EDISON

Orexo

Interim Q118 results

Profitability continues

Pharma & biotech

Orexo reported an operational quarter in line with guidance. Total revenues of SEK139.7m in Q118 represented an increase of about 10% vs Q117. Orexo's key product, Zubsolv, saw revenues in the US increase by 15% vs Q117 to SEK131.1m. Improved working capital management and cost of goods sold (CoGS) efficiencies promise to deliver another full year of profitability in FY18 and beyond. We have rebuilt our model and our new valuation is SEK2.2bn or SEK63 per share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/16	705.9	35.6	0.8	0.0	42.0	N/A
12/17	643.7	29.7	0.7	0.0	52.6	N/A
12/18e	729.3	107.7	2.9	0.0	12.2	N/A
12/19e	887.2	163.1	4.5	0.0	7.8	N/A

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

Zubsolv: Double-digit US growth set to continue

Exclusive and competitive market access contracts have grown Zubsolv sales. This is not as easy as it sounds in the US market for retail and hospital distribution of products to treat opioid dependency, where the level of reimbursement depends on whether the patient is covered by commercial insurance or by Medicare/Medicaid. Thus, the exclusive contracts that Orexo has signed should enable it to maintain the 26% y-o-y growth in US dollar sales of Zubsolv.

Focus on operational discipline in 2018

Q1's CoGS was higher than we expected as the Zubsolv tablets sold came from relatively more expensive batches than will be the case from H2. The long-term focus on profitability was illustrated by the reduction in working capital, which helped increase net cash by SEK106m during the quarter. Q1's decreased inventory from working capital efficiencies is expected to continue at the same level despite volume increases. CoGS should start to improve in H2 and we estimate that gross profit margin will increase to c 75% from 2019 vs 65% in Q118.

Financials: FY18 guidance unchanged

Management reiterated its FY18 guidance including a third year of positive EBITDA. It expects both Zubsolv revenue growth and profitability to continue from increased market share and cost control, respectively. It also anticipates operating expenses of c SEK500m (our estimate is SEK432m) and modest royalties from the EU launch of Zubsolv.

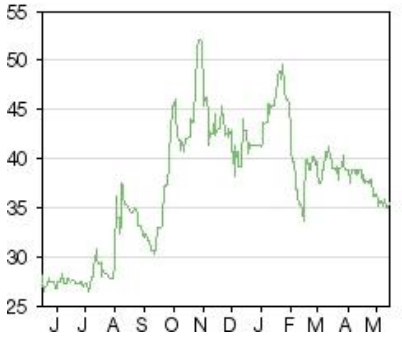
Valuation: SEK2.2bn or SEK63 per share

We have rebuilt our model to allow any changes in patent litigation to be incorporated quickly by adjusting the terminal value, and have made significant changes to the rebate and exchange rates. Our model explicitly values Orexo's in-line products, with an emphasis on improved profitability from efficiency gains, in the Zubsolv franchise.

15 May 2018

Price	**SEK35.50**
Market cap	**SEK1,247m**
	$/SEK8.81
Net debt (SEKm) at end March 2018	127
Shares in issue	34.6m
Free float	37.6%
Code	ORX
Primary exchange	NASDAQ OMX Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(8.5)	5.5	29.6
Rel (local)	(12.3)	0.8	31.2
52-week high/low	SEK52.0	SEK26.4	

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 (also filed in Europe). It also has two clinical assets and three preclinical programmes.

Next events

Q218 results	11 July 2018
Zubsolv EU launch	Q218
Potential Actavis IP appeal outcome	Q218
Q318 results	October 2018

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Q118 results

Q118 revenues of SEK139.7m were 9.6% ahead of Q117 (SEK127.4m) driven by the strong growth in US sales of Zubsolv at SEK131.1m vs SEK114.1m in Q117, an increase of 14.9%. End-user demand (from the IMS Health prescription database), wholesaler stocking and a price increase all contributed to local currency growth of 26.2%. We estimate that the strong US dollar translated to the Swedish krone represented about a SEK13m headwind.

We have updated our model to reflect prevailing FX rates and actual Q1 revenues for Zubsolv, Abstral (lower US royalties of SEK5.8m due to the correction of estimates by Orexo's licensee) and Edluar (similarly lower royalties of SEK2.8m vs our previous estimates due to a correction by partner Mylan). Abstral and Edluar are not key to our investment thesis for Orexo.

Operating costs in Q118 were SEK113.1m (Q117: SEK104.9m). Management guided to a total operational spend of about SEK500m in FY18 including a modest increase in its US salesforce and increased costs related to the development projects. A Q117 net loss was expected and delivered at SEK25.9m. Cash and cash equivalents were SEK437.5m at 31 March 2018 (SEK250.6m at the same point in 2017), while cash flow from operating activities was strong at SEK106.0m for the quarter (SEK28.2m for Q117). The change in cash flow from operating activities comprised increased provisions for payer rebates – which had a positive impact on cash flow – and reduced inventory and receivables.

As Q118 was in line with the previously issued guidance, the outlook for 2018 was unchanged. A third full year of EBITDA profitability is expected driven by growth in Zubsolv revenue in the US and cost-control programmes, which we discuss below as drivers of our valuation. Management attributes the growth in US sales of Zubsolv to the exclusive contracts it signed in the quarter and we assume that they will continue and assist volume growth for at least one year. Exhibit 2 provides a detailed summary of our financial model.

Patents

We consider that a no-holds barred generic market for buprenorphine/naloxone sublingual tablets is unlikely in the near term. This is because two new Zubsolv US patents ('421 and '900) have been issued and were listed in the Orange Book in 2016. This IP is in the litigation queue with Actavis behind the '330 patent. In addition, the generic Suboxone and Subutex products from Actavis are also the subject of a patent infringement case on Orexo's valid '996 patent. The potential for backdated royalties on sales of these Actavis products that have already been launched 'at risk' create the possibility of a settlement between Actavis and Orexo. Any settlement could extend Zubsolv's US exclusivity beyond a point that many investors are expecting as a trade-off for damages.

The announcement on the Paragraph IV litigation against Actavis regarding Zubsolv in the US could come at any time in the next two months. The continued validity of the patent would retain exclusivity until 2032. If Orexo loses the appeal on the validity of the '330 patent, the two new patents could be used in court against Actavis.

Valuation and revised assumptions

Our valuation of Orexo has decreased to SEK2.2bn or SEK63 per share (vs SEK2.7bn or SEK78.4 per share previously) after rebuilding our model (see Financials section). We outline our new financial assumptions in Exhibit 1 below. We have made significant changes to the rebate levels, gross margins and exchange rates that have, in part, resulted in a lower valuation. We have also assumed that the high historic Zubsolv CoGS from Q1 continue, but taper in the run-up to Q119.

As we show in Exhibit 1, the working capital improvements and CoGS efficiencies implemented in Q118 start to affect profitability from Q318. In addition, we assume that the recently signed exclusive contracts that helped grow Zubsolv sales in Q1 are multi-year agreements that continue to generate volume growth, albeit gradually in 2018. The success of the US commercialisation of Zubsolv brings the generic threat to that franchise that makes patent litigation a binary event. It is for this reason that we have built a new model for Orexo that extends our forecasts until 2027 and introduces a terminal value that assumes an extended period of Zubsolv market exclusivity and the recent pipeline advancements. Our terminal value represents 44% of our valuation of Orexo and our SEK63 per share represents a fair value premium of 77.5% over the current share price. Clearly, investors are concerned about the uncertainty caused by the generic threat to Zubsolv in the US just at the time when Zubsolv is the only branded product to gain market share in Q118. Management attributes Q1 growth to the exclusive and competitive contracts that appear to generate higher volume sales and which we expect will run for more than a year. We have assumed that Orexo's corporate tax rate is kept low for the foreseeable future by use of its non-operating losses.

Exhibit 1: Revised model key assumptions to 2022

Assumption	2017	2018e onwards
US market		
US opioid dependency treatment market growth	11.2%	8.2%
US Zubsolv market share	5.0%	7.5%*
US Zubsolv sales growth post-rebates (in SEK)	0.8%	16.1% (2018), 21.6% (2019), 8.2% (from 2020)
US Zubsolv rebate level	64.2%	65%
Europe		
European Zubsolv market share	0%	0.2% (2018), 1% (2019), 1.5% (2020), 3% (2021), 5% (2022)
European Zubsolv royalty growth post-rebates (in SEK)	0%	580% (2019), 53% (2020), 104% (2021), 70% (2022)
European Zubsolv rebate level	0%	40%
Corporate		
Gross profit margin	74.5%	68.8% (2018), 75% (from 2019)
Operating profit margin	8.92%	16.3% (2018), 22.2 % (2019), 13.6%** (2020), 14.6% (2021), 15.7% (2022)
Average Zubsolv rebate US	64.2%	65%
Tax rate	22%	5.4% (2018), (3%) from 2018
Average Zubsolv rebate EU	NA	40%
Total Zubsolv revenues post-rebates (SEKm)	491.4	574.6 (2018), 724.5 (2019), 798.7 (2020), 920.4 (2021), 1,059.3 (2022)
Total product sales	643.7	729.3 (2018), 887.2 (2019), 848.9 (2020***), 970.4 (2021), 1,111.0 (2022)
Horizon value (2018-27)	SEK1.23bn	
Terminal value (2027-)	SEK970m	

Source: Edison Investment Research, Orexo. Note: FX rate assumptions – SEK8.80/$ and SEK10.51/€; WACC 10.0%. *Ramps gradually from 5% to 7.5% from the end of 2017 to the end of 2018 on signing exclusive contracts. **Assuming increased legal costs after 2019. ***Loss of Abstral exclusivity in the EU in 2019.

Much of Zubsolv's market share gains have come from exclusive contracts, some of which have only been signed in the last quarter. As we assume that they are multi-year agreements, they might be expected to continue past any initial appeal judgement of the '330 case. Indeed, Orexo may have emulated an Amgen strategy when the biotechnology company signed exclusive contracts with US payers in advance of a biosimilar launch of one of Amgen's largest products. Amgen was able to retain preferred formulary status even in the advent of biosimilar competition.

Of course, there is a cost to contracts where higher volumes are compensated for by higher rebates, although in Q118 these were offset by a c 6% price increase. Previously we used rebates ranging from 40% to 55%, although because of the weighting of the public segment, the average was closer to 55%. Our model now reflects a 65% rebate level across all three US Zubsolv segments (public, commercial and cash), which may be too conservative but on a par with our estimates of an average rebate level in Q1, and one that would ensure volumes after Q1. The Q118 results demonstrate that improved contractual market access brings volume demands, which outweigh the rebates, and the Zubsolv brand was able to grow in the US by nearly 15% (by value in SEK) in what is usually the weakest quarter.

One of the reasons for rebuilding our model was to include a terminal valuation that we could adjust in the event of the invalidation of the '330 patent and the absence of other avenues to maintain exclusivity. As Amgen has taught us, exclusivity is not only generated by patents but could also be contractual. We have previously explored scenarios where Orexo switches to a branded generic strategy in the US, which our new model could be changed to reflect and could only be achieved with the CoGS reduction programme outlined below. Our model currently assumes that branded sales will continue with the sales growth and rebate levels detailed in Exhibit 1.

However, higher rebates are trending the market towards generic pricing. Brand loyalty among physicians and patients, particularly those patients with commercial insurance, may make a traditional generic launch less attractive to Orexo's competitors than it would have been in 2013 when rebates were only c 35%.

The other reason for rebuilding our model with a terminal value that can be modified easily, but currently represents a diffuse view of Orexo's value beyond the expiry of the '996 patent, is that there are components of Orexo's valuation that we have not explicitly valued. The existing products and their continued exclusivity (excluding Abstral in the EU beyond 2019) comprise the horizon period value and the assumptions on which they are based, as detailed in Exhibit 1. Orexo's pipeline and the continued validity of the '330 patent comprise the terminal value. Orexo's R&D pipeline continues to develop with more visibility disclosed in the Q1 results, and should now include its business development efforts. The pipeline is beginning to show results with a naloxone rescue medication about to enter clinical trials. Another development product is OX382, which is a swallowable buprenorphine formulation, but is not without risk as other companies have tried unsuccessfully to develop such a product. The acquisition or licensing of a product that is complementary with Zubsolv's US commercial infrastructure is a good use of Orexo's strong cash generation, as Orexo's management has pointed out. In the same way as reductions in CoGS can leverage profitability when demand increases volumes of a product, having more than one product for sales representatives to discuss with a physician in the same sales call increases the chances of generating greater sales.

Cost-reduction efficiencies

Orexo highlighted two efficiency programmes in its Q1 results that will have positive long-term effects on its profitability. The first was the working capital reduction, which has at points in Zubsolv's history included up to SEK500m in inventory. A rise in demand driven by the improved market access agreements resulted in increased inventory drawdown. We estimate this component of working capital to trend closer to SEK150m. Inventory at this level is expected to continue.

The most significant factor affecting Orexo's Q118 results was the detail on its manufacturing efficiency programme directed at dramatically lowering the CoGS for Zubsolv. CoGS amounted to SEK48.5m in Q118, up from SEK46.2m in Q117 and with a gross margin of 65%. The Zubsolv batches that were sold, and will continue until H2, were all manufactured in relatively expensive campaigns resulting from higher active pharmaceutical ingredient (API), tableting and packaging

costs, and the unfavourable SEK/US$ exchange rates. We have estimated that CoGS in FY18 will be SEK177m, after which time efficiencies will result in gross profit margins approaching 75% by Q119. We will revisit gross profit margin improvements after Q119.

Exhibit 2: Financial summary

SEKm	2014	2015	2016	2017	2018e	2019e
Year end 31 December	**IFRS**	**IFRS**	**IFRS**	**IFRS**	**IFRS**	**IFRS**
INCOME STATEMENT						
Revenue	570.3	643.3	705.9	643.7	729.3	887.2
Cost of Sales	(107.4)	(136.1)	(149.6)	(164.4)	(177.9)	(171.4)
Gross Profit	462.9	507.3	556.3	479.3	551.4	715.8
Reported operating profit	(25.0)	(169.0)	51.7	57.4	118.9	196.8
Net Interest	(27.6)	(22.1)	(16.1)	(27.7)	(11.2)	(33.7)
Profit before tax (reported)	(52.6)	(191.1)	35.6	29.7	107.7	163.1
Reported tax	(4.0)	(6.9)	(6.5)	(6.5)	(6.4)	(4.9)
Profit after tax (reported)	(56.6)	(198.0)	29.0	23.2	101.3	158.2
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0
Net income (reported)	(56.6)	(198.0)	29.0	23.2	101.3	158.2
Basic average number of shares outstanding	33.0	34.0	35.0	35.0	34.9	35.0
EPS - basic reported (SEK)	(1.73)	(5.74)	0.84	0.67	2.90	4.52
EPS – normalised fully diluted (SEK)	(1.73)	(5.74)	0.84	0.67	2.90	4.52
Dividend per share	0.0	0.0	0.0	0.0	0.0	0.0
Revenue growth (%)	32.8	12.8	9.7	(8.8)	13.3	21.6
Gross margin (%)	81.2	78.8	78.8	74.5	75.6	80.7
BALANCE SHEET						
Fixed assets	289.5	185.9	185.1	176.5	166.4	158.1
Intangible assets	197.0	159.1	138.2	121.0	109.3	98.8
Tangible assets	29.1	24.7	22.1	20.1	21.7	23.9
Investments & other	63.4	2.1	24.8	35.4	35.4	35.4
Current assets	936.4	830.4	833.7	827.4	960.2	1,126.7
Stocks	478.1	398.9	344.2	250.2	150.0	150.0
Debtors	173.8	233.4	178.5	249.3	297.2	328.2
Cash & cash equivalents	284.5	198.1	282.4	327.9	513.0	648.5
Other	0.0	0.0	28.6	0.0	0.0	0.0
Current liabilities	(268.1)	(251.6)	(309.5)	(349.9)	(349.9)	(349.9)
Creditors	0.0	0.0	0.0	0.0	0.0	0.0
Short-term borrowings	(1.9)	0.0	0.0	0.0	0.0	0.0
Other	(266.2)	(251.6)	(309.5)	(349.9)	(349.9)	(349.9)
Long-term liabilities	(502.8)	(498.3)	(399.0)	(324.9)	(324.9)	(324.9)
Long-term borrowings	(493.8)	(494.4)	(397.8)	(319.1)	(319.1)	(319.1)
Other long-term liabilities	(9.0)	(3.9)	(1.3)	(5.8)	(5.8)	(5.8)
Net assets	455.0	266.5	310.3	329.1	451.8	610.1
Shareholders' equity	455.0	266.5	310.3	329.1	423.6	590.8
CASH FLOW						
Operating cash flow before WC and Tax	(35.5)	(119.4)	67.5	108.1	115.0	171.0
Working capital	(451.8)	17.2	88.7	0.0	69.5	(31.0)
Exceptional & other	(19.0)	(20.6)	(20.8)	(37.2)	(11.2)	(33.7)
Tax	(4.0)	(6.9)	(7.5)	0.0	(6.4)	(4.9)
Net operating cash flow	(487.3)	(102.2)	156.2	146.6	184.5	140.0
Capex	(71.7)	(4.1)	0.5	(1.6)	(3.6)	(4.4)
Acquisitions/disposals	0.0	21.8	5.0	0.0	0.0	0.0
Equity financing	349.3	3.8	2.2	0.1	0.0	0.0
Other	390.1	(1.2)	(92.8)	(85.5)	0.0	0.0
Net cash flow	180.4	(81.9)	71.1	59.6	185.1	135.5
Opening net debt/(cash)	(105.6)	(284.5)	(198.1)	(282.4)	(327.9)	(513.0)
FX	(1.5)	(4.5)	13.3	(14.1)	0.0	0.0
Closing net debt/(cash)	(284.5)	(198.1)	(282.4)	(327.9)	(513.0)	(648.5)

Source: Company accounts, Edison Investment Research

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