Crossject

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Orphan disease status for Zeneo® Midazolam in the US

Significant news - 03/02/2018

Fact

The group indicated it had obtained orphan drug status for Zeneo® Midazolam from the FDA for the treatment of "status epilepticus", i.e. epileptic crises of over five minutes.

Analysis

Orphan drug designation is granted by the FDA to novel therapeutics for diseases or conditions affecting fewer than 200,000 patients in the US or greater than 200,000 patients if there is no reasonable expectation that the production cost of the drug will be covered by its sales. Such a designation allows the drug developer to be eligible for a 7-year period of US marketing exclusivity upon approval of the drug, as well as, in some cases, tax credits for clinical research costs, the ability to apply for annual grant funding, clinical trial design assistance, and the waiver of Prescription Drug User Fee Act (PDUFA) filing fees. As a reminder, market approval for Zeneo® Midazolam should be asked in FY19 for both the US and Europe.

Impact

As such, the news does not change our estimates but it is positive given the benefits expected from this designation and it was unsurprisingly welcomed by the market.



Fabrice FARIGOULE pharma@alphavalue.eu +33 (0) 1 70 61 10 50

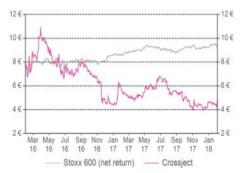
+33 (0) 1 70 61 10 50 corporate.alphavalue.com

AlphaValue is contracted by Crossject to provide equity research on Crossject, using AlphaValue's unique and transparent methods and procedures. Target price and opinion are thus exclusively determined by those methods and procedures.

Buy	Upside: 235%
Target Price (6 months)	€ 16.1
Share Price	€ 4.80
Market Cap. €M	42.3
Price Momentum	GOOD
Extremes 12Months	3.91 🕨 6.80
Bloomberg	ALCJ FP Equity
Reuters	ALCJ.PA







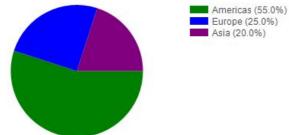
PERF	1 w	1m	3	m	12m	
Crossject	8.11%	5.26%	21.	2% -	14.2%	
Pharma	-5.02%	-5.00%	-4.8	33%	5.07%	
STOXX 600	-3.12%	-0.55%	-1.7	4%	7.22%	
Last updated: 0	6/11/2017	12/15A	12/16A	12/17E	12/18E	
Adjusted P/E (x)		-8.05	-7.64	-12.9	-13.5	
Dividend yield (%)	0.00	0.00	0.00	0.00	
EV/EBITDA(R) (x)		-7.51	-9.19	-15.8	-8.92	
Adjusted EPS (€)		-0.88	-0.98	-0.41	-0.36	
Growth in EPS (%	b)	n/a	n/a	n/a	n/a	
Dividend (€)		0.00	0.00	0.00	0.00	
Sales (€M)		2.37	1.43	2.00	2.00	
EBIT margin (%)		ns	ns	-196	ns	
Attributable net p	rofit (€M)	-5.73	-6.66	-3.22	-3.09	
ROE (after tax) (%	%)	-49.2	-88.4	-44.0	-44.6	
Gearing (%)		-91.3	-62.3	-46.4	-183	
Company Valuation - Company Financials						

Company Valuation - Company Financials



Sales by Geography

Consolidated P&L Accounts



Asia (20.0%)

12/16A 12/17E 12/18E

			,	
Sales	€M	1.43	2.00	2.00
Change in sales	%	-39.8	40.2	0.00
Change in staff costs	%	5.41	17.7	12.2
EBITDA	€M	-5.52	-2.57	-2.97
EBITDA(R) margin	%	-387	-129	-148
Depreciation	€M	-1.77	-1.35	-1.35
Underlying operating profit	€M	-7.29	-3.92	-4.32
Operating profit (EBIT)	€M	-7.29	-3.92	-4.32
Net financial expense	€M	-1.06	-0.30	-0.30
of which related to pensions	€M		0.00	0.00
Exceptional items & other	€M	0.59	0.00	0.00
Corporate tax	€M	1.10	1.00	1.52
Equity associates	€M			
Minority interests	€M			
Adjusted attributable net profit	€M	-6.66	-3.22	-3.09
NOPAT	€M	-5.10	-2.74	-3.02
Cashflow Statement				
EBITDA	€M	-5.52	-2.57	-2.97
Change in WCR	€M	-0.33	0.46	0.21
Actual div. received from equity holdi	€M	0.00	0.00	0.00
Paid taxes	€M	0.00	1.00	1.52
Exceptional items	€M	0.00	0.00	0.00
Other operating cash flows	€M	0.00	0.00	0.00
Total operating cash flows	€M	-5.85	-1.11	-1.23
Capital expenditure	€M	-6.00	-0.50	-0.53
Total investment flows	€M	-6.00	-0.50	-0.53
Net interest expense	€M	-1.06	-0.30	-0.30
Dividends (parent company)	€M			
Dividends to minorities interests	€M	0.00	0.00	0.00
New shareholders' equity	€M	4.10	4.30	0.00
Total financial flows	€M	9.00	0.96	10.9
Change in cash position	€M	-2.85	-0.65	9.16
Free cash flow (pre div.)	€M	-12.9	-1.91	-2.06
Per Share Data				
No. of shares net of treas. stock (year	Mio	7.11	8.64	8.64
Number of diluted shares (average)	Mio	6.80	7.87	8.69
Benchmark EPS	€	-0.98	-0.41	-0.36
Restated NAV per share	€			
Net dividend per share	€	0.00	0.00	0.00

Valuation Summary

Benchmarks	Value	Weight
DCF	€ 21.5	40%
NAV/SOTP per share	€ 18.2	40%
P/E	€ 2.40	5%
EV/Ebitda	€ 0.00	5%
P/Book	€ 2.40	5%
Dividend Yield	€ 0.00	5%
TARGET PRICE	€ 16.1	100%

Largest comparables

- Faes Farma Hikma Pharmaceuti...
- Ipsen
- Stada Arzneimittel UCB

NAV/SOTP	Calculation
INA 100 II	ouloulation

Balance Sheet		12/16A	12/17E	12/18E
Goodwill	€M	0.00	0.00	0.00
Total intangible	€M	2.51	2.17	1.83
Tangible fixed assets	€M	5.78	5.27	4.78
Financial fixed assets	€M	0.10	0.10	0.10
WCR	€M	-2.17	-2.63	-2.84
Other assets	€M	1.97	2.97	3.21
Total assets (net of short term liab.)	€M	8.24	7.93	7.14
Ordinary shareholders' equity	€M	6.28	8.36	5.51
Quasi Equity & Preferred	€M			
Minority interests	€M			
Provisions for pensions	€M	0.00	0.00	0.00
Other provisions for risks and liabilities	€M	0.12	0.12	0.12
Total provisions for risks and liabilities	€M	0.12	0.12	0.12
Tax liabilities	€M	0.00	0.00	0.00
Other liabilities	€M	4.52	4.52	16.6
Net debt (cash)	€M	-2.69	-5.08	-15.1
Total liab. and shareholders' equity	€M	8.24	7.93	7.14
Capital Employed				
Capital employed after depreciation	€M	6.22	4.91	3.88
Profits & Risks Ratios				
ROE (after tax)	%	-88.4	-44.0	-44.6
ROCE	%	-82.1	-55.9	-77.9
Gearing (at book value)	%	-62.3	-46.4	-183
Adj. Net debt/EBITDA(R)	х	0.49	1.97	5.09
Interest cover (x)	х	-6.88	-13.1	-14.4
Valuation Ratios				
Reference P/E (benchmark)	x	-7.64	-12.9	-13.5
Free cash flow yield	%	-24.2	-4.21	-4.97
P/Book	х	8.48	5.44	7.52
Dividend yield	%	0.00	0.00	0.00
EV Calculation				
Market cap	€M	53.3	45.5	41.5
+ Provisions	€M	0.12	0.12	0.12
+ Unrecognised acturial losses/(gains)	€M	0.00	0.00	0.00
+ Net debt at year end	€M	-2.69	-5.08	-15.1
+ Leases debt equivalent	€M	0.00	0.00	0.00
- Financial fixed assets (fair value)	€M			
+ Minority interests (fair value)	€M			
= EV	€M	50.7	40.5	26.5
EV/EBITDA(R)	x	-9.19	-15.8	-8.92
EV/Sales	х	35.5	20.2	13.2

Analyst : Fabrice Farigoule, Changes to Forecasts : 06/11/2017.

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