

# Orexo

Corporate update

## Zubsolv growing in a challenging environment

US net sales of Zubsolv (for the treatment of opioid dependence) grew 10% y-o-y to SEK124.1m in a market where volume growth was driven by the larger (46% of all subscriptions), less profitable and more competitive public segment (Zubsolv has 27% market access). Despite a testing quarter we believe the market's view of Zubsolv's prospects is too pessimistic; Q3/Q417 should gain from the addition of Zubsolv to the state of Wisconsin's preferred formulary for its Medicaid programme. Additionally, Zubsolv recently gained a preferred (now reimbursable) position on the CVS Caremark 2018 formulary, taking its access to the commercial sector to over 90%. Abstral royalties, which are loaded to H217, should aid in achieving FY17 forecasts.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/15**	646.2	(203.6)	(6.1)	0.0	N/A	N/A
12/16	705.9	35.6	0.8	0.0	41.5	N/A
12/17e	688.0	43.4	0.7	0.0	47.4	N/A
12/18e	729.1	93.1	2.2	0.0	15.1	N/A

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

## Zubsolv: Optimising investment to capture growth

The whole opioid dependence market grew 9.8%, but was mainly driven by the growth in the less profitable public segment where Zubsolv currently has lower market access (27%; cash: 100%; commercial: 80%), thus limiting y-o-y overall Zubsolv demand growth to 7.6%. In addition, the positive effect of stocking and currency offset the reductions in net pricing, resulting in Zubsolv y-o-y US net sales growth of 10% to SEK124.1m. Orexo is optimising its investment strategy to focus on growth in all segments including capturing market access in the public segment; the addition of Zubsolv to the state of Wisconsin's preferred formulary should aid Q3/4 volumes.

## Financials: New lower-cost guidance

Orexo still expects y-o-y Zubsolv net sales growth (market growth and share gains) and positive EBITDA for FY17; however, the company now expects lower FY17 operating expenses of SEK475m (H1:SEK218m) versus previous estimates of SEK500-510m (on current FX rates). This is driven by ongoing cost control and lower legal fees. As a result our normalised FY17 PBT forecast has increased to SEK43.4m, aided by H217 loading of Abstral royalties. Positive operating cash flow (SEK47.1m) was achieved in Q217, for the seventh successive quarter.

## Valuation: SEK3.32bn or SEK96/share on DCF basis

Rolling forward and updating our model for the revised FY17 guidance and Q3 FX rates (\$/SEK8.44 vs 8.69) increases our valuation slightly to SEK3.32bn (SEK96/share) vs SEK3.28bn (SEK95/share) previously. We continue to have confidence in Orexo's initiatives to secure US market share gains via improved market access which, coupled with legislative changes, are sources of potential upside, as is Zubsolv ex-US and further pipeline or business developments. Our forecasts for Zubsolv are unchanged in US dollar terms.

## Pharma & biotech

8 August 2017

**Price** **SEK33.20**
**Market cap** **SEK1,147m**

\$/SEK8.44

Net debt (SEKm) at end June 2017 45.7

Shares in issue 34.5m

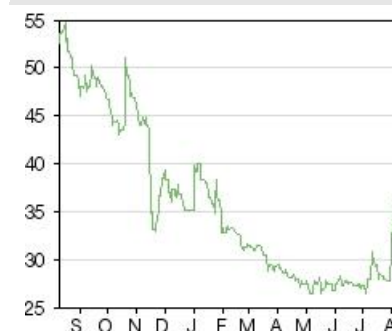
Free float 37.6%

Code ORX

Primary exchange NASDAQ OMX Stockholm

Secondary exchange N/A

## Share price performance



% 1m 3m 12m

Abs 19.4 25.7 (36.3)

Rel (local) 21.3 29.8 (44.6)

52-week high/low SEK54.8 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). Orexo also has two clinical assets and three preclinical programmes.

## Next events

Q317 results 19 October 2017

Zubsolv: possible EMA approval Q417

Potential Actavis IP appeal ruling Q417 onwards

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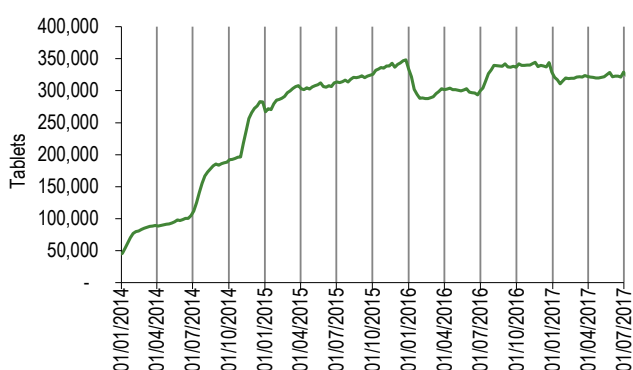
## Zubsolv market access is key to growth

The opioid dependence market grew 9.8% y-o-y, the core of which was driven by growth in the public segment (Managed Medicaid, FFS Medicaid, Medicare Part D). Orexo has limited access to the public segment (27%), as such volume growth for Zubsolv is limited under current market conditions. Additional lower net pricing in the public segment limits revenue growth. Orexo will look to grow its access to the public market to maintain volume growth, but revenue growth will likely come from the higher-value commercial and cash segments where Orexo currently has unrestricted access to 80% (Zubsolv: 39% of market volume) and 100% (Zubsolv: 15% of market volume) of patients respectively.

Orexo reported Zubsolv US net revenues of SEK124.1m in Q217 (+10%) versus Q216 (SEK112.8m) and up 8.8% on Q117 (SEK114.1m). The limited market access to the public segment (in addition to lower reimbursement prices) has dragged on Zubsolv's growth rates and revenues. Net revenues in Q217 benefited from wholesaler stocking compared to the previous quarter. A price increase of 6% implemented on 1 January 2017 aided net tablet pricing, but this was largely offset by higher gross to net deductions due to pricing pressure and a changed payor mix favouring the lower-priced public segment. A stronger US dollar (c +7% y-o-y) against the Swedish krona boosted Zubsolv revenues in Orexo's reporting currency.

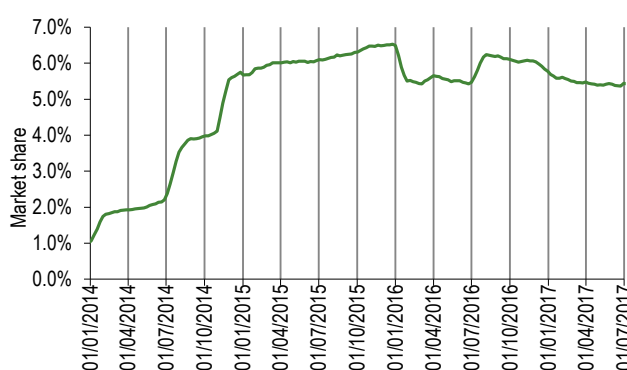
Exhibits 1 and 2 show the progression of growth in both Zubsolv net revenue and market share since launch. Average market share by volume (rolling four weeks) was 5.4% (Q217) vs 5.6% (Q117), with average market share by dollar value of 5.8% (Q217) vs 5.9% (Q117).

**Exhibit 1: Zubsolv tablet volumes (four-week average)**



Source: Symphony, Bloomberg. Note: Gridlines separate quarters.

**Exhibit 2: Zubsolv market share (four-week average)**



Source: Symphony, Bloomberg. Note: Gridlines separate quarters.

Orexo expects sustained year-on-year growth in Zubsolv net revenues driven by strong market growth; however, the company highlights that a continued skew towards the public segment will make revenue growth from market share difficult. Volume market drivers include ongoing expansion in the prescriber base (impact of C275 certification and the Comprehensive Addiction and Recovery Act, CARA 2016), translating into an increase in patients that are able to access treatment. The public segment is largely driving opioid dependency market growth in the US versus the more profitable commercial and cash segments. The public segment, accounting for c 44% of the current opioid dependence market by volume, is the fastest-growing segment, supported by increased access (including via C275 physicians). Consequently, Orexo is focusing its efforts on winning market share here, as shown by recent new contracts (the state of Wisconsin and Medicare Part D, ESI). However, as it is associated with high rebates (Managed Medicaid and FFS Medicaid typically base their agreements on the best price in commercial plans plus an additional discount), increased public share for Zubsolv will decrease overall gross to net rebates.

## Market access update

Improvements in market access are materialising: the majority of existing formulary positions for Zubsolv have been confirmed for 2018 and, furthermore, new contracts have been gained in both the commercial and public segments with effect from 2018. Importantly, we anticipate a pick-up in Q3/Q417, as within the public segment Zubsolv has been added to the preferred formulary of the state of Wisconsin's public fee for service Medicaid programme (effective 1 July). Additionally, Q3/Q4 are dynamic quarters as ongoing negotiations for formulary positioning with payers and pharmacy benefit managers (PBMs) crystallise. We provide an update on the three different segments of the market below.

### Commercial (private insurance)

- The commercial segment represents 39% of the total market and 54.3% of Zubsolv business in Q2 (Q1: 53%). Zubsolv currently has unrestricted access to more than 80% (90% from 1 January 2018) of the business in the commercial segment.
- Zubsolv's prescription volume in this segment grew 4.7% compared to Q117 (the entire buprenorphine/naloxone market commercial segment grew 3.4 % in volume compared to Q117, and 3.3% compared to Q216. Zubsolv's market share remained unchanged at 7.4%. After the negative impact on Q1 volumes due to the withdrawal of UnitedHealth Group (UHG) from the Affordable Care Act's exchange plans, Zubsolv's Q2 UHG volumes resurged.
- In Q217, Blue Cross of Arizona added Zubsolv as the only preferred branded product, along with generics. Orexo signed an exclusive contract with a regional PBM company from 1 January 2018; the impact of this will depend on the PBM's ability and timing in implementing the formulary change with its clients (insurance companies).
- In Q317, CVS Caremark placed Zubsolv in a preferred party position with the market-leading branded product (Suboxone); this means Zubsolv's position has changed from non - reimbursable to reimbursed as a preferred product. This gives Orexo access to CVS Caremark's largest patient population of over 25 million people and takes Zubsolv's US access to above 90% of the commercial sector. Zubsolv lost CVS Caremark in January 2016, where it previously held preferred formulary position. The new agreement sees Zubsolv having co-preferred parity formulation with another brand (Suboxone); as such, there will be no forced switching to Zubsolv. Orexo expects the positive impact on market share to be initially limited.

### Cash (cash and vouchers)

- The cash segment represents 15% of the total market and 13.4% of Zubsolv business in Q2 (Q1: 14%). Zubsolv has access to 100% of the business in the cash segment.
- Zubsolv's market share in the cash segment remained stable at 4.9% in Q217 (the entire cash segment grew 0.4% in volume during Q217 compared to Q117, and declined 1% versus Q216. This segment is the most sensitive to price and discount programmes and has been affected more recently by aggressive pricing of generics.

### Public (Managed Medicaid, FFS Medicaid, Medicare Part D)

- The public segment represents 46% of the total market with Zubsolv access at 27%, representing 32.3% of Zubsolv business in Q2 (Q1: 32%). The public segment continues to be the fastest growing segment in the buprenorphine/naloxone market, driven by increased access to publicly financed insurers for opioid-dependent patients. This segment grew 5.7% in volume during Q2 vs Q117 and 19.6 % compared to Q216. Zubsolv market share in Q2 decreased slightly to 3.7% in Q217 from 3.9% in Q117, largely due to the decline in CareSource (a managed Medicaid plan).

As mentioned above, with effect from 1 July 2017 Zubsolv has been added to the state of Wisconsin's public fee for service Medicaid preferred formulary programme. Medicare Part D, ESI (PBM) has also added Zubsolv to the preferred formulary position effective 1 January 2018. FFS Medicaid in Maryland will be retaining Zubsolv in a preferred formulary position. However, Orexo anticipates a minimal financial impact given the significantly reduced rebate level, and expects some negative effects on volume and market share starting from 1 July 2017.

## Pipeline update

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Pipeline progression has been made over the course of Q217, with the \$2.5m (c SEK22m) milestone payment from AstraZeneca on the start of Phase I trials for the respiratory programme OX-CLI (also known as AZD9898). Orexo now has two clinical assets (the other being Phase III-ready acute pain programme OX51) and three preclinical projects (OX-MPI [inflammation] plus two novel formulation technologies). A new preclinical product, OX382 has been added to the pipeline and the company plans to move it into a Phase I trial within the next six to nine months. The project is in the exploratory phase and aims to test the new formulation technology that Orexo is developing.

Revenues from marketed products on which Orexo receives royalties demonstrated a mixed quarter. Royalties from Abstral increased to SEK9.7m (vs SEK5.4m in Q216), while Edluar royalties declined to SEK3.4m (SEK4.5m).

## Valuation

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We have updated our Orexo valuation to SEK3.32bn or SEK96/share vs SEK3.28bn or SEK95/share. Orexo's enhanced focus on cost control has prompted us to revise our 2017 expense expectations downwards. We maintain our Zubsolv forecasts (Exhibit 6) in US dollar terms for 2017 and beyond. However, the SEK value of these has altered due to updating our model with the current rate of SEK8.44/US\$ (from SEK8.69/US\$ when we [last published](#) our forecasts). We also roll forward our model to reflect the passage of time.

Our explicit DCF-based valuation out to 2030 assumes a WACC of 10%, a long-term tax rate of 30% after 2016 and no terminal value. We estimate a long-term gross margin of 85% on Zubsolv by 2025, with the operating margin gradually trending to 50% in the long term. We include a modest revenue contribution from global Abstral and Edluar royalties until 2020, at which point we assume for simplicity that all revenues relate to Zubsolv.

Orexo continues to trade at a significant discount to our per share valuation (current share price of SEK28.1 vs a 52-week low of SEK26) due to continued uncertainty about the generic threat, with the market pricing in limited Zubsolv prospects. Our model suggests that the current share price is supported in a scenario whereby Zubsolv does not improve its penetration from 6% overall market and 10% new patients, rebating remains high (50-55%) and it loses 80% of peak revenues in the first year post-genericisation (ie in 2020). This assumes a worst case scenario of generic entry in 2019. See our note Orexo 'More signs of pipeline promise' for details of our scenario analysis.

**Exhibit 3: Zubsolv revenue assumptions to 2022**

Assumption	2016	2017e	2018e	2019e	2020e	2021e	2022e
<b>US current market</b>							
US Zubsolv sales (current) – pre-rebates (\$m)	115.9	129.1	148.3	167.6	199.3	230.9	263.0
US Zubsolv sales (current) – post-rebates (\$m)	54.5	59.4	73.8	89.7	109.6	127.0	144.6
US Zubsolv sales (current) – post-rebates (SEKm)	481.8	510.5	622.1	756.5	924.4	1,071.2	1,219.9
<b>US new patients</b>							
US Zubsolv sales (new) – pre-rebates (\$m)		4.6	6.3	8.3	13.0	22.8	33.5
US Zubsolv sales (new) – post-rebates (\$m)		2.1	3.0	4.0	6.4	11.4	16.8
US Zubsolv sales (new) – post-rebates (SEKm)		18.1	25.5	33.8	53.9	96.2	141.4
<b>Total US Zubsolv sales – post-rebates (SEKm)</b>	<b>481.8</b>	<b>528.7</b>	<b>647.7</b>	<b>790.4</b>	<b>978.3</b>	<b>1,167.3</b>	<b>1,361.3</b>
<b>Europe</b>							
European Zubsolv sales – pre-rebates (€m)			1.0	5.2	10.6	16.2	22.1
European Zubsolv sales – post-rebates (€m)			0.6	3.4	7.4	12.2	17.7
European Zubsolv sales – post-rebates (SEKm)			5.9	32.6	71.6	117.4	170.3
<b>Total European Zubsolv net royalty (SEKm)</b>			<b>0.6</b>	<b>3.3</b>	<b>7.2</b>	<b>11.7</b>	<b>17.0</b>
<b>Total Zubsolv revenues – post-rebates (SEKm)</b>	<b>481.8</b>	<b>528.7</b>	<b>648.3</b>	<b>793.6</b>	<b>985.4</b>	<b>1,179.1</b>	<b>1,378.3</b>
<b>Total product sales (SEKm)*</b>	<b>598.2</b>	<b>665.7</b>	<b>707.3</b>	<b>833.1</b>	<b>1,001.0</b>	<b>1,179.1</b>	<b>1,378.3</b>

Source: Edison Investment Research, Orexo. Note: In the US, assumes SEK8.44/\$ FX rate, peak market share of 10% (current market) and 15% (new patients) with long-term rebate of 45% (current market) and 50% (new patients). In Europe, SEK9.64/€, peak market share of 20% and average 20% rebate. \*Total product sales include revenues from products other than Zubsolv until 2020.

## Q2 financials

Q217 net revenues of SEK159.1 were 15.4% down on Q216 (SEK188.2m), although the prior period included a €7m (SEK65.4m) upfront payment from Mundipharma, which acquired the ex-US global rights to Zubsolv in Q216. However, Q217 revenues benefited from the \$2.5m (SEK22m) AstraZeneca milestone payment on OX-CLI Phase I start. Zubsolv sales growth was the primary driver of Q217 net revenues, with US revenue of SEK124.1m (up 10% on Q216: SEK112.8m). Exhibit 4 summarises the Q217 revenue breakdown and our FY17 forecasts.

**Exhibit 4: Actual and forecast revenue breakdown per product (SEKm)**

	Actual Q217	Change on Q216*	Old FY17e	New FY17e	Notes
Zubsolv US	124.1	+10%	536.6	528.7	Tablet volumes vs Q416 affected by UnitedHealth Group exiting ACA healthcare exchanges and decreased WellCare Managed Medicaid market share (patients switching insurance companies). 6% price rise from 1 January and positive dosage mix change offset some of increased rebate. Main patent to 2032.
Zubsolv ROW	0.0	-	0.0	0.0	No major milestones anticipated from Mundipharma in FY17.
Abstral royalties	9.7	+80%	126.1	125.1	US generic entry (Actavis) from June 2018 (or earlier under certain undisclosed conditions), ahead of September 2019 patent expiry. Partnered with ProStrakan (Europe): 15% royalty on net sales >€42.5m; Sentyln (US): low double-digit royalty; Kyowa Hakko Kirin (Japan) single-digit royalty.
Edluar royalties	3.4	-24%	12.0	12.5	Sold by Mylan (US, Canada and EU). Generic competition in North America in 2017.
<b>Total product revenue</b>	<b>137.2</b>	<b>+12%</b>	<b>674.8</b>	<b>666.2</b>	
Other revenue	21.8	+100%	21.7	21.8	\$2.5m AstraZeneca milestone on OX-CLI Phase I start received in Q217. SEK65m upfront payment received from Mundipharma in Q216.
<b>Total revenue</b>	<b>159.1</b>	<b>-15%</b>	<b>696.5</b>	<b>688.0</b>	

Source: Edison Investment Research, Orexo. Note: \*Restated Q116 figures.

COGS increased 5.6% over Q216 (SEK35.8m vs SEK33.9) and were all related to Zubsolv US, attributable to the Zubsolv repackaging project (now complete) and variability in indirect production costs (connected to periods in which production activity is low), with some contribution from a lower gross to net on account of the payer mix (higher Medicaid volumes). Gross to net levels continue to be under pressure; however, we expect increased manufacturing efficiencies and enhancements in the global supply chain to generate a further improvement in COGS. The effect of this will become

more apparent from FY18 as existing inventories are consumed. For FY17, lower COGS is the key driver of our new higher PBT forecast.

Operating costs for Q217 were SEK113.5m (Q216: SEK142.2m), reflecting ongoing cost management, the conclusion of Zubsolv-related R&D and lower legal spend. The ongoing impact of field force optimisation and targeting investment into areas with favourable market access reduced sales costs to SEK49.7m (Q216: SEK56.4m). R&D investment increased compared with Q216 (SEK39.1.3m vs SEK28.7m). Admin expenses of SEK22.4m (Q216: SEK62.7m) were markedly lower following conclusion of the first round of Zubsolv patent infringement litigation vs Actavis in November (see our Outlook note [The highs and lows of 2016](#) for a detailed analysis of the ongoing litigation).

Orexo has lowered guidance on operating expenses to SEK475m (from SEK500-510m) for FY17; we expect total opex of SEK475.2m for FY17, comprising lower sales expenses of SEK212.8m vs FY16, an increase in R&D spend to SEK159.7m and lower admin costs of SEK102.8m due to the anticipated decrease in legal expenses.

Orexo delivered a Q217 operating profit of SEK9.8m with profit before tax of SEK4.7m and EBITDA profit of SEK15.0m. Continued working capital improvements meant that Orexo delivered a seventh consecutive quarter of positive operating cash flow (SEK48.7m). This has further reduced net debt to SEK45.7m at end-March 2017, with SEK294.3m of cash and cash equivalents on the balance sheet. Significant Zubsolv inventory (SEK292.9m in raw material and finished product), as well as expected business development income (which is not included in our forecasts), will contribute to improving future cash flow generation from operations.

We have updated our model in line with the new guidance. A summary is provided in Exhibit 6 overleaf, with the main changes to our forecasts presented in Exhibit 5.

**Exhibit 5: Changes to estimates**

	Revenue (SEKm)			PBT (SEKm)			EPS (SEK)		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
2017e	696.5	688.0	(1.1)	29.3	43.4	48.1	0.4	0.7	75.0
2018e	750.1	729.1	(2.8)	82.8	93.1	12.4	1.9	2.2	15.8

Source: Edison Investment Research. Note: SEK/US\$ rate updated to 8.44 from 8.69.



**Exhibit 6: Financial summary**

SEKm	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>				
Revenue	646.2	705.9	688.0	729.1
Cost of Sales	(150.2)	(149.6)	(146.0)	(139.9)
Gross Profit	496.0	556.3	542.0	589.2
R&D Expenses	(172.6)	(132.3)	(159.7)	(167.7)
Sales Expenses	(297.5)	(240.6)	(212.8)	(220.2)
General and Administrative Expenses	(141.5)	(161.6)	(102.8)	(105.9)
EBITDA	(99.9)	76.7	87.8	117.6
Operating Profit (before amort. and except.)	(180.6)	51.7	63.4	95.5
Intangible Amortisation	(80.7)	(25.0)	(22.9)	(22.2)
Other	(65.0)	29.9	(1.8)	0.0
Exceptionals	0.0	0.0	0.0	0.0
Operating Profit	(261.3)	26.7	40.5	73.3
Net Interest	(23.0)	(16.1)	(20.0)	(2.3)
Other	0.0	0.0	0.0	0.0
Profit Before Tax (norm)	(203.6)	35.6	43.4	93.1
Profit Before Tax (IFRS)	(284.3)	10.6	20.5	71.0
Tax	(6.4)	(6.5)	(18.5)	(18.6)
Deferred tax	0.0	0.0	0.0	0.0
Profit After Tax (norm)	(210.0)	29.1	24.9	74.5
Profit After Tax (IFRS)	(290.7)	4.1	2.0	52.3
Average Number of Shares Outstanding (m)	34.6	34.5	34.5	34.5
EPS - normalised (ore)	(607)	84	72	216
EPS - IFRS (SEK)	(6.1)	0.8	0.8	2.2
Dividend per share (ore)	0.0	0.0	0.0	0.0
Gross Margin (%)	76.8	78.8	78.8	80.8
EBITDA Margin (%)	(15.5)	10.9	12.8	16.1
Operating Margin (before GW and except.) (%)	(27.9)	7.3	9.2	13.1
<b>BALANCE SHEET</b>				
Fixed Assets	200.3	185.1	164.7	143.8
Intangible Assets	155.5	138.2	115.3	93.1
Tangible Assets	24.7	22.1	24.6	25.9
Other	20.1	24.8	24.8	24.8
Current Assets	819.7	833.7	891.3	655.3
Stocks	402.6	344.2	300.1	249.1
Debtors	219.0	207.1	188.5	199.8
Cash	198.1	282.4	402.7	206.5
Other	0.0	0.0	0.0	0.0
Current Liabilities	(251.6)	(309.5)	(714.8)	(379.7)
Creditors	(251.6)	(309.5)	(374.8)	(378.4)
Short term borrowings	0.0	0.0	(340.0)	(1.3)
Long Term Liabilities	(498.3)	(399.0)	(0.6)	(0.6)
Long term borrowings	(494.4)	(397.8)	0.0	0.0
Other long term liabilities	(3.9)	(1.3)	(0.6)	(0.6)
Net Assets	270.1	310.3	340.6	418.8
<b>CASH FLOW</b>				
Operating Cash Flow	(84.1)	184.5	204.6	161.1
Net Interest	(25.1)	(28.3)	(20.0)	(2.3)
Tax	0.0	0.0	(3.6)	(15.0)
Capex	(4.1)	(1.4)	(1.0)	(1.2)
Acquisitions/disposals	21.8	6.8	0.0	0.0
Financing	3.8	2.2	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	(87.7)	163.8	180.0	142.5
Opening net debt/(cash)	211.8	296.3	115.4	(62.7)
HP finance leases initiated	0.0	0.0	0.0	0.0
Exchange rate movements	(2.5)	(13.3)	0.7	0.0
Other	5.7	30.4	(2.7)	0.0
Closing net debt/(cash)	296.3	115.4	(62.7)	(205.2)

Source: Edison Investment Research, Orexo accounts. Note: FY15 figures restated at FY16 results.

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