

Orexo

Worst-case scenario averted

The court ruling upholding the validity of the Orexo '996 Zubsolv patent precludes Actavis from launching a generic before September 2019. Orexo has 30 days to decide whether to appeal the court decision that a second patent ('330 with 2032 expiry) is invalid. A worst-case scenario allowing imminent launch of Actavis generic(s) has been averted. Zubsolv's IP portfolio includes two additional patents ('900 and '421) that extend to 2032, which coupled with the prospect of an appeal on '330, means that significant hurdles remain ahead of Actavis generic launch.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/14	570.3	(52.6)	(1.6)	0.0	N/A	N/A
12/15	643.2	(191.2)	(5.7)	0.0	N/A	N/A
12/16e	728.1	42.8	1.0	0.0	36.7	N/A
12/17e	898.8	153.7	2.6	0.0	14.1	N/A

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

Multi-layer IP strategy for Zubsolv

Actavis is the only company to file ANDAs for generic Zubsolv to date. The recent ruling relates to the June 2016 court hearing concerning the first ANDA (filed 2014 covering Zubsolv 1.4mg and 5.7mg); the court decision upheld the validity of the [8,454,996](#) US patent but found [8,940,330](#) invalid. Since the first ANDA filing, the FDA has approved four further Zubsolv dose strengths and two new patents have been issued ([9,259,421](#) and [9,439,900](#)). Actavis's second ANDA was filed in 2015; Orexo responded by initiating two additional infringement suits. The first suit has an October 2017 trial date; the second (related to '421) is pending a court date.

Actavis generic launch: Not until Q319 at earliest

Orexo has one valid patent to September 2019 ('996), two extending to 2032 ('421 and '900) and is evaluating its strategy for appealing the '330 ruling. Overlap of the various ANDA filings and patents challenged by Actavis means the court decision in this first case is likely to affect the process/outcome of the subsequent suits. An appeal outcome, plus rulings on subsequent suits is expected from 2018. The new worst-case scenario is Actavis generic launch in 2019, which gives Orexo at least three years to prepare for a switch to a branded generic marketing strategy.

Financial forecasts and valuation maintained

We maintain our financial forecasts and valuation of SEK4.54bn or SEK131/share as we continue to model Zubsolv genericisation in 2032. Management has guided that legal/admin costs for FY17 and FY18 will be in line with FY15 and FY16. The appeal process is shorter (typically 12 months) and less costly than full litigation. The ruling has no direct impact on sales and marketing costs, or negative impact on sales until at least 2020. Promotion of a branded generic typically requires lower investment. Management also confirmed the solid performance of Zubsolv so far in Q4, with both patient numbers and mgs/Rx increasing in a growing market.

Patent litigation update

Pharma & biotech

28 November 2016

Price **SEK36.7**

Market cap **SEK1,273m**

SEK8.84/US\$

Net debt (SEKm) at end September 2016 219.2

Shares in issue 34.7m

Free float 49%

Code ORX

Primary exchange NASDAQ OMX Stockholm

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (21.9) (25.9) (48.3)

Rel (local) (22.5) (28.3) (48.8)

52-week high/low SEK70.0 SEK32.9

Business description

Orexo is a Swedish speciality pharma company, with expertise in drug delivery/reformulation technologies (in particular sublingual formulations) and a US commercial infrastructure for opioid dependence therapy Zubsolv.

Next events

Decision to appeal '330 ruling End 2016

FY16 results 26 Jan 2017

Second Actavis IP infringement case Oct 2017

Zubsolv: possible EMA approval Q417

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Exhibit 1: Financial summary

	SEKm	2014	2015	2016e	2017e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		570.3	643.2	728.1	898.8
Cost of Sales		(107.4)	(136.1)	(150.3)	(161.3)
Gross Profit		462.9	507.1	577.8	737.5
EBITDA		(12.5)	(88.4)	86.3	173.1
Operating Profit (before GW and except.)		(25.0)	(169.1)	64.6	166.4
Intangible Amortisation		0.0	0.0	0.0	0.0
Other		16.5	(64.6)	15.9	0.0
Exceptionals		0.0	0.0	0.0	0.0
Operating Profit		(25.0)	(169.1)	64.6	166.4
Net Interest		(27.6)	(22.1)	(21.7)	(12.6)
Other		0.0	0.0	0.0	0.0
Profit Before Tax (norm)		(52.6)	(191.2)	42.8	153.7
Profit Before Tax (IFRS)		(52.6)	(191.2)	42.8	153.7
Tax		(4.0)	(6.9)	(6.8)	(65.8)
Deferred tax		0.0	0.0	0.0	0.0
Profit After Tax (norm)		(56.6)	(198.1)	36.1	88.0
Profit After Tax (IFRS)		(56.6)	(198.1)	36.1	88.0
Average Number of Shares Outstanding (m)		34.3	34.6	34.5	34.5
EPS - normalised (öre)		(165)	(573)	105	255
EPS - IFRS (SEK)		(1.6)	(5.7)	1.0	2.5
Dividend per share (SEK)		0.0	0.0	0.0	0.0
Gross Margin (%)		81.2	78.8	79.4	82.1
EBITDA Margin (%)		(2.2)	(13.7)	11.8	19.3
Operating Margin (before GW and except.) (%)		(4.4)	(26.3)	8.9	18.5
BALANCE SHEET					
Fixed Assets		289.5	185.9	163.8	158.0
Intangible Assets		259.2	159.1	142.4	142.4
Tangible Assets		29.1	24.7	21.4	15.6
Other		1.2	2.1	0.0	0.0
Current Assets		936.4	830.4	940.2	1,070.7
Stocks		478.1	398.9	308.8	176.7
Debtors		173.8	233.4	179.5	221.6
Cash		284.5	198.1	451.9	672.4
Other		0.0	0.0	0.0	0.0
Current Liabilities		(268.1)	(251.6)	(304.8)	(341.0)
Creditors		(265.6)	(251.6)	(304.8)	(341.0)
Short term borrowings		(2.5)	0.0	0.0	0.0
Long Term Liabilities		(502.8)	(498.3)	(498.5)	(498.5)
Long term borrowings		(493.8)	(494.4)	(496.1)	(496.1)
Other long term liabilities		(9.0)	(3.9)	(2.4)	(2.4)
Net Assets		455.0	266.4	300.7	389.2
CASH FLOW					
Operating Cash Flow		(455.7)	(73.2)	275.8	263.6
Net Interest		(31.6)	(29.0)	(26.9)	(12.6)
Tax		0.0	0.0	0.0	(29.5)
Capex		(71.7)	(4.1)	(1.6)	(1.0)
Acquisitions/disposals		0.0	21.8	11.0	0.0
Financing		341.7	3.8	2.1	0.0
Dividends		0.0	0.0	0.0	0.0
Other		0.0	0.0	0.0	0.0
Net Cash Flow		(217.3)	(80.7)	260.4	220.6
Opening net debt/(cash)		135.4	211.8	296.3	44.2
HP finance leases initiated		0.0	0.0	0.0	0.0
Exchange rate movements		1.5	4.5	6.7	0.0
Other		139.4	(8.3)	(15.0)	0.1
Closing net debt/(cash)		211.8	296.3	44.2	(176.5)

Source: Edison Investment Research, Orexo accounts

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