

Basilea Pharmaceutica

Derazantinib interim iCCA data promising

Corporate update

Pharma & biotech

10 January 2019

Price **CHF48.54**

Market cap **CHF573m**

US\$1.00CHF

Net cash (CHFm) at 30 June 2018 51.3

Shares in issue (including 1m treasury shares) 11.8m

Free float 91.46%

Code BSLN

Primary exchange SIX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 5.7 (5.5) (39.2)

Rel (local) 6.3 (2.5) (32.8)

52-week high/low CHF79.7 CHF38.7

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 three oncology drug candidates in clinical development.

Next events

FY18 results 19 February

Ceftobiprole top-line data H219
(Phase III ABSSSI study)

BAL101553 Phase IIa data H219
(glioblastoma & ovarian cancer)

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Basilea has reported positive interim results from the derazantinib Phase II registration trial in intrahepatic cholangiocarcinoma (iCCA, bile duct cancer). The promising efficacy shown highlights the potential for the product in FGFR-driven solid tumours, an unmet need. Full data are expected to be available once the study has completed (mid-2020). Basilea in-licensed derazantinib from ArQule in April 2018. The asset is a complementary addition to its oncology portfolio and the company now has three diversified, early/mid-stage clinical assets targeting cancer resistance in its portfolio. We anticipate increased investor focus on the oncology strategy at Basilea. We value Basilea at CHF115/share.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHF)	DPS (c)	P/E (x)	Yield (%)
12/16	66.0	(50.9)	(5.06)	0.0	N/A	N/A
12/17	101.5	(18.9)	(1.78)	0.0	N/A	N/A
12/18e	124.0	(29.6)	(2.74)	0.0	N/A	N/A
12/19e	137.3	(26.7)	(2.48)	0.0	N/A	N/A

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

Derazantinib shoring up the oncology pipeline

Derazantinib is a tyrosine kinase inhibitor (pan FGFR) with potential utility across a range of cancers that test positive for FGFR genetic aberrations. Its most advanced indication is for iCCA (second line for FGFR2 fusion), Phase II studies in other FGFR-driven tumours are expected to initiate in mid-2019. Although there are no approved targeted therapies for iCCA, the discovery of FGFR2 fusions in ~10–20% of patients could change the treatment paradigm for these patients. While small patient populations in iCCA are expected, there is an unmet need and thus the FDA and EMA have granted orphan drug designation.

Interim analysis promising; await full data mid-2020

The interim analysis of the Phase II study, based on the subset of 29 patients (42 enrolled on the study) who had at least one post-baseline imaging assessment, showed an objective response rate of 21% and disease control rate (partial response or stable disease) of 83%. Safety and tolerability were confirmed as seen in previous studies. Full data from the iCCA trial should be available mid-2020, the trial is expected to enrol 100 patients. We model 2023 launch following a traditional development path including a Phase III trial.

Valuation: rNPV of CHF1,239m or CHF115/share

Our valuation remains unchanged at CHF1,239m or CHF115/share. We include derazantinib for only iCCA in our model (peak sales of \$59.4m), but the valuation is largely based on Cresemba (worldwide) and antibiotic Zevtera (ex-US), plus net cash of CHF51.3m at 30 June 2018. We also include risk-adjusted contributions for Zevtera (US), BAL101553 and BAL3833. Basilea has provided a preliminary update to FY18 results; unaudited revenue for 2018 of CHF133m vs our CHF124m estimate is partly driven by a strong sales ramp up of Cresemba. The company also reported a cash position of c CHF223m at 31 December 2018 (preliminary, unaudited). We will update our model once the audited financials are published.

Exhibit 1: Financial summary

	CHF'000s	2016	2017	2018e	2019e
December		US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue		65,984	101,521	124,010	137,255
Cost of Sales		(5,347)	(9,025)	(11,994)	(12,429)
Gross Profit		60,637	92,496	112,015	124,826
Research and development (gross)		(48,449)	(53,493)	(102,500)	(113,000)
SG&A		(56,077)	(53,139)	(33,861)	(33,415)
EBITDA		(41,570)	(12,236)	(21,877)	(18,819)
Operating Profit (before amort. and except.)		(43,789)	(14,036)	(24,223)	(21,361)
Intangible Amortisation		(100)	(100)	(123)	(228)
Exceptionals		0	0	0	0
Other		0	0	0	0
Operating Profit		(43,889)	(14,136)	(24,346)	(21,589)
Net Interest		(7,065)	(4,890)	(5,375)	(5,375)
Profit Before Tax (norm)		(50,854)	(18,926)	(29,598)	(26,736)
Profit Before Tax (reported)		(50,954)	(19,026)	(29,721)	(26,964)
Tax		(333)	(334)	(26)	(26)
Profit After Tax (norm)		(51,187)	(19,260)	(29,624)	(26,763)
Profit After Tax (reported)		(51,287)	(19,360)	(29,747)	(26,991)
Average Number of Shares Outstanding (m)		10.1	10.8	10.8	10.8
EPS - normalised fully diluted (CHFc)		(505.74)	(178.36)	(274.34)	(247.83)
EPS - (reported) (CHFc)		(506.73)	(179.28)	(275.47)	(249.95)
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross Margin (%)		91.9	91.1	90.3	90.9
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		59,264	58,189	59,640	61,188
Intangible Assets		232	326	526	726
Tangible Assets		8,878	7,768	9,019	10,367
Investments		50,154	50,095	50,095	50,095
Current Assets		268,494	292,976	220,988	173,249
Stocks		14,931	15,320	16,431	13,621
Debtors		2,492	4,955	5,776	6,393
Cash		239,030	260,724	186,805	141,259
Other		12,041	11,977	11,977	11,977
Current Liabilities		(72,914)	(79,491)	(54,144)	(66,713)
Creditors		(72,914)	(79,491)	(54,144)	(66,713)
Short term borrowings		0	0	0	0
Long Term Liabilities		(289,844)	(313,114)	(284,293)	(247,903)
Long term borrowings		(195,466)	(196,224)	(195,466)	(195,466)
Other long term liabilities		(94,378)	(116,890)	(88,827)	(52,437)
Net Assets		(35,000)	(41,440)	(57,808)	(80,178)
CASH FLOW					
Operating Cash Flow		(75,003)	19,014	(64,597)	(35,827)
Net Interest		0	0	(5,375)	(5,375)
Tax		0	0	(26)	(26)
Capex		(394)	(711)	(3,720)	(4,118)
Acquisitions/disposals		0	0	0	0
Financing		0	0	0	0
Other		(51,021)	2,633	558	(200)
Dividends		0	0	0	0
Net Cash Flow		(126,418)	20,936	(73,161)	(45,546)
Opening net debt/(cash)		(169,982)	(43,564)	(64,500)	8,661
HP finance leases initiated		0	0	0	0
Other		0	(0)	0	0
Closing net debt/(cash)		(43,564)	(64,500)	8,661	54,207

Source: Company data, Edison Investment Research

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