EDISON

Orexo

Initiation of coverage

Building the Zubsolv franchise

Pharma & biotech

Orexo's investment case centres on the commercial success of Zubsolv, a sublingual tablet for the maintenance treatment of opioid dependence. The US launch in September, through Orexo's own sales infrastructure, is so far proceeding to management expectations. Reimbursement clarity should increase Zubsolv's potential (an improved position is expected in H114), while longer-term market development and R&D investment in label expansion/lifecycle management will help build a defensible franchise. The outcome of pricing reviews and new clinical data, available from 2014, could expand Zubsolv's current label and take market share from the current market leader, Reckitt Benckiser's Suboxone. We value Orexo at SEK6.7bn or SEK203/share ($1.03bn or $31/share).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/11	200	(128)	(4.4)	0.0	N/A	N/A
12/12	326	(77)	(2.5)	0.0	N/A	N/A
12/13e	428	(106)	(3.4)	0.0	N/A	N/A
12/14e	646	(38)	(1.2)	0.0	N/A	N/A

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

A good start for Zubsolv: CVS Caremark listing

Reimbursement is central to capturing market share. Zubsolv is currently priced at par with Suboxone (cheaper than generics) but has less favourable reimbursement. Confirmed coverage by CVS Caremark (c 10% of the market) is a significant step, which may have wider repercussions with other commercial payers. From January, Zubsolv will be the only branded product (with Tier II status) covered by CVS Caremark restricted plans; doctors will have to consider alternatives to Suboxone.

Next steps: Competitive differentiation

Orexo has an opportunity to develop the growing opioid dependence market and position Zubsolv as the Suboxone alternative. It will seek label extension if the Phase III induction trial is positive; clinical differentiation would support a premium price. Data from other studies exploring preference, adherence and switching could reinforce the marketing message, helping overcome Suboxone brand loyalty.

Not forgetting Abstral

We expect Zubsolv revenues to surpass those of Abstral in 2014. Abstral, a sublingual fentanyl tablet, is the leading immediate-release fentanyl formulation in Europe, and a leading US position is targeted following re-launch in 2013. Abstral licensing provides evidence of management's proven commercial execution.

Valuation: SEK6.7bn vs EV of SEK5.6bn

Our DCF-based valuation of SEK6.7bn (SEK203/share) assumes a 25% peak market share and average 35% rebate. There is uncertainty over the profile of Zubsolv's launch trajectory, but achievement of higher penetration or improved net margin levels would represent upside.

7 January 2014

Price	**SEK170**
Market cap	**SEK5,512m**
	SEK6.5/US$
Net debt (SEKm) at FY13e	103.0
Shares in issue (000s)	32,882
Free float	N/A
Code	ORX
Primary exchange	NASDAQ OMX Stockholm
Secondary exchange	US OTC

Share price performance

%	1m	3m	12m
Abs	1.8	41.1	230.1
Rel (local)	(9.2)	29.2	176.0
52-week high/low	SEK182.0	SEK48.5	

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

FY13 results	30 January 2014
Zubsolv reimbursement decisions	H114
Zubsolv clinical data at ASAM	10-13 April 2014
Q114 results	25 April 2014

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Investment summary

Company description: Formulation specialist

Orexo AB, an emerging Swedish pharmaceutical company founded in 1995, is a product-based drug delivery company with expertise in reformulation technologies (in particular sublingual formulations). It has 120 employees, newly established US commercial operations in New Jersey and a Swedish R&D facility. Orexo has three marketed proprietary drugs. It sells core drug Zubsolv (opioid dependence) itself, with Abstral (cancer breakthrough pain) and Edluar (insomnia) sold by partners. Its subsidiary, Kibion, sells two diagnostic products for *Helicobacter pylori* (the bacterium linked to gastric ulcers). Orexo also has a pipeline of reformulations of approved compounds and collaboration projects with Astra Zeneca and Boehringer Ingelheim. The company adopted the name Orexo in 2003 and listed on NASDAQ-OMX Stockholm in November 2005, raising SEK333m gross (3.7m shares at SEK90). It subsequently raised SEK250m in June 2011 (6.6m shares at SEK38) and listed an ADR in November 2013. Non-cash acquisitions include Biolipox (a Swedish inflammation research-based biotech) in November 2007 and PharmaKodex (a UK drug delivery company) in February 2009.

Valuation: SEK6.7bn represents significant upside potential

We value Orexo at SEK6.7bn or SEK203 per share ($1.03bn or $31 per share) based on a DCF out to 2030, assuming a standard 10% WACC, a long-term tax rate of 30% after 2016 and no terminal value. Key Zubsolv assumptions are a 25% peak market share of a growing $1.7bn market and an average 35% rebate. We also include a modest revenue contribution from global Abstral royalties and the Kibion business (growing 2% a year). We estimate a gross margin of 85% on Zubsolv, with the operating margin trending to 50% in the long term. We model a step-up in sales expenses in FY15, when its commercialisation partner, Publicis Touchpoint Solutions, begins to earn a greater share of Zubsolv profits. More clarity on factors that may influence Zubsolv's market penetration or Orexo's operating margin is expected as the launch proceeds.

Financials: Profitable in 2015, but working capital needed

Net revenues for the nine-month period to 30 September 2013 (9M13) grew 36% to SEK329.9m, predominantly due to Abstral milestones of SEK110.8m and royalties of SEK173.5m. Costs increased 16%, reflecting Zubsolv R&D and marketing activities and the cost of setting up the US subsidiary. The 9M13 EBIT loss of SEK107.9m included a SEK43.9m impairment charge. The post-tax loss was SEK117.1m (SEK3.97/share). At end-September 2013, cash and equivalents were SEK91.9m (net cash of SEK35.1m). We expect revenues from 2014 onwards will be primarily attributable to Zubsolv, R&D spend will be maintained and COGS will be comparable to other speciality pharma companies. Net margin will trend towards 50%. The newly secured two-year SEK200m credit facility will largely fund Orexo's working capital requirements before the company reaches profitability in 2015 (according to our model), although we also model a SEK100m shortfall.

Sensitivities: To be clarified with Zubsolv launch progress

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 sensitivities relate to Zubsolv, with the outcome of reimbursement discussions, ongoing clinical trials and Reckitt Benckiser's strategic review of its pharma division being critical. These will all have a significant bearing on Zubsolv's sales trajectory and peak sales potential, by influencing pricing and prescriber/patient uptake vs Suboxone and generics. Other sensitivities include the performance of Abstral (in Europe, the US and beyond). We do not value the technology platform, R&D pipeline and collaborations, which could represent upside.

Outlook: Building the Zubsolv franchise

Commercial success of Zubsolv, a sublingual tablet for the maintenance treatment of opioid dependence, is central to Orexo's investment case. Zubsolv was launched in the US in September 2013 through Orexo's own commercial infrastructure, and so far launch is proceeding to management expectations. Various initiatives, including securing competitive reimbursement, should drive future sales growth. The outcome of pricing reviews is due in early 2014, and new clinical data, available from 2014, could expand Zubsolv's current label and take market share from the current market leader, Reckitt Benckiser's Suboxone. Longer-term lifecycle management plans will further boost this franchise. We value Orexo at SEK6.7bn or SEK203 per share ($1.03bn or $31 per share), on account of the significant Zubsolv opportunity.

Zubsolv, a buprenorphine and naloxone (bup/nal) combination, is the most important of three marketed drugs developed in house using Orexo's proprietary sublingual reformulation technology. It is expected to become the main revenue contributor in 2014, with sales of c SEK500m. That position is currently held by Abstral, a sublingual fentanyl tablet indicated for cancer breakthrough pain, sold by partners ProStrakan (Europe) and Galena Biopharma (US), which generated total in-market revenues of SEK350m ($54m) in 2012 (with Orexo receiving double-digit royalties). Orexo also sells two *Helicobacter pylori* diagnostics (the bacterium associated with gastric ulcers) through its non-core subsidiary, Kibion. Exhibit 1 provides an overview of the marketed products.

Exhibit 1: Orexo marketed products

Product	Indication	Partners	Notes
Zubsolv	Maintenance treatment of opioid dependence	-	Sublingual buprenorphine/naloxone tablet. FDA approved (July 2013); launched September 2013 through own commercial infrastructure. Reimbursement negotiations ongoing; expected to complete during H114. Clinical data and preference studies show superiority to Suboxone tablets and film (Reckitt Benckiser): significant advantages include improved taste, dissolve time, easier compliance, reduced tablet size, and lower dosage (enhanced bioavailability of buprenorphine).
Abstral	Relief of breakthrough cancer pain	ProStrakan (EU/ RoW); Galena (US); Kyowa Hakko Kirin (Japan)	Sublingual fentanyl tablet. EMA approved (2008); launched in most EU countries and expected to become market leader in fast-acting fentanyl products (2012 sales of SEK350m, $54m). FDA approved (January 2011): launched in April 2011 by ProStrakan, but US rights returned to Orexo under new agreement in June 2012 and subsequently sold to Galena in March 2013. Approved in Canada in February 2011 and in Japan in September 2013.
Edluar	Short-term insomnia	Meda (global)	Sublingual zolpidem tablet. FDA approved (March 2009), launched August 2009. EMA approved (June 2012), launched 2013. Priced in line with branded competitors (eg Sanofi's Ambien).
Diabact UBT	Diagnostic breath test for *H. pylori* (gastric ulcers)	Kyowa Hakko Kirin (Japan)	Launched in 2000; sold in >60 countries in Europe, the Middle East, Latin America and Asia by subsidiary Kibion. Laboratory analysed urea breath test to diagnose *H. pylori* based on Orexo's patented rapidly dissolving tablet technology.
Heliprobe System	Diagnostic doctor's office tests for *H. Pylori*	-	Launched in 2001; sold in >60 countries in Europe, the Middle East, Latin America and Asia by subsidiary Kibion. Urea breath test diagnostic with ability to obtain on-site test results.

Source: Edison Investment Research; Orexo

Zubsolv is the cornerstone of Orexo's strategy to become a fully integrated speciality pharma company. The company recently set up commercial operations in the US to market and sell Zubsolv and has an established R&D capability in Sweden, which developed Zubsolv and the rest of the pipeline using proprietary drug delivery technology. Orexo has historically focused on developing improved treatments using its proprietary technologies to reformulate existing drugs to produce novel patent-protected drugs with various therapeutic advantages. These have shorter development timelines and lower associated risk as the active ingredients are known, well-characterised and already approved by regulators. However, following a 2010 strategic review and completion of a SEK250m rights issue in June 2011, Orexo refocused resources into developing three parallel proprietary programmes (OX219, OX51, OX27), with the intention of capturing a larger proportion of revenues by launching and marketing the one with the greatest commercial potential: this was Zubsolv (formerly OX219). This plan has begun to come to fruition under a commercially experienced management team, which was restructured in 2013.

Zubsolv: A compelling market opportunity

Orexo intends to become a fully integrated pharmaceutical company by building a defensible opioid dependence franchise around Zubsolv. Zubsolv, a sublingual formulation of buprenorphine (an opioid that eases withdrawal) and naloxone (an opioid antagonist that deters abuse by blocking the high), was launched in the US in September 2013. It is indicated as a maintenance therapy, competing against market-leading brand Suboxone film (Reckitt Benckiser, launched in 2010, IP protection to 2022) and two generic bup/nal tablets (launched March 2013 by Actavis and Amneal). It is priced in line with Suboxone; lower than the generic competition.

The opioid dependence market dynamics are attractive and while Reckitt Benckiser is employing a number of approaches to protect its Suboxone franchise, uncertainty remains about the fate of the RB pharmaceutical division (reportedly up for sale). Orexo has an opportunity to develop this market and position Zubsolv as an effective branded alternative to Suboxone with targeted investment. The launch period of a new drug is always a period of uncertainty. However, Orexo believes it can increase Zubsolv's potential in the short term by reimbursement clarity (an improved position, at least similar to Suboxone, is expected in H114) and in the long term through market development (including the currently unaddressed part of the market) and R&D investment in label expansion and new product/life cycle management initiatives. Exhibit 2 shows our SWOT analysis of the Zubsolv opportunity.

Exhibit 2: 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** 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 predominantly results from high-dose pain relief; buprenorphine is an effective analgesic, thus has the potential to assist in decreasing the dose of other opioids, helping dependence issues to be bypassed; potential to improve documentation for Zubsolv to address the continuing pain part of the market. ■ **Government policy:** addiction medicine is a focus area; a petition has 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

In December 2012, before filing, Orexo management's gross sales expectations for Zubsolv were $500m three years after launch, based on the fact that it would need to establish its position in a

market with a dominant brand where generics would also be available by the time of its launch. Market dynamics are now better understood and we believe that Zubsolv's peak sales potential could be higher – $542m in 2016 (pre-rebates) – through a combination of capturing market share and ongoing market growth. We also expect continued growth once 'peak' sales are achieved. Nevertheless, there is uncertainty about the timing of peak sales – and the level of rebating/discounting – until the launch trajectory becomes apparent.

Orexo aims to take market share from Suboxone by initially emphasising the formulation advantages of Zubsolv. These include accelerated disintegration time (approximately three minutes vs 15 minutes for generic tablets and six minutes for Suboxone film), reduced tablet size, improved taste (menthol instead of an actively disliked citrus flavour that patients seek to mask in a variety of ways) and mouth feel (some patients have localised mucosal reactions to Suboxone film), and the same bioavailability of buprenorphine despite a lower dose. However, brand loyalty to Suboxone (by both physicians and patients) is a hurdle that will need to be overcome. Data from ongoing studies exploring preference, adherence and switching from Suboxone could further reinforce the Zubsolv marketing message, and improved reimbursement will be the key driver of capturing market share. Zubsolv is currently priced more cheaply than generics, in line with Suboxone, but has less favourable reimbursement than its competition, a situation that will change during 2014.

Current opioid dependence market and the opportunity

Opioid dependence is a medical condition in which an individual is unable to stop using opioids (prescribed analgesics or illegal drugs). Treatment is long term, but important in reducing morbidity (physical and psychological) and mortality, and limiting indirect social costs. In the US there are 48 million chronic opioid users, of which five million are estimated to be dependent. Only a minority are adequately treated as only two million are diagnosed; of these individuals, only 750,000 are treated. Diagnosis and treatment rates are so 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 and all have a 100-patient cap at any one time) and affordability (lack of financial coverage/insurance).

Treatment options include methadone, buprenorphine monotherapy and psychosocial therapy, although combined bup/nal therapy is most common – 500,000 patients undergo this form of therapy. This market segment is growing, partly driven by price but also increased prescriptions: for the 12 months from November 2012, growth was 15% by value (excluding rebates, co-pays and other discounts) and 13% by volume. The market exhibits strong brand loyalty, but is also highly dynamic: new prescriptions need to be written each month and patient turnover is 25% per quarter, creating room for new product uptake. Patients are initially given a 15-day prescription, after which they undergo a urine screen before moving to a standard 30-day prescription (the maximum permitted due to the abuse potential of bup/nal therapies). The first one-to-three months of treatment is the critical period for adherence to therapy; if patients remain on treatment after three months, they typically stabilise and treatment becomes chronic/long term.

At the Zubsolv launch, the market was split c 85% to Suboxone film and c 15% to generics by volume. This division between the branded and generic markets is likely to be maintained as long as generics are priced similarly to the market alternatives. Generics have the same deficiency in taste and dissolve time as Suboxone tablets (the reference product), which affects treatment adherence. Zubsolv was approved under the 505(b)(2) pathway after demonstrating bioequivalence (albeit at a lower dose) to Suboxone tablets. Withdrawal[1] of Suboxone tablets in March 2013 (on patent expiry) created an unusual situation with pricing dynamics. To stimulate switching, Reckitt Benckiser priced Suboxone film at a 40% discount to Suboxone tablets, while the AB-rated

[1] Reckitt Benckiser announced the proposed withdrawal of Suboxone tablets (35% market share) in September 2012, allowing a six-month period for switching to Suboxone film.

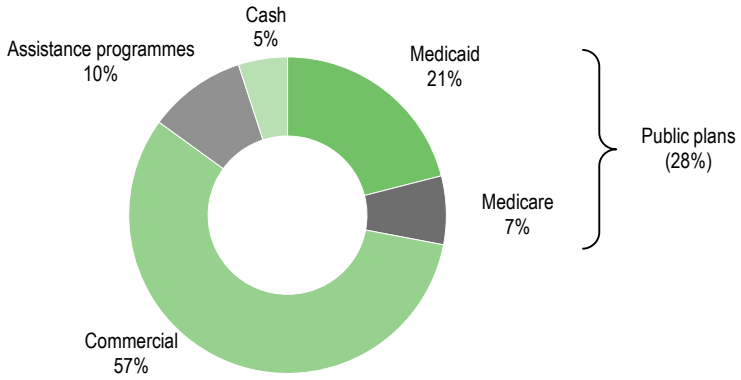
(substitutable) generic tablets were priced at a 20% discount (ie a 20% premium to the film). Consequently, price pressure and market share gains from generics are not expected unless there is a new generic entrant. New entrants are not expected in the short to medium term. There have been no additional filings for generic tablets, although three companies have filed bup/nal film products[2] with the FDA (ahead of Suboxone film patent expiry) and are being sued for patent infringement by Reckitt Benckiser.

500,000 bup/nal treated patients only account for 10% of the opioid dependence market; hence Zubsolv's potential target market could be larger. Higher diagnosis and treatment rates could result if documentation, policy and cost (improved coverage) issues are addressed; Orexo intends to develop and grow the market by doing this. Areas of focus are likely to 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 treatment. Importantly, no other companies are focusing on opioid dependence despite the patient need. Reasons for this include the difficulties in conducting opioid/addiction trials, the presence of an entrenched brand and the specialist prescriber base.

Zubsolv launch update and reimbursement status

Zubsolv has shown steady growth in prescribing trends in the first 12 weeks on the market,[3] capturing nearly 2% market share by volume. It is available in more than 10,000 pharmacies, and Q314 saw stocking in of Zubsolv with a gross sales value of SEK65m, although only SEK0.5m of gross sales were recognised reflecting launch two weeks before end Q3. Orexo's focus for 2014 is to accelerate Zubsolv's launch trajectory and market share gains through commercial execution (prescriber education and ensuring a smooth process for patients) and improving market access. Reimbursement is the key driver behind market share. Exhibit 3 shows the market segmentation by payer.

Exhibit 3: Buprenorphine/naloxone market by payer ($)



Source: Orexo, IMS data

Ahead of launch, Orexo secured initial reimbursement and currently has Tier III status ($50-75 patient co-pay) for c 70% of the bup/nal market. Orexo is in discussions to ensure that Zubsolv has coverage by all major plans and there is an improvement in coverage by public plans (currently reimbursed for around one-third of publicly covered patients) during H114. Current reimbursement status is less favourable than Suboxone film (Tier II, $20-40 co-pay) and generics (Tier I, $0-10 co-pay), but should be at least similar to Suboxone within one year of launch. Co-pay levels are

[2] BDIS's Bunavail filed an NDA for branded bup/nal film Bunavail (7 July 2014 PDUFA date), while IntelGenex/Par Pharmaceutical and Actavis have filed ANDAs for generic bup/nal film.

[3] Due to extrapolation, there are significant limitations to prescribing data captured by Wolters Kluwer and IMS in the launch phases. Nevertheless, general trends shown are accurate, especially regarding the number of prescriptions rather than the dollar value as the impact of co-pays and other discounts may not be captured.

important for patients and so improved reimbursement for Zubsolv is vital for increased penetration. Additionally, Zubsolv is not universally listed by formularies at present, creating perceived uncertainty around reimbursement, which can be an obstacle to prescribing. The conclusion of pricing reviews in Q413 and the January update of pharmacy listings should improve this situation, broaden market access and boost prescribing rates. Depending on the plan, Zubsolv is expected to be Tier II or III, and all commercial plans should have co-pay support. Progress could be slower with Medicaid and Medicare, as there are several plans per state; coverage by the most important is targeted. Securing public coverage is particularly important with high prescribers. However, increased coverage by public plans will have an impact on margins. Medicaid rebates are at least 23% higher than under commercial price plans and there is a 'best price' requirement, hence increasing public coverage will boost Zubsolv's market penetration, but incremental volume growth will be partially offset by a lower average price point.

Zubsolv's confirmed coverage by pharmacy benefit manager CVS Caremark opens a significant opportunity that may have wider repercussions with other payers. This multi-year contract means Zubsolv will be the only branded product covered by CVS Caremark restricted plans (c 10% of the total bup/nal market and c 20% of the commercial segment), where it will have Tier II status. The withdrawal of Suboxone's listing was announced in July (a few days after Zubsolv approval), becoming effective from 1 January, when all doctors on CVS will be forced to consider alternatives to Suboxone. Over the course of 2014, it will become clearer whether switching is to generics or to Zubsolv (affecting Zubsolv's actual market share gain), but it is likely that the rate of Zubsolv prescriptions, which has been relatively linear so far, will accelerate.

Commercial activities

Zubsolv is promoted by a dedicated field force under a fixed-term risk-sharing partnership between Orexo and Publicis Touchpoint Solutions (PTS). Initial commercial investment by Orexo is limited to its in-house US infrastructure of 20people as the cost of the 50-FTE field force is borne by PTS until Zubsolv delivers a profit. The field force is currently deployed in regions with the best market access position; as this improves from early-2014, the field force will be moved and likely expanded as PTS has a contractual commitment to increase the field force with improved market access. The cash flow generated by Zubsolv is the primary determinant of the timing of economic benefit to PTS; it is back-end loaded, giving PTS a strong incentive to promote Zubsolv. At the end of the contractual period, Orexo will have a choice on how to proceed: options include continuing the agreement, internalising the sales force, or starting again and building up a new sales infrastructure. Exhibit 4 outlines the structure of the PTS relationship.

Exhibit 4: Structure of Publicis Touchpoint Solutions (PTS) contract

Phase	Comment	Orexo	PTS
Investment period	Phase runs from launch to break-even. Investment by both companies in partnership; gross margin shared in proportion to investment made (determines cost recovery).	Bulk of recovered costs as includes late-stage development costs.	Costs relate to field force (initially 50 FTEs).
Break-even	Revenues offset all Zubsolv costs (field force, US office, marketing, R&D). Both parties recover more than their investment (return is governed by the contract).	All Zubsolv revenues booked in Orexo P&L, with limited own SG&A. Payment of royalty to PTS is included within SG&A rather than COGS.	Carries costs until profit delivered. PTS is compensated for initial investment with an undisclosed model, which is likely to be higher costs compared to actual expenses for a period of time.
Profitable	Phase runs from achievement of positive cash flow to the end of the contract (December 2016).		Earns flat single-digit royalty on profit and 1:1 cost cover of field force.

Source: Edison Investment Research. Note: Length of each phase depends on Zubsolv's sales progress/when break-even is reached.

Promotional activities are focused on high prescribers as approximately a quarter (5,800) of doctors certified in addiction medicine account for 94% of total bup/nal prescriptions. Initially the top 1,000 prescribers are being targeted; six weeks into launch, c 800 of these had tested Zubsolv. The week-on-week increase in total prescriptions has been steady, with a clear correlation seen between field promotion and prescription volume, highlighting the importance of physician education. However,

the number of doctors prescribing Zubsolv is rising faster than the number of prescriptions, revealing use on limited patients as doctors familiarise themselves, and gain experience, with the drug. This is reflected in prescribing data: an average prescription length of 20-22 days suggests a large proportion of 15-day trials, some of which should convert to longer-term therapy.

Developing a sustainable, competitive advantage

Zubsolv's FDA approval was on the basis of demonstrating bioequivalence to Suboxone tablets; it did not need to show clinical differentiation. Strong preference for the Zubsolv formulation has been demonstrated in an open-label preference/acceptance study (study 005)[4], in which nine out of 10 participants showed a preference for Zubsolv over Suboxone film. Combined sales of Suboxone tablets and film were £837m ($1.3bn) in 2012, confirming the substantial potential market for Zubsolv. Orexo is now investing in clinically differentiating Zubsolv, aiming to broaden the label, and in lifecycle initiatives that leverage its formulation expertise. Three clinical studies of Zubsolv are underway (Exhibit 5). Depending on the status of FDA discussions/filings, early data from these trials could be presented at future conferences, most likely at the American Society of Addiction Medicine (ASAM) in April 2014.

Exhibit 5: 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). Study completion: December 2013.	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

Orexo's Zubsolv lifecycle strategy is to develop and expand the market by focusing on consumer preference, drawing parallels with the nicotine replacement market for smoking cessation. This will be achieved through continuous launches of modified formulations, eg flavours (currently menthol). A broader dosage should become available in early 2014; new flavours will be ready for regulatory filing in 2014 (as a 505(b)(2) application referencing Zubsolv), although the timing of filing of finished product extensions will depend on the commercial opportunity and competitive dynamics. Product extensions may also improve Zubsolv's IP position. Granted patents currently include a platform patent applicable to Abstral and Edluar, and a unique bup/nal formulation patent, both of which run until 2019. A specific Zubsolv formulation patent is pending, which would extend patent life to 2032.

[4] Jönsson et al. A novel buprenorphine/naloxone tablet formulation for the treatment of opioid dependence. Poster presented at the American Society of Addiction Medicine conference (25-28 April 2013).

Other marketed products and partners

Orexo has historically generated revenues through diagnostics subsidiary, Kibion, and royalties from two out-licensed sublingual therapies (Abstral and Edluar). Kibion sells *H. pylori* diagnostics Diabact UBT and Heliprobe system, and was the main contributor to pre-2010 revenues (SEK40.7m in 2009). Despite continued growth in Kibion's sales, its contribution has been surpassed by Abstral. Kibion is a legacy business operating as an independent subsidiary within Orexo. There are no active divestment plans as this would detract management attention from Zubsolv at a critical point in the company's evolution, although serious approaches would be considered. Edluar is sold by Meda (Orexo is eligible for double-digit royalties), but sales growth is slow (contributing SEK6.3m to 2012 revenues) as it competes within a generic insomnia market.

Abstral: A European market leader with US potential

Abstral is a sublingual transmucosal immediate-release fentanyl (TIRF) product, used for treatment of breakthrough pain in cancer patients who are already receiving opioid analgesics for chronic pain. Around 60% of cancer patients with otherwise well-controlled chronic pain experience breakthrough cancer pain (BCP), or short periods of intense pain, three to seven times a day. All approved products for BCP are TIRFs, but come in varied formulations – lozenge (Actiq, Teva and generics), buccal tablet (Fentora, Teva), intranasal spray (Subsys, Insys Therapeutics; Lazanda, Depomed) and buccal film (Onsolis, Meda/BDSI). Abstral is approved and marketed in the EU and US by ProStrakan and Galena respectively; it was launched in Japan by Kyowa Hakko Kirin in December 2013. Deal structures are outlined in Exhibit 6; Orexo bears no costs.

Exhibit 6: Abstral partners and deal structures

Partner	**ProStrakan** (EU and RoW ex-US and Japan)	**Galena Biopharma** (US)	**Kyowa Hakko Kirin** (Japan)
Structure	June 2012 restructuring of royalty/milestone schedules of original deals (2005 EU licence, expanded to include North America in 2008) included purchase of Orexo's 50% share in Nordic JV. US rights returned to Orexo on 1 January 2013. Orexo receives total net cash consideration of £55m over 24 months (£22.5m in 2012; £20m in 2013 and £12.5m in 2014).	Deal signed March 2013. **Upfront payment:** $10m.	Deal signed 2003.
Milestones	**EU**: Up to £10m when annual sales exceed certain thresholds. **RoW:** Further development and sales milestones.	$5m within one year of signing. Undisclosed milestones on pre-specified sales levels. Received September 2013.	$2.25m on approval. Received September 2013.
Royalties	**EU:** 15% on annual sales >€42.5m, 20% of sales >€60m. **RoW**: 15% on net sales; 20% on annual sales >€12.5m.	Low double digit.	Single digit.

Source: Edison Investment Research, Orexo

Abstral is the leading TIRF product in Europe with 27% market share at end-Q313; its share has grown steadily since first launch in 2008. €39m of sales (up 29% on the previous period) were booked by ProStrakan in the first nine months of 2013; Orexo receives a 15% royalty on annual sales over €42.5m. The main driver of growth is the increasing importance of cancer-supportive care products as the use of opioid analgesics rises in general and as new oncology drugs improve survival. Orexo aims to replicate Abstral's European success in the US with re-launch by new partner Galena Biopharma.

Abstral was initially launched in the US in 2011 by ProStrakan, although only modest sales were achieved as the US BCP market was in decline due to the genericisation of key drugs (Actiq) and the restrictive distribution scheme imposed by the REMS requirement for newly approved fentanyl-based drugs, which put them at a disadvantage against the incumbents. In March 2012, a REMS became a TIRF class requirement; the market (estimated at $388m in 2012 by Healthcare Analytics) has since stabilised. Subsys, launched March 2012, has a similar therapeutic profile to Abstral and has become the US market leader (>30% share). Galena's strategy for Abstral is centred on building and leveraging relationships with medical oncologists. These physicians represent the majority of TIRF prescribers for tumour and treatment-related cancer pain and are a common target prescriber base with Galena's Phase III breast cancer immunotherapy NeuVax.

Galena is conducting clinical trials at centres where its dedicated Abstral sales force is addressing the commercial opportunity.

Orexo's technologies and early-stage R&D pipeline

Orexo's roots are in reformulating known active pharmaceutical ingredients using its drug delivery technologies (Exhibit 7). Its R&D pipeline consists of four programmes (Exhibit 8), two of which are in house (based on its formulation technologies) and two are partnered NCE projects. However, Orexo's R&D capabilities are currently directed into lifecycle initiatives for Zubsolv.

OX51 (acute procedure-induced pain) and OX27 (BCP) form the in-house R&D pipeline, although investment in their development is either minimal or temporarily dormant until Zubsolv generates sustainable revenues. The next expected pipeline development is confirmation of the development and regulatory strategy for OX51, a sublingual formulation of alfentanil, a strong IV painkiller with a broad spectrum of potential use. Orexo's financial investment in OX51 is limited, but it is investing time in assessing the optimal path forward. Following positive Phase II data in prostate biopsies, pursuing this indication is the less risky regulatory pathway, but would limit the market potential.

Orexo also has early-stage collaboration programmes with AstraZeneca and Boehringer Ingelheim on the two remaining assets, both of which are new chemical entities that are not based on its delivery technologies. Orexo retains an interest in downstream economics if these projects are successful, but all development and financial risk resides with its partners.

Exhibit 7: Selected Orexo drug delivery technologies

Technology	Products	Notes
Sublingual mucoadhesive tablet	Zubsolv; Abstral; Edular	Consists of API carrier particles and substances that attach the tablet/drug particles to the mucous membrane. Rapidly disintegrates/dissolves when placed under the tongue, permitting API absorption into the bloodstream via the mucous membrane. Speed of effect, reliability of both dosage and absorption is greater than that of swallowed tablets. Technology is suited for treating acute symptoms where a fast-acting effect is desirable (eg acute pain).
Oral fast-dissolving tablet	Diabact UBT	Patented technology for the rapid dissolution of API, which increases bioavailability (disintegration of the tablet exposes a larger surface area) and has a fast-acting effect (tablet dissolves faster and more completely).
Xerosol	-	Encapsulation technology to improve or modulate oral transmucosal drug delivery. Can be complementary to sublingual tablet technology as it facilitates a different drug uptake profile.
Taste transformation	Zubsolv	Various related technologies to disguise/improve the taste of bitter/unpleasant tasting drugs without delaying absorption.
Accustar	-	'Solid Syrup' technology allows improved mouth feel, waterless administration, rapid dissolution and controlled delivery.

Source: Edison Investment Research, Orexo. Note: API = active pharmaceutical ingredient.

Exhibit 8: Orexo's R&D pipeline

Product	Indication	Stage	Notes
In-house programmes			
OX51 (sublingual alfentanil tablet)	Procedure induced pain	Phase II	Evaluating regulatory pathways following positive Phase II placebo-controlled dose-finding study in prostate biopsies. Endpoint of analgesic efficacy met. Statistically significant dose response for all three doses vs placebo with respect to maximal pain experience. Safe and well-tolerated in all dose groups with no effect on local tolerability or quantitative scales for assessment of sedation or drowsiness vs placebo. Alfentanil is suited to providing rapid short-term pain relief for short procedures (including prostate biopsies, relocation of fractures, minor surgery, obstetrics/gynaecology), minimising the need for general or local anaesthesia. Orexo market research suggests sales potential of c $250m annually and potential for premium pricing over current options.
OX27 (sublingual sufentanil tablet)	Breakthrough cancer pain	Dormant (Phase I)	Dormant since Q212 due to prioritisation of resources to further Zubsolv development. Preclinical data showed that the API is absorbed and eliminated quickly; a subsequent clinical trial confirmed potential for more frequent dosing (6x daily) than the standard 4x daily for fentanyl-based breakthrough pain products.
Partnered NCE programmes			
OX-MPI	Inflammatory pain	Preclinical	Selective prostaglandin E2 (PGE2) inhibitor. Demonstrated 'powerful relief' from inflammatory pain, good safety profile, no CV/GI side-effects in preclinical models. Exclusive €250m research, development and commercialisation agreement with **Boehringer Ingelheim** (signed 2005): milestones and royalties on future sales are payable to Orexo (first milestone received in 2010 on candidate selection). Boehringer is responsible for development and marketing, although Orexo has co-marketing rights in the Nordic region and Baltic states.
OX-CLI	Respiratory diseases	Preclinical	Undisclosed novel therapy for respiratory diseases. Rights to conduct further preclinical research/evaluation granted to **Astra Zeneca** in 2013, which has option to acquire resulting compounds. On option exercise, Orexo is eligible for undisclosed future development milestones and royalties. Previously under collaboration with Ortho-McNeil-Janssen/Janssen (2010-11).

Source: Edison Investment Research, Orexo. Notes: API = active pharmaceutical ingredient; NCE = new chemical entity.

Valuation

We value Orexo at SEK6.7bn or SEK203 per share ($1.03bn or $31 per share) based on a DCF valuation out to 2030, which assumes a WACC of 10%, a long-term tax rate of 30% after 2016 and no terminal value. 10% is our standard WACC assumption for companies with approved products and minimal development risk. Our key Zubsolv revenue assumptions are presented in Exhibit 9, based on assumed peak market share of 25% and an average 35% rebate level.

We estimate gross margin of 85% on Zubsolv, with the operating margin trending to 50% in the long term. We model a significant step-up in sales expenses in FY15, when PTS begins to earn a greater share of Zubsolv profits. We also include a modest revenue contribution from global Abstral royalties (taking into account respective deal structures with partners, including the fixed royalty receipts from ProStrakan outlined in Exhibit 6) and the Kibion diagnostics business (growing 2% a year) until 2020, at which point we assume, for simplicity, that all revenues relate to Zubsolv.

Exhibit 9: Zubsolv revenue assumptions to 2020

Assumption	2013	2014	2015	2016	2017	2018	2019	2020
Market size ($m)	1,700	1,904	2,094	2,283	2,466	2,638	2,796	2,936
Market growth rate		10%	10%	9%	8%	7%	6%	5%
% of peak market share	0.5%	20%	61%	95%	100%	100%	100%	100%
Implied market share	0.2%	5%	15%	24%	25%	25%	25%	25%
Zubsolv sales – pre rebates ($m)	3.7	94.1	311.5	542.2	616.4	659.5	699.1	734.1
Zubsolv sales – post rebates ($m)	2.4	61.2	202.5	352.4	400.6	428.7	454.4	477.1
Total Zubsolv sales – post rebates (SEKm)	15.5	397.5	1,315.9	2,290.7	2,604.2	2,786.5	2,953.7	3,101.4
Total product sales (SEKm)	419.9	646.4	1,477.4	2,427.3	2,780.2	2,987.9	3,164.6	3,317.0

Source: Edison Investment Research, Orexo. Note: Assumes SEK6.5/$ FX rate, peak market share of 25% and average 35% rebate.

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). Upside may also result if Orexo could attain improvements in net margin approaching, but not reaching, the levels achieved in Reckitt Benckiser's pharmaceutical division (64% in FY12), which is the most relevant peer for Orexo. We highlight that achieving comparable net margin would be unlikely given that Reckitt Benckiser benefits from significant economies of scale, coupled with the fact that Orexo is investing significantly in building its Zubsolv franchise. Exhibit 10 presents a sensitivity analysis exploring these factors.

Exhibit 10: Impact of net margin and Zubsolv market share on Orexo's valuation

		Zubsolv market penetration					
Operating margin		10%	15%	20%	25%	30%	35%
	40%	39	80	121	162	203	244
	45%	47	92	138	183	228	273
	50%	56	105	154	203	253	302
	55%	64	118	171	224	277	330
	60%	73	130	187	245	302	359

Source: Edison Investment Research

The shaded area indicates the market penetration and operating margin combinations supported by the current SEK170 share price. 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.

We do not explicitly value the ex-US opportunity for Zubsolv, although Orexo is investigating the regulatory pathway options for other markets. We note that Suboxone tablets are still data protected in Europe until 2016 and highlight that the US opportunity is more significant. Reckitt

Benckiser does not split out global Suboxone sales by region, but market estimates indicate that the US accounts for over 75% to c 90% of revenue.

Sensitivities

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

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 we currently assume. In particular, the future of Reckitt Benckiser's pharma division is 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 Orexo's technology platforms or early-stage R&D pipeline/collaborations in our valuation, which may represent upside.

Financials

Orexo's net revenues for the nine-month period to 30 September 2013 (9M13) were SEK329.9m, up 36% from SEK242.7m in 9M12. These revenues predominantly related to Abstral and in 9M13 consisted of one-time payments of SEK110.8m ($15m from the sale of US rights and $2.25m Japanese approval milestone) and royalty revenues of SEK173.5m (9M12: SEK115.7m). Q314 saw Zubsolv stocking in of SEK65m, although only SEK0.5m of sales were recognised. Overall expenses for the period increased by 16% over 9M12, reflecting Zubsolv marketing activities and the cost of setting up the US subsidiary (sales costs increased to SEK83.4m from SEK42.7m), one-time admin expenses of SEK13.9m for Abstral in the US and developing the US commercial strategy, and R&D spend related to Zubsolv clinical studies (SEK191m up from SEK166.2m).

9M13 EBIT loss was SEK107.9m (9M12: loss of SEK57.7m), including a SEK43.9m impairment charge for OX-NLA. Orexo has guided towards an EBIT loss of around SEK30m for Q413, due to the continued conservative revenue recognition approach. The post-tax loss was SEK117.1m or a loss of SEK3.97 per share (9M12: loss of SEK63.6m or SEK2.14 per share). At end September 2013, cash and equivalents stood at SEK91.9m, representing net cash of SEK35.1m. Novo's SEK111m convertible bond was converted in August, removing the overhang.

Our forecasts are summarised in Exhibit 11. We expect that revenues from 2014 will primarily be attributable to Zubsolv, and provide more detail on the breakdown of our Zubsolv growth expectations in Exhibit 9. This may be affected by stocking in at distributors and subsequent re-ordering patterns, as well as Orexo's revenue recognition policy.[5] On 20 December 2013, Orexo confirmed that c $11m (c SEK72m) of Zubsolv had been supplied to wholesalers since launch, of which approximately one-third is expected to be recognised as gross income (pre rebates and discounts) in 2013. Orexo currently has SEK200m 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 to12-month lead time on buprenorphine and to ensure there are no quota issues. Current R&D spend levels are maintained given the ongoing Zubsolv clinical trials and lifecycle initiatives, and we assume that c SEK35m is capitalised each quarter. Our COGS estimates are comparable with other speciality pharma companies; management has confirmed that there is flexibility in gross margin to cover a range of Zubsolv price points. Our net margin estimates trend towards 50%.

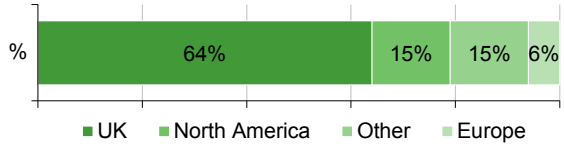
Orexo has recently secured a SEK200m two year revolving credit facility with Danske Bank. SEK100m is available for immediate drawdown, with the remainder becoming available when undisclosed Zubsolv revenue milestones are reached. This facility will be used to fund working capital requirements before profitability is reached in 2015 (according to our model), although we forecast a funding shortfall of SEK100m. We highlight that through astute commercial deal making, Orexo has secured more than SEK700m in net payments related to Abstral since mid-2012, largely funding Zubsolv's commercial launch preparations.

[5] As Zubsolv is still in an early phase of its launch, revenues are currently recognised based on actual patient demand for Zubsolv, rather than on the basis of supplies to wholesalers.

Exhibit 11: Orexo financial summary

SEK m's	2010	2011	2012	2013e	2014e	2015e	2016e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue	210	200	326	428	646	1,477	2,427
Cost of Sales	(26)	(29)	(28)	(39)	(95)	(233)	(380)
Gross Profit	184	171	298	389	552	1,244	2,047
EBITDA	(48)	(112)	(62)	(47)	(10)	381	1,149
Operating Profit (before GW and except.)	(55)	(120)	(68)	(96)	(16)	376	1,143
Intangible Amortisation	(1)	(0)	(1)	(0)	(7)	(16)	(20)
Other	29	3	(7)	(5)	0	0	0
Exceptionals	(26)	(271)	(10)	(44)	0	0	0
Operating Profit	(82)	(392)	(79)	(140)	(23)	360	1,123
Net Interest	(7)	(8)	(8)	(10)	(23)	(31)	(30)
Other	0	0	0	0	0	0	0
Profit Before Tax (norm)	(63)	(128)	(77)	(106)	(38)	345	1,114
Profit Before Tax (FRS 3)	(89)	(399)	(88)	(150)	(45)	328	1,093
Tax	0	7	2	0	0	0	(328)
Deferred tax	0	0	0	0	0	0	0
Profit After Tax (norm)	(63)	(120)	(75)	(106)	(38)	345	786
Profit After Tax (FRS 3)	(89)	(392)	(86)	(150)	(45)	328	765
Average Number of Shares Outstanding (m)	23.4	27.2	29.4	30.8	32.9	32.9	32.9
EPS - normalised (SEK)	(2.7)	(4.4)	(2.5)	(3.4)	(1.2)	10.5	23.9
EPS - FRS 3 (SEK)	(3.8)	(14.4)	(2.9)	(4.9)	(1.4)	10.0	23.3
Dividend per share (SEK)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	87.5	85.5	91.5	90.9	85.4	83.8	84.3
EBITDA Margin (%)	(22.8)	(56.3)	(19.0)	(11.0)	(1.5)	26.4	47.3
Operating Margin (before GW and except.) (%)	(26.3)	(60.0)	(21.0)	(22.5)	(2.4)	26.1	47.1
BALANCE SHEET							
Fixed Assets	449	190	189	213	346	474	600
Intangible Assets	407	151	135	171	305	433	560
Tangible Assets	42	39	35	33	32	31	31
Other	0	0	19	10	10	10	10
Current Assets	264	356	293	447	695	1,047	2,048
Stocks	8	27	28	267	389	511	520
Debtors	99	57	18	157	266	356	599
Cash	136	247	228	4	22	161	910
Other	21	26	19	19	19	19	19
Current Liabilities	(140)	(118)	(169)	(484)	(910)	(1,060)	(1,421)
Creditors	(140)	(118)	(169)	(381)	(507)	(657)	(1,019)
Short term borrowings	0	0	0	(102)	(402)	(402)	(402)
Long Term Liabilities	(104)	(117)	(122)	(18)	(18)	(18)	(18)
Long term borrowings	(94)	(115)	(114)	(5)	(5)	(5)	(5)
Other long term liabilities	(10)	(2)	(8)	(14)	(14)	(14)	(14)
Net Assets	468	311	191	159	114	443	1,209
CASH FLOW							
Operating Cash Flow	(35)	(112)	34	(246)	(113)	320	930
Net Interest	(8)	(5)	(5)	(6)	(23)	(31)	(30)
Tax	0	0	0	0	0	0	0
Capex	(3)	(5)	(5)	(82)	(146)	(149)	(152)
Acquisitions/disposals	0	(10)	12	0	0	0	0
Financing	0	245	(52)	11	0	0	0
Dividends	0	0	0	0	0	0	0
Other	0	(13)	0	0	0	0	0
Net Cash Flow	(46)	100	(17)	(324)	(282)	139	748
Opening net debt/(cash)	(75)	(41)	(132)	(115)	103	385	246
HP finance leases initiated	0	0	0	0	0	0	0
Exchange rate movements	0	0	(0)	0	0	0	0
Other	13	(9)	(1)	106	0	0	0
Closing net debt/(cash)	(41)	(132)	(115)	103	385	246	(503)

Source: Edison Investment Research, Orexo financial statements

Contact details	Revenue by geography (2012)
Virdings allé 32 A SE - 753 50 Uppsala Sweden +46 (0)18 780 88 00 hwww.orexo.com/en/	

CAGR metrics		Profitability metrics		Balance sheet metrics		Sensitivities evaluation	
EPS 10-14e	N/A	ROCE 2013e	N/A	Gearing 13e	N/A	Litigation/regulatory	●
EPS 12-14e	N/A	Avg ROCE 10-14e	N/A	Interest cover 13e	N/A	Pensions	○
EBITDA 10-14e	N/A	ROE 2013e	N/A	CA/CL 13e	0.9	Currency	◖
EBITDA12-14e	N/A	Gross margin 2013e	90.9%	Stock days 13e	228.1	Stock overhang	○
Sales 10-14e	32.4%	Operating margin 2013e	N/A	Debtor days 13e	133.7	Interest rates	◖
Sales 12-14e	40.8%	Gr mgn / Op mgn 2013e	N/A	Creditor days 13e	91.2	Oil/commodity prices	○

Management team

CEO: Nikolaj Sørensen

Mr Sørensen has been CEO since February 2013, having joined Orexo in October 2011 as chief commercial officer. He has international commercial experience of the pharmaceuticals industry from roles at Pfizer and Boston Consulting Group. He was a board member of the Swedish Pharmaceutical Industry Association (LIF) until 2012, and holds an MSc in business and economics.

EVP and CFO: Henrik Juuel

Mr Juuel has been EVP and chief financial officer since July 2013. He has extensive experience in the life sciences industry, having been CFO for NNE Pharmaplan and GN Resound, and holding several senior finance positions at Novo Nordisk. He is a board member at Baslev AS and holds an MSc in economics and business administration.

President of Orexo US: Robert DeLuca

Mr DeLuca has been president of US operations since 2013. He has extensive experience in establishing commercial operations in the US, with a background in market access, marketing and sales. He was most recently chief commercial officer at Archimedes Pharmaceutical and previously held positions at Sanofi-Aventis, Schering-Plough, Berlex and Pharmacia.

Chairman: Martin Nicklasson

Dr Nicklasson has been chairman since 2012. He is also chairman of Farma Holding AS, a board member of Pozen Inc, Oasmia AB, Biocrine AB and Denator AB, and a member of the Royal Academy of Engineering Sciences (IVA). His previous roles include CEO at Swedish Orphan Biovitrum, senior management roles at Astra/AstraZeneca with responsibilities for global drug development and marketing and business development, and CEO at AstraZeneca Sweden AB. He was also CEO at Astra Hässle AB and responsible for R&D within KABI. He holds MSc Pharm and PhD degrees and is associate professor at the Faculty of Pharmacy, Uppsala University.

Principal shareholders	(%)
Novo A/S	29.6
Healthcap	17.0
Arbejdsmarkedets Tillaegspension (ATP)	5.7
Abingworth	3.7
Orexo AB	3.4
Försäkringsaktiebolaget Avanza pension	3.2
Brohuvudet AB	2.8

Companies named in this report

Actavis (ACT:US), Amneal, Astra Zeneca (AZN:LN); Biodelivery Sciences International (BDSI:US); Boehringer Ingelheim; Galena Biopharma (GALE:US); Insys Therapeutics (INSY:US); IntelGenex (IGXT:US); Kyowa Hakko Kirin (4151:JP); Meda (MEDAA:SS); Par Pharmaceuticals; ProStrakan; Reckitt Benckiser (RB/:LN).

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