

Orexo

Regulatory update

Vorvida submitted to the FDA

Orexo announced on 6 March 2020 that it has submitted an application to the FDA for its vorvida digital therapy for the treatment of heavy drinking. It expects a hearing from the FDA on the approval status of the program in Q220 and to commercialize the product in H220 if it is cleared. The product uses cognitive behavioral therapy coupled with machine learning and has been vetted in a randomized, controlled study to reduce problematic drinking episodes.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/18	783.1	92.2	3.99	0.0	12.7	N/A
12/19	844.8	227.9	6.33	0.0	8.0	N/A
12/20e	775.4	200.3	5.62	0.0	9.0	N/A
12/21e	918.6	245.5	6.82	0.0	7.4	N/A

Note: *PBT and EPS are reported.

Clinically proven to reduce drinking

The company licensed US rights to vorvida from GAIA in Q419. The product is already launched in Germany and Switzerland by GAIA (although no details have been released). Vorvida was studied in 2015 in a randomized, controlled trial in Germany (n=608), which showed a significant reduction in alcohol consumed per day and binge drinking days per month at both three and six months (p<0.001 for all measurements).

FDA to determine how vorvida is to be classified

The realm of digital health products is relatively new and the regulatory process is still in a state of flux. There is no well-defined pathway for devices like vorvida, but instead the FDA decides whether it should be subject to review on a case-by-case basis depending on the risk to human health. The current application submitted by the company is through a 513(g) request in which it is seeking feedback on how it will be classified, and a response is expected in the statutory 60 days.

Value highly dependent on marketing, partnering

Digital therapies face significant hurdles in the marketplace and as yet there are no clear success stories for behavioral health products like vorvida. The value of the program will be highly depending on how and to which stakeholders the product is marketed. Given that drinking is a significant drain on health resources, we can envision a scenario in which it is marketed to payors to reduce costs. The company has not provided any details regarding its strategy yet, but we expect more information at the company's capital markets day on 17 March.

Valuation: Unchanged at SEK3.65bn

Our valuation remains unchanged at SEK3.65bn or SEK105.27 per share. We are holding off adding vorvida to our forecasts until the company achieves its initial sales, which we expect to follow its roll-out in H220, assuming the FDA review goes according to plan.

Pharma & biotech

10 March 2020

Price **SEK50.8**
Market cap **SEK1,763m**

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	(15.8)	(18.1)	(32.7)
Rel (local)	(0.1)	(8.7)	(34.5)

52-week high/low SEK85.70 SEK50.80

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

Capital markets day 17 March 2020

OX125 first-in-human studies H120

OX-MPI Phase I results H120

OX124 pivotal trial H220

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Exhibit 1: 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
Joint ventures & associates (post tax)									
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)
Minority interests									
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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