

Orexo

Earnings update

Record quarter reflecting shifting US market

Orexo reported a record performance for Q319 with revenue of SEK231.2m (+6.7% year-on-year). The top line was lifted by a combination of factors including currency and a shift in the reimbursement landscape for Zubsolv in the US toward higher-margin business, translating into a record EBIT of SEK105.9m, over three times that of Q318, and SEK135.7m in operating cash flow. Orexo ended the period with SEK813m in cash (SEK524m net), which we expect the company will reinvest in new assets and its pipeline, including the initiation of a Phase I study of OX338 (complete in Q419).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	643.7	29.7	0.67	0.00	96.6	N/A
12/18	783.1	92.2	3.99	0.00	16.2	N/A
12/19e	874.9	292.0	8.48	0.00	7.6	N/A
12/20e	860.1	271.1	7.59	0.00	8.5	N/A

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

Improved margins driven by lower rebates

The company reported US Zubsolv sales of SEK182.7m for Q319, up 10% year-on-year, 3% in constant currency. Importantly, however, this is on the back of slightly lower volume (-4% year-on-year) as the product transitions out of exclusivity arrangements with a number of payers toward competitive reimbursement markets, which have lower rebates. Combined with other operational efficiencies instituted by the company these factors translated to an EBIT margin of 45.8%, compared to 16.0% for the same period in 2018.

Expanding markets and new geographies

Although unit sales of Zubsolv were down slightly due to these payer dynamics, the US opiate treatment market continues to expand significantly. According to the company's data, the market expanded 14% on a unit basis from Q318. Additionally, in a step to expand its ex-US footprint, the company signed a licence agreement with Mundipharma to supply Zubsolv in Australia and New Zealand.

OX338 enters the clinic

In October 2019, the company initiated a Phase I clinical study of OX338, a sublingual formulation of ketorolac. Currently ketorolac is labelled for oral use only following an IV or IM induction, and the sublingual formulation would potentially allow patients to skip these initial injections. The Phase I study will examine the pharmacokinetics of the product; it is expected to complete quickly (in Q419) and provide results in 2020.

Valuation: Increased to SEK4.21bn

We have increased our valuation of Orexo to SEK4.21bn or SEK121.30 per share, from SEK3.46bn, or SEK98.79 per share. This increase is driven by improved profitability to reflect the improved margins in the current Q319 report. Our revenue estimates remain roughly the same.

Pharma & biotech

31 October 2019

Price **SEK64.7**
Market cap **SEK2245m**

SEK9.69/US\$

Net cash (SEKm) at end Q319 524

Shares in issue 34.7m

Free float 54.18%

Code ORX

Primary exchange NASDAQ QMX Stockholm

Secondary exchange OTCQX

Share price performance



% 1m 3m 12m

Abs 20.7 (9.6) 5.4

Rel (local) 15.6 (14.9) (10.0)

52-week high/low SEK85.70 SEK51.60

Business description

Orexo is a Swedish speciality pharma company with expertise in drug delivery/reformulation technologies (particularly sublingual formulations) and US commercial infrastructure for its opioid dependence therapy, Zubsolv (marketed by Orexo in the US and being out-licensed to partners ex-US). It has three other clinical assets including OX124, which has reported positive Phase I results.

Next events

OX338 Phase I complete Q419

FY19 results 30 January 2020

Analyst

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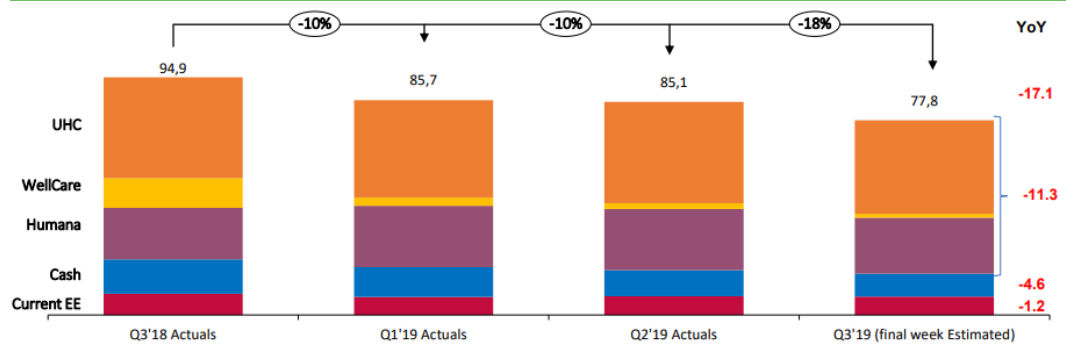
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Shift from exclusive agreements pays off

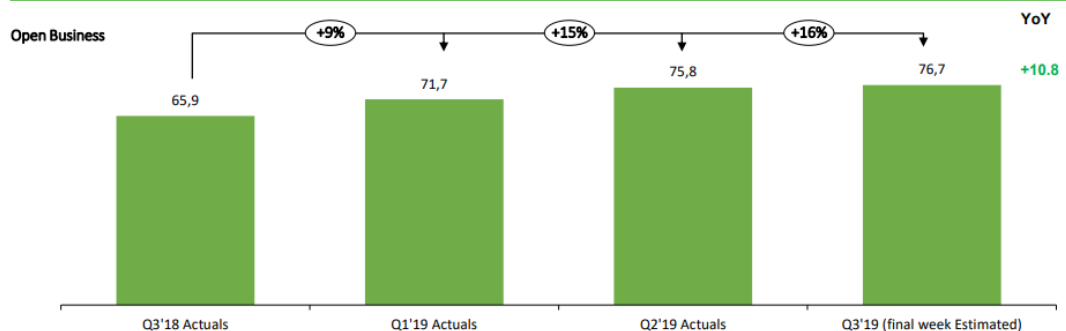
The revenue mix for the company continues to evolve as volume that was previously generated through exclusive agreements with payers shifts into competitive markets. These exclusive agreements are made at the cost of high rebates to payers. Additionally, the company is seeing contraction in the cash-pay market, which is likely due to pricing pressure from reduced cost generics. Although the total volume has declined, revenue has continued to expand as the non-exclusive payer market has fewer rebates attached. These market shifts are reflective of the increased penetration of generics, but the market shifts have also been away from branded Suboxone. CVS Caremark was recently the first pharmacy benefit manager (PBM) to block branded Suboxone. We are very impressed that the company has been able to improve its profitability so substantially in the face of this shifting market, which has led to the record earnings seen in Orexo's latest earnings report.

Exhibit 1: Volume (in thousands) from formerly exclusive formularies and cash-pay markets



Source: Orexo

Exhibit 2: Volume (in thousands) from competitive markets (ex cash-pay)

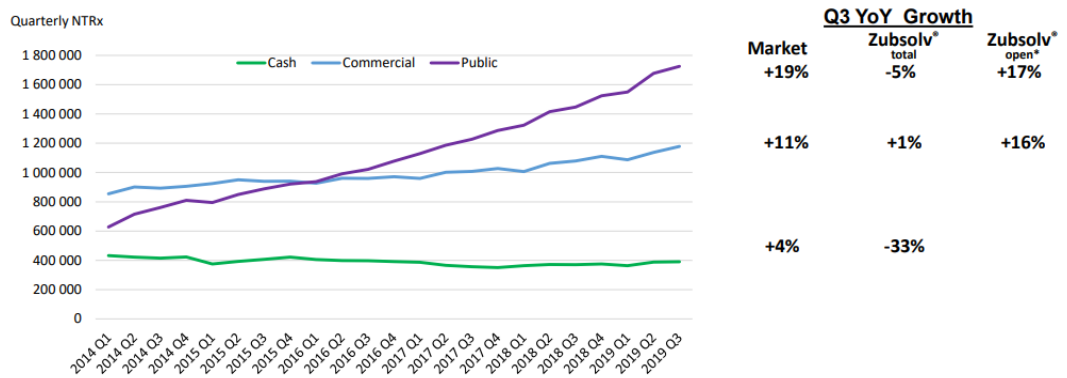


Source: Orexo

Market expansion driven by public payers

We believe there will be continued support of pricing and reimbursement as the opiate epidemic continues and public pressure remains. The company stated it believes the recent major settlements with companies involved in the epidemic will increase the amount of public funds available for treatment, which may improve the market landscape. This increased public awareness and support is reflected mostly in the market growth seen from public payers, which expanded 19% over the past 12 months.

Exhibit 3: Buprenorphine/naloxone market growth by payer type



Source: Orexo

OX338: Sublingual ketorolac enters clinic

The company's latest development project to enter the clinic is OX338, a sublingual formulation of the power NSAID (non-steroidal anti-inflammatory drug) ketorolac. The product entered a Phase I study focused on pharmacokinetics in October 2019. Ketorolac is an NSAID similar to ibuprofen but significantly more potent and capable of providing opiate levels of pain relief. It is typically used in a post-surgical setting as an alternative to opiates to provide a short period of pain relief. However, its potency also translates to higher risks of complications, particularly ulcers, which necessitate a specific dosing schedule. Oral ketorolac is labelled for use to follow-up on IV ketorolac for up to five days. The sublingual formulation could potentially be used as an alternative to the IV induction period. Given that the efficacy of the drug is not in question and the adverse event profile is well understood, we expect the ongoing pharmacokinetic study to be highly informative to whether the product is a viable alternative to IV.

Valuation

We have increased our valuation of Orexo to SEK4.21bn or SEK121.30 per share, from SEK3.46bn, or SEK98.79 per share. This is driven primarily by carrying forward the improved margins seen in Orexo's Q319 earnings report. We forecast PBT margins of 33% and 32% for 2019 and 2020 respectively (up from 25% and 22% previously). Our revenue expectations remain roughly unchanged. We expect a lag in revenue for 2020 compared to 2019 due to the loss of a significant portion of Abstral royalties, as the European contract with Kyowa Kirin expires at YE19 and US partner Sentyln will withdraw the product from sale in Q419. Additionally, our valuation is increased as a result of increased net cash (SEK524m, from SEK376m at H119).

Exhibit 4: Financial summary

	SEKm	2017	2018	2019e	2020e	2021e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT						
Revenue		643.7	783.1	874.9	860.1	934.7
Cost of Sales		(164.4)	(171.8)	(120.5)	(112.1)	(116.7)
Gross Profit		479.3	611.3	754.4	748.0	818.0
Reported operating profit		57.4	95.8	264.6	229.4	253.7
Joint ventures & associates (post tax)						
Profit before tax (reported)		29.7	92.2	292.0	271.7	312.6
Reported tax		(6.5)	45.7	(2.1)	(8.2)	(9.4)
Profit after tax (reported)		23.2	137.9	289.9	263.6	303.3
Minority interests		0.0	7.0	(6.4)	0.0	0.0
Basic average number of shares outstanding ('m)		35.0	34.6	35.0	34.7	34.7
EPS - basic reported (SEK)		0.67	3.99	8.48	7.59	8.74
BALANCE SHEET						
Fixed assets		176.5	227.1	307.3	310.8	315.3
Intangible assets		121.0	103.9	99.4	89.8	81.1
Tangible assets		20.1	20.0	22.7	35.8	48.9
Investments & other		35.4	103.2	185.3	185.3	185.3
Current assets		827.4	1,059.5	1,347.5	1,607.6	1,906.4
Stocks		250.2	173.6	150.0	159.2	159.2
Debtors		249.3	296.1	332.1	273.6	297.3
Cash & cash equivalents		327.9	589.8	865.4	1,174.7	1,449.9
Other		0.0	0.0	0.0	0.0	0.0
Current liabilities		(349.9)	(483.4)	(538.0)	(538.0)	(538.0)
Creditors		0.0	0.0	0.0	0.0	0.0
Short-term borrowings		0.0	0.0	0.0	0.0	0.0
Other		(349.9)	(483.4)	(538.0)	(538.0)	(538.0)
Long-term liabilities		(324.9)	(327.1)	(335.7)	(335.7)	(335.7)
Long-term borrowings		(319.1)	(320.6)	(289.2)	(289.2)	(289.2)
Other long-term liabilities		(5.8)	(6.5)	(46.5)	(46.5)	(46.5)
Minority interests						
CASH FLOW						
Operating cash flow before WC and Tax		108.1	70.6	274.5	275.9	316.0
Working capital		0.0	116.7	(82.2)	49.3	(23.6)
Exceptional & other		(37.2)	(14.3)	4.2	42.3	59.0
Tax		0.0	(18.1)	(12.5)	(8.2)	(9.4)
Net operating cash flow		146.6	187.3	192.3	325.2	292.4
Capex		(1.6)	(6.8)	(16.9)	(15.8)	(17.2)
Acquisitions/disposals		0.0	0.0	0.0	0.0	0.0
Equity financing		0.1	0.0	0.0	0.0	0.0
Other		0.0	0.4	43.0	0.0	0.0
Net cash flow		145.1	261.9	218.4	309.4	275.2
Opening Net debt (cash)		115.4	(8.8)	(269.2)	(576.2)	(885.5)
Other		(20.9)	(1.5)	88.6	0.0	0.0
Closing Net debt (cash)		(8.8)	(269.2)	(576.2)	(885.5)	(1,160.7)

Source: Orexo reports, Edison Investment Research

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