EDISON

Orexo

Q1 results

Putting CVS Caremark in the past

Pharma & biotech

Orexo has successfully navigated a challenging Q116 with the loss of CVS Caremark exclusive status at restricted plans, emerging with positive operating cash flow due to working capital and a focus on cost control (total spend down 17% vs Q4). In the near term, management priorities are Zubsolv revenue growth, balanced with appropriate sales investment to target profitability. Investment will increase as Zubsolv's market access and reimbursement position improves, and federal legislation is passed significantly expanding the available market. Global expansion with a potential new ex-US partner for Zubsolv represents further upside; a deal is targeted for Q216, with European filing planned 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	674	(72)	(2.0)	0.0	N/A	N/A
12/17e	927	77	1.6	0.0	N/A	N/A

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

Zubsolv: Balanced investment to capture growth

Increased investment in promotional activities depends on opportunities to gain market share: market access improvements and legislative change nationally. Increasing the number of patients with unrestricted access to Zubsolv and further growing the profitable cash and commercial segments are a key focus. Federally, proposed changes to government policy would expand access to opioid dependence treatment through both current and new prescribers.

Financials: Positive cash flow, focus on cost control

Cost control across all line items reduced core operating costs (ex-FX gains/losses) by 17% q-o-q. R&D was lower due to the completion of trials, with selling expenses down 15% on account of adjusting field force investment to reflect Zubsolv's market access position. Orexo will continue to optimise salesforce deployment and investment, but is maintaining flexibility to benefit from the impact of new legislation. Q216 guidance is for R&D spend of c SEK40m, flat sales expenses of c SEK60m, and admin costs between SEK35-40m. Inventory release and potential business development income should contribute to improved operating cash flow.

Valuation: SEK4.3bn or SEK125/share on a DCF basis

Our updated valuation of SEK4.31bn or SEK125/share (previously SEK4.24bn or SEK123/share) reflects the enhanced focus on cost control and the moderation of our Zubsolv FY16 sales expectations in US dollar terms (due to uncertainty in the timing of the implementation of federal changes in an election year). We maintain our Zubsolv forecasts in US dollar terms for 2017 and beyond; any changes are due to updating FX. We continue to have confidence in Orexo's initiatives to secure market share gains via improved market access, which, coupled with legislative changes, are sources of potential upside, as are deals (Zubsolv ex-US or OX51) or new pipeline disclosures.

9 May 2016

Price	**SEK46.0**
Market cap	**SEK1,592m**
	SEK8.00/US$
Net debt (SEKm) at end-March 2016	261.9
Shares in issue	34.6m
Free float	49%
Code	ORX
Primary exchange	NASDAQ OMX Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(24)	(2.8)	(52.9)
Rel (local)	(22.2)	(4.3)	(47.5)
52-week high/low	SEK101.0	SEK42.2	

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

First data from RESOLV	Q216
Zubsolv ex-US partnering deal	Mid-2016
Q216 results	July 12 2016
Updates on US plans to increase access to treatment	2016

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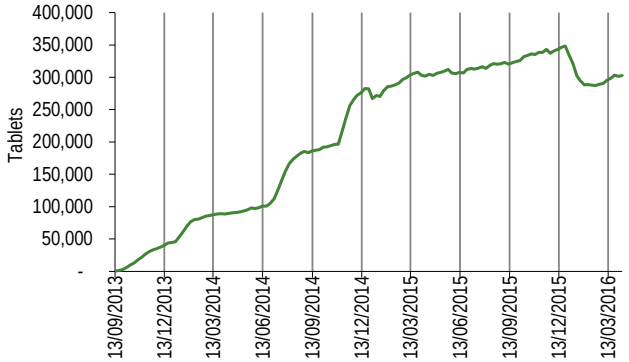
Edison profile page

Maintaining flexibility ahead of market evolution

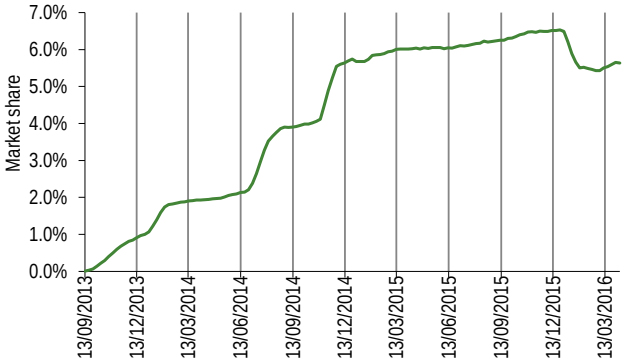
Orexo has navigated a challenging quarter when the anticipated effect of the CVS Caremark loss was keenly felt, reducing market share to 5.7% by volume vs 6.5% at end-Q415 (Exhibits 1 and 2). In line with guidance, this change in formulary status had a 15% negative effect on sales; although, positively, c 20-25% of CVS Caremark unrestricted business was retained. Overall, quarter-on-quarter Zubsolv sales fell from to SEK120.3m to SEK98.4m, with the key drivers shown in Exhibit 3. On a year-on-year basis, Zubsolv net sales growth of 4% resulted from the improved gross:net ratio, a price increase (a 5% rise implemented in February 2016) and increased mg/Rx (pricing is linear hence growth on a mg basis outstripped volume growth).

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



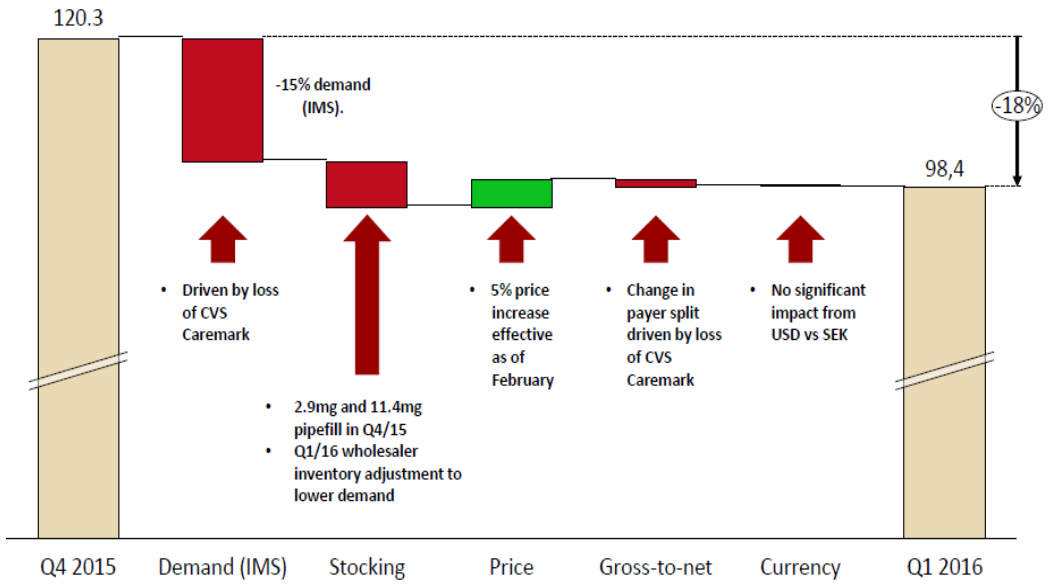
Source: Wolters Kluwer, Bloomberg. Note: Gridlines separate quarters.

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



Source: Wolters Kluwer, Bloomberg. Note: Gridlines separate quarters.

Exhibit 3: Zubsolv net revenue development Q415 vs Q116 (SEKm)



Source: Orexo IMS demand analysis

Orexo had positive cash flow from operations in Q116, which was underpinned by the enhanced focus on cost control (down 15% vs Q4). Priorities for management are revenue growth and balancing this with expenditure to achieve profitability. Our current forecasts suggest that the company is adequately financed to sustainability. In Exhibit 4, below, we highlight the key events in 2016 that will have a bearing on this strategy.

Exhibit 4: Orexo 2016 potential news flow

Programme	Timing	Event	Comments
Zubsolv (US)	Ongoing	Improvement in market access position	Priority to grow market share. Focus on Commercial (high profit) and managed Medicaid (associated with high prescribing physicians and significant volume).
	Mid-year	RESOLV study data	Fully recruited >1,000-pt registry study collecting real world data on what the important factors are in determining clinical outcomes. Data will be leveraged to capture market opportunities and inform the characterisation of a clinical approach and formal guidelines to guide treatment practice with Zubsolv.
	H216+	Federal initiatives	Proposals to increase patient cap and broader potential prescriber base, which would increase overall buprenorphine market: more patients would be able to be treated, and more new patients would seek therapy. Orexo maintains flexibility to increase investment into promotion once there is movement on a federal level.
	Q416	FDA approval of low dose	Sixth and final dose approval. Zubsolv has the broadest range of doses on the market. A variety of dose levels has compliance benefits and minimises diversion, and helps meet patient need for dose tapering.
Zubsolv (ex-US)	Q216	Partnership	Progress with a potential partner has been good, hence Orexo is hoping to finalise a deal in Q216. Ongoing PK bioequivalence study (as Suboxone tablets in Europe differ to those marketed in the US) to complete in H216 with potential for filing by year end.
OX-51	2016	Out-licensing deal for development and commercialisation	Open dialogue with interested parties; continuing assessment of right indication for Phase III development, which will inform the profile of the optimal partner.
Pipeline	H216	Disclosure of new development projects	Technical proof of principle achieved in a number of undisclosed early-stage drug delivery projects in addiction medicine. More detail to be shared when IP protection secured.
Corporate	12 July	Q216 results	Update on Zubsolv net revenues and sales initiatives.
	20 October	Q316 results	
Competitive landscape	Q216+	Ruling on Indivior patent infringement suits	Actavis and Par have filed ANDAs for generic buprenorphine/naloxone film with Indivior filing for patent infringement as 30-month stay has expired. No generic film is approved, but ruling could change the competitive landscape if it clears the way for potential new entrants mid-term.

Source: Edison Investment Research; Orexo

Orexo is dynamically managing its investment in its Zubsolv salesforce to ensure that it achieves a positive return. Future investment in promotional activities would rise as opportunities to gain market share become clearer; these include market access on a more localised level and legislative change nationally. Orexo is actively working to expand market access (which is a facilitator of growth) with a particular focus on increasing the number of patients with unrestricted access to Zubsolv (eg fee for service Medicaid) and continuing to grow the profitable cash and commercial segments (including securing restrictive contracts, provided they are profitable). On a federal level, changes to government policy have been proposed (outlined in more detail in the following section), which would represent new growth opportunities by expanding access to opioid dependence treatment through both current and new prescribers.

Current status of legislative proposals

Access to medically assisted treatment is an important contributing factor to the large treatment gap between the number of individuals diagnosed with opioid dependence and those that actually receive therapy. US policymakers are increasingly focusing on the issue, with three separate proposals to increase access to buprenorphine-based therapies for opioid addiction currently under consideration (Exhibit 5). These proposals outline two key changes to current regulations which would expand access to treatment: increasing the patient cap per physician, and increasing the number of potential prescribers to include nurse practitioners and physician assistants.

Exhibit 5: Proposals under consideration at US governmental level

	Proposal	Key access initiatives	Status
Administration	US Department of Health and Human Services (HHS)	Increase of patient cap to 200. Certified doctors must also provide patients with access to behavioural health services and implement a plan to prevent diversion. HHS can propose future adjustments if the revised cap is not sufficient to meet demand.	Support confirmed by The White House on 29 March 2016.
Senate committee	Comprehensive Addiction and Recovery Act (CARA), S.524	Increase of patient cap to 500, and expansion of prescribing authority to nurse practitioners and physicians' assistants.	Passed the Senate on 10 March 2016 by a vote of 94 to one.
House committee	Comprehensive Addiction and Recovery Act (CARA), H.R.953	Increase of patient cap to 250, and expansion of prescribing authority to nurse practitioners and physicians' assistants.	Pending.

Source: Edison Investment Research

At present, physicians are only permitted to prescribe buprenorphine to up to 100 patients after they have been certified for one year (in the first year of post-certification practice, the cap is 30 patients). This, coupled with the fact that only around 6,000 out of 30,000 certified physicians are active in treating opioid dependence, means that access to timely treatment is limited. Resultant waiting lists have serious implications for relapse, overdose or death. Increasing the patient cap from 100 to 200-500 (depending on the proposal) and authorising nurse practitioners and physician assistants to prescribe buprenorphine would reduce waiting lists and potentially provide an improved incentive for physicians to certify and start up addiction clinics. This would increase the overall market for buprenorphine therapies: more patients would be able to be treated, with an expectation that more new patients would seek therapy.

An important question remains with respect to the timing of any formal changes. Implementation of improved HHS guidelines could be imminent (Orexo anticipates that the first effects of this will be seen in H216), although the timetable for legislative change is less well-defined in Edison's view. In order to change legislation at a federal level, the relevant bills must be passed by both the Senate and the House prior to being signed by the president in order to be enacted in law. While opioid dependence is clearly a high-profile issue and has received bipartisan attention, its chance and timeline of passage are likely to also be determined by political considerations, not least because 2016 is an election year.

Nevertheless, if the goal of improving access to treatment is realised, it could significantly expand the current >$2bn US opioid dependence market. Access to treatment has increased linearly over the past decade; however, these federal initiatives would be an important inflection point in the growth trajectory, and while the impact will not be immediate, they serve to reinforce our long-term Zubsolv sales forecasts. Zubsolv is well-positioned to benefit. Data suggest a general trend towards Zubsolv taking greater share when the market is growing, with prescribing to new patients outweighing switching of existing patients; consequently any initiatives that result in increasing the proportion of new patients seeking treatment may provide Zubsolv with the opportunity to increase market share. Additionally, we note that the HHS proposal requires physicians to implement plans to reduce diversion; preferential prescribing of Zubsolv could form part of this due to its bioequivalence to Suboxone at a lower dose and decreased potential for abuse (lower street value).

Valuation

Our Orexo valuation has been updated to SEK4.31bn or SEK125/share (from SEK4.24bn or SEK123/share). Orexo's enhanced focus on cost control has prompted us to revise our 2016 expense expectations downwards; we also moderate our Zubsolv sales expectations in US dollar terms for the remainder of 2016 in anticipation of future legislative change and the impact that an election year may have on the timing of implementation. 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 SEK8.00/US$ (from SEK8.39/US$ when we last published our forecasts). We also roll forward our model to reflect the passage of time.

Exhibit 6: Zubsolv revenue assumptions to 2021

Assumption	2015	2016e	2017e	2018e	2019e	2020e	2021e
Zubsolv sales – pre-rebates ($m)	107.0	133	190	259	351	471	647
Zubsolv sales – post-rebates ($m)	51.9	64	95	142	210	306	421
Total Zubsolv sales – post-rebates (SEKm)	416.7	512.8	760.2	1,139.6	1,682.4	2,451.1	3,366.2
Total product sales (SEKm)	643.2	632.9	927.1	1,213.6	1,730.2	2,475.3	3,366.2

Source: Edison Investment Research, Orexo. Note: Assumes SEK8.00/$ FX rate, peak market share of 25% and average 35% rebate.

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.

Evidence of a growth step-up or the implementation of government plans to increase access to treatment could lead us to positively revise our Zubsolv forecasts. In addition, before securing partnerships that should clarify timelines, we do not explicitly value the ex-US Zubsolv opportunity (a partnering update is expected during Q215), nor OX51, which could both provide upside to our forecasts. Pipeline expansion would also represent a source of additional currently unquantified valuation upside.

Financials

Orexo's Q116 net revenues of SEK151m were up marginally on the same period in 2015 (Q115: SEK149m), but this masked a change in the revenue mix. Exhibit 7 details Orexo's Q116 revenue breakdown and our full-year per product estimates. Zubsolv revenues were the main contributor to revenues in both periods; in Q115, one-off Abstral milestones of c SEK35m were recognised, while in Q116, Orexo received a $5m (SEK40.8m) milestone from AstraZeneca in relation to option exercise to OX-CLI rights. Zubsolv Q116 net revenues were SEK98.4, up 4.1% compared to Q115 (SEK94.5m) and down 18.2% on Q415 (SEK120.3m).

Exhibit 7: Revenue breakdown per product (SEKm)

Revenue SEKm	Q116	Change on Q115	Old FY16e	New FY16e	Notes
Abstral royalties	8.2	+18.8%	98.4	106.2	Patent dispute settled with Actavis: US generic entry from June 2018 (or earlier under certain undisclosed conditions), ahead of the Sept 2019 patent expiry. Partnered with ProStrakan (Europe): 15% royalty on net sales >€42.5m; Sentynl (US rights acquired from Galena in Nov 2015): low double-digit royalty; Kyowa Hakko Kirin (Japan) single-digit royalty.
Abstral milestones	-	-100%	-	-	
Edluar royalties	3.6	-14%	13.9	13.9	Sold by Meda in the US, Canada and EU.
Zubsolv	98.4	+4.1%	577.6	512.8	CVS Caremark loss effect in Q116; 5% price rise to take effect in Q2.
Kibion	-	-100%	-	-	Divested 30 April 2015.
Total product revenue	151.0	+1.3%	689.9	632.9	
Other revenue	40.8	N/A	-	40.8	US$5m from AstraZeneca on option exercise (rights to OX-CLI)

Source: Edison Investment Research, Orexo

Core operating costs (excluding FX gains/losses) for Q116 were SEK140.9m, down 17% on Q415 (SEK169.9m), due to cost control across all line items. R&D spending fell from SEK56.1m to SEK45.0m as the RESOLV study nears conclusion and Zubsolv-related costs have fallen. Future Zubsolv R&D spending is expected in connection with ensuring the ex-US data package meets regulatory requirements. Other project-based R&D costs will be incurred in relation to new development programmes that will be disclosed once IP is secured. Adjustment of the field force to reflect Zubsolv's market access position helped reduced selling expenses by 15% to SEK60.8m vs SEK71.9m; Orexo will on an ongoing basis optimise sales force deployment and investment based on market conditions. Consequently, we believe that there could be more meaningful movement in future sales expenditure as legislative change would provide a market opportunity for Orexo to increase Zubsolv revenues, at which point we would expect further investment in sales infrastructure. Admin expenses, which include investment in the maintenance and protection of IP, were also lower at SEK35.1m vs SEK41.9m.

Management has provided cost guidance for Q216, but not for the second half of the year as Orexo is maintaining flexibility given the potential for increased investment in order to benefit from the impact of legislative change. Guidance for Q216 is for R&D spend of c SEK40m, sales expenses to remain broadly at the same level as Q116 (ie c SEK60m) and admin costs in the region of SEK35-40m. We have updated our model in line with new guidance; a summary is provided in Exhibit 9 overleaf, with the main changes to our forecasts presented in Exhibit 8.

Exhibit 8: Changes to estimates

	Revenue (SEKm)			PBT (SEKm)			EPS (SEK)		
	Old	New	Change	Old	New	Change	Old	New	Change
2016e	690	674	(2.3%)	(115)	(72)	37.4%	(3.2)	(2.0)	37.5%
2017e	957	927	(2.5%)	28	77	175%	0.6	1.6	167%

Source: Edison Investment Research. Note: SEK/US$ rate updated to 8.00 from 8.39.

Orexo's net debt at end March 2016 stood at SEK261.9m, with SEK233m of cash and equivalents. The company maintains a solid cash position, which has benefited from positive operating cash flow in Q116. Significant Zubsolv inventory (SEK382.5m 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.

Exhibit 9: Financial summary

SEK m	2014	2015	2016e	2017e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	570	643	674	927
Cost of Sales	(107)	(136)	(135)	(170)
Gross Profit	463	507	539	757
EBITDA	(13)	(88)	(41)	98
Operating Profit (before GW and except.)	(25)	(169)	(54)	92
Intangible Amortisation	0	0	0	0
Other	17	(65)	(4)	0
Exceptionals	0	0	0	0
Operating Profit	(25)	(169)	(54)	92
Net Interest	(28)	(22)	(18)	(15)
Other	0	0	0	0
Profit Before Tax (norm)	(53)	(191)	(72)	77
Profit Before Tax (IFRS)	(53)	(191)	(72)	77
Tax	(4)	(7)	4	(23)
Deferred tax	0	0	0	0
Profit After Tax (norm)	(57)	(198)	(68)	54
Profit After Tax (IFRS)	(57)	(198)	(68)	54
Average Number of Shares Outstanding (m)	34.3	34.6	34.6	34.6
EPS - normalised (ore)	(164.8)	(572.9)	(195.8)	155.3
EPS - IFRS (ore)	(1.6)	(5.7)	(2.0)	1.6
Dividend per share (ore)	0.0	0.0	0.0	0.0
Gross Margin (%)	81.2	78.8	80.0	81.7
EBITDA Margin (%)	(2.2)	(13.7)	(6.1)	10.5
Operating Margin (before GW and except.) (%)	(4.4)	(26.3)	(8.0)	9.9
BALANCE SHEET				
Fixed Assets	290	186	174	169
Intangible Assets	259	159	153	153
Tangible Assets	29	25	19	14
Other	1	2	1	1
Current Assets	936	830	810	886
Stocks	478	399	222	186
Debtors	174	233	166	229
Cash	285	198	421	471
Other	0	0	1	1
Current Liabilities	(268)	(252)	(293)	(310)
Creditors	(266)	(252)	(293)	(310)
Short term borrowings	(3)	0	0	0
Long Term Liabilities	(503)	(498)	(498)	(498)
Long term borrowings	(494)	(494)	(495)	(495)
Other long term liabilities	(9)	(4)	(3)	(3)
Net Assets	455	266	193	248
CASH FLOW				
Operating Cash Flow	(456)	(73)	233	72
Net Interest	(32)	(29)	(20)	(15)
Tax	0	0	(2)	(6)
Capex	(72)	(4)	(1)	(1)
Acquisitions/disposals	0	22	11	0
Financing	342	4	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(217)	(81)	221	50
Opening net debt/(cash)	135	212	296	74
HP finance leases initiated	0	0	0	0
Exchange rate movements	2	5	(2)	0
Other	139	(8)	3	0
Closing net debt/(cash)	212	296	74	24

Source: Edison Investment Research, Orexo accounts

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