bladder/ureter, breast, endometrial and ovarian cancer (Exhibit 6).

Furthermore, the success of targeted or immune therapies is often limited by the emergence of resistance and/or clinical benefit in only a subset of patients (eg PD-(L)1 overexpression, as per prescription label detail for Keytruda in metastatic bladder cancer). Therefore, the rationale for combination therapy (targeted therapy plus immune modulation with a checkpoint inhibitor) is whether working synergistically will lead to enhanced tumour responses. Preclinical work on mouse models with erdafitinib plus PD(L)1 inhibitor led to tumour control accompanied by tumour-intrinsic, FGFR pathway inhibition, expansion of T-cell clones and immunologic changes in the tumour microenvironment to support enhanced antitumour immunity. In many cancer indications, immune checkpoint inhibition utilising PD(L)1 inhibitors is increasingly becoming standard of care, with use in the first-line setting expanding. Combination use of drugs (chemotherapy, targeted therapy, VEGFR inhibition, immune modulations) is the future for cancer treatment. Drugs with good tolerability at efficacious, therapeutic doses are ideal candidates for combination therapy.

Competitive landscape

Several FDA-approved tyrosine kinase inhibitors have now been identified as FGFR inhibitors: regorafenib (advanced CRC and drug-resistant GIST), ponatinib (drug-resistant CML and Philadelphia chromosome-positive ALL) and pazopanib (renal carcinoma and sarcoma). However, as these non-selective, multi-kinase inhibitors have demonstrated limited response in FGFR-mutated cancers, it is hypothesised that multi-kinase activity limits the therapeutic doses required for FGFR inhibition due to dose-limiting toxicities mediated through blocking other kinase pathways.

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. Multiple FGFR inhibitors are progressing through clinical trials in monotherapy or in combination with other therapeutic classes. We list the most advanced drugs below. Exhibit 7 highlights that derazantinib's main differentiation is fewer off-target side effects and thus improved tolerability (lower adverse events include central serous retinopathy, stomatitis, hand-foot syndrome to date), 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. 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. This will distinguish derazantinib as it will likely be the third drug to market in cholangiocarcinoma and UC, after Balversa and pemigatinib. We discuss key FGFR inhibitors below.

- Janssen's erdafitinib (Balversa) is approved by the FDA for UC on the basis of Phase II clinical trial BLC2001 (32.2% ORR, 95% CI 22.4, 24.0, median duration of response 5.4 months [95% CI (4.2, 6.9)]. However, there were no responses to Balversa in the FGFR2 fusion patient population (n=6). Erdafitinib is in clinical trials for other FGFR-driven cancers including lung, breast and cholangiocarcinoma; we note that PD-(L)1 combination trials are underway.
- BridgeBio's infigratinib Phase III in cholangiocarcinoma FGFR2 fusions, translocations and a clinical trial in UC with FGFR3 aberrations is planned.
- Incyte's Phase II FIGHT-202 trial evaluated pemigatinib monotherapy (selective FGFR inhibitor) for locally advanced metastatic cholangiocarcinoma patients with FGFR2 fusions or arrangements (ORR 36%, mPFS 6.9 months with median follow-up of 15 months). Incyte filed an NDA in this indication in November 2019. It has initiated a Phase III FIGHT trial for the first-line treatment of patients with cholangiocarcinoma with FGFR2 fusions or rearrangements. Incyte has also initiated a trial in UC (FGFR3 genetic changes) and, importantly, will look at tumour-agnostic development. This is an all-comers trial for any solid tumour expressing FGFR1/2/3 fusions and rearrangements or activating point mutations (FIGHT-207).

Exhibit 7: FGFR inhibitors – differences in safety profile

	Cholangiocarcinoma				Urothelial cancer	
	DZB[1] (N=44)	INF[2] (N=71)	FUT[3] (N=45)	PEM[4] (N=146)	PEM[5] (N=108)	ERD[6]* (N=99)
Dosing regimen	300mg QD	125mg Q4W QD for 3w	16 mg, 20 mg or 24 mg QD	13.5mg Q3W QD for 2w	13.5mg Q3W QD for 2w	8 mg QD (titr. to 9mg)
Most frequent safety events	Phosphorus⇧ Nausea Vomiting	Phosphorus⇧ Fatigue Stomatitis	Phosphorus⇧ Constipation AST↑	Phosphorus⇧ Alopecia Diarrhoea	Diarrhoea Alopecia Constipation	Phosphorus⇧ Stomatitis Dry mouth
Blood phosphorus⇧†	59%	73%	80%	60%	31%	73%
Fatigue†	43%	49%	*NR*	42%	32%	≥21%
Alopecia†	20%	38%	*NR*	49%	*NR*	≥27%
Dry eye/xerophthalmia†	16%	32%	*NR*	25%	*NR*	≥19%
Central serous retinopathy	0%	*NR*	*NR*	4%	*NR*	21%
Alanine aminotransferase (ALT) ⇧	30%	*NR*	31%	*NR*	*NR*	41%[7]
Hand-foot syndrome/PPE	0%	27%	22%	>5%**	*NR*	≥22%
Nail toxicities	<5%	*NR*	*NR*	42%	*NR*	52%
Stomatitis	11%	45%	22%	35%	34%	≥55%

Source: Basilea corporate presentations. Note: DZB = derazantinib, INF = infigratinib (BGJ398), FUT = futibatinib (TAS-120), PEM = pemigatinib (INCB54828), ERD = erdafitinib.

Lisavanbulin biomarker strategy to optimise tumour selection

Lisavanbulin (BAL101553), an internally developed microtubule-targeting tumour checkpoint controller, is being evaluated in Phase I/IIa clinical trials in advanced solid tumours. BAL101553 is a prodrug of the active moiety BAL27862. BAL27862 is a novel microtubule-destabilizing drug, 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. Basilea is exploring a biomarker programme to optimise patient and tumour selection for lisavanbulin's clinical trial programme (Exhibit 8) in glioblastoma (GBM) and ovarian carcinoma. Further studies are likely to centre on Basilea's biomarker stratified approach to clinical oncology, with preclinical and clinical

data suggesting that the plus-end binding protein (EB1) appears to be a predictive biomarker for a response.

Exhibit 8: Lisavanbulin clinical trials

Clinical study	Notes
Phase IIa expansion (weekly 48-hour IV in patients with recurrent GBM or platinum-resistant ovarian cancer	NCT02895360 interim data review completed
Phase I dose-escalation (daily oral) in patients with recurrent glioblastoma	NCT02490800
Phase I study (daily oral) in combination with radiotherapy in patients with newly diagnosed glioblastoma	NCT03250299, collaboration with Adult Brain Tumor Consortium (ABTC), which is funded by the US National Cancer Institute (NCI) Expected to complete patient recruitment mid-2020

Source: Edison Investment research

Following confirmed efficacy signals from the Phase I and Phase IIa expansion study in GBM patients (NCT02490800 and NCT02895360), Basilea is planning a Phase II biomarker-driven study. Full data from the Phase I dose-escalation study (oral dose) in recurrent GBM patients is expected in H120. The Phase I study initiated by the Adult Brain Tumor Consortium (ABTC) is also being conducted in the US, investigating BAL101553 in combination with radiotherapy in patients with newly diagnosed GBM, who have a reduced sensitivity to the standard-of-care chemotherapy drug temozolomide (Temodal).

BAL3833: Alternative formulation work ongoing

In late 2018, BAL3833 completed a Phase I dose-escalation study in patients with advanced solid tumours. A maximum tolerated dose (MTD) could not be determined with the current formulation, and as such a recommended Phase II dose (RP2D) could not be established. With BAL3833 now requiring reformulation work and moving back to the preclinical stage of development, we will not ascribe any value to this asset until there is a clearer timeline for its development. BAL3833 is an oral small-molecule, panRAF/SRC kinase inhibitor that inhibits both BRAF, CRAF and SRC kinases, which are involved in cell growth. BRAF mutations are found in certain cancers, most notably melanoma. BAL3833 was in-licensed, along with a family of other compounds, by Basilea in April 2015 under an agreement with the Institute of Cancer Research (ICR), Cancer Research UK (CRUK), the Wellcome Trust and the University of Manchester.

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, progress 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

We have updated our valuation of Basilea to CHF1.18bn or CHF109/share (vs CHF1.08bn or CHF100/share previously). We have increased derazantinib peak sales in iCCA and include the UC indication for the first time. Additionally, we roll forward our DCF, update for spot FX rates and reflect a net debt position CHF19.5m at 30 June 2019. Our valuation is based on an NPV analysis, which includes the main portfolio of products and net debt. Cresemba, based on $0.788bn peak

sales, is worth CHF910.5m. We also include Zevtera in Europe, in addition to risk-adjusted contributions for the US opportunity and the earlier-stage pipeline.

For derazantinib, we have revised our assumptions in iCCA and now include the expanded patient cohort in FIDES-01 (FGFR2 amplification and mutation), while our previous numbers reflected iCCA patients with FGFR2 fusion. We now forecast that $147.0m peak sales across the US and Europe (2028) could be achieved in this indication alone (previously $59m) based on 75% penetration in this highly unmet indication. We have also included derazantinib in UC with activating molecular FGFR aberrations (fusion, amplification and mutation). We forecast peak sales of $481.8m in the UC indication alone (US pricing $18,400 per month, six months duration with 10% peak penetration; EU pricing is 75% of US prices assumption).

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 UC 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.

We include an indicative valuation for BAL101553, and for simplicity assume that this asset will be partnered after completion of the Phase II trials, in exchange for a royalty on sales (starting at 15%, given we have assumed partnering once proof-of-concept data become available). The breakdown of our valuation is shown in Exhibit 9.

Exhibit 9: Basilea rNPV valuation

Product	Indication	Launch	Peak sales (US$m)	NPV (CHFm)	Probability	rNPV (CHFm)	NPV/share (CHF/share)
Cresemba (isavuconazole)	Severe mould infections	2015 (US); 2016 (EU); 2018 (RoW); 2022 Japan	788	910.5	75–100%*	859.8	79.6
Zevtera/Mabelio (ceftobiprole)	Severe bacterial infections	2015 (EU); 2018 (RoW); 2023 (US); 2023 (China)	550	278.2	75–100%**	231.2	21.4
BAL101553	Tumour resistance	2023	500	181.0	20%	28.8	2.7
Derazantinib	iCCA and UC	2023	629	194.8	40%	77.9	7.2
Net debt at 30 June 2019				(19.5)	100%	(19.5)	(1.8)
Valuation				**1,545.0**		**1,178.2**	**109.1**

Source: Edison Investment Research. Note: *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: Break-even in 2021

Basilea reported growth of 5.5% in total revenues to CHF63.2m in H119 (H118: CHF59.9m), driven largely by the strong sales performance of antifungal drug Cresemba. Total revenues include CHF52.9m (+91%) contributions from Cresemba and Zevtera, which represent a mix of royalties on sales, product sales, contract revenues and milestones. Given that Zevtera still accounts for a minority of these combined revenues (we assume ≤9%), the performance reflects stronger than anticipated Cresemba revenues (≥91%). Other revenue of CHF10.0m (H118: CHF13.3m) comprises mainly BARDA reimbursements related to the Phase III ceftobiprole trials required for a US registration.

Basilea FY19 total revenue guidance is CHF128–133m, with contributions from Cresemba and Zevtera updated to CHF105–110m. Estimated FY19 operating loss is CHF22–27m, which is commensurate with the lower BARDA revenue expectations related to lower US ceftobiprole Phase III TARGET clinical trial expenses. We forecast total revenues of CHF132.9m and CHF134.2m in FY19 and FY20 respectively, and a slight increase in total revenues, as the reduction in our

forecast deferred revenues recognised offsets Cresemba revenue growth. We forecast a stable operating cost base in 2019 and 2020, and expect that break-even is achievable in 2021 and sustainable profitability (at the operating profit level) from 2022 – the major swing factors to this being timing (and amount) of milestones received, actual R&D expenses for the year and any potential in-licensing deals. We forecast operating losses of CHF22.5m and CHF18.6m in 2019 and 2020, respectively, and operating profit of CHF0.8m in 2021.

Basilea reported gross cash (including financial investments) of CHF178m at 30 June 2019. The company has a convertible bond in issue, which is not due for conversion until 2022. We calculate net debt at end 2019 of CHF42.3m based on CHF154.7m in cash and CHF197.0m of unsecured convertible bonds. Our financial model suggests that current cash and financial instruments will be sufficient to fund operations beyond 2020, even in the absence of any milestone payments.

Exhibit 10: Financial summary

CHF'000s	2017	2018	2019e	2020e	2021e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	101,521	132,555	132,860	134,231	151,447
Cost of Sales	(9,025)	(20,299)	(20,669)	(15,489)	(16,499)
Gross Profit	92,496	112,256	112,191	118,742	134,947
Research and development (gross)	(55,055)	(104,942)	(103,000)	(105,000)	(101,000)
SG&A	(54,491)	(31,409)	(31,679)	(32,390)	(33,123)
EBITDA	(15,150)	(22,272)	(19,912)	(15,863)	3,832
Operating Profit (before amort. and except.)	(16,950)	(23,972)	(22,260)	(18,411)	1,070
Intangible Amortisation	(100)	(123)	(228)	(237)	(245)
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(17,050)	(24,095)	(22,488)	(18,648)	825
Net Interest	(1,976)	(7,065)	(5,420)	(5,417)	(5,417)
Profit Before Tax (norm)	(18,926)	(31,037)	(27,680)	(23,828)	(4,347)
Profit Before Tax (reported)	(19,026)	(31,160)	(27,908)	(24,065)	(4,592)
Tax	(334)	(192)	(26)	(26)	(26)
Profit After Tax (norm)	(19,260)	(31,229)	(27,706)	(23,855)	(4,373)
Profit After Tax (reported)	(19,360)	(31,352)	(27,934)	(24,091)	(4,619)
Average Number of Shares Outstanding (m)	10.8	10.8	10.8	10.8	10.8
EPS - normalised (CHFc)	(178.36)	(289.19)	(256.57)	(220.90)	(40.50)
EPS - (reported) (CHFc)	(179.28)	(290.33)	(258.68)	(223.09)	(42.77)
Dividend per share (CHFc)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	91.1	84.7	84.4	88.5	89.1
EBITDA Margin (%)	N/A	N/A	N/A	N/A	2.5
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	0.7
BALANCE SHEET					
Fixed Assets	58,189	7,013	8,623	10,066	11,802
Intangible Assets	326	372	572	772	972
Tangible Assets	7,768	6,424	7,834	9,077	10,613
Investments	50,095	217	217	217	217
Current Assets	292,976	274,738	210,510	167,037	135,210
Stocks	15,320	14,411	17,000	10,609	8,363
Debtors	4,955	3,757	6,188	6,252	7,054
Cash	260,724	223,908	154,660	117,515	87,131
Other	11,977	32,662	32,662	32,662	32,662
Current Liabilities	(79,491)	(66,684)	(64,754)	(52,564)	(235,246)
Creditors	(79,491)	(66,684)	(64,754)	(52,564)	(39,780)
Short term borrowings	0	0	0	0	(195,466)
Long-Term Liabilities	(313,114)	(281,754)	(242,749)	(230,749)	(16,343)
Long-term borrowings	(196,224)	(196,982)	(196,982)	(196,982)	(1,516)
Other long-term liabilities	(116,890)	(84,772)	(45,767)	(33,767)	(14,827)
Net Assets	(41,440)	(66,687)	(88,370)	(106,210)	(104,578)
CASH FLOW					
Operating Cash Flow	19,014	(79,210)	(59,616)	(27,475)	(20,197)
Net Interest	0	0	(5,420)	(5,417)	(5,417)
Tax	0	0	(26)	(26)	(26)
Capex	(711)	(419)	(3,986)	(4,027)	(4,543)
Acquisitions/disposals	0	0	0	0	0
Financing	0	0	0	0	0
Other	3,391	42,813	(200)	(200)	(200)
Dividends	0	0	0	0	0
Net Cash Flow	21,694	(36,816)	(69,248)	(37,145)	(30,384)
Opening net debt/(cash)	(43,564)	(64,500)	(26,926)	42,322	79,467
HP finance leases initiated	0	0	0	0	0
Other	(758)	(758)	0	(0)	0
Closing net debt/(cash)	(64,500)	(26,926)	42,322	79,467	109,851

Source: Company accounts, Edison Investment Research

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Management team

CEO: Mr David Veitch	CFO: Mr Adesh Kaul
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.	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	

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