EDISON

Basilea Pharmaceutica

FY16 results update

Steady as she goes

Pharma & biotech

Basilea reported a solid set of 2016 numbers ahead of guidance, driven by higher than expected product sales in H216 combined with lower than expected operating costs. Cresemba (for invasive mould infections), in particular, continues to pick up momentum both in the EU and the US through US partner Astellas. Zevtera's US pivotal Phase III clinical trial programme for bacterial infections remains on track to initiate in mid-2017. Multiple distribution and commercialisation agreements signed in H216 should lead to international launches starting from 2018 for both products. We value Basilea at CHF1,048m or CHF97/share (excl. treasury shares).

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHF)	DPS (CHF)	P/E (CHF)	Yield (%)
12/15	52.8	(61.3)	(6.07)	0.0	N/A	N/A
12/16	66.0	(50.9)	(4.69)	0.0	N/A	N/A
12/17e	88.3	(37.5)	(3.37)	0.0	N/A	N/A
12/18e	95.1	(36.5)	(3.22)	0.0	N/A	N/A

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

FY16 results: Guidance beaten; still room to grow

Basilea reported total revenues of CHF66m in FY16 (+25%), including product sales of CHF7.1m (relating to the first full year in which both brands have been available in Europe), which beat guidance of CHF5m. This was due to Cresemba uptake in the EU, although Zevtera uptake remains lacklustre (we have lowered our peak sales expectations accordingly). Basilea reported CHF7.3m in royalties on $46m of US Cresemba sales reported by Astellas. 2017 guidance for product sales and royalties (on US sales) stands at CHF15m and CHF14m respectively. In 2018 both products should benefit from international launches following the slew of distribution deals in H216; we anticipate further deals in 2017.

Mid-2017 Zevtera US clinical programme to initiate

Following the announcement of the BARDA contract (up to $100m) to develop Zevtera for the US, Basilea has submitted the Phase III study Special Protocol Assessments (SPAs) with the FDA. Phase III trials in skin and bacteraemia (bloodstream) infections should start mid-year and a 2021 US launch date could be feasible. In terms of value, the US is the largest market for branded hospital antibiotics representing a major opportunity. We expect Basilea to look for a commercialisation partner in the US once the pivotal clinical development programme is underway.

Valuation: rNPV of CHF1,048m or CHF97/share

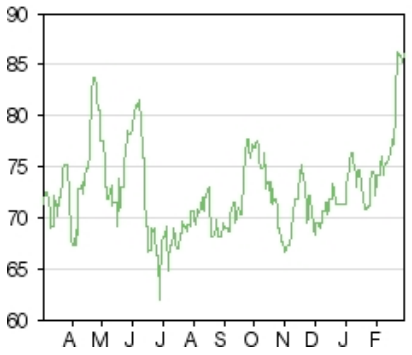
We have lowered our valuation to CHF1,048m (from CHF1,091m), mainly as a result of reducing our peak sales expectations for Zevtera non-US sales and rolling forward our DCF, offset by a lower net cash position. Our valuation is based on an NPV of the main portfolio of products and net cash. Cresemba, based on $600m peak sales globally, is worth c 72% of our rNPV and underpins c 88% of the current market cap. We include Zevtera in Europe/RoW (albeit with reduced expectations), in addition to risk-adjusted contributions for the US opportunity and the earlier-stage pipeline.

1 March 2017

Price	**CHF86.00**
Market cap	**CHF1016m**

Net cash (CHFm) at 31 December 2016	93.6
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	19.2	25.4	21.1
Rel (local)	15.7	15.5	11.2
52-week high/low	CHF86.2		CHF62.0

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	Mid-2017
2017 half year results	10 August 2017

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Edison profile page

Guidance beaten – driven by Cresemba

Basilea reported a solid set of 2016 numbers ahead of guidance, driven by higher than expected product sales (Cresemba for mould infections and Zevtera/Mabelio for bacterial infections). Total revenues were reported at CHF66m for FY16 (+25%), including product sales of CHF7.1m, which beat guidance of CHF5m. In H116, cumulative product sales were reported as CHF1.9m, indicating that sales in the second half amounted to CHF5.2m, which we believe reflects stronger than expected growth in Cresemba sales. Zevtera sales remain lacklustre; as mentioned in previous reports, sales of antibiotics such as Zevtera/Mabelio in particular take time to build post launch, given the requirement for regional reimbursement across Europe and the need to be added to individual hospital formularies. Basilea reported CHF7.3m in royalties on $46m of US Cresemba sales; Astellas has guided $56m in sales for the financial year 1 April 2016 to 31 March 2017. We note that guidance has increased from the $45m pegged at Basilea's interim results, which reflects favourably on Cresemba's US momentum to date in its second year on the market.

Basilea reported an operating loss of CHF43.9m in FY16, beating guidance (CHF48-60m). R&D expenses were lower than expected (as a result of a decrease in pre-launch costs booked in R&D in previous years). However, with the Zevtera PIII US programme poised to start and the ongoing oncology pipeline programmes, we expect R&D expenses to increase in 2017 to CHF54.7m from CHF48.4m in 2016. We therefore forecast an operating loss of CHF33.1m. Basilea reported cash and cash equivalents of CHF289m at year end December 2016. Our financial model suggests that current cash should be sufficient to fund operations beyond 2019, even in the absence of any milestone payments.

Basilea has provided financial guidance for FY17; total product sales are expected at CHF15m, royalties on US Cresemba sales at ~CHF14m and operating loss in the region of approximately CHF3m per month on average, indicating an operating loss of ~CHF36m for the year. We anticipate a doubling in product sales to CHF14m in 2017, driven mainly by Cresemba. We expect both products to benefit from international launches in 2018 following the slew of distribution deals in H216; we anticipate further deals in 2017. However, given the slower than expected uptake for Zevtera, we have revisited our global peak sales expectations (see below) and have revised our ex-US sales estimates downwards.

Significant progress in partnering deals in 2016

Basilea made significant progress in partnering deals in 2016. Basilea's existing partnerships now cover more than 40 countries internationally, as well as the countries that Basilea is directly commercialising. The agreement with Hikma has been extended in the MENA region to cover Cresemba, in addition to the original agreement on Zevtera. Other distribution agreements signed in the year include Grupo Biotoscana (GBT) for 19 counties in Latin America and Unimedic Pharma in the Nordics (Cresemba and Zevtera). Basilea has entered a development and commercialisation partnership with Asahi Kasei Pharma (AKP) for Cresemba in Japan; AKP will oversee the clinical trial programme required for Japanese approval. Further deals should be anticipated in 2017 as Basilea looks to leverage both products globally through regionally relevant partners. According to Basilea, more than one-third of sales opportunities for novel anti-fungal agents reside in ex-US and the major European countries.

For more detail on the deals, see our note Licensing double act, published on 16 September 2016.

Cresemba momentum growing in Europe and US

Basilea is commercialising Cresemba (isavuconazole, a broad-spectrum antifungal drug) alone in key European markets (including the UK, Germany, Italy and France) through a fee-for-service contract salesforce via an agreement with Quintiles. We believe that Cresemba accounts for ~85% of the CHF7.1m product sales reported in 2016. In the US, licence partner Astellas launched the product in April 2015 for treating both invasive aspergillosis and invasive mucormycosis. Basilea reported CHF7.3m in royalties on $46m of US Cresemba sales. Astellas has guided $56m in sales for the financial year 1 April 2016 to 31 March 2017. We note that guidance has increased from the $45m pegged at Basilea's interim results. The Swissmedic review of the marketing authorisation for Cresemba is ongoing and expected to complete in 2017; we anticipate a launch in late 2017 or early 2018.

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 note that the latest guideline issued by the European Conference on Infections in Leukaemia (ECIL) recommends Cresemba for the first-line treatment of invasive aspergillosis in leukaemia and hematopoietic stem cell transplant patients. Specifically, it states that "isavuconazole is as effective as voriconazole with a better safety profile". The company believes that this recommendation underscores the potentially important clinical role of Cresemba in the treatment of patients with these life-threatening infections.

We forecast total Cresemba peak sales potential of $600m, with Cresemba contributing c 72% to our valuation. We will maintain our current assumptions until we have more visibility on the start of the bridging trials in Japan and the timing of a potential launch in these newly partnered markets.

Zevtera US opportunity, BARDA contract funds US development

Zevtera uptake in Europe remains slow, as expected; sales of antibiotics such as Zevtera/Mabelio take time to build post launch, given the requirement for regional reimbursement across Europe, plus the need to be added to individual hospital formularies. We anticipate that the bulk of Zevtera's opportunity resides in its fate in the US market. In terms of value, the US represents about 70-80% of the total global market for newer-branded hospital antibiotics.

In March 2016, the Biomedical Advanced Research and Development Authority (BARDA), a division of the US Department of Health and 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 an additional up to $80m potentially due contingent on achieving predefined development milestones by BARDA over a 4.5-year period. The company has submitted the Phase III study protocols seeking agreement on SPAs with the FDA and trials should initiate mid-year (we expect three 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.

Importantly, the BARDA contract provides a path to create further value by enabling non-dilutive funding for the programme before seeking a commercialisation partner for the US market. Additionally, results from the US clinical trial programme could be used to support supplementary indications in Europe and other territories, leveraging Zevtera's potential use further.

Given the slower than expected uptake for Zevtera, we have revisited our global peak sales expectations and reduced our non US sales forecasts. We have reduced our peak sales estimates

to $513m from $556m, consisting of $85m peak sales for Zevtera in Europe (for the currently approved indications) and $428m 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 Riding the crest of the antimicrobial wave published on 23 March 2016.

Oncology pipeline assets data expected in 2018

In 2016 Basilea moved forward with its oncology pipeline. BAL101553 is a highly soluble prodrug of BAL27862, which induces tumour cell death through activation of a checkpoint important for tumour cell division. In December 2016 the company announced the expansion of the BAL101553 clinical Phase I/IIa oral formulation study to include patients with recurrent or progressive glioblastoma (brain cancer) after prior radiotherapy with or without chemotherapy.

BAL3833 is a panRAF/SRC kinase inhibitor in Phase I development in advanced solid tumours. Preclinical data suggest that BAL3833 has activity in KRAS-driven cancer models, suggesting it could have clinical utility in major tumour types beyond BRAF-driven melanoma. The Phase I dose escalation study is ongoing.

The Phase I/IIa and Phase I dose escalation studies evaluating BAL101553 and BAL3833 respectively in patients with solid tumors are due to complete by year end, with results available in H118.

Valuation: rNPV of CHF1,048m or CHF97/share

Our updated Basilea valuation is CHF1,048m (from CHF1,091m previously), primarily as a result of adjustments to our Zevtera assumptions and rolling forward our DCF, offset by a lower net cash position at end December 2016 (CHF93.6m vs CHF116m at end June 2016). 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 ~72% of our rNPV and underpins c 88% 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. Given the slower than expected uptake for Zevtera, we have reduced our peak sales estimates to $513m from $556m, consisting of $85m peak sales for Zevtera in Europe (for the currently approved indications) and $428m for RoW (including $317m for the US opportunity, which is risk-adjusted). We have increased our probability for US Zevtera to 75% from 50% given that the US pivotal Phase III clinical trial programme for bacterial infections is on track to initiate in mid-2017. The breakdown of our valuation is shown in Exhibit 1.

Exhibit 1: Basilea rNPV summary

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	758.2	100%	758.2	70.2
Zeftera/Mabelio (ceftobiprole)	Severe bacterial infections	2015 (EU)	85	51.7	100%	51.7	4.8
		2018 (RoW); 2019 (US)	428	138.5	75%	103.8	9.6
BAL101553	Tumour resistance	2022	500	132.6	20%	35.4	3.3
BAL3833	Tumour resistance	2023	500	68.8	15%	5.8	0.5
Net Cash/(Debt)				93.6	100%	93.6	8.7
Valuation				**1,243.3**		**1,048.5**	**97.1**

Source: Edison Investment Research, Basilea Pharmaceutica. *Excluding treasury shares

Financials: FY17 guidance provided

Basilea reported FY16 product sales of CHF7.1m on sales of anti-microbial agents Cresemba and Zevtera/Mabelio in Europe and royalties on US Cresemba sales of CHF7.3m. Total revenues increased 25% in FY16 (reported at CHF66.0m) vs FY15 (reported at CHF52.8m). Basilea reported contract revenues of CHF57.7m in FY16, reflecting an increase in royalty income relating to Cresemba on US sales; the company reported CHF7.3m in royalties on $46m of US Cresemba sales. Astellas has guided $56m in sales for the financial year 1 April 2016 to 31 March 2017. At this stage our peak sales forecasts of $600m are unchanged, but we will be closely monitoring Cresemba's sales evolution. Conversely, as discussed above, we have decreased our peak sales expectations of Zevtera to $513m from $556m based on currently approved indications.

Costs and operating expenses were lower than the previous year, at CHF104.5m (FY16) vs CHF114.3m (FY15), and accounted for a large reduction in R&D costs offsetting a slight increase in SG&A and the reporting of CHF3m in the COGS line. We note that our cost of sales assumptions relate purely to cost of goods sold; this differs from Basilea's reported cost of sales, which includes manufacturing, capacity reservation, shipping and handling costs (Edison accounts for these costs in SG&A). Thus, during the launch period, cost of sales as reported by Basilea is higher than our forecast cost of sales. We forecast 2017 R&D spend of CHF54.7m; our forecasts assume that Basilea will contribute around 30% of the total $120-150m development costs for Zevtera's US Phase III development between 2017 and 2020, 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 2016 was CHF56.1m. 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 3% increase in underlying G&A. We estimate that S&M spend in 2016 was around CHF33m for the ongoing build-out of a contract salesforce via Quintiles. We believe CHF37-39m of S&M spend should support commercialisation of both Zevtera and Cresemba in the five major European markets.

Overall, we now forecast total operating expenses of CHF116.3m in 2017 from CHF104.5m in 2016. We forecast an operating loss of CHF33.1m for FY17, which is slightly below company guidance of CHF3m average operating loss per month.

Management has confirmed financial guidance for 2017, highlighted in Exhibit 2 below, alongside our estimates for the year.

Exhibit 2: Our forecasts are in line with 2017 company guidance

	Outlook	Edison estimates
Product sales	CHF15m/year	CHF14.9m
Royalties on US sales of Cresemba	CHF14m/year	CHF13.9m
Operating expenses	CHF10m/month	CHF118.3m/year
Operating loss	CHF3m*/month	CHF33m/year

Source: Basilea Pharmaceutica, Edison Investment Research. Note: *On average. Basilea's guidance was last updated in February 2017.

Cash could be sufficient beyond 2019

Basilea reported cash and equivalents, including liquid assets, of CHF289m at year-end December 2016 compared to CHF115.8m at June 2016. This includes proceeds from the convertible bond, which we record on the balance sheet as long-term debt at CHF195m. 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, even in the absence of any milestone payments.

Exhibit 3: Financial summary

CHF'000s	2015	2016	2017e	2018e	2019e
December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	52,825	65,984	88,343	95,123	108,744
Cost of Sales	0	(5,347)	(5,185)	(6,383)	(10,345)
Gross Profit	52,825	60,637	83,158	88,740	98,399
Research and development	(60,075)	(48,449)	(54,653)	(57,149)	(60,201)
EBITDA	(58,885)	(41,570)	(30,737)	(29,967)	(25,122)
Operating Profit (before amort. and except.)	(61,285)	(43,789)	(33,061)	(32,429)	(27,737)
Intangible Amortisation	(200)	(100)	(100)	(123)	(9)
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(61,485)	(43,889)	(33,161)	(32,552)	(27,745)
Net Interest	(35)	(7,065)	(4,425)	(4,108)	(3,649)
Profit Before Tax (norm)	(61,320)	(50,854)	(37,486)	(36,537)	(31,386)
Profit Before Tax (reported)	(61,520)	(50,954)	(37,586)	(36,660)	(31,395)
Tax	(83)	(333)	(26)	(26)	(26)
Profit After Tax (norm)	(61,403)	(51,187)	(37,513)	(36,563)	(31,413)
Profit After Tax (reported)	(61,603)	(51,287)	(37,613)	(36,686)	(31,421)
Average Number of Shares Outstanding (m)	10.1	10.9	11.1	11.4	11.6
EPS - normalised (c)	(607.22)	(469.16)	(336.93)	(321.94)	(271.26)
EPS - normalised fully diluted (CHFc)	(607.22)	(469.16)	(336.93)	(321.94)	(271.26)
EPS - (reported) (CHFc)	(6.09)	(4.70)	(3.38)	(3.23)	(2.71)
Dividend per share (CHFc)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	91.9	94.1	93.3	90.5
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	13,870	59,264	59,450	59,719	60,358
Intangible Assets	346	232	132	9	0
Tangible Assets	10,724	8,878	9,165	9,557	10,204
Investments	2,800	50,154	50,154	50,154	50,154
Current Assets	384,865	268,494	183,389	125,366	84,437
Stocks	9,579	14,931	10,710	8,743	8,503
Debtors	1,545	2,492	2,420	2,606	2,979
Cash	364,688	239,030	158,217	101,975	60,914
Other	9,053	12,041	12,041	12,041	12,041
Current Liabilities	(68,836)	(72,914)	(56,768)	(36,700)	(47,222)
Creditors	(68,836)	(72,914)	(56,768)	(36,700)	(47,222)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(315,043)	(289,844)	(253,723)	(239,723)	(215,333)
Long term borrowings	(194,706)	(195,466)	(195,466)	(195,466)	(195,466)
Other long term liabilities	(120,337)	(94,378)	(58,257)	(44,257)	(19,867)
Net Assets	14,856	(35,000)	(67,653)	(91,339)	(117,760)
CASH FLOW					
Operating Cash Flow	(67,780)	(70,203)	(73,711)	(49,254)	(34,123)
Net Interest	0	(7,065)	(4,425)	(4,108)	(3,649)
Tax	0	(333)	(26)	(26)	(26)
Capex	(1,009)	(1,980)	(2,650)	(2,854)	(3,262)
Acquisitions/disposals	0	0	0	0	0
Financing	(0)	1,000	0	0	0
Other	12,645	(47,837)	0	0	0
Dividends	0	0	0	0	0
Net Cash Flow	(56,143)	(126,418)	(80,813)	(56,242)	(41,061)
Opening net debt/(cash)	(226,125)	(169,982)	(43,564)	37,249	93,491
HP finance leases initiated	0	0	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)	(169,982)	(43,564)	37,249	93,491	134,552

Source: Edison Investment Research, Basilea Pharmaceutica

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