EDISON

Orexo

Preliminary results

2014: Focused on further delivery

Pharma & biotech

Zubsolv has captured 1.9% market share (by volume) in the first 18 weeks since launch. Orexo is focused on maximising Zubsolv's commercial potential through further improvement in market access and lifecycle management. Securing reimbursement on par with competition (particularly at larger commercial payers) should drive near-term sales growth, and new clinical data could expand Zubsolv's current label and take market share from Reckitt Benckiser's Suboxone film (>80% market share). Management expects to obtain 25-30% market share within three years of launch. We value Orexo at SEK7.9bn (US$1.2bn).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/12	326	(77)	(2.5)	0.0	N/A	N/A
12/13	429	(109)	(3.6)	0.0	N/A	N/A
12/14e	701	(7)	(0.2)	0.0	N/A	N/A
12/15e	1,626	464	14.1	0.0	11.4	N/A

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

Zubsolv: Steady market share gains

Prescribing data shows steady growth in volumes and value: more physicians are prescribing Zubsolv, and writing longer prescriptions. The impact of Tier II status at CVS Caremark and Medimpact, and at other health plans, coupled to a 25% increase in the field force should start to be evident in Q1. Zubsolv is now available in over 13,000 pharmacies; promisingly, all wholesalers have reordered.

Opioid dependence: A growing market

The US buprenorphine/naloxone market was worth $1.9m at end-2013; continued double-digit is growth expected. The inclusion of addiction therapy as an essential benefit under the Affordable Care Act provides an obligation for insurer coverage. Physician and patient education should improve diagnosis/treatment rates and adherence. Earlier diagnosis could expand the number of treating physicians; access to treatment along with affordability is a significant bottleneck.

Financials: Investing in the foundations for growth

An EBIT loss of SEK139.7m reflected investment in infrastructure for Zubsolv launch and in R&D. Given high initial rebating and conservative revenue recognition tying revenues to prescriptions, wholesalers' stocking of SEK70m (gross sales value) translated into recognition of SEK7.3m of net Zubsolv sales. Introduction of a high-scale manufacturing proces should improve COGS from late-2014/early2015.

Valuation: SEK7.9bn ($1.2bn or $37/share)

Recent market growth has increased our DCF-based valuation to SEK7.9bn or SEK239/share (previously SEK6.7bn, SEK203/share), assuming a 25% peak market share and average 35% rebate. At this early stage in the launch, uncertainty over the profile of Zubsolv's trajectory remains.

10 February 2014

Price	**SEK161.00**
Market cap	**SEK5,297m**
	SEK6.45/US$
Net debt (SEKm) FY13	136
Shares in issue	32.9m
Free float	N/A
Code	ORX
Primary exchange	NASDAQ OMX Stockholm
Secondary exchange	US OTC

Share price performance

%	1m	3m	12m
Abs	(5.3)	13.2	190.1
Rel (local)	(4.6)	9.8	149.9
52-week high/low	SEK182.0	SEK48.7	

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 Zubsolv). It has three marketed drugs, two diagnostics and multiple commercial/research partnerships.

Next events

Zubsolv reimbursement decisions	H114
Zubsolv clinical data at ASAM	10-13 April 2014
Q114 results	25 April 2014
Launch of potential line extensions	Q314

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Orexo datasheet

Exhibit 1: Zubsolv SWOT analysis

Strengths	Weaknesses
■ **Bioequivalent to Suboxone**, but at a **lower buprenorphine dose**. ■ **Formulation expertise**: accelerated disintegration time, reduced tablet size, improved taste and mouth feel. Generics have similar composition to Suboxone tablet and the same actively disliked citrus taste. ■ **Preference data**: comparator data vs Suboxone (tablet and film) presented at ASAM 2013. ■ **Lower abuse potential than alternatives**: contains less buprenorphine (5.7mg or 1.4mg) than Suboxone film (8mg or 2mg) and has a higher class of child-resistant packaging (F1 vs F2). Generic tablets have highest abuse potential (supplied in a bulk tablet bottle). Diversion with Suboxone could be payer driver for reimbursement. ■ **Only branded product covered by CVS Caremark and Medimpact** restricted plans. ■ **Limited imminent competition from new therapies**: the FDA rejected Titan's Probuphine buprenorphine implant; Reckitt Benckiser is suing BDIS and IntelGenX/Par Pharmaceuticals for patent infringement.	■ **Current reimbursement:** improved coverage at major commercial plans and public plans expected H114. Parity to Suboxone targeted. Level of patient co-pay (ie the out-of-pocket expense paid by a patient) is important. ■ **Prescriber caution:** patient experience is key. Physicians want to get own experience and prescribe initially to a small number of patients. ■ **Resistance to switching by doctors:** there is little switching, particularly in the case of well-treated patients. ■ **Different dosing to Suboxone:** despite identical bioavailability, the perception barrier needs to be overcome for patients to accept switching and be confident in efficacy. ■ **Pricing:** currently at a lower price to generics and on par with Suboxone film, as it has no proven clinical advantage (should be addressed by ongoing studies). ■ **Launch hurdles:** need to build brand and infrastructure support for prescribers and payers (make it easier to treat opioid dependence).
Opportunities	**Threats**
■ **Underserved and dynamic market**: only 2m of the estimated 5m opioid-dependent individuals are currently diagnosed, and of these, 750,000 are treated. 25% patient turnover by quarter; average 6 months on therapy. ■ **Label extension**: if induction is approved, Zubsolv would have a proven clinical advantage over Suboxone, supporting premium pricing. ■ **Lifecycle initiatives:** new dosages, new flavours/tastes. ■ **Potential to develop treatment paradigm:** research into treatment guidelines/documentation; tapering off (lowering dose); early identification of pain patients likely to become opioid dependent. ■ **Addressing the cause**: dependence mainly results from high-dose pain relief; buprenorphine is an effective analgesic, thus has the potential to assist in decreasing dose of other opioids, helping to bypass dependence; potential to improve documentation to address the continuing pain part of the market. ■ **Government policy:** addiction medicine is a focus area; addiction treatment classed as 'essential benefit' under the Affordable Care Act; a petition has also been raised to increase the patient cap to shorten treatment waiting lists. ■ **Other territories (in particular Europe and China)**: opioid addiction is a developed country problem. Growth is driven by increased/liberal prescription of opioids for pain relief and illegal opioid abuse.	■ **Strength of Suboxone brand**: high brand recognition with Suboxone, and the brand name is used interchangeably with generics. ■ **Patient and physician loyalty to Suboxone** (and Reckitt Benckiser): Reckitt Benckiser was instrumental in building awareness, developing and initially funding the opioid dependence treatment market. ■ **Uncertainty over future of Reckitt Benckiser's pharma division**: the company is reportedly examining various options for this division including sale, spin off or retention. The outcome of Reckitt Benckiser's decision may affect the investment it or a future owner will put behind promotion of Suboxone. ■ **Potential competition:** BDIS's Bunavail (bup/nal film), which has a 7 July 2014 PDUFA date. In addition, ANDAs for generic bup/nal film have been filed by IntelGenex/Par Pharmaceuticals (July 2013) and Actavis (November 2013).

Source: Edison Investment Research

Exhibit 2: Ongoing Zubsolv clinical studies

Study	Patients (n)	Design	Outcome
Induction (Study 007)	300	Phase III randomised active-controlled non-inferiority trial of Zubsolv for induction treatment of opioid dependence. Two-day induction on Zubsolv or buprenorphine sublingual tablets (blinded) before moving to open-label Zubsolv therapy for three to 28 days. Primary endpoint: treatment retention (proportion of pts in each arm completing the two-day induction phase and receiving treatment on day three). Results due: H114.	FDA filing to expand label to include induction as well as maintenance therapy: would support premium price. Buprenorphine monotherapy is the current standard of care for induction.
Switch (Study 006)	708	Phase III (Induction, STabilization, Adherence and Retention Trial: ISTART) randomised parallel group non-inferiority study to assess early treatment efficacy of Zubsolv vs Suboxone film (during first 15 days of treatment) and to explore switching. Primary endpoint: proportion of randomised subjects retained in treatment on day 15. Study completion: March 2014.	Improve understanding of treatment adherence, preference and switching. Provide clinical documentation to reinforce Zubsolv marketing message.
Long-term follow up (Study 008)	700	Phase IV multi-centre, open-label, single-arm, 24-wk, follow-up study to assess safety, efficacy and treatment adherence for maintenance treatment of opioid dependence with Zubsolv. Patients enrolled from 006 and 007 studies. Study completion: September 2014.	Improve understanding of treatment experience in real world patient setting. Inform design of future studies.

Source: Edison Investment Research, Clinicaltrials.gov, Orexo

Exhibit 3: Orexo marketed products

Product	Indication	Partners/notes
Zubsolv	Maintenance treatment of opioid dependence	Sold through Orexo's US commercial operation. Sublingual buprenorphine/naloxone tablet.
Abstral	Relief of breakthrough cancer pain	ProStrakan (EU/ RoW); Galena (US); Kyowa Hakko Kirin (Japan). Sublingual fentanyl tablet.
Edluar	Short-term insomnia	Meda (global). Sublingual zolpidem tablet.
Diabact UBT	Diagnostic breath test for *H. pylori*	Kyowa Hakko Kirin (Japan)
Heliprobe System	Diagnostic doctor's office tests for *H. Pylori*	-

Source: Edison Investment Research, Orexo

Update: 2014 – focused on further delivery

The US approval and launch of Zubsolv, Orexo's sublingual buprenorphine and naloxone (bup/nal) tablet for the maintenance treatment of opioid dependence, in 2013 marked the watershed in the company's transition to a fully integrated speciality pharmaceutical company. The focus in 2014 is to develop Zubsolv's commercial potential through further improvement of managed care coverage and execution in the lifecycle management programme. Securing competitive reimbursement – at least comparable to the competition – should drive future sales growth, and new clinical data later this year could expand Zubsolv's current label and take market share from the current market leader, Reckitt Benckiser's Suboxone film (>80% market share). The US bup/nal opioid dependence market was worth $1.9bn at end-2013; management expects to capture 25-30% of this market within three years of Zubsolv launch. We value Orexo at SEK7.9bn or SEK239/share ($1.2bn or $37/share), on account of the significant Zubsolv opportunity.

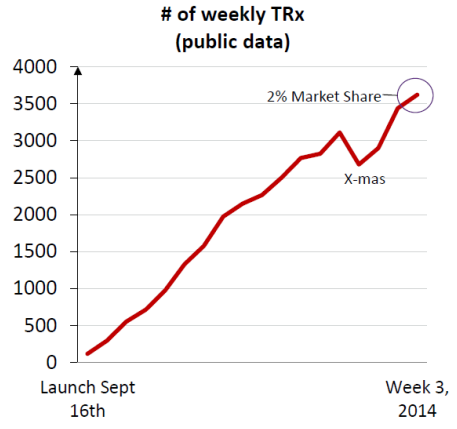
Orexo launched Zubsolv in the US in September 2013 through its own commercial infrastructure, and so far management is pleased with progress since launch. The launch period of a new drug is always a period of uncertainty, however, there have been a number of significant achievements in the first 18 weeks of Zubsolv's launch. Prescribing trends (both by volume and value) are on a positive trajectory. Progress is also being made with improving market access/reimbursement, despite the strength of the Suboxone brand and ongoing efforts by Reckitt Benckiser to protect its franchise through heightened field force efforts. Orexo has also established stable and scalable Zubsolv manufacturing in the US, which will reduce COGS in the next two to three years.

The US bup/nal opioid dependence market has also grown from $1.7bn at end-Q313 to $1.9bn at end-Q413 reflecting increased volumes. Growth drivers (unmet medical need) will be resilient for the foreseeable future; hence we now expect Zubsolv's peak sales potential could also be higher – $606m in 2016 pre-rebates (previously $542m) – through a combination of capturing market share and ongoing market growth. We also expect continued growth once 'peak' sales are achieved. Nevertheless, there remains uncertainty about the timing of peak sales – and the level of rebating/discounting – until the launch trajectory becomes more apparent.

Zubsolv launch and reimbursement progress

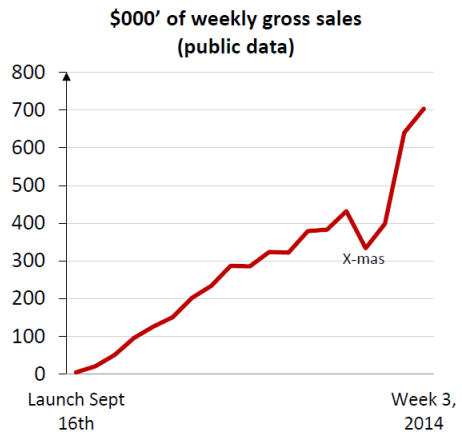
Since launch Zubsolv has shown consistent growth in prescribing trends by both volume and value (Exhibits 4 and 5), with the trajectory steepening in January. Market share by volume is now 1.9%.

Exhibit 4: Volume growth – total prescriptions (TRx)



Source: Orexo, Woulters Kluwer weekly data

Exhibit 5: Value growth – gross sales (pre-rebates)



Source: Orexo, Woulters Kluwer weekly data

The week-on-week increase in prescription trends has largely been steady. The dip over the Christmas period can be attributed to public holidays and adverse US weather conditions (clinics

closed due to snowstorms). Importantly, improved reimbursement and targeted sales led to a >60% upflift in gross sales in the first week of 2014 in part due to larger prescriptions being written. The volume of tablets sold in the first two weeks ofJanuary doubled. Average Zubsolv prescription size is now approaching that of competitors (30 doses/TRx) at 27 tablets/TRx from c 16 tablets/TRx at launch. This reflects continued prescribing of Zubsolv; patients are initially given a 15-day prescription, after which they undergo a urine screen before moving to the standard 30-day prescription. Orexo data indicates that c 2,000 doctors have now prescribed Zubsolv and most have continued writing prescriptions.

The increasing awareness of Zubsolv (40% of specialists at launch vs 92% now) driven by field promotion efforts is strongly correlated with increasing prescription volumes. Consequently, Orexo and its marketing partner, Publicis Touchpoint Solution (PTS), are expanding the 50-strong field force by 25% from late January. The focus remains on regions with the best market access position (ie where there are a high proportion of patients with favourable coverage/reimbursement); with the field force being moved as the market access situation improves. The initial target of the top 1,000 prescribers is also being broadened to the top 3,000.

Reimbursement is the key driver behind market share gains and co-pay levels are important for patients and so improved reimbursement for Zubsolv is vital for increased penetration. Parity with Suboxone film (Tier II status, $20-40 co-pay) in the majority of plans within one year of launch is targeted. Orexo has made significant progress on this front, securing listing with two large pharmacy benefit managers (PBMs), CVS Caremark and Medimpact (representing c 10% and c2% of the total bup/nal market respectively), effective 1 January 2014. With both PBMs, Zubsolv is the only branded product covered by restricted plans where it has Tier II status, though generics (Tier I, $0-10 co-pay) are also available. Over the course of 2014, it will become clearer whether switching is predominantly to generics (which saw a modest uptick) or to Zubsolv (affecting ultimate market share gain), but it is likely to accelerate the rate of Zubsolv prescriptions. Zubsolv has also secured Tier II status with several commercial and public health plans,[1] as well as for some large state Medicaid programmes (New York, New Jersey and Tennessee).

Further market access improvements are expected during 2014. Nearer-term, this is likely to be with larger players in the commercial sector; the move to parity with these should translate to an enhanced launch trajectory and market share gains this year. In addition, as market access improves/parity is achieved, existing patient support programmes (eg co-pay support cards and limited free samples) will become more restrictive, aligning with industry standards in 2014. These support programmes were established to ensure that patients were not financially penalised by filling their Zubsolv prescriptions as, at launch, Orexo had Tier III status ($50-75 patient co-pay) for c 70% of the bup/nal market. Discounting has impacted the gross:net prescription value ratio following initial launch; introduction of restrictions will improve the net sales value per prescription in the medium term. Longer-term, the gross to net ratio will depend on the mix of patients (ie cash vs commercial vs Medicaid coverage).

Market development and developing the market opportunity

Opioid dependence diagnosis and treatment rates are low due to a combination of factors, including social stigma, limited access to treatment in parts of the US (6,000 physicians actively treat opioid dependence, all have a 100-patient cap) and affordability (lack of financial coverage/insurance). Unmet patient need remains significant given that opioid dependence is a chronic relapsing condition; addressing this need underpins the expectation of continued double-digit market growth. The bup/nal market increased to $1.9m at the end of 2013. The inclusion of addiction treatment as one of 10 ‘essential health benefits’ under the Affordable Care Act should also have a positive

[1] Blue Cross Shield of Massachusetts, Optum Rx and University of Pittsburgh Medical Center Health Plan.

impact on access to treatment, given the significantly higher prevalence of addiction problems among uninsured, as insurance companies are obliged to cover essential health benefits.

Orexo's initial strategy is to capture market share through emphasising Zubsolv's formulation advantages[2] and preference data over Suboxone film; however, the potential target market could be larger as the 500,000 bup/nal treated patients currently only account for 10% of the opioid dependence market. Orexo intends to grow the Zubsolv opportunity through label expansion and lifecycle initiatives, and by further expanding the market.

Zubsolv is indicated as a maintenance therapy, competing against Suboxone film and two generic bup/nal tablets. It is priced in line with Suboxone; lower than generics. Three clinical studies are underway that should clinically differentiate Zubsolv over the competition. The first, an induction study, is fully recruited and is expected to render results in H114; positive data would form the basis for an FDA filing to expand the Zubsolv label to include induction as well as maintenance therapy. Approval of an induction label could support a premium price over Suboxone. The other studies, a switch study from Suboxone to demonstrate treatment adherence and preference, and a cohort study to understand real world treatment experience, continue to recruit patients and should read out from H214. Study data will be used to further reinforce the Zubsolv marketing message.

Physician and patient education is core to Orexo's market expansion strategy in order to improve diagnosis and treatment rates. Increased awareness of opioid dependent and treatment options should translate into (a) more physicians diagnosing and treating more patients, and (b) more patients seeking and adhering to treatment (dropout rates are high). The RISE patient support programme has been established as an education tool for potential patients. Orexo is also seeking to address documentation, policy and cost (coverage) issues to improve diagnosis and treatment rates. Areas of focus include the continuing pain part of the market as well as earlier treatment of patients, which, according to prescribers, substantially improves the chance of successful therapy. A move towards earlier diagnosis could expand the number of treating physicians (currently a significant bottleneck) as it would involve the primary care setting. At present, primary care represents the largest physician group although addiction specialists are the highest prescribing.

Orexo is also developing an expanded Zubsolv product offering by leveraging its formulation expertise and focusing on consumer preference. Extension products include broader dosages (to limit risk of diversion and meet patient need for tapering therapy) and new flavours to expand patient choice. The first new product is expected to be ready to launch in Q314, although the precise timing will be influenced by commercial factors. We note that extension products will benefit from better COGS as these will be manufactured under the new larger-scale process.

Valuation

Our updated Orexo model ascribes an increased company valuation of SEK7.9bn or SEK239 per share ($1.2bn or $37 per share) vs SEK6.7bn or SEK203 per share previously. This change is predominantly driven by recent growth in the bup/nal market (the gross market was valued at $1.9bn, before rebates and other deductions, at end-Q413 vs $1.7bn at end-Q313). We have also made minor changes to the model, including updating FY13 net debt to SEK136m, FX rates (now SEK6.45/$, SEK8.8/€ and SEK10.7/£), the number of shares outstanding and also rolling 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. Key Zubsolv revenue assumptions are shown in Exhibit 6, based on assumed peak market share of 25% and an average 35% rebate level.

[2] Accelerated dissolve time, smaller tablet size, improved taste/mouth feel, same buprenorphine bioavailability despite a lower dose.

Exhibit 6: Zubsolv revenue assumptions to 2020

Assumption	2014	2015	2016	2017	2018	2019	2020
Market size ($m)	2,128	2,341	2,551	2,756	2,948	3,125	3,282
Market growth rate	10%	10%	9%	8%	7%	6%	5%
% of peak market share	20%	61%	95%	100%	100%	100%	100%
Implied market share	5%	15%	24%	25%	25%	25%	25%
Zubsolv sales – pre rebates ($m)	105.2	348.1	606.0	688.9	737.1	781.3	820.4
Zubsolv sales – post rebates ($m)	68.4	226.3	393.9	447.8	479.1	507.9	533.3
Total Zubsolv sales – post rebates (SEKm)	440.9	1,459.4	2,540.5	2,888.2	3,090.4	3,275.8	3,439.6
Total product sales (SEKm)	700.7	1,625.9	2,680.8	3,067.8	3,295.2	3,490.2	3,658.8

Source: Edison Investment Research, Orexo. Note: Assumes SEK6.45/$ FX rate, peak market share of 25% and average 35% rebate.

We estimate gross margin of 85% on Zubsolv, with the operating margin trending to 50% in the long term. We model a significant increase in sales costs in FY15, when PTS begins to earn a greater share of Zubsolv profits. We include a modest revenue contribution from global Abstral royalties (taking into account respective deal structures with partners, including the fixed royalty receipts from ProStrakan) and the Kibion diagnostics business (growing 2% pa) until 2020, at which point we assume, for simplicity, that all revenues relate to Zubsolv. We do not explicitly value the ex-US Zubsolv opportunity, although Orexo is exploring regulatory pathway options in other markets.

Various factors could have an impact on our valuation, either through their influence on Zubsolv's market penetration (eg reimbursement, pricing and competition) or on operating margin (PTS pay-away/cost of promotion, revenue split between commercial and public plans, level of rebates). We emphasise that Zubsolv is still at an early stage in its launch and therefore there is a still a significant degree of uncertainty and operational risk surrounding the launch trajectory. However, more clarity is expected as the launch proceeds.

Sensitivities

Orexo is subject to various sensitivities common to speciality pharmaceutical companies, including commercialisation (pricing, reimbursement, uptake and competition), manufacturing and financing risks. The most important specific sensitivities, both on the upside and downside, relate to Zubsolv, which is currently early in its launch and is Orexo's main value driver.

Our valuation is based on our estimates for Zubsolv's net price (ie after co-pay or other discounts) and penetration, which we believe are reasonable. The outcome of reimbursement discussions with payers is a key near-term sensitivity, which will have a significant bearing on Zubsolv's sales trajectory and peak sales potential. Reimbursement status is a critical determinant of prescriber and patient uptake vs Suboxone and generics. A successful outcome in the ongoing clinical trials and approval of a label extension for induction therapy should support a higher price. However, unknown future pricing or competitive dynamics could also lead to a different price than our current assumption. The future of Reckitt Benckiser's pharma division is also an important sensitivity, as it could determine the level of future promotion of and investment into the Suboxone brand.

Non-Zubsolv related sensitivities include the performance of Abstral in Europe, its US re-launch trajectory and potential approvals and launches in other regions. Also, we do not include value of the technology platforms and early-stage R&D pipeline/collaborations, which could represent upside.

Financials

Orexo's FY13 net revenues were 58% higher than FY12 at SEK429.4m, and predominantly related to Abstral, including one-time payments of SEK110.8m and royalties of SEK246m. Zubsolv is still in

an early phase of its launch; consequently revenues are recognised based on actual patient demand for Zubsolv, rather than on the basis of supplies to wholesalers. SEK70m of Zubsolv was sold to suppliers, but only SEK7.3m of net sales were recognised, reflecting both initial prescribing patterns and the impact of short-term promotional launch campaigns on net sales. Orexo's revenue split by product for previous years and our revenue estimate for FY14 is shown in Exhibit 7.

Exhibit 7: Orexo revenue breakdown by product

Revenue SEKm	FY14e	FY13	FY12	Notes
Abstral royalties	201.2	246.0	175.2	European market share now 27% (ProStrakan); 5% US market share (Galena). Japan launched in December 2013. Abstral expected to be launched in further markets (Middle East) in 2014. FY14e includes recognition of staged payments from ProStrakan following 2012 deal restructuring.
Abstral milestones	-	110.8	29.3	FY13 included one-time payments of $15m from sale of US rights and $2.25m Japanese approval milestone
Edluar royalties	8.9	8.7	6.3	Sold by Meda in US, Canada and EU. 2013 EU launches included Germany, Italy, Sweden and Belgium; further launches expected in 2014.
Zubsolv	440.9	7.3	-	SEK70m of sales to US wholesalers; SEK7.3m in net sales recognised.
50% share in ProStrakan JV	-	-	8.0	JV sold to ProStrakan in June 2012 as part of restructuring of original EU and US licensing deals.
Kibion	49.8	48.8	48.3	FY13 sales impacted by temporary loss of reimbursement in Turkey and Saudi Arabia import restrictions. Distributor network restructured in 2013.
Total (marketed products)	**700.7**	**421.6**	**267.1**	
Partner-financed R&D costs	-	6.2	23.8	FY13: revenues related solely to Abstral approval in Japan.
License income(R&D projects)	-	1.6	36.7	FY12: SEK36.7m of deferred revenue related to OX-CLI recognised.
Other	-	-	-1.3	
Total	**700.7**	**429.4**	**326.3**	

Source: Edison Investment Research, Orexo

Zubsolv marketing activities and the cost of setting up the US subsidiary contributed to an increase in operating costs to SEK539.8m, up from SEK377.9m in FY12. The major cost contributors were sales expenses which increased to SEK125.1m (FY12: SEK62.0m), admin expenses (SEK126.4m vs SEK82.6m in FY12) and increased R&D spend reflecting the ongoing Zubsolv clinical studies (SEK238.2m up from SEK216.2m). In FY13 SEK91.5m of the cost of these studies was capitalised.

FY13 EBIT loss of SEK139.7m (FY12: loss of SEK79.4m) included a SEK43.9m impairment charge for OX-NLA. The post-tax loss was SEK154.9m (FY12: loss of SEK85.9m). At end FY13, cash and equivalents stood at SEK105.6m, representing net debt of SEK136m (SEK100m of which relates to draw down of the Danske Bank credit facility). After year end, Orexo increased its two year revolving credit facility by SEK70m to SEK270m. The facility will fund working capital requirements before profitability is reached in 2015 (according to our model).

Our financial forecasts are summarised in Exhibit 8 overleaf. We expect that revenues from 2014 will primarily be attributable to Zubsolv; detail on our Zubsolv growth expectations is shown in Exhibit 6. These estimates may be affected by stocking in at distributors and subsequent re-ordering patterns, as well as Orexo's revenue recognition policy. Orexo currently has SEK383.4m of Zubsolv inventory (both raw material and finished product) on the balance sheet, and we expect that proportionally similar levels will be maintained given the nine to 12-month lead time on buprenorphine, the need to ensure there are no quota issues and reassure payers that there is consistency in and security of Zubsolv supply. Current R&D spend levels are maintained given the ongoing Zubsolv clinical trials and lifecycle initiatives; we assume that c SEK35m is capitalised each quarter. Our COGS estimates are comparable with other speciality pharma companies; Orexo has confirmed that the increasing use of high-scale manufacturing capabilities from later-2014/early 2015 should drive future COGS improvement, reaching an optimised level in two to three years. Our net margin estimates trend towards 50%.

Exhibit 8: Financial summary

SEKm	2011	2012	2013	2014e	2015e	2016e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	200	326	429	701	1,626	2,681
Cost of Sales	(29)	(28)	(29)	(103)	(257)	(420)
Gross Profit	171	298	400	597	1,369	2,261
EBITDA	(112)	(62)	(45)	27	502	1,357
Operating Profit (before GW and except.)	(120)	(68)	(96)	22	496	1,351
Intangible Amortisation	(0)	(1)	0	(8)	(17)	(21)
Other	3	(7)	(6)	0	0	0
Exceptionals	(271)	(10)	(44)	0	0	0
Operating Profit	(392)	(79)	(139)	14	479	1,330
Net Interest	(8)	(8)	(14)	(29)	(33)	(30)
Other	0	0	0	0	0	0
Profit Before Tax (norm)	(128)	(77)	(109)	(7)	464	1,321
Profit Before Tax (FRS 3)	(399)	(88)	(153)	(15)	446	1,300
Tax	7	2	(2)	0	0	(390)
Deferred tax	0	0	0	0	0	0
Profit After Tax (norm)	(120)	(75)	(111)	(7)	464	931
Profit After Tax (FRS 3)	(392)	(86)	(155)	(15)	446	910
Average Number of Shares Outstanding (m)	27.2	29.4	30.8	32.9	32.9	32.9
EPS - normalised (SEK)	(4.4)	(2.5)	(3.6)	(0.2)	14.1	28.3
EPS - FRS 3 (SEK)	(14.4)	(2.9)	(5.0)	(0.5)	13.6	27.7
Dividend per share (SEK)	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	85.5	91.5	93.2	85.2	84.2	84.3
EBITDA Margin (%)	(56.3)	(19.0)	(10.5)	3.9	30.9	50.6
Operating Margin (before GW and except.) (%)	(60.0)	(21.0)	(22.2)	3.1	30.5	50.4
BALANCE SHEET						
Fixed Assets	190	189	228	355	476	596
Intangible Assets	151	135	195	323	444	565
Tangible Assets	39	35	33	33	32	31
Other	0	19	0	0	0	0
Current Assets	356	293	544	638	1,132	2,350
Stocks	27	28	383	425	563	575
Debtors	57	18	55	288	401	661
Cash	247	228	106	(75)	168	1,114
Other	26	19	0	0	0	0
Current Liabilities	(118)	(169)	(597)	(833)	(1,001)	(1,428)
Creditors	(118)	(169)	(360)	(426)	(594)	(1,021)
Short term borrowings	0	0	(237)	(407)	(407)	(407)
Long Term Liabilities	(117)	(122)	(14)	(14)	(14)	(14)
Long term borrowings	(115)	(114)	(4)	(4)	(4)	(4)
Other long term liabilities	(2)	(8)	(10)	(10)	(10)	(10)
Net Assets	311	191	161	147	594	1,504
CASH FLOW						
Operating Cash Flow	(112)	34	(254)	(181)	419	1,123
Net Interest	(5)	(5)	(12)	(29)	(33)	(30)
Tax	0	0	0	0	0	0
Capex	(5)	(5)	(107)	(141)	(144)	(146)
Acquisitions/disposals	(10)	12	0	0	0	0
Financing	245	(52)	19	0	0	0
Dividends	0	0	0	0	0	0
Other	(13)	0	0	0	0	0
Net Cash Flow	100	(17)	(354)	(351)	242	946
Opening net debt/(cash)	(41)	(132)	(115)	136	486	244
HP finance leases initiated	0	0	0	0	0	0
Exchange rate movements	0	(0)	3	0	0	0
Other	(9)	(1)	101	0	0	0
Closing net debt/(cash)	(132)	(115)	136	486	244	(703)

Source: Edison Investment Research, Orexo accounts

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