EDISON

Basilea Pharmaceutica

Post interim results update

Moving on up

Pharma & biotech

Basilea has made a solid start to the first half of 2016, with anti-microbial agents Cresemba and Zevtera continuing their respective European roll-outs. Ongoing dialogue with the FDA on the SPA protocol for Zevtera's Phase III US clinical trial programme means US trials should initiate in H117. Together, these underpin the current valuation with upside potential from further partnering deals for Cresemba, Zevtera and the early-stage oncology pipeline, which in itself is making progress, albeit at an early stage. We value Basilea at CHF1,091m or CHF101/share.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHF)	DPS (CHF)	P/E (x)	Yield (%)
12/14	42.6	(41.2)	(4.14)	0.0	N/A	N/A
12/15	52.8	(61.3)	(6.07)	0.0	N/A	N/A
12/16e	61.2	(54.1)	(4.96)	0.0	N/A	N/A
12/17e	88.6	(35.6)	(3.20)	0.0	N/A	N/A

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

Cresemba and Zevtera underpin current share price

Basilea has confirmed its 2016 outlook following the interim results. We anticipate a CHF5m sales contribution for FY16 from Cresemba for mould infections and Zevtera for bacterial infections against a backdrop of an ongoing European roll-out for both. Basilea has a contract salesforce in place (via Quintiles) to commercialise these in the core European markets, with product overlap likely to drive future operational synergies. Partnering activities, particularly for Zevtera in the US, could provide upside.

Anticipate pipeline progress through 2016/17

Following the award of the BARDA contract (up to $100m) for the US development of Zevtera, we anticipate its US phase III clinical trials could start in H117. The company is in discussions with the FDA to finalise the Phase III study Special Protocol Assessments (SPAs). Oncology assets BAL101553 and BAL3833 are making progress in targeting drug resistant tumour types; there could be synergies between the anti-infectives and oncology pipelines as a large number of invasive fungal and bacterial infections develop in leukemia cancer patients that are immunocompromised owing to treatment with aggressive chemotherapies.

Valuation: rNPV of CHF1,091m or CHF101/share

Our updated Basilea valuation is CHF1,091m (from CHF1,114m) primarily reflecting a push back of the early stage pipeline by a year, lower R&D expenses (some due to phasing) and a lower net cash position at the interim results (CHF116m vs YE 15 CHF170m). Our valuation is based on an NPV analysis, which includes the main portfolio of products and net cash. Cresemba, based on $600m peak sales, is worth c 65% of our rNPV and underpins c 90% of the current market cap. We also include Zevtera in Europe, in addition to risk-adjusted contributions for the US opportunity and the earlier-stage pipeline.

30 August 2016

Price	**CHF68.2**
Market cap	**CHF805m**

Net cash (CHFm) at July 2015	115.8
Shares in issue* *Including 1m treasury shares	11.8m
Free float	90.4%
Code	BSLN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(3.5)	(13.1)	(31.8)
Rel (local)	(4.1)	(12.0)	(26.8)
52-week high/low	CHF108.8		CHF59.5

Business description

Basilea is a Swiss biopharmaceutical company focused on anti-infectives and oncology. Its lead products are Cresemba, an antifungal that is approved in the US and Europe, and Zevtera, an anti-MRSA broad-spectrum antibiotic, approved in Europe for pneumonia.

Next events

Zevtera initiate PIII US studies	H117
FY16 results	20 February 2017

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Cresemba and Zevtera sales contribution building

Basilea has provided full-year 2016 product revenue guidance of CHF5m, which represents sales booked on Cresemba and Zevtera in Europe. In H116, cumulative product sales were reported as CHF1.9m, reflecting the ongoing roll-out of both assets. As mentioned in prior reports, sales of antibacterial agents in particular take time to build post launch, given the requirement for regional reimbursement, plus they need to be added to individual hospital formularies.

Cresemba launches in Europe; US momentum building

Cresemba (isavuconazole a broad-spectrum antifungal drug) was approved in the US in March 2015 for treating both invasive aspergillosis and invasive mucormycosis and has been launched by US partner, Astellas. In Europe, formal European Medicines Agency (EMA) approval was granted in October 2015. Basilea is commercialising Cresemba alone in key European markets (including the UK, Germany, and Italy; launch in France anticipated for H216) through a fee-for-service contract salesforce via an agreement with Quintiles. This agreement provides dedicated sales representatives who are trained by Basilea, in addition to market access and administrative support. Basilea could potentially seek to bring the commercial infrastructure in-house in the future. Cresemba launched in the UK and Germany in Q116 and in Italy and Austria in Q216. We expect further European launches during 2016 (pricing and reimbursement need to be agreed in each country, which takes time). In the US, partner Astellas has reported sales of $19m in H116 and has guided $45m in sales for the financial year 1 April 2016 to 31 March 2017. Basilea is entitled to a tiered royalty on Cresemba sales starting in the mid-teens and ramping up to mid-20s with up to CHF290m of sales milestones. It recently announced an extension to its distribution agreement with Hikma to include Cresemba in addition to Zevtera for the MENA region. Basilea will seek further partners in other territories.

With broad-spectrum activity against fungal moulds in addition to safety and other benefits (including fewer drug interactions and once-daily dosing) over current standard treatments, we believe Cresemba could have a unique position in this growing market, even in the face of increasing genericisation. We forecast global peak sales potential of $600m, with Cresemba contributing c 65% to our valuation.

Zevtera: BARDA contract funds US development

In March 2016 the Biomedical Advanced Research and Development Authority (BARDA), a division of the US Department of Health & Human Services Office, entered into a contract with Basilea for the Phase III development of Zevtera for the US market. Under the terms of the contract, Basilea will receive up to $20m over the initial 18-month period, with up to an additional $80m potentially due contingent on exercisable options by BARDA over a 4.5-year period. The company is preparing Phase III study protocols seeking agreement on SPAs with the FDA. Importantly, the BARDA contract removes the timing uncertainty for the Phase III clinical trial programme that would support Zevtera's US regulatory filing and provides a path to create further value by enabling non-dilutive funding for the programme before seeking a commercialisation partner for the US market. Basilea anticipates the US Phase III programme could start in H117; (we expect 3 to 3.5 years duration), implying that a US 2021 launch date could be feasible with an initial focus of bacteraemia and acute bacterial skin and skin structure infections. Staphylococcus aureus bacteraemia (presence of bacteria in the blood) is an indication where few antibiotics are currently approved and which the FDA considers an area of unmet need. Thus, Basilea intends to conduct a bacteraemia study to further differentiate Zevtera from available cephalosporins.

Total Zevtera peak sales of $556m forecast

We continue to forecast $100m peak sales for Zevtera in Europe (for the currently approved indications) and $456m for RoW (including $317m for the US opportunity, which is risk adjusted). Phase III data from the US trials, if positive, could be used to expand Zevtera's EU/RoW label to include Staphylococcus aureus bacteraemia and acute skin and skin structure infections indications. Our current peak sales estimates for EU/RoW do not include these indications, hence this could provide upside to our financial forecasts.

For more detail on Cresemba and Zevtera see our note dated March 2016, Riding the crest of the antimicrobial wave.

Oncology: The second pillar slowly forging forward

To complement the primary focus on anti-infectives, Basilea also has an early-stage pipeline focused on oncology products that target resistance to current traditional chemotherapies. Basilea's oncology clinical pipeline contains BAL101553 and BAL3833 for drug-resistant cancers. There could be synergies between the anti-infectives and oncology pipelines as a large number of invasive fungal and bacterial infections develop in leukemia cancer patients that are immunocompromised owing to treatment with aggressive chemotherapies.

BAL101553 for drug-resistant tumours, including taxane resistance

BAL101553 is a highly soluble prodrug of BAL27862, which induces tumour cell death through activation of a checkpoint important for tumour cell division. BAL27872 targets microtubules with a binding site and mechanism of action distinct from that of currently approved microtubule-targeting agents (MTA; such as Taxol, Taxotere, Abraxane, Jevtana and the Vinca alkaloids).

BAL3833 for BRAF resistance and other refractory solid tumours

BAL3833 is a panRAF kinase inhibitor in Phase I development in advanced solid tumours. BAL3833 inhibits both BRAF and CRAF, part of the RAF family of kinases, and inhibits SRC, which are involved in cell growth. BRAF mutations are found in certain cancers most notably melanoma, with BRAF inhibitors such as Zelboraf approved to treat melanoma patients with a BRAF mutation. Preclinical data suggest that BAL3833 has activity in models resistant to current BRAF inhibitors.

Valuation: rNPV of CHF1,091m or CHF101/share

Our updated Basilea valuation is CHF1,091m (from CHF1,114m) primarily reflecting a push back of the early stage pipeline by a year, lower R&D expenses (some due to phasing) and a lower net cash position at the interim results (CHF116m at end June 2016 vs CHF170m) at end December 2015.Our valuation is based on an NPV analysis, which includes the main portfolio of products and net cash. Cresemba, based on $600m peak sales, is worth nearly 65% of our rNPV and underpins c 90% of the current market cap. We also include Zevtera in Europe, in addition to risk-adjusted contributions for the US opportunity and the earlier-stage pipeline.

We have made minor changes to our assumptions; this includes pushing out the potential launch dates of the early-stage pipeline by a year; we now expect BAL101553 to launch in 2022 (vs 2021) and BAL3833 in 2023 (vs 2022) and the associated phasing of R&D costs accordingly. The breakdown of our valuation is shown in Exhibit 1.

Exhibit 1: 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)	600	772.8	100%	772.8	71.6
Zeftera/Mabelio (ceftobiprole)	Severe bacterial infections	2015 (EU)	100	82.5	100%	82.5	7.6
		2018 (RoW); 2019 (US)	430	161.0	50%	85.3	7.9
	Chronic hand eczema	2018 (US)	45*	0.0	50%	0.0	0.0
BAL101553	Tumour resistance	2022	500	123.3	20%	30.9	2.9
BAL3833	Tumour resistance	2023	500	63.3	15%	3.3	0.3
Net cash end June 2016				115.8	100%	115.8	10.7
Valuation				**1,318.7**		**1,090.7**	**101.0**

Source: Edison Investment Research, Basilea Pharmaceutica

Financials: FY16 guidance confirmed

Management has confirmed the financial guidance for 2016 highlighted below in Exhibit 2, alongside our estimates for the year.

Exhibit 2: Our forecasts are in line with 2016 company guidance

	Outlook		Edison estimates
Operating expenses	CHF9-10m/month	CHF108-120m/year	CHF109.9m
Operating loss	CHF4-5m/month	CHF48-60m/year	CHF49.3m
Product sales	CHF5m/year		CHF4.6m

Source: Basilea, Edison Investment Research. Note: Basilea's guidance was last updated in August 2016.

Basilea reported H116 product sales of CHF1.9m on sales of anti-microbial agents Cresemba and Zevtera in Europe. Management has guided that the product sales contribution from these two compounds should be CHF5.0m for the year. Total revenues increased 19% in H116 (reported CHF29.7m) vs H115 (reported at CHF24.9m). Contract revenues increased 14% to CHF27.8m in H116, reflecting an increase in royalty income relating to Cresemba. We have increased our revenue assumptions for 2016 to CHF61.2m from CHF59.3m, reflecting an increase in our expected royalty on Cresemba US sales; Astellas reported $19m in H116 and is guiding $45m for financial year 1 April 2016 to 31 March 2017. We had forecast $32m in Cresemba US sales for FY16 and have revised this up to $42m. At this stage our peak sales forecast of $600m are unchanged but we will be closely monitoring Cresemba's sales evolution.

Costs and operating expenses were largely flat, at CHF54.6m (H116) vs CHF55.0m (H115), accounted for a reduction in R&D costs offsetting an increase in SG&A and the reporting of CHF3m in the COGS line. (We note that our cost of sales assumptions relates purely to cost of goods sold; this differs from Basilea's reported cost of sales, which includes manufacturing, capacity reservation, shipping and handling costs. Thus, during the launch period, cost of sales as reported by Basilea is higher than our forecast cost of sales. We now forecast 2016 R&D spend of CHF54.7m from CHF62m reflecting the overall reduction in R&D costs versus our original expectations. We expect this to increase; our forecasts assume that Basilea will contribute around 30% of the total $120-150m development costs for Zevtera's US Phase III development, with BARDA funding the rest. Future R&D spend will also depend on partnering activities for the earlier-stage assets, although we do not anticipate any deals for either BAL101553 or BAL3833 until Phase II proof-of-concept data become available.

SG&A in 2015 was CHF54.1m. Although Basilea does not explicitly split out spend on G&A and S&M, we believe underlying G&A costs are around CHF21m (evidenced by SG&A spend of CHF21.3m in 2013 when there were no S&M-related expenses). We forecast a marginal 1-2% increase in underlying G&A. We estimate that S&M spend in 2015 was around CHF33m for the ongoing build-out of a contract salesforce via Quintiles. We believe CHF32-35m of S&M spend

should support commercialisation of both Zevtera and Cresemba in the five major European markets, hence we do not expect any further significant upticks in the near term.

Overall, we now forecast total operating expenses of CHF109.9m from CHF117.3m in 2016 (-4% compared to 2015 owing to the slight decrease in R&D spend offset by continued growth in other operating expenses, albeit more modestly. We forecast operating loss of CHF49.3m for FY16, which is at the lower end of company guidance of CHF48-60m for the year.

Cash could be sufficient beyond profitability

Basilea reported cash and equivalents, including liquid assets, of CHF115.8m at end June 2016 compared to CHF170m at end December 2016. This includes the CHF200m convertible bond (which we record on the balance sheet as long-term debt). The convertible bond is due in 2022 and has a conversion price of CHF126 (based on a 30% premium to the volume weighted average share price on 9 December 2015, which was CHF97). The coupon is 2.75%, or CHF5.5m/year, which is paid semi-annually in arrears. Our financial model suggests current cash should be sufficient to fund operations beyond 2019 forecast profitability, even in the absence of any milestone payments.

Exhibit 3: Financial summary

CHF'000s	2014	2015	2016e	2017e	2018e
December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	42,634	52,825	61,208	88,605	105,084
Cost of Sales	0	0	(661)	(2,426)	(5,210)
Gross Profit	42,634	52,825	60,547	86,179	99,875
Research and development	(54,377)	(60,075)	(54,701)	(60,410)	(63,309)
EBITDA	(39,239)	(58,885)	(46,803)	(28,711)	(19,823)
Operating Profit (before amort. and except.)	(41,539)	(61,285)	(49,142)	(31,162)	(22,420)
Intangible Amortisation	(291)	(200)	(206)	(117)	0
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(41,830)	(61,485)	(49,348)	(31,279)	(22,420)
Net Interest	311	(35)	(4,948)	(4,425)	(4,108)
Profit Before Tax (norm)	(41,228)	(61,320)	(54,090)	(35,587)	(26,528)
Profit Before Tax (reported)	(41,519)	(61,520)	(54,296)	(35,704)	(26,528)
Tax	(26)	(83)	(26)	(26)	(26)
Profit After Tax (norm)	(41,255)	(61,403)	(54,116)	(35,613)	(26,554)
Profit After Tax (reported)	(41,546)	(61,603)	(54,323)	(35,730)	(26,554)
Average Number of Shares Outstanding (m)	10.0	10.1	10.9	11.1	11.4
EPS - normalised (c)	(414.46)	(607.22)	(496.01)	(319.87)	(233.81)
EPS - normalised fully diluted (c)	(414.46)	(607.22)	(496.01)	(319.87)	(233.81)
EPS - (reported) (CHF)	(4.17)	(6.09)	(4.98)	(3.21)	(2.34)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	98.9	97.3	95.0
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	12,807	13,870	13,072	13,162	13,718
Intangible Assets	224	346	117	0	0
Tangible Assets	12,157	10,724	10,155	10,362	10,918
Investments	426	2,800	2,800	2,800	2,800
Current Assets	244,571	384,865	288,045	212,221	170,531
Stocks	4,904	9,579	7,650	10,710	7,137
Debtors	1,171	1,545	1,677	2,428	2,879
Cash	226,125	364,688	269,935	190,300	151,732
Other	12,371	9,053	8,783	8,783	8,783
Current Liabilities	(61,690)	(68,836)	(70,638)	(53,345)	(33,276)
Creditors	(61,690)	(68,836)	(70,638)	(53,345)	(33,276)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(137,756)	(315,043)	(260,997)	(228,997)	(217,197)
Long term borrowings	0	(194,706)	(194,706)	(194,706)	(194,706)
Other long term liabilities	(137,756)	(120,337)	(66,291)	(34,291)	(22,491)
Net Assets	57,931	14,856	(30,518)	(56,959)	(66,224)
CASH FLOW					
Operating Cash Flow	(71,461)	(67,780)	(87,962)	(72,526)	(31,281)
Net Interest	0	0	(4,948)	(4,425)	(4,108)
Tax	0	0	(26)	(26)	(26)
Capex	(1,247)	(1,009)	(1,836)	(2,658)	(3,153)
Acquisitions/disposals	0	0	0	0	0
Financing	0	(0)	0	0	0
Other	24,937	12,645	20	0	0
Dividends	0	0	0	0	0
Net Cash Flow	(47,772)	(56,143)	(94,753)	(79,635)	(38,568)
Opening net debt/(cash)	(273,898)	(226,125)	(169,982)	(75,229)	4,406
HP finance leases initiated	0	0	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)	(226,125)	(169,982)	(75,229)	4,406	42,974

Source: Basilea accounts, Edison Investment Research. Note: During 2013 Basilea distributed CHF5.0/share, equivalent to CHF48m to shareholders, which we classify as a dividend. This followed a shareholder request (from HBM Healthcare Investments, which held 24.97%) that was approved at the 2013 AGM.

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