

Basilea Pharmaceutica

Interim results

Momentum continues

Basilea reported good momentum in H121 in all parts of the business. While total revenues declined to CHF54.2m (reflecting the phasing out of deferred revenues booked), actual in-market sales of Cresemba (severe mould infections) and Cresemba related income increased. Management has thus upgraded FY21 guidance for revenue to CHF134–144m (vs CHF128–138m) and operating loss to CHF7–17m (vs prior expected loss of CHF13–23m). We expect an event-driven 18 months ahead, with multiple R&D-related inflection points for its oncology assets derazantinib and lisavanbulin (glioblastoma). Basilea plans to progress a potential first-in-class kinase inhibitor into the clinic in early 2022, taking the oncology R&D pipeline tally to three assets. We value Basilea at CHF1.26bn.

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	141.4	(23.5)	(1.84)	0.0	N/A	N/A
12/22e	140.5	(18.4)	(1.43)	0.0	N/A	N/A

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

Cresemba sales growth momentum continues

In the near term, Cresemba (isavuconazole) is the major revenue driver. Global in-market sales exceeded \$266m in the 12 months to end March 2021, as the product benefits from multiple worldwide partnerships including Astellas in the United States and Pfizer in Europe. Zevtera's (ceftobiprole) fortunes rest on the outcome of the ongoing [Phase III ERADICATE](#) trial in bacteriemia. Top-line data due in H122 will inform the US NDA filing strategy and will be pivotal to partnering negotiations. We now forecast higher R&D costs in FY22, with potential for break-even in FY23, based on ongoing Cresemba sales growth and an out-licensing deal for derazantinib in 2022 with the assumption that a partner will fund registrational trials.

Oncology portfolio catalysts ahead

Basilea is focusing on longer-term value creation, which is dependent on crystallising value from its mid-stage oncology pipeline consisting of in-licensed asset derazantinib (multiple solid tumour indications) and in-house developed product lisavanbulin (glioblastoma). The latter received FDA Orphan Drug Designation for the treatment of malignant glioma in July. While we forecast derazantinib's first route to market is in iCCA in 2023, multiple data readouts expected in 2021/22 from FIDES-02 (UC) and FIDES-03 (GC) will determine combination strategies and its potential differentiation from the competition.

Valuation: rNPV of CHF1.26bn or CHF106 per share

Our revised valuation is CHF1.26bn or CHF106/share, versus CHF1.17bn or CHF99/share previously. For Cresemba we increase our near-term revenues reflecting higher than anticipated milestones from partners, and our peak sales forecasts remain unchanged for all assets. Our valuation is based on an NPV analysis for marketed products and a risk-adjusted NPV for the pipeline. We have rolled forward our model and reflect net debt of CHF65.0m at 30 June 2021.

Pharma & biotech

29 September 2021

Price CHF44.1
Market cap CHF570m

	\$1.12/CHF
Net debt (CHFm) at 30 June 2021	65.0
Shares in issue	12.9m
Free float	90%
Code	BSLN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(7.0)	(4.9)	(9.0)
Rel (local)	0.7	(0.6)	(18.3)
52-week high/low	CHF61.0	CHF42.8	

Business description

Basilea Pharmaceutica is focused on oncology and infectious diseases. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). Its oncology R&D pipeline includes two clinical-stage assets, derazantinib and lisavanbulin.

Next events

Derazantinib monotherapy & combination FIDES-02 interim data in urothelial cancer	H221
Ceftobiprole Phase III ERADICATE top-line data for bacteraemia (SAB)	H122
Derazantinib monotherapy FIDES-03 interim data in gastric cancer	H122

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2021 momentum to continue across the business

The first half of 2021 has been marked by progress across all business areas; this includes the commercial progress of lead asset Cresemba (isavuconazole), broadening of the early-stage oncology pipeline and the strategic divestment of the China R&D subsidiary. In terms of financial highlights, the phasing out of deferred revenues booked (related to upfront and development/regulatory milestones on out-licenced assets from prior periods) means the top line now mainly reflects current period revenues (royalties on sales, milestones and product sales to partners).

The next 12–18 months will continue to be dominated by evolving Cresemba sales and importantly a slew of datapoints that are expected across the oncology portfolio and for Zevtera (ceftobiprole) in bacterial infections. Exhibit 1 highlights the key catalysts ahead in 2021 and 2022. We note that Zevtera's fortunes rest on the outcome of the ongoing US [Phase III ERADICATE trial](#) and, on the basis of positive results (expected in H122), its potential approval in the United States given this is the critical market for the asset. A potential US launch date of 2023 is feasible, with an initial focus on *Staphylococcus aureus bacteraemia* (SAB) and acute bacterial skin and skin structure infections (ABSSSI). We forecast \$550m in peak sales, comprising US peak sales of \$317m in 2027, predicated on securing a US commercialisation partner. A partnering deal in the United States is now likely in 2022 (vs 2021) as data from ERADICATE will be pivotal to negotiations.

Exhibit 1: Key catalysts in 2021/22

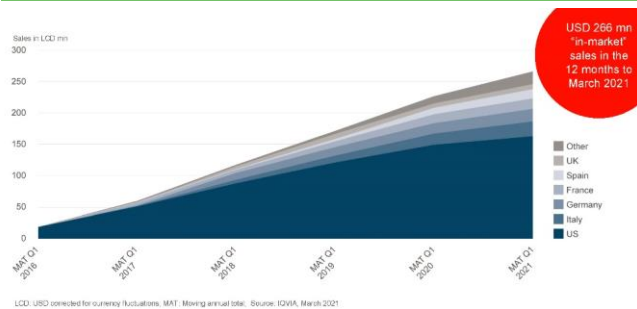
		H1 2021	H2 2021	H1 2022	H2 2022
Isavuconazole		✓ Complete patient enrolment in phase 3 study in Japan	File NDA in Japan		
Ceftobiprole			Complete patient enrolment in SAB phase 3 study	Topline results from SAB phase 3 study	
Derazantinib	FIDES-01 (iCCA)	✓ Topline results (FGFR2 gene fusions)		Topline results (other FGFR2 genetic aberrations)	
	FIDES-02 (urothelial cancer)	✓ Interim results (other FGFR2 genetic aberrations)	Interim results in monotherapy and combination therapy with alectuzumab in patients refractory to prior FGFR inhibitors	Interim results in monotherapy (400 mg/day) in 2nd-line FGFR inhibitor naive patients and alectuzumab combination in 1st-line cisplatin-ineligible patients	
	FIDES-03 (gastric cancer)			Interim results in monotherapy (400 mg/day) and recommended phase 2 dose with ramucirumab/paclitaxel	Interim efficacy 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	
Novel kinase inhibitor (for cancer therapy)			Recommended phase 2 dose in phase 1 study in newly-diagnosed glioblastoma in combination with radiotherapy	File IND application	Initiate phase 1 study

Source: Basilea corporate presentation

Cresemba ex-US is making an increasing contribution to growth

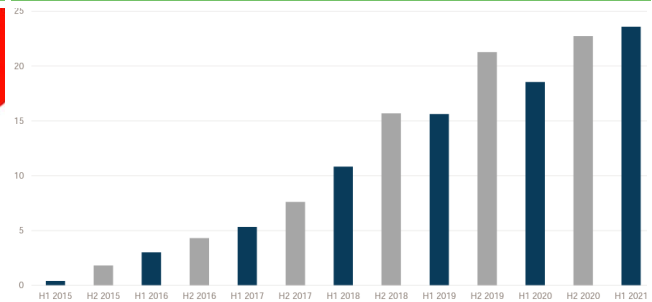
Cresemba sales have continued to grow, benefiting from international launches by partners in new markets and growth in existing markets. Cresemba is a broad-spectrum antifungal for the treatment of severe, life-threatening fungal infections. It is available in the United States and major European countries through regional partners including Astellas in the United States and Pfizer in most of Europe. In-market sales of Cresemba increased to \$266m in the 12 months ending 31 March 2021 (+18% y-o-y vs the prior comparable period) and Basilea reported Cresemba royalty income of CHF23.6m in H121 (+27% y-o-y). Cresemba is currently available in 54 countries, with the aim of increasing to 60 by end 2021 and 70 by end 2022. Exhibit 2 highlights the increasing contribution from the key EU5/other markets. Further launches will aid growth in 2021 and beyond. Partner Asahi Kasei Pharma recently reported positive results from a [Phase III clinical trial](#) in deep-seated mycoses in Japanese patients. Asahi plans to file the NDA in Japan shortly for the treatment of deep-seated mycoses, including invasive aspergillosis, chronic pulmonary aspergillosis, mucormycosis and cryptococcosis. We note that global sales of many best-in-class antifungals are split c 25% US and c 75% rest of world (RoW), highlighting the importance of the opportunity outside the US for Cresemba.

Exhibit 2: Cresemba in-market sales



Source: Basilea corporate presentation

Exhibit 3: Cresemba royalty revenue growth (CHFm)



Source: Basilea corporate presentation

Derazantinib data key to establishing differentiation

Multiple catalysts (Exhibit 1) including interim and top-line results from the entire FIDES clinical programme in intrahepatic cholangiocarcinoma (iCCA; bile duct cancer), urothelial cancer (UC) and gastric cancer (GC) are expected throughout 2021 and 2022. 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, given the constantly evolving and increasingly competitive landscape, Basilea may elect to build up a considerable data package ensuring derazantinib is truly differentiated to enable it to potentially take a larger market share. This could delay filing by one to two years but could ensure value optimisation from this unique fibroblast growth factor receptor (FGFR) inhibitor.

Derazantinib is an oral kinase inhibitor that targets FGFR1/2/3, VEGFR2 and CSF1R kinases. 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. Among FGFR inhibitors, derazantinib's profile is unique as in addition to its ability to inhibit FGFR receptor tyrosine kinase, it has activity against other receptor tyrosine kinases (it 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) and antiangiogenic agents is being examined; in combination with Roche's Tecentriq (atezolizumab) in UC and GC, and in combination with Eli Lilly's VEGFR antibody Cymraza (ramucirumab) and paclitaxel (chemotherapy) in GC.

iCCA provides competitive clinical proof-of-concept

In September, Basilea presented updated data (early August cut-off) from the open-label [Phase II FIDES-01 study](#) highlighting further improvements in efficacy in iCCA patients with FGFR2 gene fusions (n=103, cohort 1) at ESMO 2021. The median progression-free survival (mPFS) of 8.0 months (vs 7.8 months previously) is in the upper range of peers in the FGFR inhibitor class and other efficacy outcomes are also encouraging (21.4% objective response rate, ORR, 75.7% disease control rate). Importantly, 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). These data establish a competitive clinical proof-of-concept as monotherapy with potential read across to other cancers where FGFR2 aberrations are implicated. Enrolment into cohort 2 (FGFR2 gene mutations or amplifications) is ongoing (top-line results expected in H122). This cohort remains important as it could provide differentiating data versus competitors.

Combinations key to larger opportunities in urothelial and gastric cancer

With the competitive landscape evolving in UC and GC, Basilea is strategically exploring a [higher dose of derazantinib \(400mg per day\)](#) to maximise efficacy and differentiate it from existing

therapies. Derazantinib's favourable safety profile and good tolerability provide an improved value proposition versus competitors and could prove advantageous for use in rational combinations with other therapies. Interim results from FIDES-02 (UC) for the higher-dose monotherapy and combination with Tecentriq are expected in H122, while interim results from FIDES-03 (GC) for the higher-dose monotherapy and recommended Phase II dose of the combination with Cyramza and paclitaxel are expected in H122.

Valuation

Our revised valuation is CHF1.26bn or CHF106/share, versus CHF1.17bn or CHF99/share previously. Our valuation is based on a net present value (NPV) analysis for marketed products and a risk-adjusted NPV for the pipeline. We have rolled forward our model and reflect net debt of CHF65.0m at 30 June 2021. The breakdown of our valuation is shown in Exhibit 4.

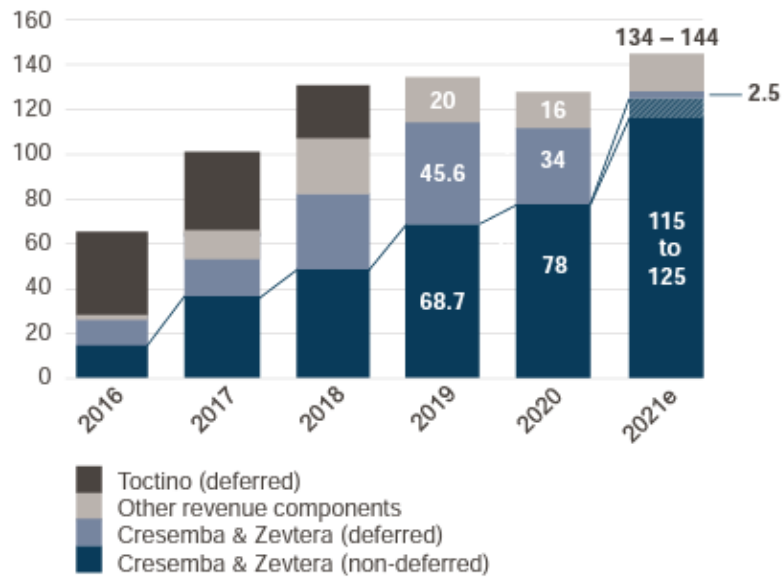
Exhibit 4: Basilea rNPV valuation							
Product	Indication	Launch	Peak sales (US\$m)	NPV (CHFm)	Probability of success	rNPV (CHFm)	NPV/share (CHF/share)
Cresemba (isavuconazole)	Severe mould infections	2015 (US); 2016 (EU); 2018 (RoW); 2022 Japan	818	875.5	75–100%*	829.2	69.8
Zevtera/Mabelio (ceftobiprole)	Severe bacterial infections	2015 (EU); 2018 (RoW); 2023 (US)	550	247.0	75–100%**	202.2	17.0
Lisavanbulin	Glioblastoma	2023	500	244.0	35%	82.3	6.9
Derazantinib	iCCA, urothelial cancer and gastric cancer	2023 (iCCA); 2024 (urothelial); 2025 (gastric)	934	415.3	50%	207.6	17.5
Net debt at 30 June 2021				(65.0)	100%	(65.0)	(5.5)
Valuation				1,716.7		1,256.3	105.8

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

H121 financial results

Basilea reported a decline of 22% in total revenues to CHF54.2m in H121 (H120: CHF69.3m), reflecting the phasing out of the deferred revenue component, which relates to prior upfront payments and milestones received across numerous assets. Importantly non-deferred revenues (which represent a mix of royalties on sales, product sales to partners and milestones mainly related to Cresemba) grew 26% to CHF46.1m (H120: CHF36.5m) reflecting a strong in-market sales performance. Exhibit 5 illustrates that management expects deferred revenues to be CHF2.5m in FY21 versus CHF33.8m in FY20. Management has upgraded its FY21 guidance for revenue to CHF134–144m (vs CHF128–138m) and an operating loss of CHF7–17m (vs the prior expected loss of CHF13–23m), mainly on the basis of increased confidence in Cresemba sales performance for the year.

Exhibit 5: Evolution of reported revenues



Source: Basilea corporate presentation

During FY21 Basilea will benefit from milestone payments from partners based on Cresemba sales, associated with meeting predetermined and undisclosed sales levels. Importantly the Cresemba and Zevtera non-deferred revenue lines include milestones as well as royalties on sales. Milestone payments are by nature volatile, and we expect lower milestones in FY22, but we expect an increase in royalties received on Cresemba sales. We also expect a decline in API sales to Pfizer, as it is expected to assume responsibility for API manufacturing in FY22. We forecast total revenues of CHF141.4m in FY21 and CHF140.5m in FY22. We expect R&D and SG&A expenses to remain relatively flat at CHF100.0m and CHF29.4m respectively, and forecast an operating loss of CHF15.3m in FY21. We now forecast a sustained operating loss of CHF11.1m in FY22 due to higher R&D expenses of CHF99.0m (vs CHF78.7m) to support the expanding clinical pipeline, with potential for break-even in 2023. In terms of when sustainable profitability (at operating profit level) can be achieved; the major swing factors to this are the timing (and amount) of milestones received, actual R&D expenses for the year and any potential in-licensing deals.

Basilea expects reported gross cash (including financial investments) of CHF165–170m at end 2021, slightly higher than prior guidance of CHF155–160m given at the FY20 results. This guidance excludes any potential impact from the repurchase of the outstanding convertible bond (maturity in 2022). We calculate net debt at 30 June 2021 of CHF65.0m based on CHF162.8m in cash and investments and CHF227.9m in unsecured convertible bonds.

Exhibit 6: 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	141,439	140,455
Product revenues (Cresemba and Zevtera)	105,900	114,461	112,032	126,091	134,142
Cost of sales	(20,299)	(18,868)	(24,054)	(27,319)	(22,696)
Gross profit	112,256	115,513	103,575	114,121	117,759
Research and development expenses (net)	(104,942)	(102,662)	(97,410)	(100,000)	(99,000)
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)	(13,819)	(9,447)
Reported operating income	(24,095)	(17,200)	(8,222)	(15,322)	(11,054)
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)	(23,628)	(18,551)
Profit before tax (normalised)	(31,060)	(22,282)	(29,602)	(23,510)	(18,429)
Income tax expense (includes exceptional items)	(192)	(40)	(55)	0	0
Net income (reported)	(31,352)	(22,422)	(14,722)	(23,628)	(18,551)
Net income (normalised)	(31,252)	(22,322)	(29,657)	(23,510)	(18,429)
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)	(185.0)	(143.5)
Adjusted EPS (CHF c)	(288.4)	(207.5)	(288.5)	(184.1)	(142.5)
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	56,092	43,400
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	11,625	11,544
Other current assets	33,536	31,025	31,854	31,854	31,854
Total current assets	274,738	184,860	223,528	232,778	214,559
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)	(78,687)	(93,713)
CASH FLOW STATEMENT					
Reported net income	(31,352)	(22,422)	(14,722)	(23,628)	(18,551)
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)	(28,675)	1,570
Cash from operations (CFO)	(79,210)	(63,836)	(54,134)	(45,919)	(10,492)
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	61,599
Increase/(decrease) in cash and equivalents	(25,805)	(62,931)	(44,030)	(4,657)	(12,692)
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	61,599	48,907
Net (debt)/cash	26,052	(68,716)	(77,896)	(83,909)	(97,957)

Source: company accounts, Edison Investment Research

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