EDISON

# Orexo

Business update

## Updates from the capital markets day

Pharma & biotech

**On 17 March 2020 Orexo held a capital markets day at which it provided an update on its programs and estimates of the impact of COVID-19 on its business. In short, Orexo is predicting a limited impact from the virus, which is consistent with our estimates. It also highlighted its development pipeline, which will be a major focus of the company. It will be launching its next product, vorvida for problem drinking, in Q320 if the FDA signs off.**

| Year end | Revenue (SEKm) | PBT* (SEKm) | EPS* (SEK) | DPS (SEK) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/18 | 783.1 | 92.2 | 3.99 | 0.0 | 11.8 | N/A |
| 12/19 | 844.8 | 227.9 | 6.33 | 0.0 | 7.4 | N/A |
| 12/20e | 775.4 | 200.3 | 5.62 | 0.0 | 8.4 | N/A |
| 12/21e | 918.6 | 245.5 | 6.82 | 0.0 | 6.9 | N/A |

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

## Limited impact of COVID-19 expected

We forecast Zubsolv sales of SEK747.6m for 2020, which is a slight increase over 2019 (SEK719.2m), similar to company guidance and a relatively conservative starting assumption. We note this is in the context of 14% annualized market growth, so even if there are disruptions, we expect demand to remain high. Moreover, the supply chain for Zubsolv is wholly in the US, which should limit the risk of supply-side disruptions.

## Pipeline front and center

The company provided a pipeline update of its three lead drug development programs. OX124 is being developed as a more potent naloxone spray to address the increased presence of fentanyl (pivotal study late 2020). OX125 is also an opioid overdose rescue treatment but using the longer half-life nalmefene (first-in-human study in Q220). Finally the company's sublingual ketorolac OX338 is aimed at simplifying the treatment algorithm for that drug, which typically includes an injection with follow-up tablets (new study being planned, targeting NDA submission in 2022).

## Pricing of vorvida revealed: $600–1,000 per treatment

The company announced in the meeting the expected price point for vorvida, its digital therapeutic for problem drinking: $600–1,000 per treatment. We feel this seems high, especially for an unvetted market, but it is substantially less than even the least expensive in-person treatment options and is roughly in line with digital counselling. This may provide cost savings to payers in the long run, but we expect the company will have an uphill battle demonstrating these benefits.

## Valuation: Unchanged at SEK3.65bn or SEK105.27

Our valuation remains unchanged at to SEK3.65bn or SEK105.27 per share. We expect to update our valuation when data on the development programs become available or if vorvida gains early traction.

**20 March 2020**

| | |
|---|---|
| **Price** | **SEK46.95** |
| **Market cap** | **SEK1,630m** |
| | SEK9.64/US$ |
| Net cash (SEKm) at 31 December 2019 | 527 |
| Shares in issue | 34.7m |
| Free float | 54% |
| Code | ORX |
| Primary exchange | NASDAQ QMX Stockholm |
| Secondary exchange | OTCQX |

### Share price performance


| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | (26.8) | (24.3) | (39.4) |
| Rel (local) | 6.3 | 1.7 | (28.0) |
| 52-week high/low | SEK85.70 | SEK41.25 | |

### Business description

Orexo is a Swedish pharma company focused on pharmaceuticals and, recently, digital therapeutics. Its lead product is Zubsolv, an opioid dependence therapy marketed by Orexo in the US and being out-licensed to partners worldwide. It has three other clinical assets and two digital therapies, of which three are expected to be launched in the US by the end of 2021.

### Next events

| | |
|---|---|
| OX125 first-in-human studies | Q220 |
| OX-MPI Phase I results | H120 |
| OX124 start pivotal trial | H220 |

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## Zubsolv outlook and COVID-19 impact

During the capital markets day, the company briefly outlined its outlook for Zubsolv sales and how it has been affected by the ongoing COVID-19 pandemic. As we have outlined in previous notes, the product is currently undergoing a shift in how reimbursement is structured as it shifts to non-exclusive agreements (the so-called open market). This is ongoing and expected to translate into volume reductions, albeit with better margins. An encouraging detail that the company communicated is that new prescriptions in the CVS Caremark channel have remained especially strong. CVS Caremark removed Suboxone from its formulary in October 2019, which has translated to increased sales, accounting for 80% of new Zubsolv prescriptions in 2020 to date (2,229 of 2,759 prescriptions). The removal of Suboxone from other formularies could similarly drive growth, although this cannot be guaranteed.

The company also provided feedback on the expected impact on sales of the COVID-19 pandemic. It stated that as of the most recent data to February, it has not seen a major impact of the disease (we note the most severe restrictions on the movement of people and the most severe disruptions to commerce have occurred since then). The company noted that the supply chain for Zubsolv is wholly in the US, so it expects disruption from the supply side to be limited. Sales have been redirected to digital channels, which we expect to be less of a burden for an already established product such as Zubsolv.

The company guided toward 2020 revenue in line with 2019 (SEK719.2m), which is comparable to our estimates (SEK747.6m). We are not adjusting our estimates on account of COVID-19 as we expect this market to be relatively resilient in the face of the disease. The market has been growing at a rate of 14% (in 2019), which was well above our expected growth rate for Zubsolv and we expect this to be able to absorb minor market disruptions. Moreover, as a category III scheduled drug, we expect patients to be able to order drug electronically during quarantine periods. The company noted that its estimates are contingent on the current pandemic peaking in late spring, consistent with many models, and that it may update its assumptions if this is not the case. We note that we may update our projections as the situation develops.

## Revisiting the pipeline

As Zubsolv has brought the company to profitability, it has a renewed focus on progressing and expanding its pipeline. As part of the capital markets day, the company provided an update on these plans and a review of its products.

### OX124

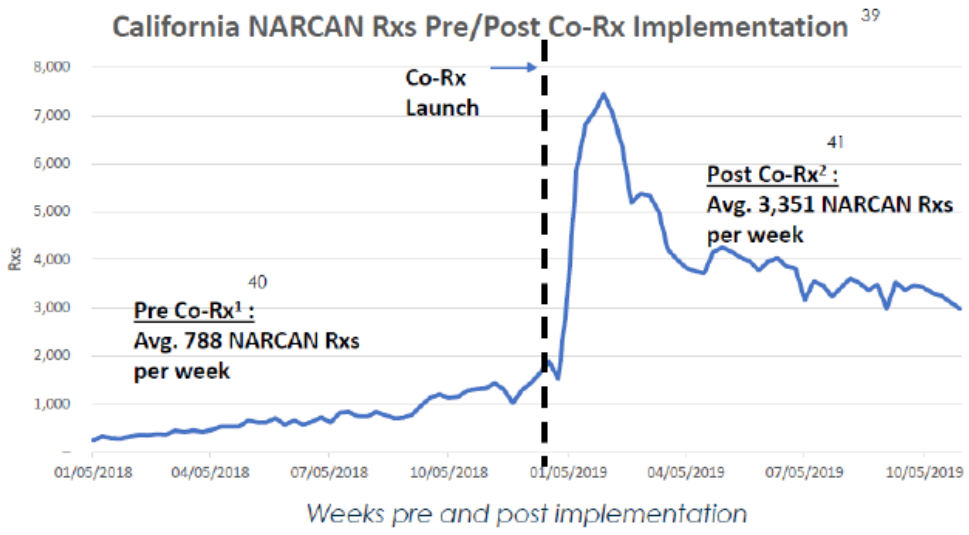
The most advanced development-stage pharmaceutical product is OX124, a nasal naloxone spray for the rescue of opioid overdose patients. In its presentation, the company highlighted the particular pharmacokinetic profile of the drug, which differentiates it from the other commercially available naloxone products. One problem with the current standard of care is that naloxone only has a half-life of two hours, but opioid overdoses increasingly involve fentanyl, which has a 12-hour or longer half-life. The goal with OX124 is to provide a product that delivers more naloxone at once and would be expected to provide more extended protection. The company noted that up to 34% of patients require a second dose of the leading product Narcan for it to be effective.

An additional tailwind the company highlighted is that there is increasing support in the US for mandatory co-prescription of naloxone with opioid products. Such measures have passed in nine states; their passing corresponds to a surge in Narcan volume (Exhibit 1). Five additional states

have this legislation on the table for 2020. The company notes that a 10% market share in 2026 would correspond to $90m in sales.

The company intends to initiate a pivotal study for OX124 in late 2020 and file an NDA in mid-2021 for a 2022 commercial launch of the product. An important fact to note is that because of ethical concerns (one cannot treat opioid overdose patients in such a study), it will essentially be a pharmacokinetics trial with healthy volunteers and we estimate approximately 90 patients (based on the Narcan precedent).

**Exhibit 1: Impact of mandatory co-prescription on California sales of Narcan**




Source: Orexo

## OX125

OX125 is the company's nalmefene-based nasal spray for opioid overdose rescue. Nalmefene is a longer-lasting opioid antagonist with a half-life of eight hours. The company envisions this being the most useful in situations where prolonged stabilization will be needed, such as in remote areas or for protection against opioid-based chemical weapons. The company does not expect it to eclipse naloxone-based products, given their dominance, but to fill in the alternative niches. It believes it can capture 5% of the overdose market this way, which translates to approximately $50m in sales. The company will need to carry out two clinical studies, with a first-in-human study planned to initiate in Q220. It forecasts a commercial launch in 2023.

## OX338

OX338 is a sublingual ketorolac formulation that Orexo is developing. Ketorolac is a powerful NSAID that can provide opiate levels of pain relief without addiction potential. The main limitation of the drug is that severe adverse effects limit it to short-term use. The drug is typically given as a single injection following surgery with patients taking home tablets of the same drug. The company's goal is to improve on this treatment algorithm by using a sublingual formulation that provides immediate relief and that avoids the need for two separate treatment modalities (by avoiding the initial injection, and allowing additional doses of the product to be taken home instead of ketorolac tablets) . The company previously completed a Phase I study of the drug and reported in January 2020 that it would revisit the formulation of the drug (although further details were not provided), with the goal of re-entering the clinic soon. The company is targeting filing an NDA with the FDA in 2022 to support a 2023 launch.

## Vorvida strategy

Orexo outlined its strategy for the launch of vorvida for the first time. It is hoping to launch the product without the need for additional clinical studies and this proposal is being reviewed by the FDA.

As part of the presentation, the company outlined the expected pricing for the product in the range of $600–1,000 per treatment. In our opinion, it is aggressive to assume that payers would support this cost structure for a digital product. However, we note this is substantially less than in-person treatment, with courses of outpatient therapy ranging from $5,000–10,000 (according to multiple providers). Compared to digital counselling, we believe the product is similarly priced. For instance, Talkspace starts at $260 per month and we would assume a minimum three-month engagement for substance abuse. However, we note this is for human interaction (whereas vorvida is automated) and is primarily a cash-pay market.

Insurance coverage for addiction treatment is mandated in many US states, so this pricing may serve as a cost-cutting measure for payers. According to the company, there are 16.6 million heavy alcohol users in the US (five or more binge drinking days in a month) and 1.5 million already in treatment, which would translate to $160m in sales if the company can capture 0.75% and 10% of these markets respectively. However, as we have previously stated, given the uncharted territory for this product, we are withholding estimates until we can gauge early adoption.

It is unclear if the market can support such disruptive technology, but there are some signals that these products can gain payer support. For instance, Germany recently passed the Digital Care Act, which requires reimbursement for certain digital therapies. Additionally, pharmacy benefits managers Express Scripts and CVS Caremark have recently taken the first steps towards setting up digital ‘formularies’ of products they will reimburse. As these processes get more formalized, we expect less friction in these markets.

One facet of this uncharted territory is that the company has not definitively identified how it intends to market the product or to whom. Possibilities include marketing directly to payers as a method of cost reduction, arrangements with provider networks to augment their offerings, or through traditional drug channels. We assume Orexo will take advantage of multiple strategies.

If the FDA determines that the clinical support for vorvida is sufficient, Orexo expects to soft-launch the product in Q320. The investment thesis for its digital therapy for opioid dependence (OXD01) is similar and Orexo plans to perform a clinical study in 2021 to support a 2022 filing.

## Valuation

Our valuation remains unchanged at to SEK3.65bn or SEK105.27 per share. Prior to revising our estimates, we need to see initial in-human data for the drug development programs and initial market traction for the digital health products. The company ended the year with SEK527m net cash, which we believe should be sufficient when paired with increasing revenue to support the current development programs.

## Financials

Our financial forecasts remain unchanged. We may update our revenue estimates if COVID-19 has a greater than expected market impact or if vorvida shows significant early sales.

## Exhibit 2: Financial summary

| SEKm | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020e | 2021e |
|---|---|---|---|---|---|---|---|---|
| Year end 31 December | IFRS | IFRS | IFRS | IFRS | IFRS | IFRS | IFRS | IFRS |
| **INCOME STATEMENT** | | | | | | | | |
| Revenue | 570.3 | 643.3 | 705.9 | 643.7 | 783.1 | 844.8 | 775.4 | 918.6 |
| Cost of Sales | (107.4) | (136.1) | (149.6) | (164.4) | (171.8) | (105.6) | (74.8) | (82.5) |
| Gross Profit | 462.9 | 507.3 | 556.3 | 479.3 | 611.3 | 739.2 | 700.6 | 836.1 |
| Reported operating profit | (25.0) | (169.0) | 51.7 | 57.4 | 95.8 | 231.2 | 164.1 | 199.3 |
| Profit before tax (reported) | (52.6) | (191.1) | 35.6 | 29.7 | 92.2 | 227.9 | 200.3 | 245.5 |
| Reported tax | (4.0) | (6.9) | (6.5) | (6.5) | 45.7 | (8.8) | (6.0) | (7.4) |
| Profit after tax (reported) | (56.6) | (198.0) | 29.0 | 23.2 | 137.9 | 219.1 | 194.3 | 238.1 |
| Minority interests | 0.0 | 0.0 | 0.0 | 0.0 | 7.0 | (3.4) | 0.0 | 0.0 |
| | | | | | | | | |
| Basic average number of shares outstanding (m) | 33.0 | 34.0 | 35.0 | 35.0 | 34.6 | 34.9 | 34.6 | 34.9 |
| EPS - basic reported (SEK) | (1.73) | (5.74) | 0.84 | 0.67 | 3.99 | 6.33 | 5.62 | 6.82 |
| | | | | | | | | |
| **BALANCE SHEET** | | | | | | | | |
| Fixed assets | 289.5 | 185.9 | 185.1 | 176.5 | 227.1 | 279.9 | 294.3 | 317.5 |
| Intangible assets | 197.0 | 159.1 | 138.2 | 121.0 | 103.9 | 113.9 | 105.6 | 95.4 |
| Tangible assets | 29.1 | 24.7 | 22.1 | 20.1 | 20.0 | 22.0 | 44.9 | 78.2 |
| Investments & other | 63.4 | 2.1 | 24.8 | 35.4 | 103.2 | 143.9 | 143.9 | 143.9 |
| Current assets | 936.4 | 830.4 | 833.7 | 827.4 | 1,059.5 | 1,221.2 | 1,396.5 | 1,611.4 |
| Stocks | 478.1 | 398.9 | 344.2 | 250.2 | 173.6 | 131.8 | 156.1 | 161.5 |
| Debtors | 173.8 | 233.4 | 178.5 | 249.3 | 296.1 | 272.6 | 231.4 | 271.8 |
| Cash & cash equivalents | 284.5 | 198.1 | 282.4 | 327.9 | 589.8 | 816.8 | 1,009.0 | 1,178.1 |
| Other | 0.0 | 0.0 | 28.6 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Current liabilities | (268.1) | (251.6) | (309.5) | (349.9) | (483.4) | (461.1) | (461.2) | (461.2) |
| Creditors | 0.0 | 0.0 | 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 | 0.0 | 0.0 |
| Other | (266.2) | (251.6) | (309.5) | (349.9) | (483.4) | (461.2) | (461.2) | (461.2) |
| Long-term liabilities | (502.8) | (498.3) | (399.0) | (324.9) | (327.1) | (333.6) | (333.6) | (333.6) |
| Long-term borrowings | (493.8) | (494.4) | (397.8) | (319.1) | (320.6) | (289.6) | (289.6) | (289.6) |
| Other long-term liabilities | (9.0) | (3.9) | (1.3) | (5.8) | (6.5) | (44.0) | (44.0) | (44.0) |
| | | | | | | | | |
| **CASH FLOW** | | | | | | | | |
| Operating cash flow before WC and Tax | (31.1) | (124.7) | 60.0 | 108.1 | 109.8 | 240.3 | 202.2 | 246.7 |
| Working capital | (451.8) | 17.2 | 88.7 | 38.5 | 114.1 | 38.4 | 16.9 | (45.9) |
| Exceptional & other | (8.5) | (1.6) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Tax | 4.0 | 6.9 | 7.5 | 0.0 | 18.1 | 12.2 | 6.0 | 7.4 |
| Net operating cash flow | (487.3) | (102.2) | 156.2 | 146.6 | 242.0 | 290.9 | 225.2 | 208.2 |
| Capex | (71.7) | (4.1) | 0.5 | (1.6) | (3.6) | (26.4) | (33.0) | (39.1) |
| Acquisitions/disposals | 0.0 | 21.8 | 5.0 | 0.0 | (2.5) | 0.0 | 0.0 | 0.0 |
| Equity financing | 349.3 | 3.8 | 2.2 | 0.1 | 0.0 | 2.0 | 0.0 | 0.0 |
| Other | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | (55.8) | 0.0 | 0.0 |
| Net cash flow | (209.7) | (80.7) | 163.9 | 145.1 | 235.8 | 210.8 | 192.2 | 169.1 |
| Opening net debt/(cash) | (1.5) | 209.3 | 296.3 | 115.4 | (8.8) | (269.2) | (527.2) | (719.4) |
| Other | (1.2) | (6.3) | 17.0 | (20.9) | 24.6 | 47.2 | 0.0 | 0.0 |
| Closing net debt/(cash) | 209.3 | 296.3 | 115.4 | (8.8) | (269.2) | (527.2) | (719.4) | (888.5) |

Source: Orexo reports, Edison Investment Research

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