

# Basilea Pharmaceutica

## Ceftobiprole hits its TARGET

Basilea has announced positive top-line data from the Phase III TARGET trial which is evaluating Zevtera/Mabelio (ceftobiprole) in the treatment of acute bacterial skin and skin structure infections (ABSSSI). Ceftobiprole, a broad spectrum antibiotic, met primary and secondary efficacy endpoints including non-inferiority to standard of care vancomycin plus aztreonam in the intent-to-treat population. While this news is positive, 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) is expected in H221. A US launch date of 2022/23 for ceftobiprole could be feasible, with a focus on SAB and ABSSSI. We value Basilea at CHF1,082m or CHF100/share.

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	134.4	(31.9)	(2.95)	0.0	N/A	N/A
12/20e	149.5	(4.8)	(0.45)	0.0	N/A	N/A

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

### Zevtera fortunes reside in US market

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 2019 and 2020. We believe the major commercial opportunity for Zevtera resides in the US market. Data from the TARGET study could be used to support a post-marketing label extension outside the US.

### TARGET hitting efficacy and safety

The TARGET trial 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%). 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 an upcoming scientific conference. We forecast \$550m in peak sales for ceftobiprole; comprising US peak sales of \$317m in 2027, this is predicated on securing a US commercialisation partner.

### Valuation: rNPV of CHF1,082m or CHF100/share

We value Basilea at CHF1,082m. Our valuation is based on an NPV analysis, which includes the main portfolio of products (anti-infectives Cresemba and Zevtera/Mabelio, oncology assets BAL101553 and Derazantinib) and net cash of CHF26.1m at 31 December 2018.

Positive clinical trial results

Pharma & biotech

6 August 2019

Price **CHF34.86**

Market cap **CHF415m**

US\$1.00/CHF

Net cash (CHFm) at 31 December 2018 (excluding restricted cash) 26.1

Shares in issue (including 1.1m treasury shares) 11.9m

Free float 91.46%

Code BSLN

Primary exchange SIX

Secondary exchange N/A

#### Share price performance



% 1m 3m 12m

Abs (6.5) (23.4) (47.9)

Rel (local) (2.8) (22.3) (50.3)

52-week high/low CHF69.05 CHF34.06

#### Business description

Basilea Pharmaceutica is focused on anti-infectives and oncology. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). The R&D pipeline includes two oncology drug candidates in clinical development.

#### Next events

H119 results 20 August 2019 (1600 CEST)

Derazantinib + Tecentriq Phase I/II trial start (urothelial cancer) H219

BAL101553 Phase IIa data (glioblastoma & ovarian cancer) H219

#### Analysts

Dr Susie Jana +44 (0)20 3077 5700

Sean Conroy +44 (0)20 3681 2534

Daniel Wilkinson +44 (0)20 3077 5734

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

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**Exhibit 1: Financial summary**

	CHF'000s	2016	2017	2018	2019e	2020e
December		US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
<b>PROFIT &amp; LOSS</b>						
Revenue		65,984	101,521	132,555	134,380	149,543
Cost of Sales		(5,347)	(9,025)	(20,299)	(24,371)	(27,438)
Gross Profit		60,637	92,496	112,256	110,008	122,105
Research and development (gross)		(48,449)	(55,055)	(104,942)	(105,000)	(90,400)
SG&A		(56,077)	(54,491)	(31,409)	(31,679)	(31,319)
EBITDA		(41,570)	(15,150)	(22,272)	(24,094)	3,184
Operating Profit (before amort. and except.)		(43,789)	(16,950)	(23,972)	(26,443)	623
Intangible Amortisation		(100)	(100)	(123)	(228)	(237)
Exceptionals		0	0	0	0	0
Other		0	0	0	0	0
Operating Profit		(43,889)	(17,050)	(24,095)	(26,671)	386
Net Interest		(7,065)	(1,976)	(7,065)	(5,417)	(5,417)
Profit Before Tax (norm)		(50,854)	(18,926)	(31,037)	(31,860)	(4,794)
Profit Before Tax (reported)		(50,954)	(19,026)	(31,160)	(32,088)	(5,031)
Tax		(333)	(334)	(192)	(26)	(26)
Profit After Tax (norm)		(51,187)	(19,260)	(31,229)	(31,886)	(4,821)
Profit After Tax (reported)		(51,287)	(19,360)	(31,352)	(32,114)	(5,057)
Average Number of Shares Outstanding (m)		10.1	10.8	10.8	10.8	10.8
EPS - normalised fully diluted (CHFc)		(505.74)	(178.36)	(289.19)	(295.28)	(44.64)
EPS - (reported) (CHFc)		(506.73)	(179.28)	(290.33)	(297.39)	(46.83)
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		91.9	91.1	84.7	81.9	81.7
EBITDA Margin (%)		N/A	N/A	N/A	N/A	2.1
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	0.4
<b>BALANCE SHEET</b>						
Fixed Assets		59,264	58,189	7,013	8,668	10,556
Intangible Assets		232	326	372	572	772
Tangible Assets		8,878	7,768	6,424	7,879	9,567
Investments		50,154	50,095	217	217	217
Current Assets		268,494	292,976	274,738	230,207	192,503
Stocks		14,931	15,320	14,411	26,708	18,793
Debtors		2,492	4,955	3,757	6,259	6,965
Cash		239,030	260,724	223,908	164,578	134,083
Other		12,041	11,977	32,662	32,662	32,662
Current Liabilities		(72,914)	(79,491)	(66,684)	(81,666)	(58,657)
Creditors		(72,914)	(79,491)	(66,684)	(81,666)	(58,657)
Short term borrowings		0	0	0	0	0
Long Term Liabilities		(289,844)	(313,114)	(281,754)	(249,759)	(235,759)
Long term borrowings		(195,466)	(196,224)	(196,982)	(196,982)	(196,982)
Other long term liabilities		(94,378)	(116,890)	(84,772)	(52,777)	(38,777)
Net Assets		(35,000)	(41,440)	(66,687)	(92,550)	(91,356)
<b>CASH FLOW</b>						
Operating Cash Flow		(75,003)	19,014	(79,210)	(49,655)	(20,365)
Net Interest		0	0	0	(5,417)	(5,417)
Tax		0	0	0	(26)	(26)
Capex		(394)	(711)	(419)	(4,031)	(4,486)
Acquisitions/disposals		0	0	0	0	0
Financing		0	0	0	0	0
Other		(51,021)	3,391	42,813	(200)	(200)
Dividends		0	0	0	0	0
Net Cash Flow		(126,418)	21,694	(36,816)	(59,330)	(30,495)
Opening net debt/(cash)		(169,982)	(43,564)	(64,500)	(26,926)	32,404
HP finance leases initiated		0	0	0	0	0
Other		0	(758)	(758)	0	0
Closing net debt/(cash)		(43,564)	(64,500)	(26,926)	32,404	62,899

Source: Company accounts, Edison Investment Research

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Frankfurt +49 (0)69 78 8076 960  
Schumannstrasse 34b  
60325 Frankfurt  
Germany

London +44 (0)20 3077 5700  
280 High Holborn  
London, WC1V 7EE  
United Kingdom

New York +1 646 653 7026  
1,185 Avenue of the Americas  
3rd Floor, New York, NY 10036  
United States of America

Sydney +61 (0)2 8249 8342  
Level 4, Office 1205  
95 Pitt Street, Sydney  
NSW 2000, Australia