EDISON

Basilea Pharmaceutica

Interim results

Data-driven catalysts ahead

Pharma & biotech

Basilea has reported good momentum in 2019, with positive clinical data from key studies on Zevtera/Mabelio and derazantinib. Cresemba sales have continued to grow, benefiting from international launches by partners in new markets and growth in existing markets. Despite significant R&D investment, operating losses have narrowed to CHF13.2m (H118: CHF20.4m). Basilea is well funded, with gross cash and investments of CHF177.9m sufficient to fund operations beyond 2020 to multiple R&D inflection points. Pivotal data in 2020/21 could lead to filings for derazantinib (oncology) and Zevtera (US NDA for the treatment of resistant bacterial infections). We value Basilea at CHF1,077m.

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	143.2	(13.8)	(1.28)	0.0	N/A	N/A

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

Global sales of Cresemba exceed $170m

Total in-market Cresemba (isavuconazole) sales reported by partners exceeded $170m (12 months to 31 March 2019). Basilea received a $5m milestone payment in January from partner Pfizer based on strong Cresemba EU sales (cumulative basis). Cresemba is available in 33 countries, including the US and Europe through multiple partners, and by year-end Basilea expects Cresemba to be available in 40 countries. Zevtera/Mabelio (ceftobiprole) sales remain lacklustre and the US remains the significant value driver for the product (potential launch in 2022/23).

Multiple positive clinical data to date

Basilea recently announced positive top-line data on ceftobiprole from the Phase III TARGET trial for treatment of ABSSSI. TARGET is one of two cross-supportive Phase III trials required for the US filing. The other, ERADICATE, is expected to report in H221. Derazantinib posted positive interim results in the FIDES-01 registrational phase II study in iCCA and FIDES-02 Phase I/II has been initiated in combination with immunotherapy for urothelial cancer. Preclinical work in multiple other tumours types expressing FGFR genetic aberrations is ongoing.

Financials: Profitability from 2021

Revised guidance for FY19 operating loss is CHF22–27m from CHF20–30m, due to the lower BARDA revenue expectations from the reduction in ceftobiprole Phase III expenses. Cresemba and Zevtera sales contributions guidance has narrowed to CHF105–110m (from CHF100–110m). We believe the growing revenue contribution from Cresemba translates into profitability from 2021.

Valuation: CHF1,077m or CHF100 per share

Our revised valuation of CHF1,077m vs CHF1,082m previously reflects a slight adjustment of our 2019 revenue and operating loss expectations. We update FX, roll forward our DCF and revise for net debt of CHF19.5m at 30 June.

22 August 2019

Price	**CHF44.84**
Market cap	**CHF533m**
	$1.02/CHF, €0.92/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	23.1	6.5	(23.5)
Rel (local)	24.2	4.0	(29.5)
52-week high/low	CHF62.0		CHF34.1

Business description

Basilea Pharmaceutica is focused on anti-infectives and oncology. 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 BAL101553 and derazantinib.

Next events

BAL101553 Phase IIa data (glioblastoma & ovarian cancer, IV dose)	H219
Derazantinib top-line results Phase II registrational studies in iCCA (FGFR2 fusion cohort)	H220
Ceftobiprole Phase III ERADICATE data for SAB	H221

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Edison profile page

2019 off to a good start

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 revenue performance reflects stronger than anticipated Cresemba revenues (≥91%). The commercialisation of Cresemba and Zevtera (ex US) is largely in the hands of multiple licensing and/or distribution partners. Revenues as reported can be split into product revenues, contract revenues, R&D services and other revenues (which mainly comprises the BARDA reimbursements). Exhibit 1 provides details of the H119 revenue breakdown. Basilea has multiple licensing deals in place for its commercially available anti-infective products, Cresemba and Zevtera. More than 100 countries are covered by strong regional and global partnerships. So far Basilea has received $245m 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. Other revenue of CHF10.0m (H118: CHF13.3m), comprises mainly BARDA reimbursements related to the Phase III ceftobiprole trials required for a US registration.

Exhibit 1: Basilea H119 total revenue breakdown

Revenues (CHFm)	H119	H118	Notes
Total revenues	**63.2**	**59.9**	**83% attributable to Cresemba**
From Cresemba and Zevtera	*52.9*	*27.7*	**91% attributable to Cresemba**
Product revenues	25.4	6.5	Cresemba upfront payment and sales to Pfizer of CHF21.5m (H118: CHF4.9m) Other product revenue from Zevtera/Cresemba distribution agreements of CHF3.9m (H118: CHF1.6m) **85% attributable to Cresemba**
Contract revenues	27.7	40.1	
Royalties on sales	*15.7*	*10.2*	Cresemba sales royalties from Astellas CHF11.7m (H118: CHF8.5m) Cresemba sales royalties from Pfizer CHF4.0m (H118: CHF1.7m) **100% attributable to Cresemba**
Milestone payments	*5.0*	*0.0*	Cresemba sales milestone from Pfizer CHF5.0m **100% attributable to Cresemba**
Other Cresemba and Zevtera contract revenues	*7.0*	*11.0*	Deferred revenue recognition from Astellas for Cresemba of CHF5.4m (H118: CHF5.4m) Deferred revenue recognition from Asahi for Cresemba of CHF0.7m (H118: CHF0.7m) Deferred revenue recognition from Gosun for Zevtera of CHF0.3m (H118: CHF0.3m) Deferred revenue recognition from Zevtera/Cresemba distribution agreements of CHF0.6m (H118: CHF2.6m) **87% attributable to Cresemba**
Other contract revenue	*0.0*	*18.9*	Deferred revenue recognition from Stiefel of CHF0.0m (H118: CHF18.8m)
R&D services revenue	0.1	0.0	
Other revenues	10.0	13.3	CHF9.9m BARDA reimbursements related to expenses for the US Phase III ceftobiprole trials (H119: CHF13.2m)

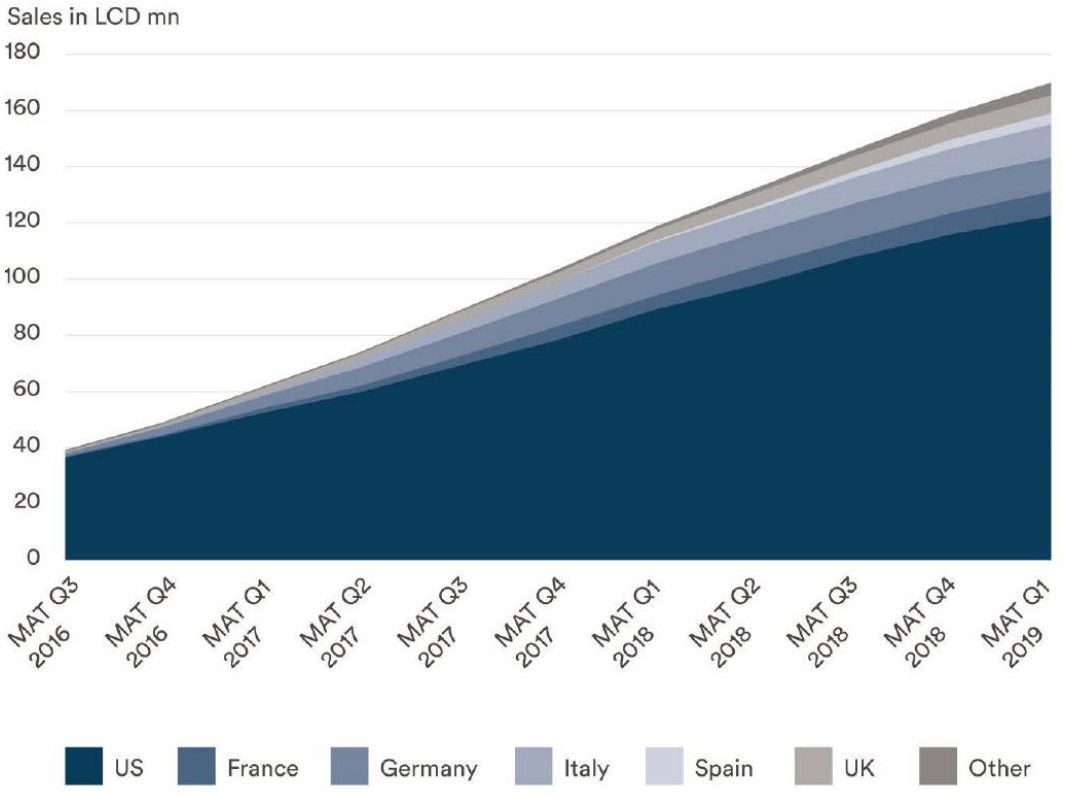
Source: Edison Investment Research, Basilea reports and presentations

Basilea has updated its FY19 total revenue and operating loss guidance. It now guides to total revenues of CHF128–133m, with contributions from Cresemba and Zevtera updated to CHF105-110m from CHF100–110m previously. Estimated FY19 operating loss is CHF22–27m from CHF20–30m, which is commensurate with the lower BARDA revenue expectations related to lower US ceftobiprole Phase III TARGET clinical trial expenses. BARDA is partially funding (c 70%) the US registrational trials, which will end with the completion of the ERADICATE trial in H221. Basilea reported operating loss of CHF13.2m in H119 (H118: CHF20.4m) with costs benefiting from a reduction in R&D expenses. We have increased our R&D expense forecast for 2020 to CHF105m from CHF90m reflecting the ramp up in preclinical and clinical studies we anticipate across the pipeline. This translates into a forecasted operating loss of CHF8.6m in 2020. In H119, net cash used for operating activities decreased to CHF45.4m (H118: CHF60.4m reflected one-time effects in the period – $10m upfront payment to ArQule plus cost of in-licensing some preclinical assets).

Cresemba continues 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 $170m in the 12 months ending 31 March 2019 (+42% vs comparable period; we note in-market sales at 31 March 2018 were just over $120m). 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 60 countries by end 2021. Further launches will aid growth in 2021 and beyond. We note that prior to loss of exclusivity, global sales of best-in-class antifungals are split c 25% US and c 75% RoW, highlighting the opportunity ex-US for Cresemba.

Exhibit 2: Cresemba sales growth in key launched markets



Source: Basilea presentations. Note: In-market sales for 12 months to 31 March 2019 c $170m; LCD = US$ corrected for currency fluctuations; MAT = moving annual total.

Zevtera hits its TARGET

Zevtera/Mabelio (ceftobiprole) is a broad-spectrum antibiotic for the treatment of Gram-positive infections, including methicillin-resistant *Staphylococcus aureus* (MRSA), which are resistant to a number of existing antibiotics, 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. Further roll-outs are expected (ex-US) in 2019 and 2020. However, the major commercial opportunity for Zevtera resides in the US market. The US filing is contingent on data from two cross-supportive studies: TARGET in acute bacterial skin and skin structure infections (ABSSSI) and ERADICATE in Staphylococcus aureus bacteraemia (SAB) bloodstream infections. Data from ERADICATE are expected in H221 and a US launch date of 2022/23 is feasible, with an initial focus on SAB and ABSSSI.

In August 2019, Basilea reported that ceftobiprole met primary and secondary efficacy endpoints in the TARGET study, demonstrating non-inferiority to standard-of-care vancomycin plus aztreonam in the intent-to-treat population. In the difficult US intravenous IV market, Basilea believes Zevtera's profile can be differentiated in the key SAB indication by its breadth of activity against methicillin-resistant/sensitive *Staphylococcus aureus* (MRSA and MSSA), both Gram-negative and Gram-positive pathogens, and effectiveness in the pulmonary setting vs existing products vancomycin and daptomycin respectively. With such strong data from the TARGET study, it could be used to support label extensions outside the US. However, this will be done on a country-by-country basis and will be dependent on the partner and the potential economic gain of label expansion into ABSSSI.

Derazantinib: Urothelial carcinoma studies broaden its scope

Basilea's approach to the development and commercialisation of its oncology portfolio will depend on the clinical profile of its assets and whether data are supportive of use in a wider range of cancer indications. Phase II asset, derazantinib, a pan-FGFR (fibroblast growth factor receptor) inhibitor could be the first oncology asset to market, which we forecast in 2023 on the basis of an additional Phase III registration trial in iCCA. The Phase II study (FIDES-01) for derazantinib in intrahepatic cholangiocarcinoma (iCCA) reported promising interim data in January 2019; full data are expected in mid-2020. We note that if these data are overwhelmingly positive, they could form the basis of an accelerated approval in iCCA. In the near term, Basilea will look to add maximum value to derazantinib through broadening its utility beyond iCCA, and a Phase Ib/II trial (FIDES-02) in urothelial carcinoma (UC) patients has now been initiated. Across four sub studies in FIDES-02, derazantinib will be investigated as a 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. With annual mortality from bladder cancers across North America and Europe estimated at c 85,000, the opportunity is significant (source: GloboCan). We currently only value the opportunity for derazantinib in iCCA, but highlight that it has the potential to present upside to our base case assumptions. 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 competitive. In April 2019, Janssen's FGFR inhibitor, Balversa (erdafitinib), was the first-in-class drug approved by the US FDA for the treatment of UC (second line and above; FGFR2/3 +ve). Consensus currently forecasts that Balversa sales could reach $1.2bn by 2024 (source: EvaluatePharma).

Beyond its ability to inhibit FGFRs, derazantinib's ability to inhibit colony stimulating factor 1 receptor (CSF1R) could provide additional synergies in combination with a PD-(L)1 antibody compared to other FGFR inhibitors in the clinic. CSF1R has emerged as an attractive target in immunoncology as it mediates the differentiation of macrophages into a tumour-promoting phenotype (M2) from a tumouricidal phenotype (M1). It is thought that inhibition of CSF1R could improve immune responses to tumours. However, tolerability is a 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.

BAL101553: Phase IIa data expected in H219

BAL101553 is an internally developed microtubule-targeting tumour checkpoint modulator that is currently in three clinical studies, with a primary focus on treating patients with glioblastoma multiforme (GBM). Top-line data are expected in H219 from a Phase IIa expansion study (48-hour IV dose) in patients with recurrent GBM and platinum-resistant ovarian cancer. Additionally, a Phase I dose-escalation study (oral dose) in recurrent GBM patients is expected to complete enrolment in H219, with full results available 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). 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.

Valuation: rNPV of CHF1,077m or CHF100 per share

Our updated Basilea valuation is CHF1,077m (from CHF1,082m) and reflects a slight adjustment of our 2019 revenue and operating loss expectations. Notably, we reduce BARDA-related revenues and R&D expense. We update FX, roll forward our DCF and revise for net debt of CHF19.5m at 30 June 2019. The breakdown of our valuation is shown in Exhibit 3.

Exhibit 3: Basilea rNPV valuation

Product	Indication	Launch	Peak sales ($m)	Value (CHFm)	Probability	rNPV (CHFm)	NPV/share* (CHF/share)
Cresemba (isavuconazole)	Severe fungal infections	2015 (US); 2016 (EU); 2018 (ROW); 2022 Japan	788	888.7	75-100%**	839.6	77.7
Zevtera/Mabelio (ceftobiprole)	Severe bacterial infections	2015 (EU); 2018 (RoW); 2023 (US); 2023 (China)	550	268.5	75-100%***	223.1	20.7
BAL101553	Tumour resistance	2023	500	174.0	20%	27.7	2.6
BAL3833	Tumour resistance	2024					
Derazantinib	iCCA	2023	59	19.0	30%	5.7	0.5
Net cash/(debt) at 30 June 2019				(19.5)	100%	(19.5)	(1.8)
Valuation				**1,330.7**		**1,076.7**	**99.7**

Source: Edison Investment Research. Note: *Per share calculation excludes one million treasury shares and is based on 10.8m shares outstanding. **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.

Exhibit 4: Financial summary

CHF'000s	2017	2018	2019e	2020e
December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	101,521	132,555	132,860	143,231
Cost of Sales	(9,025)	(20,299)	(20,669)	(15,489)
Gross Profit	92,496	112,256	112,191	127,742
Research and development (gross)	(55,055)	(104,942)	(103,000)	(105,000)
SG&A	(54,491)	(31,409)	(31,679)	(31,319)
EBITDA	(15,150)	(22,272)	(19,912)	(5,786)
Operating Profit (before amort. and except.)	(16,950)	(23,972)	(22,260)	(8,341)
Intangible Amortisation	(100)	(123)	(228)	(237)
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(17,050)	(24,095)	(22,488)	(8,577)
Net Interest	(1,976)	(7,065)	(5,417)	(5,417)
Profit Before Tax (norm)	(18,926)	(31,037)	(27,677)	(13,758)
Profit Before Tax (reported)	(19,026)	(31,160)	(27,905)	(13,994)
Tax	(334)	(192)	(26)	(26)
Profit After Tax (norm)	(19,260)	(31,229)	(27,703)	(13,784)
Profit After Tax (reported)	(19,360)	(31,352)	(27,931)	(14,021)
Average Number of Shares Outstanding (m)	10.8	10.8	10.8	10.8
EPS - normalised (CHFc)	(178.36)	(289.19)	(256.54)	(127.65)
EPS - (reported) (CHFc)	(179.28)	(290.33)	(258.65)	(129.84)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	91.1	84.7	84.4	89.2
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	58,189	7,013	8,623	10,329
Intangible Assets	326	372	572	772
Tangible Assets	7,768	6,424	7,834	9,340
Investments	50,095	217	217	217
Current Assets	292,976	274,738	210,513	170,847
Stocks	15,320	14,411	22,651	10,609
Debtors	4,955	3,757	6,188	6,671
Cash	260,724	223,908	149,012	120,906
Other	11,977	32,662	32,662	32,662
Current Liabilities	(79,491)	(66,684)	(70,754)	(54,564)
Creditors	(79,491)	(66,684)	(70,754)	(54,564)
Short term borrowings	0	0	0	0
Long Term Liabilities	(313,114)	(281,754)	(236,749)	(222,749)
Long term borrowings	(196,224)	(196,982)	(196,982)	(196,982)
Other long term liabilities	(116,890)	(84,772)	(39,767)	(25,767)
Net Assets	(41,440)	(66,687)	(88,367)	(96,137)
CASH FLOW				
Operating Cash Flow	19,014	(79,210)	(65,267)	(18,166)
Net Interest	0	0	(5,417)	(5,417)
Tax	0	0	(26)	(26)
Capex	(711)	(419)	(3,986)	(4,297)
Acquisitions/disposals	0	0	0	0
Financing	0	0	0	0
Other	3,391	42,813	(200)	(200)
Dividends	0	0	0	0
Net Cash Flow	21,694	(36,816)	(74,896)	(28,106)
Opening net debt/(cash)	(43,564)	(64,500)	(26,926)	47,970
HP finance leases initiated	0	0	0	0
Other	(758)	(758)	0	0
Closing net debt/(cash)	(64,500)	(26,926)	47,970	76,076

Source: Company accounts, Edison Investment Research

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