

Orexo

Good things come in threes

Orexo has delivered on three key newsflow items, which should contribute to driving increased Zubsolv use in the treatment of opioid addiction. Submission of Zubsolv's MAA with the EMA means that first launch ex-US could come from 2018 onwards. FDA approval of a new low dose provides greater dosing flexibility. Positive data from the RESOLV real world study will be leveraged in educating new and existing prescribers to improve their treatment programmes. Ahead of Q316 results we maintain our SEK5.13bn (SEK149/share) valuation highlighting that uncertainty due to the ongoing Actavis litigation continues to weigh on the share price; resolution is expected in H216.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/14	570	(53)	(1.6)	0.0	N/A	N/A
12/15	643	(191)	(5.7)	0.0	N/A	N/A
12/16e	753	25	0.5	0.0	N/A	N/A
12/17e	989	137	2.2	0.0	N/A	N/A

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

Mundipharma files Zubsolv in Europe

Orexo's global ex-US partner Mundipharma has filed the Zubsolv MAA with the EMA suggesting that first EU launches are possible in 2018. Precise timelines would be contingent on reimbursement decisions, which differ between EU member states. The MAA covers six dose strengths (including the newly approved US low dose) but does not trigger any milestone; the next milestone is expected on approval.

FDA approves unique low dose

A new 0.7mg buprenorphine /0.18 mg naloxone Zubsolv tablet will be available in early 2017. Approval of this dose gives Zubsolv the broadest available dose range (six doses) increasing physician dosing flexibility and enabling tapering of patients to the lowest effective maintenance dose, without compromising tablet or packaging integrity through 'dose splitting' (tablet breakage).

RESOLV: Completed study = valuable database

The 1,080-pt REZOLV study provides a substantial real-world clinical database for Orexo to leverage in its dialogue with key stakeholders (physicians, politicians and payers) to optimise and improve access to opioid dependence therapy. Of 978 evaluable patients, 77.6% were classed as treatment successes. Numerous factors correlated with positive treatment outcomes: older age, partner support, employment, heroin rather than injectable opioid addiction. Prior failed treatment had a negative impact on success, but physician experience had no bearing.

Valuation: SEK5.1bn or SEK149/share on a DCF basis

We maintain our SEK5.13bn or SEK149/share valuation ahead of Q316 results. This already includes potential European Zubsolv sales revenues (assuming launch in late 2018, conservative €100m peak sales and a 10% net royalty) but not potential Mundipharma milestones as their magnitude and timing are undisclosed.

Regulatory news

Pharma & biotech

7 October 2016

Price **SEK44.10**

Market cap **SEK1,526m**

SEK8.57/US\$

Net debt (SEKm) end-June 2016 242.6

Shares in issue 34.6m

Free float 49%

Code ORX

Primary exchange NASDAQ OMX Stockholm

Secondary exchange N/A

Share price performance



52-week high/low SEK73.50 SEK42.00

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

Q316 results	20 October
Actavis ANDA 30-month stay expires	November
FY16 results	26 January

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Exhibit 1: Financial summary

	SEK m	2014	2015	2016e	2017e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		570.3	643.2	752.9	989.4
Cost of Sales		(107.4)	(136.1)	(143.9)	(182.2)
Gross Profit		462.9	507.1	608.9	807.2
EBITDA		(12.5)	(88.4)	60.7	156.2
Operating Profit (before GW and except.)		(25.0)	(169.1)	45.1	150.1
Intangible Amortisation		0.0	0.0	0.0	0.0
Other		16.5	(64.6)	1.8	0.0
Exceptionals		0.0	0.0	0.0	0.0
Operating Profit		(25.0)	(169.1)	45.1	150.1
Net Interest		(27.6)	(22.1)	(20.2)	(12.8)
Other		0.0	0.0	0.0	0.0
Profit Before Tax (norm)		(52.6)	(191.2)	24.8	137.3
Profit Before Tax (IFRS)		(52.6)	(191.2)	24.8	137.3
Tax		(4.0)	(6.9)	(6.0)	(60.7)
Deferred tax		0.0	0.0	0.0	0.0
Profit After Tax (norm)		(56.6)	(198.1)	18.8	76.6
Profit After Tax (IFRS)		(56.6)	(198.1)	18.8	76.6
Average Number of Shares Outstanding (m)		34.3	34.6	34.6	34.6
EPS - normalised (öre)		(165)	(573)	54	221
EPS - IFRS (SEK)		(1.6)	(5.7)	0.5	2.2
Dividend per share (SEK)		0.0	0.0	0.0	0.0
Gross Margin (%)		81.2	78.8	80.9	81.6
EBITDA Margin (%)		(2.2)	(13.7)	8.1	15.8
Operating Margin (before GW and except.) (%)		(4.4)	(26.3)	6.0	15.2
BALANCE SHEET					
Fixed Assets		289.5	185.9	168.5	163.3
Intangible Assets		259.2	159.1	147.8	147.8
Tangible Assets		29.1	24.7	19.5	14.3
Other		1.2	2.1	1.2	1.2
Current Assets		936.4	830.4	967.6	1,088.4
Stocks		478.1	398.9	295.7	199.6
Debtors		173.8	233.4	185.6	244.0
Cash		284.5	198.1	486.3	644.8
Other		0.0	0.0	0.0	0.0
Current Liabilities		(268.1)	(251.6)	(349.3)	(385.8)
Creditors		(265.6)	(251.6)	(349.3)	(385.8)
Short term borrowings		(2.5)	0.0	0.0	0.0
Long Term Liabilities		(502.8)	(498.3)	(497.8)	(497.8)
Long term borrowings		(493.8)	(494.4)	(495.5)	(495.5)
Other long term liabilities		(9.0)	(3.9)	(2.3)	(2.3)
Net Assets		455.0	266.4	289.0	368.1
CASH FLOW					
Operating Cash Flow		(455.7)	(73.2)	300.6	196.4
Net Interest		(31.6)	(29.0)	(23.7)	(12.8)
Tax		0.0	0.0	(0.4)	(24.2)
Capex		(71.7)	(4.1)	(0.8)	(0.9)
Acquisitions/disposals		0.0	21.8	11.0	0.0
Financing		341.7	3.8	0.0	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)	286.6	158.5
Opening net debt/(cash)		135.4	211.8	296.3	9.2
HP finance leases initiated		0.0	0.0	0.0	0.0
Exchange rate movements		1.5	4.5	(1.6)	0.0
Other		139.4	(8.3)	2.1	0.0
Closing net debt/(cash)		211.8	296.3	9.2	(149.3)

Source: Orexo, Edison Investment Research

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