EDISON

Orexo

Q2 results

Margins, Maryland and Mundipharma

Pharma & biotech

Orexo's Q216 results pointed to positive Zubsolv momentum with evidence of net revenue growth, improving margins and encouraging market access developments. Financial discipline contributed to a Q216 SEK12.1m operating profit and a second successive quarter of positive operating cash flow. The new Maryland FFS Medicaid agreement should help boost Zubsolv's penetration into the public market segment and ongoing expansion in US prescribing rights will be a key growth driver longer term. Ex-US, the recent Mundipharma licensing deal provides access to the global opioid dependence market. In the near term, however, uncertainty due to the ongoing Actavis litigation weighs on the current share price.

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.

Positive developments for Zubsolv and the US market

The Maryland FFS agreement makes Zubsolv the exclusive preferred product on the Maryland state formulary from July. The HHS increase of the patient cap (to 275 from 100) and Congress passage of the Comprehensive Addiction and Recovery Act 2016 (enactment into law is pending presidential signature) means that legislative changes to increase access to treatment become increasingly tangible.

Financials: Positive operating cash flow in H116

Growth in all products underpinned a 49% increase in Q216 revenue (SEK188.2m) vs Q215; Zubsolv net sales were SEK112.8m (Q215: SEK91.1m). The €7m (SEK65.4m) Mundipharma upfront was booked in Q216. Zubsolv gross margin improved: 70% in Q216 vs 60% in Q215 (67% in Q116). Q2 costs were as guided, albeit the split differed (admin higher due to legal costs). H2 cost guidance is for R&D of SEK80m, sales expense of SEK80m and admin in line with H1. Inventory release and c SEK75-80m of Mundipharma receivables should contribute to H216 positive operating cash flow.

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

Our updated valuation of SEK5.13bn or SEK149/share (previously SEK4.31bn or SEK125/share) reflects the impact of new H216 cost guidance (+SEK9/share), updated FX rates (+SEK12/share) and inclusion of Europe Zubsolv revenues (+SEK3/share) assuming launch in late-2018, conservative €100m peak sales and a 10% net royalty. We do not include potential Mundipharma milestones as their magnitude and timing are undisclosed. We maintain our US Zubsolv forecasts, however, the SEK value of these has moved with FX rates. 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 development.

10 August 2016

Price	**SEK52.5**
Market cap	**SEK1,817m**
	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

%	1m	3m	12m
Abs	(6.3)	12.9	6.3
Rel (local)	(12.2)	5.8	11.5
52-week high/low	SEK74.0	SEK42.0	

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. Mundipharma holds a licence to global ex-US Zubsolv rights.

Next events

Final RESOLV study results	August
Q316 results	20 October
Actavis ANDA 30-month stay expires	November
Zubsolv: potential EMA filing by Mundipharma	Q416/Q117

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Update: Steps in the right direction

Orexo's Q216 results provided further evidence of positive Zubsolv momentum with encouraging trends in net revenue growth as the 5% price rise had its first full quarter of impact, coupled with decreasing COGS, and a key market access win in the public segment. Costs were in line with guidance, although the split differed: the Mundipharma deal lowered R&D spend, which was offset by higher than expected admin costs incurred in relation to the IP infringement case against Actavis. Uncertainty about the outcome of this litigation, in our view, has dampened recent share price performance. However, Orexo management remains confident on the validity of all the five patents pertaining to Zubsolv, the last of which expires in 2032. With the completion of the court hearing and the expiry of Actavis's 30-month stay in November, a court decision is expected in H216. We provide further discussion in the Sensitivities section below.

The main body of this report focuses on three important recent developments, which should drive future Zubsolv revenue growth and potentially also market share gains in the US.

- **The Mundipharma ex-US global licensing deal**: access to the global opioid dependence market is a key growth driver for Orexo and this deal opens up the ex-US Zubsolv opportunity. At this stage, pending further disclosures, we include a modest contribution for Europe.
- **US legislative changes:** legislative changes increasing access to treatment should positively increase the overall market and potentially also Zubsolv's market share as greater gains have been captured in growing markets. These initiatives include the US Department of Health and Human Services' (HHS) increase to the patient cap (to 275 from 100) and Congress passage of the Comprehensive Addiction and Recovery Act.
- **Exclusive preferred status at Maryland FFS Medicaid**: Zubsolv's penetration into the public segment has historically lagged that of the more profitable commercial and cash segments. However, increased penetration into the public segment is important in driving volumes, and while rebating decreases the gross:net ratio, implementation investment is limited.

Mundipharma to take Zubsolv global

In line with guidance for a Q216 deal, in June Orexo out-licensed exclusive global ex-US Zubsolv rights to Mundipharma in exchange for a €7m upfront payment (received in Q216) and further undisclosed economics. Deal terms include regulatory and commercial milestones and up to low double-digit net sales royalties. Orexo will also be reimbursed for specific expenses incurred in relation for preparatory work required ahead of Zubsolv commercialisation ex-US (we assume this includes the cost of the ongoing European bioequivalence trial). Responsibility for filing and launch of Zubsolv now rests with Mundipharma.

Access to the global opioid dependence market is a key growth driver for Orexo; this deal expands access to the Zubsolv market opportunity, which in turn has the potential to significantly grow Orexo's revenues and also improve gross margins as Zubsolv production volumes increase.

A global pain player with a focus on therapy for abuse and addiction

Pain is a key franchise for Mundipharma, a network of independent companies with a presence in 48 countries. Its broad reach, coupled to the fragmented nature of the ex-US market, particularly in Europe, means that Mundipharma is well positioned. Mundipharma has focused significant research resources on opioid dependence, abuse and substitution therapy; hence Zubsolv is a complementary product that also has potential to address the continuing pain opioid dependence market segment.

Mundipharma will work with Orexo to complete the PK bioequivalence study that Orexo began in Q116 and which was previously guided to complete in H216. This study is required to support the EMA filing as Suboxone tablets marketed in Europe differ to those approved in the US. Bioequivalence data from this study, and/or from the US study, which underpinned Zubsolv's FDA approval, can be used as part of the regulatory package in various other territories. Regulatory filings in additional territories are planned, although no guidance has been provided with respect to timelines. Given that Suboxone tablets have data exclusivity into late 2016 in Europe, the earliest a Zubsolv EMA filing could take place would be around year-end. Consequently, we would anticipate first launches in 2018, although timelines would be contingent on completion of reimbursement decisions, which have varied timelines in different EU member states.

Quantifying the ex-US opportunity

According to the United Nations Office on Drugs and Crime (UNODC) 2015 World Drug Report, global prevalence of opioid use is c 32.4 million users (Exhibit 1), with 16.5 million of these using opiates. Opioids include all compounds (natural and synthetic) that act on opioid receptors, while opiates are the subset of drugs derived from opium. The majority (c 12 million) of opioid users in North America are in the US, but Asia (12 million) and Europe (4.6 million) also represent significant markets in absolute terms, while high prevalence in Oceania suggests unmet need.

Exhibit 1: Annual prevalence of opioid use

Region or sub-region	Opioids (opiates and prescription opioids)					
	Number (thousands)			Prevalence (%)		
	Best estimate	Lower	Upper	Best estimate	Lower	Upper
Africa	1,980	920	3,230	0.3	0.2	0.5
Americas	13,000	12,790	13,260	2.0	2.0	2.1
Asia	12,140	9,190	15,650	0.4	0.3	0.5
Europe	4,570	4,500	4,670	0.8	0.8	0.8
Oceania	730	590	750	2.9	2.4	3.0
Global estimate	**32,420**	**27,990**	**37,560**	**0.7**	**0.6**	**0.8**

Source: Edison Investment Research, adapted from UNODC estimates, World Drug Report 2015

Overall, the potential ex-US patient pool is c 5x larger than in the US, with c 20 million individuals afflicted by opioid dependence. International markets lag the US in terms of development, but in common with the US, only a small proportion of dependent individuals are diagnosed internationally, with even a smaller proportion treated. Hence there is opportunity to develop and grow the market for medical-assisted treatment for opioid dependence.

This report focuses on the European opportunity as timelines for Zubsolv are clearest. However, we acknowledge that China and Australia/New Zealand – regions where Mundipharma has a presence – could be important markets for Zubsolv longer term. Addiction is mainly to opiates in China, and in the coming years Indivior is seeking entry into this market; latest disclosures indicate that approval for Suboxone tablets could come in late 2018 with approval of Suboxone film following a year later. In Australia and New Zealand opioid dependence largely results from misuse of prescription opioids; this market opportunity could be nearer term. In September 2013, Suboxone tablets (approved 2005) were discontinued in Australia; US Zubsolv bioequivalence data would apply.

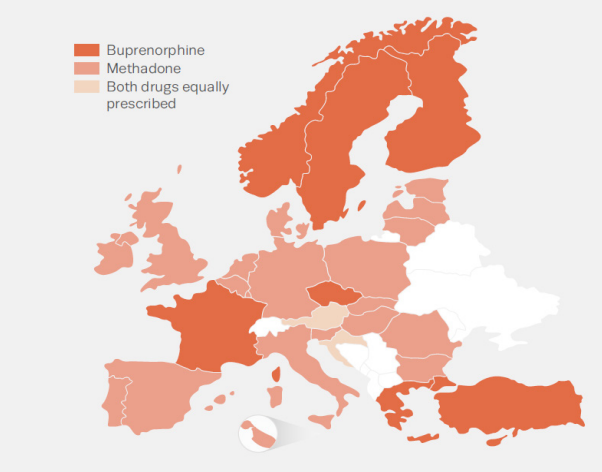
Focus on the European opioid dependence market

Latest figures from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) estimate that there were roughly 1.3 million high risk opioid users, of which, in 2014, 644,000 received substitution treatment in the EU (with Norway and Turkey representing another 36,000), a similar figure to the number receiving buprenorphine treatment in the US. This is a lower number than prior years (c 700,000 in 2013), which continues a downward trend since 2010. Five countries (France, UK, Germany, Italy and Spain) account for c 80% of patients receiving substitution therapy.

Across Europe, methadone remains the most commonly prescribed opioid substitution drug (61%) with buprenorphine, either singly or in combination, accounting for 37% of prescriptions. The share of buprenorphine-derived drugs has been increasing (28% in 2013), reflecting the ability of GPs (office-based physicians) to prescribe buprenorphine as well as specialist substance abuse clinics, which are the primary prescribers of methadone, and potential benefits over methadone. The latter include the longer half-life of buprenorphine, lower dosing frequency and abuse potential, ceiling effects limiting overdose risk and milder withdrawal symptoms.

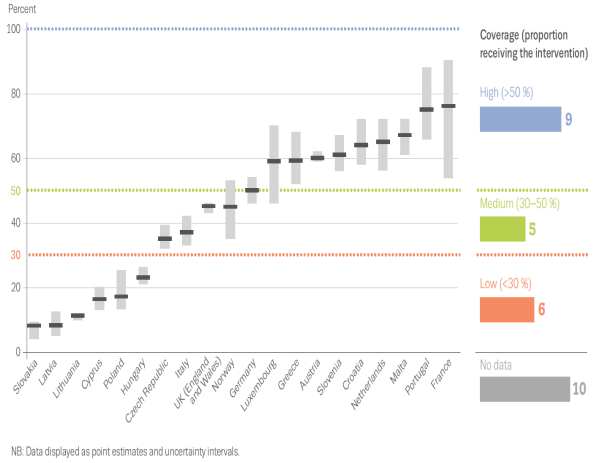
The EMCDDA (European Drug Report 2016: Trends and Developments) estimates that overall around 50% of high risk users received substitution therapy in Europe. However, there are important geographic differences between countries in the preferred drug for substitution treatment (Exhibit 2) and the percentage of opioid users receiving substitution treatment (Exhibit 3).

Exhibit 2: Principal opioid substitution drug prescribed by European country



Source: European Drug Report 2016: Trends and Developments

Exhibit 3: Estimated percentage of high risk opioid users receiving substitution treatment



Source: European Drug Report 2016: Trends and Developments

Europe is a heterogeneous market with differences in the prevalence of opioid users and opioid dependent individuals, access to substitution therapy (at the extreme end, it is illegal in Russia) and the preferred treatment modality. Nevertheless, with a significant unrecognised and undertreated patient population, there is an opportunity to increase penetration of substitution therapy through increasing awareness. At this stage, the key uncertainties relevant to Zubsolv are:

- **Market entry strategy**: the market(s) that Mundipharma seeks to enter first will have implications for reference pricing in other European countries.
- **Pricing and reimbursement environment**: opioid substitution therapy in Europe is largely government funded; with increasing price sensitivity and implementation of austerity measures in the major EU markets there is a focus towards cost containment without compromising access and quality of treatment.
- **Perception of Zubsolv clinical attributes**: various clinical features of Zubsolv (eg faster dissolve time, improved taste/mouth feel, preference data over Suboxone and lower abuse potential) may have an influence on prescribers, payer decisions and patient compliance.

  For example, administrative/labour costs represent a significant proportion of the cost of treatment, so a fast dissolve time could minimise the supervision time needed for a nurse to administer a buprenorphine/naloxone tablet. This may also support a price premium under value-based pricing as it would be offset by significant operational efficiency improvements of treatment clinics (ie savings in labour costs and time, allowing more patients to be treated).
- **Wider market evolution post generic entry**: Suboxone tablets, currently the only product with marketing exclusivity (until end-2016), are more expensive than other generically available

treatment options. The overall gross price of Suboxone tablets in Europe is significantly lower than in the US; however, in the current reimbursement environment, net prices are comparable. At present, it is unclear how the potential impact of Suboxone generics (as well as Zubsolv launch) will affect the market in terms of prescribing trends/the treatment paradigm (eg will there be a shift in preferred first-line therapy) and market evolution with respect to pricing and reimbursement and perception of abuse potential. Longer term, new branded entrants – buprenorphine depot formulations for injection and potentially Suboxone film – may stimulate further evolution.

US: Narrowing the treatment access gap

The US Department of Health and Human Services (HHS) has officially increased the patient cap that limits the number of patients to which certified physicians can prescribe buprenorphine from 100 to 275, effective 1 August. Currently, approximately 33,600 physicians are waivered to prescribe buprenorphine. Of these, two-thirds are in the first year of post-certification practice and thus are limited to treating 30 patients; the remaining third are permitted to treat 100 patients, which will rise to 275 from August. However, only around 6,000 of these certified physicians are active in treating opioid dependence.

According to data from the HHS and the White House Office of National Drug Control Policy c 650,000 individuals were prescribed buprenorphine in the US in 2014; the increased cap potentially enables an additional 90,000 patients to gain access to treatment. This is a welcome move by the HHS which has a number of immediate and longer-term impacts, including:

- Reducing a key barrier to accessing treatment: due to the patient cap, in many regions of the US it is difficult to find a qualified physician who can provide timely treatment.
- Potentially encouraging more physicians to seek board certification[1] and waivering: this would further improve access to treatment.
- Potentially decreases the potential for diversion: high demand for and low access to medically assisted treatment supports a black market, increasing the risk of diversion and exposure to an environment where addiction is prolonged.

The increased cap is a first step towards legislative changes at the federal level to increase access to medically assisted treatment of opioid dependence: other initiatives are summarised in our May 2016 Update note Putting CVS Caremark in the past. Since then, Congress has passed the Comprehensive Addiction and Recovery Act of 2016, which is now pending signature by the US president to become law. A key feature of CARA 2016 is the expansion of prescribing authority to nurse practitioners and physicians' assistants; coupled with the increase in the patient cap to 275 this should reduce waiting lists and potentially provide an improved incentive for physicians to certify and start up addiction clinics. These initiatives 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.

We expect the initial impact of the HHS change to be felt from end-Q316 reflecting the administrative lead time for physicians to receive sign off to increase their patient cap; however, this should have increasing momentum, especially once CARA 2016 is enacted into law. These changes should support the continued growth in sales and market share of Zubsolv.

Maryland FFS agreement to increase public penetration

The Maryland FFS (fee-for-service) Medicaid agreement makes Zubsolv the exclusive preferred product on the Maryland state formulary from 1 July, which should help boost Zubsolv's penetration

[1] Certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties

of the public market segment. To date, Zubsolv penetration into the more profitable commercial (41% of total market and 57% of Zubsolv business in June) and cash segments (17% and 16% respectively) has been higher, with the public segment lagging by comparison (42% of total market, 27% of Zubsolv business).

Securing this agreement is significant as Maryland is the largest FFS Medicaid state in the US with c 1.3% overall market share by value, and this decision reflects the Maryland Pharmaceutical and Therapeutics Committee favourable assessment of Zubsolv's clinical characteristics and supporting data as well as the competitive rebate offered. As this same data will be presented as part of RFPs at other Medicaid providers, additional FFS agreements may be forthcoming in the near to medium term. We note that these public payer agreements are typically reviewed annually (vs the two-year contracts that are common in the commercial segment) and there is an opportunity cost to the payer to switching preferred products regularly.

In June 2016, Orexo had access to 39% of business in the public segment; the Maryland FFS deal should increase this. Nevertheless, from prior experience and the fact that other opioid dependence products will remain available (requiring prior authorisation), Orexo does not expect to capture all of the Maryland business. Any incremental market share gains will be important in driving volumes (with corresponding COGS improvements) and while increased rebates will decrease the overall gross:net ratio, implementation investment is limited.

Sensitivities

Orexo is subject to various sensitivities common to speciality pharmaceutical companies, including commercialisation, manufacturing and financing risks. Execution risk is a key sensitivity in relation to Zubsolv: the outcome of reimbursement discussions, impact of physician education initiatives and the evolving competitive landscape could have a significant bearing on Zubsolv's US sales trajectory, peak sales potential and ultimate market share gains. Various factors could affect our valuation, either through their influence on Zubsolv's market penetration (eg reimbursement, pricing and competition) or on operating margins (cost of promotion, revenue split between commercial and public plans, level of rebates).

The key near-term sensitivity is the outcome of the Actavis patent infringement suit with respect to Zubsolv. Actavis is the first and so far only company to file an ANDA for Zubsolv generic, submitted to the FDA in June 2014; Orexo subsequently sued for patent infringement, covering the five patents listed in the Orange Book (the earliest and latest expiries of which are in September 2019 and September 2032 respectively). The 30-month Hatch-Waxman stay expires in November 2016 and the court ruling is pending following completion of the trial in June 2016. The worst-case scenario, assuming all patents are deemed invalid, could see imminent launch of an Actavis generic, whereby Orexo's marketing strategy would need to shift to that of a branded generic product: Zubsolv's peak sales opportunity may be lower, but this would be offset by a lower cost of promotion. The best-case scenario would preclude Actavis from launching its product until expiry of the last of the Zubsolv patents upheld by the court; a favourable ruling would also strengthen Orexo's IP situation, as any future ANDA filing(s) would have to target other patent claims.

In the rest of the world, the opioid dependence market is fragmented and Mundipharma will determine the markets in which Zubsolv registration is sought. At this stage, the timetable for Zubsolv commercialisation is unclear: Mundipharma has not disclosed its plans, or the precise economics that may potentially be due to Orexo. We highlight that the approval, reimbursement and launch timelines of pharmaceuticals products ex-US vary geographically. Finally, a partnering deal for OX51 and unveiling of the earlier-stage development pipeline could unlock further upside.

Valuation

We have included the impact of the Mundipharma deal, which increases our Orexo valuation to SEK5.13bn or SEK149/share (vs SEK4.31bn or SEK125/share previously). Aside from rolling forward our model to reflect the passage of time, the main changes to our model are:

- new H216 expense guidance: +SEK9/share;
- updated FX rate to SEK8.57/US$ (from SEK8.00/US$): +SEK12/share; and
- inclusion of European Zubsolv opportunity: +SEK3/share.

We maintain our Zubsolv forecasts in US dollar terms for 2017 and beyond; however, the SEK value of these has altered due to updating our model with the current SEK/US$ rate. Our key assumptions for the European Zubsolv opportunity are for launch in late-2018; sales of c €60m in year six, with peak sales of €100m (20% share of a conservative €500m market growing at 2% pa); and a net royalty of 10%. As the magnitude and timing of milestones from Mundipharma are undisclosed, these are not captured in Exhibit 4 or our full model; nevertheless, we would expect milestones to become due on approval/launch in key territories.

Exhibit 4: Zubsolv revenue assumptions to 2021

Assumption	2015	2016e	2017e	2018e	2019e	2020e	2021e
US Zubsolv sales – pre-rebates ($m)	107.0	133	190	259	351	471	647
US Zubsolv sales – post-rebates ($m)	51.9	64	95	142	210	306	421
Total US Zubsolv sales – post-rebates (SEKm)	**416.7**	**531.3**	**815.2**	**1,222.1**	**1,804.2**	**2,628.6**	**3,609.9**
European Zubsolv sales – pre-rebates (€m)				1.3	6.5	13.3	20.3
European Zubsolv sales – post-rebates (€m)				0.8	4.2	9.3	15.2
Total European Zubsolv sales – post-rebates (SEKm)				7.3	40.1	88.0	144.3
Total European Zubsolv net royalty (SEKm)				**0.7**	**4.0**	**8.8**	**14.4**
Total Zubsolv revenues – post-rebates (SEKm)	**416.7**	**531.3**	**815.2**	**1,222.8**	**1,808.2**	**2,637.4**	**3,624.4**
Total product sales (SEKm)	**643.2**	**646.8**	**989.4**	**1,300.3**	**1,858.0**	**2,662.1**	**3,624.4**

Source: Edison Investment Research, Orexo. Note: In the US, assumes SEK8.57/$ FX rate, peak market share of 25% and average 35% rebate. In Europe, SEK9.48/€, peak market share of 20% and average 20% 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 following implementation of new US legalisation to increase access to treatment could lead us to positively revise our Zubsolv forecasts. Post the Mundipharma licensing deal, we include potential European royalties in our valuation, but do not capture potential milestones which are undisclosed. In addition, we do not explicitly value the RoW opportunity (ex-US, ex-Europe) until Mundipharma discloses its intention and there is more clarity on timelines; we recognise that this could provide upside to our forecasts. Securing a partnership and defining the indication for OX51 could also unlock valuation upside, as would pipeline expansion.

Financials

Orexo's Q216 net revenues of SEK188.2m were up 49% on Q215 (SEK126.5m), reflecting growth across the product portfolio. Both periods included non-recurring revenues: SEK65.4m in relation to the €7m Mundipharma upfront in Q216, with SEK22.5m in Q215 from the Abstral fixed royalty. Exhibit 5 provides a revenue breakdown for the period and our full-year per product estimates.

Decreasing COGS of SEK33.9m in Q216 vs SEK36.4m in Q215 also points to an improving Zubsolv gross margin: 70% vs 60% in the year earlier period, and 67% in Q116.

Exhibit 5: Revenue breakdown per product (SEKm)

Revenue SEKm	Q216	Change on Q215	Old FY16e	New FY16e	Notes
Abstral royalties	5.4	+2%	106.2	101.6	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; Sentynl (acquired US rights from Galena in Nov 2015): low double-digit royalty; Kyowa Hakko Kirin (Japan) single-digit royalty.
Abstral milestones	-	N/A	-	-	
Edluar royalties	4.5	+36%	13.9	13.9	Sold by Meda in the US, Canada and EU.
Zubsolv	112.8	+24%	512.8	531.3	Q2 is first full quarter to be impacted by 5% price rise from February 2016. Main patent to 2032.
Zubsolv ex-US upfront	65.4	N/A	-	65.4	€7m received in June 2016 from Mundipharma in exchange for exclusive ex-US global licence.
Kibion	-	-100%	-	-	Divested 30 April 2015.
Total product revenue	**188.2**	**+149%**	**632.9**	**716.6**	
Other revenue	40.8	N/A	40.8	40.8	US$5m from AstraZeneca on option exercise (rights to OX-CLI).

Source: Edison Investment Research, Orexo

Total operating costs for Q216 were in line with Orexo guidance, although the split differed. Admin expenses of SEK62.7m (Q215: SEK33.1m) were higher, and R&D costs of SEK28.7m (Q215: SEK38.1m) were lower than expected (SEK40m). This reflects higher than anticipated costs in relation to the Zubsolv patent infringement case against Actavis (admin), and the impact of the Mundipharma licence agreement whereby costs previously incurred by Orexo for preparatory work for ex-US filings would be reimbursed (R&D). Sales expenses of SEK56.4m (Q215: SEK81.7m), however, were broadly in line with guidance.

Operating profit for Q216 was SEK12.1m, up from a loss of SEK77.3m in Q215, with PBT of SEK6.6m vs an SEK83m loss (Q215).

Management guidance for H216 is for sales expenditure in line with H116 (ie c SEK117m), and SEK80m in both R&D spend and admin costs. Nevertheless, this is caveated with Orexo's stated intention of managing its sales investment dynamically (ie optimising sales force deployment and investment based on market conditions) particularly given the potential for increased investment in order to benefit from the impact of legislative change. In addition, the level of cost of the Actavis IP suit remains uncertain: the 30-month stay expires in November.

We have updated our model to incorporate Q216 results, new guidance and updated FX rates; a summary is provided in Exhibit 7 overleaf, with the key forecast changes shown in Exhibit 6.

Exhibit 6: Changes to estimates

	Revenue (SEKm)			PBT (SEKm)			EPS (SEK)		
	Old	New	Change	Old	New	Change	Old	New	Change
2016e	674	753	12%	(72)	25	61%	(2.0)	0.5	70%
2017e	927	989	7%	77	137	78%	1.6	2.2	38%

Source: Edison Investment Research. Note: SEK/US$ rate updated to 8.57 from 8.00.

Net debt at end June 2016 stood at SEK242.6m, with SEK252.9m of cash and equivalents. Orexo reported positive operating cash flow for Q116 and Q216 (SEK22.5m and SEK20m, respectively). Q316 cash flow will benefit from the inflow of c SEK75-80m of receivables from Mundipharma related to the €7m upfront payment and R&D reimbursements. Furthermore, significant Zubsolv inventory (SEK379.5m in raw material and finished product) will continue to contribute to improving future cash flow generation from operations.

Exhibit 7: Financial summary

SEKm	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 (SEK)	(1.6)	(5.7)	0.5	2.2
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: Edison Investment Research, company accounts

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