EDISON

Orexo

Positive binary event

Orexo wins patent litigation appeal

Pharma & biotech

Orexo's appeal of the US District Court's invalidation of the '330 patent, which had been anticipated for some months, has been successful. Zubsolv is Orexo's largest and fastest-growing product – we anticipate sales of c SEK620m and over 25% growth in FY18. The initial invalidity of the '330 patent had weighed on the shares since 2014 and this overhang has now been removed. The exclusivity of the Zubsolv patents runs until 2019 and 2032. We have updated our valuation ahead of the Q318 results.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/16	705.9	35.6	0.84	N/A	79.4	N/A
12/17	643.7	29.7	0.67	N/A	99.6	N/A
12/18e	814.0	109.0	2.89	N/A	23.1	N/A
12/19e	949.4	159.8	4.48	N/A	14.9	N/A

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

Orexo wins its appeal of the District Court's invalidation of the Zubsolv '330 patent

We have updated our model for our sales expectations for the Q318 results and a number of other changes that now include Zubsolv US exclusivity until 2032. Orexo has done an exceptional job in growing branded Zubsolv revenues in the face of competition from a genericised opioid-dependency category. Our experience in the pricing and reimbursement space suggests that Orexo's successful US market access and reimbursement strategy for Zubsolv was eventually bound to attract a serious intellectual property challenge in an attempt to replicate the product's success.

With great rewards come potential generic threats

The commercial success of Zubsolv in the US for the treatment of opioid dependency made it an obvious and attractive target by the generic company Actavis, now owned by Teva. A long patent litigation resulted first, in the affirmation of the validity of Orexo's '996 patent, which runs until October 2019; but then the '330 patent was invalidated – and appealed by Orexo. Orexo's successful three-to-zero appeal ruling means that the '330 and other patents now remain in effect until 2032. Orexo also has outstanding patent infringement actions against Actavis' Subtex and Suboxone generics, based on the valid and not appealed '996 patent.

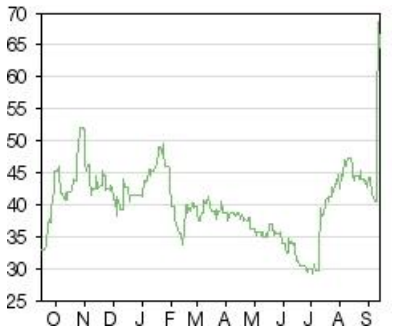
Valuation: Overhang removed; brakes off

Ahead of Orexo's Q3 results, we have increased our valuation to SEK3.3bn or SEK94.5 per share (from SEK2.52bn or SEK72.0 per share previously) to include the expected cash generation in the quarter, foreign exchange rate changes and Zubsolv exclusivity until 2032. We have also absorbed Orexo's historical SEK1.46bn tax-loss carry-forwards, which, based on our estimates, suggest Orexo's tax rate will increase to 20.6% in 2025. We have also brought forward the gross margin improvements since the more expensively produced Zubsolv batches had been sold in the higher volumes of H1.

13 September 2018

Price	**SEK66.70**
Market cap	**SEK2,365m**
	$/SEK 9.09; €/SEK10.52
Net cash (SEKm) estimated end-September 2018	204
Shares in issue	34.6m
Free float	37.6%
Code	ORX
Primary exchange	NASDAQ QMX Stockholm
Secondary exchange	NA

Share price performance



%	1m	3m	12m
Abs	36.8	92.3	110.1
Rel (local)	36.6	86.2	98.6
52-week high/low	SEK68.7	SEK29.1	

Business description

Orexo is a Swedish speciality pharma company, with expertise in drug delivery/reformulation technologies (in particular sublingual formulations) and a US commercial infrastructure for opioid dependence therapy, Zubsolv (also filed in Europe). It also has two clinical assets and three preclinical programmes.

Next events

Q318 results	25 October 2018
OX124 Phase I start	Q418

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Edison profile page

Patent overhang removed

On 10 September 2018, the US Court of Appeal declared by a three-to-zero ruling that Orexo's '330 patent was valid, offering a "significant improvement" for the treatment of opioid dependency and that its "novel formulation" provided patients with lower doses [of buprenorphine/naloxone] and less dependency. This means that the decision taken in November 2016 declaring the invalidity of the '330 patent in favour of Actavis (now Teva) has now been declared invalid.

A convoluted overhang, now resolved

Actavis's challenge of Orexo's patents had been broad, covering two patents and initially two of the dosage strengths that corresponded to Zubsolv 1.4/0.36mg, and 5.7/1.4mg buprenorphine/naloxone. In a bittersweet judgement in November 2016 by the District Court, the '996 patent protecting Zubsolv's exclusivity until September 2019 was judged as valid and would be infringed by Actavis's products. The '330 patent, due to expire in September 2032, was, however, judged to be invalid. Orexo quickly appealed the decision in December 2016 and oral arguments were heard from both sides at the Federal Appeals Court in October 2017. The final ruling from the appeal was expected to take about three to six months, although it actually took 11 months.

Meanwhile, Orexo had been doing a textbook market access job by gaining and renewing formulary access in the face of generic competition in the opioid dependency category, with exclusive and non-exclusive price-volume contractual agreements with companies like Humana (on Medicare Part D), United Health and CVS (commercial). This had resulted in Zubsolv being almost universally reimbursed in the commercial segment and, for the latest two quarters of 2018, being the only branded product in the category growing its volume market share. At the same time, Orexo had been taking advantage of the higher Zubsolv volumes with manufacturing efficiencies that have reduced its cost of goods.

It is not surprising, therefore, that Zubsolv in the US and Orexo's IP covering the drug delivery and release profile of the drug combination should be a target for generic companies, even though there is generic competition in the buprenorphine/naloxone category. The US Court of Appeal's declaration of invalidity of the District Court's judgement is now expected to have three effects:

- The case will be remanded back to the District Court for the invalidity of the earlier judgement to be confirmed.
- The '996 and '330 patents remain in force, giving Orexo market exclusivity until September 2032.
- Additional but separate patent actions by Orexo that had been on hold, can now proceed. These concerned the infringement of Orexo's previously judged valid '996 patent by Actavis' marketed generics of Subutex and Suboxone. The '996 patent was not appealed by Actavis.

We have kept our near-term model drivers unchanged, as is Orexo's 2018 guidance, although we have taken the opportunity to reflect longer-term changes to our model in the valuation section below.

Not the end of legal proceedings

With patent infringement cases initiated by Orexo against Actavis still outstanding and expected to come off hold now that the '330 appeal has been upheld, we have not made any changes to our forecast for administrative expenses (which includes legal expenses related to IP litigation) for FY18 of SEK104m.

Valuation

Following Orexo's successful appeal of the patent litigation that was a result of Actavis's challenge on the '330 patent, we have made a number of routine and more significant changes to our valuation.

Routine changes

Since Orexo is cash-generative, our valuation has been updated firstly to include the expected cash generation in Q318. We have also incorporated the changes to the exchange rates carried forward since Orexo has sales and costs in US dollars, and royalties in euros. (The US$/SEK rate moved to 9.09 from 8.78 while the €/SEK rate moved to 10.52 from 10.29.) We have also incorporated the detail in the Q2 report on Orexo's tax-loss carry-forwards by absorbing most of Orexo's losses until the tax-losses are exhausted. This suggests that, based on our estimates, Orexo will start paying meaningful tax on profits at the Swedish corporate tax rate from 2025 which, by then will be 20.6%. (We had previously estimated Orexo's tax rate at 3% based on the profit earned by a subsidiary.) We have also brought forward the gross margin improvements to US Zubsolv, as it was announced at the Q2 results that the more expensively produced inventory, which had been produced at lower volumes and had been depressing gross margins, had all been sold in the higher volumes of H1.

Changes relating to the patent infringement win

We had constructed a new financial model on Orexo earlier in 2018 with a separate horizon period running until 2027 and a terminal value representing cash flows beyond 2027. Some of those timeframes have to be redrawn and, in the first instance, the horizon period now runs until the expiry of the '330, '421 and '900 patents, which all extend until September 2032. We have assumed that Orexo continues to grow Zubsolv market share in the US and does not suffer direct generic competition until 2032.

Our valuation changes from SEK2.52bn or SEK72.0 per share previously, to SEK3.3bn or SEK94.5 per share, based on continuing US Zubsolv market share growth until 2032 (representing 72% of our valuation) and a smaller terminal value that includes any Zubsolv sales after 2032, sales of OX124 and any acquisitions of products to be sold by the US commercial team (representing 22% of our total valuation). Royalties on Zubsolv in the EU, Abstral and Edluar are smaller components of our valuation in comparison to Zubsolv in the US. The effect of the changes to our model as a result of our preparation for the Q3 results and the patent appeal win are shown in Exhibit 1.

Exhibit 1: Individual effect of valuation changes

Model component	Component valuation change
DCF extension from 2027 to 2032 and terminal valuation reduction	18.5%
Earlier gross margin improvements	15.0%
Foreign exchange rates carried forward	1.4%
Forecast Q3 cash generation	0.9%
Tax-loss absorption until 2025 and 20.6% tax rate thereafter	-9.7%

Source: Edison Investment Research. Note: component changes are shown as individual effects, while in our model the effects of foreign exchange and DCF extension, for example, are more than additive.

Minor changes expected from here

Orexo's announcement of the patent litigation win was accompanied by no expected changes to its previously announced financial guidance for FY18. We have made minor changes near term to exchange rates, for example, and the cash we expect to be generated in Q3, but the only substantive changes we expect to make to our model in the medium term are in administrative expenses to reflect legal costs (on Actavis' generic versions of Subutex and Suboxone tablets), and any damages awarded, or settlement agreed to, from the patent action against Actavis.

Financials

Orexo's Q318 financial results are expected to be announced on 25 October. We have left our estimates of the quarterly sales and expenses largely unchanged until then; our estimates for FY18 and FY19 are summarised in Exhibit 2.

We estimate net income of SEK108m for FY18 and SEK35.6m for Q318 on total revenues of SEK814m in FY18 and SEK221m for Q318. Orexo has previously guided to operational expense of SEK500m for FY18 and our model estimates SEK515m. Our 70% gross margin estimate for Q318 now rises to 80% gross margin by Q120 (previously 75%), to reflect the earlier-than-expected sales of the more expensively produced, lower-volume batches of Zubsolv in the US, which were previously expected to be in the inventory until Q219. It is important to note that gross margin is calculated only on the Zubsolv batches that Orexo sells itself in the US, although when royalties start to flow from EU Zubsolv sales via Mundipharma we may have to make an additional assumption on the toll-manufacturing margin.

Exhibit 2: Changes to our near-term estimates

	Revenue (SEKm)			PBT (SEKm)			EPS (SEK)		
	Old	New	Change	Old	New	Change	Old	New	Change
2018e	801	814	0.6%	110	109	-0.9%	2.9	2.9	0%
2019e	918	933	1.5%	161	156	-3.1%	4.5	4.4	-2.3%

Source: Edison Investment Research. Note: the US$/SEK rate was updated to 9.09 from 8.78, and the €/SEK rate was updated to 10.52 from 10.29.

Other products

Orexo's licensed products (other than Zubsolv) are sold by distributors that includ Zubsolv by Mundipharma ex-US. EU Zubsolv was launched in Q218 and we are assume minor royalties of SEK3.2m in the EU and SEK5.9m for the rest of the world for Zubsolv ex-US in FY18.

We forecast SEK121m in royalties for Abstral (fentanyl sublingual tablets for severe cancer pain) and SEK17.6m for Edluar (zolpiderm sublingual tablets for sleep disorders) in FY18.

The balance sheet is healthy

We forecast that Orexo will end Q318 with SEK524m in cash, having generated about SEK30m in the quarter. Orexo has SEK320m in debt (SEK325m including capitalised expenses). Given that the big uncertainty has passed, we will be interested in hearing the business development plans for Orexo's cash balance that could add in-licensed products to leverage its US commercial organisation.

On the conference call following the announcement of the patent appeal win, management mentioned that product acquisitions that are compatible with Orexo's US salesforce are now more likely, since potential licensors would have been restrained by the unresolved appeal and its implication for Orexo's cash balance. Now that Orexo is successfully past that point, it is possible that potential licensors and M&A partners would regard an Orexo equity component of a licensing transaction much more favourably and this could open the door to much larger transactions.

Investment summary

Specialists in drug delivery for addiction and pain

Orexo is a Swedish speciality pharmaceutical company founded in 1995 to use its drug delivery technologies to develop and market products to treat addiction and pain. Orexo's products are based on its patented drug delivery technologies and its expertise in reformulation (in particular employing sublingual formulations). It has three marketed proprietary drugs. Orexo's lead drug Zubsolv (for opioid dependence) has been sold by Orexo in the US through its dedicated salesforce since its launch in September 2013. Mundipharma has been granted the licence to the ex-US rights and launched Zubsolv in the EU in Q218. Abstral (cancer breakthrough pain) and Edluar (insomnia) are sold by partners worldwide. Orexo also has a pipeline of reformulations of approved compounds that include OX124 – a naloxone rescue medication for opioid overdose that will start Phase I in Q418. Orexo has 89 employees (excluding the c 50-strong US salesforce); US commercial operations are based in New Jersey and its R&D facility is located in Sweden. It adopted the name Orexo in 2003 and was listed on NASDAQ-OMX Stockholm in November 2005, raising SEK333m gross (3.7m shares at SEK90). Subsequent equity raises include SEK250m in June 2011 (6.6m shares at SEK38) and SEK346.3m in September 2014 (2.5m shares at SEK139).

Valuation: SEK3.3bn or SEK94.5 per share

Our valuation has been updated to include the expected cash generation in Q318, the changes to exchange rates carried forward and our estimation of the exhaustion of Orexo's tax-loss carry-forwards in 2025. Our valuation changes from SEK2.52bn or SEK72.0 per share previously, to SEK3.3bn or SEK94.5 per share based on continuing US Zubsolv market share growth until 2032 (representing 73% of our valuation) and a small terminal value that includes Zubsolv sales after 2032, sales of OX124 and any acquisitions of products to be sold by the US commercial team (representing 21% of our total valuation). Royalties on Zubsolv in the EU, Abstral and Edluar are minor components of our valuation in comparison to Zubsolv in the US. We have also brought forward the gross margin improvements to US Zubsolv, since it was announced at the Q2 results that the more expensively produced inventory had all been sold in the higher volumes of H1.

Financials: Positive EBITDA expected to continue

Orexo has guided to a third year of profitability in FY18 and we currently estimate net income of SEK108m for FY18 and SEK35.6m for Q318 on total revenues of SEK814m in FY18 and SEK221m for Q318. Orexo has guided to operational expense of SEK500m for FY18 and our model estimates SEK515m and a 70% gross margin for Q318, rising to 80% by Q120.

- The key investor concern had been the initial invalidity of the Zubsolv '330 patent, which expires in 2032. Orexo has prevailed in its appeal of the '330 patent invalidity case.
- Near-term financials have been largely unaffected by Orexo's recent win on the appeal of the validity of the '330 patent.

Investment proposition

Orexo is an operating speciality pharmaceutical company with positive cash flow and growing franchises. This means that:

- Orexo's positive cash flow should be attractive to investors who want exposure to drug development and commercialisation without the prospect of continual fund-raising. Orexo's management have committed to maintaining cash flow positive status.
- Orexo's largest product is for opioid dependence, which is a high-profile and growing issue, particularly in the US where Orexo sells the product directly.

- The opioid dependency category includes generic formulations of formerly branded products, but not Orexo's Zubsolv. Despite the availability of generics in the category, Orexo has grown its volume market share by negotiating price-volume agreements with public and private payers.
- Orexo has the capability to navigate the complicated US reimbursement space and grow the Zubsolv brand in the face of generic competition.
- Orexo's other products – Abstral and Edluar – are smaller but useful parts for the diversification of investment case, and on which Orexo earns royalties. Our model includes the expiry of the Abstral IP in the EU at the end of 2019.
- Orexo's US commercial organisation and network of ex-US licensees provide a compelling conduit for new products in the addiction management or pain space, whether they are internally developed by Orexo (as in the case of OX124), or acquired as part of Orexo's business development or M&A strategies.

Orexo is targeting the addiction and pain specialists where new products could leverage its commercial operation.

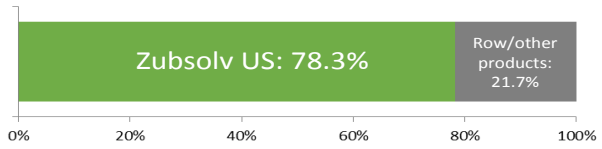
Overhang removed, some sensitivities will always remain

Although our model has been updated for a number of recent positive events at Orexo, the potential for generic companies to clog up the patent courts should not be underestimated. The US Federal Court of Appeals has remanded the erroneous invalidation by the trial judge on the '330 patent back to the District Court for review. Actavis (now Teva) may try other routes to invalidate the '330 patent, but its best attempt has probably already been rejected by the Appeals Court. Moreover, Orexo has other US Zubsolv patents ('421 and '900) that run until 2032, as well as other patent infringement actions against Actavis (Teva) based on Orexo's '996 patent, which has been judged valid (and which Actavis has not appealed). Therefore, the greater potential now is probably for Orexo to be awarded damages based on sales of Actavis's generic versions of Suboxone and Subutex that would be an upside sensitivity to our valuation.

Exhibit 3: Financial summary

SEKm	2014	2015	2016	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT						
Revenue	570.3	643.3	705.9	643.7	814.0	949.4
Cost of Sales	(107.4)	(136.1)	(149.6)	(164.4)	(183.1)	(195.7)
Gross Profit	462.9	507.3	556.3	479.3	630.9	753.6
Reported operating profit	(25.0)	(169.0)	51.7	57.4	115.6	198.2
Net Interest	(27.6)	(22.1)	(16.1)	(27.7)	(6.6)	(38.5)
Profit before tax (reported)	(52.6)	(191.1)	35.6	29.7	109.0	159.8
Reported tax	(4.0)	(6.9)	(6.5)	(6.5)	(3.8)	(4.8)
Profit after tax (reported)	(56.6)	(198.0)	29.0	23.2	105.2	155.0
Minority interests	0.0	0.0	0.0	0.0	5.3	0.0
Net income (reported)	(56.6)	(198.0)	29.0	23.2	99.9	155.0
Basic average number of shares outstanding	33.0	34.0	35.0	35.0	34.6	34.6
EPS - basic reported (SEK)	-1.73	-5.74	0.84	0.67	2.89	4.48
EPS - normalised fully diluted	-1.73	-5.74	0.84	0.67	2.88	4.47
Revenue growth (%)	32.8	12.8	9.7	(8.8)	26.5	16.6
Gross margin (%)	81.2	78.8	78.8	74.5	77.5	79.4
BALANCE SHEET						
Fixed assets	289.5	185.9	185.1	176.5	171.5	164.5
Intangible assets	197.0	159.1	138.2	121.0	106.6	96.3
Tangible assets	29.1	24.7	22.1	20.1	21.6	24.9
Investments & other	63.4	2.1	24.8	35.4	43.3	43.3
Current assets	936.4	830.4	833.7	827.4	1,083.0	1,244.9
Stocks	478.1	398.9	344.2	250.2	150.0	150.0
Debtors	173.8	233.4	178.5	249.3	392.4	413.8
Cash & cash equivalents	284.5	198.1	282.4	327.9	540.6	681.2
Other	0.0	0.0	28.6	0.0	0.0	0.0
Current liabilities	(268.1)	(251.6)	(309.5)	(349.9)	(488.5)	(488.5)
Creditors	0.0	0.0	0.0	0.0	0.0	0.0
Short-term borrowings	(1.9)	0.0	0.0	0.0	0.0	0.0
Other	(266.2)	(251.6)	(309.5)	(349.9)	(488.5)	(488.5)
Long-term liabilities	(502.8)	(498.3)	(399.0)	(324.9)	(323.7)	(323.7)
Long-term borrowings	(493.8)	(494.4)	(397.8)	(319.1)	(319.8)	(319.8)
Other long-term liabilities	(9.0)	(3.9)	(1.3)	(5.8)	(3.9)	(3.9)
Net assets	455.0	266.5	310.3	329.1	442.3	597.3
Shareholders' equity	455.0	266.5	310.3	329.1	442.3	597.3
CASH FLOW						
Operating cash flow before WC and Tax	(35.5)	(119.4)	67.5	108.1	134.6	167.5
Working capital	(451.8)	17.2	88.7	0.0	58.5	(21.4)
Exceptional & other	(19.0)	(20.6)	(20.8)	(37.2)	(16.6)	(38.5)
Tax	(4.0)	(6.9)	(7.5)	0.0	(4.5)	(4.8)
Net operating cash flow	(487.3)	(102.2)	156.2	146.6	193.1	146.1
Capex	(71.7)	(4.1)	0.5	(1.6)	(4.8)	(5.6)
Acquisitions/disposals	0.0	21.8	5.0	0.0	0.0	0.0
Equity financing	349.3	3.8	2.2	0.1	0.1	0.0
Other	0.0	0.0	0.0	0.0	0.4	0.0
Net cash flow	(209.7)	(80.7)	163.9	145.1	193.1	140.6
Opening Net debt (cash)	(1.5)	209.3	296.3	115.4	(8.8)	(220.8)
Other	(1.2)	(6.4)	17.0	(20.9)	18.9	0.0
Closing Net debt (cash)	209.3	296.3	115.4	(8.8)	(220.8)	(361.4)

Source: Orexo, Edison Investment Research

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

Management team

CEO: Nikolaj Sørensen

Mr Sørensen has been CEO since 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 the 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 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. Henrik 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, a board member of Pozen, Oasmia, Biocrine and Denator, 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. He was also CEO at Astra Hässle 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	27.9
HealthCap Venture Capital	11.5
Arbejdmarkedets Tillaegspension (ATP)	5.9
Walldov Anders	4.3
Försäkringsaktiebolaget Avanza pension	4.2
Nordnet Pensionsförsäkring	1.6
Lancelot Asset management	1.6

Companies named in this report

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