orexo



Credit Investor Presentation
February 2021

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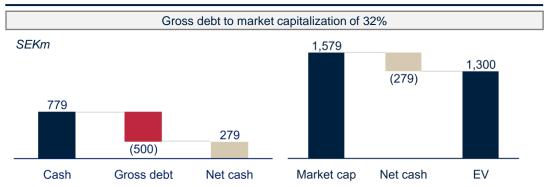


Transaction overview

Background

- Orexo AB (publ) ("Orexo") is contemplating to issue new senior unsecured bonds of up to SEK 500m (the "Bonds")
- Previous bond was issued on 13 November 2017 and was used to finance the continued commercialization of ZUBSOLV® as well as to expanding the remaining commercial portfolio and pipeline
- The proceeds from the new bond will be used to refinance Orexo's outstanding senior unsecured bonds of SEK 226m² (maturing on 13 November 2021) and for further development of traditional pharmaceutical products and broader commercialization of digital therapeutics (DTx)
- Post the Bond issue, Orexo will have a cash position of SEK 779m (current cash position of SEK 505m), net cash position SEK 279m and gross debt to market capitalization of 32%

Illustrative figures post Bond¹



The transaction



Sources and uses

Sources	SEKm	Uses	SEKm
Senior unsecured bonds	500	Repayment of existing bonds	226
		General corporate purposes ³	274
Total	500	Total	500
Post bond capital structure	SEKm	x (US Pharn	na ⁴) EBIT 2020
Senior unsecured bonds	500		1.5x
Other interest-bearing debt	-		-
Cash on balance	(779)		(2.4)x
Odon on balanco	()		· /



-) EV (enterprise value) calculated as = Market capitalization as of 29 January 2021 + gross debt (bond) estimated cash position (post the Bond issue) = SEK 1,300m
- The Company holds 74 bonds (SEK 66.6m) on its balance sheet
- Including transaction costs
- 4) US Pharma is one of the Company's three business segments, the largest, and currently only comprises ZUBSOLV®

Summary of terms

Issuer	Orexo AB (publ)
Instrument	Senior unsecured callable floating rate bonds (the "Bonds")
Volume	Up to SEK 500 million. Framework amount of SEK 1,000 million
Nominal amount	SEK 1.25 million (also minimum subscription)
Tenor	Four (4) years
Coupon	STIBOR 3m + [●] bps, p.a., with quarterly payments in arrears. STIBOR 3m floor of zero
Use of proceeds	Repayment in full of the existing bonds (SEK 225.9 million ¹) and general corporate purposes, including acquisitions
Call structure	Make-whole first 24 months, thereafter callable at 50/35/20/10% of margin after 24/30/36/42 months
Financial covenants	Maintenance test Net interest-bearing debt to EBIT for US Pharma² < 2.0x Min. cash of SEK 50 million Incurrence test (for additional debt and dividends) Net interest-bearing debt to EBITDA ≤ 2.0x Interest coverage ratio > 4.0x
Dividend restrictions	Dividends of up to 50% of previous year's net profit (subject to incurrence test being met)
Investors' put option	Investor put at 101% upon either a Change of control, a De-listing or a Listing failure (bonds not listed within 60 days from issue date)
Permitted debt	Tap issues under the bond framework, subject to incurrence test Additional debt must be <i>pari passu</i> or subordinated to the Bonds and have maturity after the Bonds Carve-out for working capital facility (up to SEK 50 million) and general basket (up to SEK 15 million)
General undertakings	Customary undertakings such as: Restrictions on additional financial indebtedness (subject to permitted debt) Negative pledge (carve out for working capital facility and general basket) Restrictions on disposals of assets Nature of business
Listing	Intention to list within 30 days on Nasdaq Stockholm
Agent	Nordic Trustee & Agency AB (publ)
Sole Bookrunner	ABG Sundal Collier
Governing law	Swedish law



- The Company holds 74 bonds (SEK 66.6m) on its balance sheet
 US Pharma is one of the Company's three business segments, the largest, and currently only comprises ZUBSOLV®

Today's presenters



Nikolaj Sørensen, President and CEO

- Chief Executive Officer since February 2013, employed since 2011
- B.Sc., and M.Sc., Copenhagen Business School, Denmark
- Member of the Board, Bioservo Technologies AB
- Senior management positions at Pfizer Inc. with a focus on commercialization in Europe and Chairman of the Board and Managing Director at Pfizer AB. Prior to Pfizer Nikolaj Sørensen served as a management consultant at Boston Consulting Group (BCG), leading several projects within M&A, commercial transformation, and turnarounds
- Holds 72,665 shares and stock options/share awards entitling to 344,163 shares



Joseph DeFeo, EVP and Chief Financial Officer

- EVP and Chief Financial Officer since November 1, 2018
- Joined Orexo US Inc. in 2013 as Vice President, Finance & Administration
- Bachelor degree in accounting from Clarion University, US, and an MBA in finance from St. Joseph's University, US.
- Several senior finance positions among others establishing of a US operations for a large Italian pharmaceutical company, Head of International Treasury and led finance for the commercial operations in the US for two major pharmaceutical companies
- Holds 3,639 shares and stock options/share awards entitling to 63,954 shares



Strong financial development since last bond issue

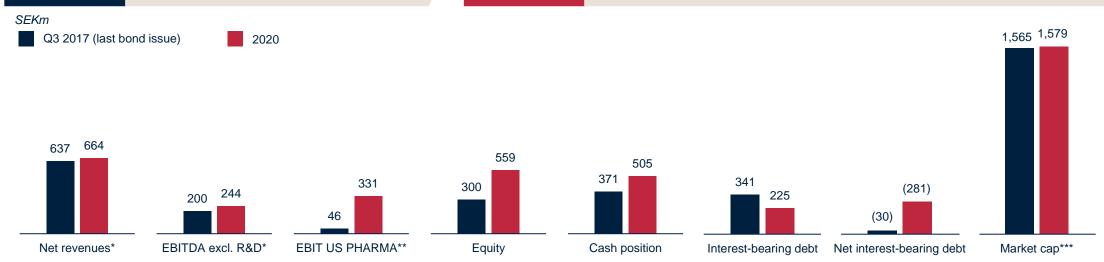
Orexo has significantly improved its financial position since its last bond issue in 2017

Q3 2017 (previous bond issue)

- Successful launches of ZUBSOLV® US, Abstral® and Edluar® completed
- ZUBSOLV® EU to be launched
- OX-CLI, OX51 in phase I and II respectively
- OX-MPI (i.e. new formulation technology) and OX382 under preclinical development

Current status and future outlook

- Significant development and growth of the lead product ZUBSOLV® in US
- Orexo has entered future growth market of digital therapeutics with 3 products (depression, alcohol use disorder, opioid use disorder)
- The digital portfolio continues to grow with a therapy for treatment of depression (i.e. deprexis®), also developed by Orexo's partner GAIA. Orexo's pharma and DTx products and the R&D pipeline are uniquely positioned to address the health need arising from covid-19





^{*} Financials as of LTM Q3 2017 and FY 2020, respectively

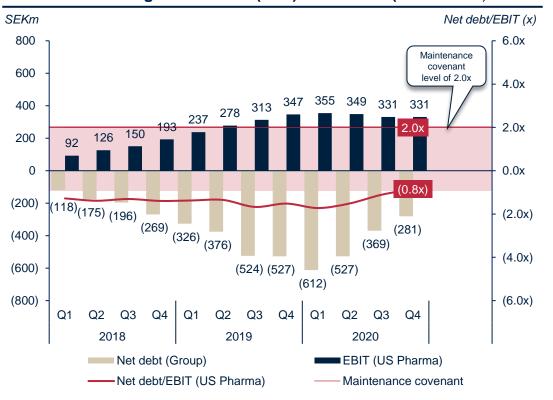
^{**} US Pharma segment comprises the distribution and sale of ZUBSOLV® (c. 94% of total revenues 2020)

^{***} Market cap as of Q3 2017 and January 29, 2021

Maintenance covenant – Net debt / EBIT US PHARMA < 2.0x

Provides downside protection for credit investors if ZUBSOLV® would generate less cash

Net interest-bearing debt to EBIT (LTM) US Pharma (ZUBSOLV®)



Comments

- Operations are monitored and presented in three business segments: US Pharma, Digital Therapeutics¹ and HQ & Pipeline², of which US Pharma contributes with the largest share of the Groups profitability
- US Pharma segment today comprises the distribution and sale of ZUBSOLV® for treatment of opioid use disorder in the US and will also comprise of OX124 once launched (expected 2023)
- The R&D costs are limited for ZUBSOLV® (e.g. maintaining licenses)
- Maintenance covenant:
 - Net interest-bearing debt to EBIT for US Pharma < 2.0x
- The net leverage maintenance covenant testing US Pharma EBIT is a good proxy for the Company's underlying cash flow generation before discretionary investments in opex for development and launch of new products
- The net leverage maintenance covenant provides downside protection for credit investors if ZUBSOLV® would generate less cash
- In addition, the terms include a maintenance covenant to test minimum cash of SEK 50m



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Introduction to Orexo

Overview of Orexo

- Orexo is a Swedish specialty pharmaceutical company with its core competence on improving administration (drug delivery technologies) of existing drugs and addresses unmet need within the growing space of substance use disorders (SUD) and mental health
- Orexo has a broad product portfolio and development pipeline of traditional pharma products and digital therapies. Orexo has developed four¹ commercial pharmaceutical products with worldwide approval, of which ZUBSOLV®, a product for treatment of opioid dependence, is its main product (94% of group sales in 2020). Furthermore, the Company's product portfolio includes Abstral®: treatment of breakthrough cancer pain, and Edluar®: treatment of sleeping problems
- Orexo's digital therapies ("DTx") are developed together with GAIA AG, leader in digital therapeutics since 2001, and deliver therapeutic interventions to patients to prevent, manage, or treat a medical disorder or disease. The therapies are developed based on established cognitive-behavioural therapy technique which is a goal-oriented psychotherapy treatment that takes a hands-on, practical approach to problem-solving
- Strategic focus on portfolio expansion through development and licensing/M&A and the Company has a strong financial position enabling investments in future growth
- Orexo is listed on Nasdaq Stockholm Mid Cap with a market cap of c. SEK 1.6 billion
- Top two largest shareholders are Novo Holdings A/S 28% and HealthCap 10%²



Corporate Headquarters (Uppsala, Sweden)

Corporate functions and Development

US Headquarters

(Morristown, New Jersey) Commercial subsidiary

Net revenues 2020

SEK 664m

Gross margin

90%

EBITDA excl. R&D 2020

SEK 244m

Equity
Dec 2020

SEK 559m

Net cash position Dec 2020

SEK 281m

Market cap Jan 29, 2021

SEK 1.6bn



Currently approved and commercialized pharma products

Three currently approved pharmaceutical products – ZUBSOLV® is generating the vast majority of cash flow







Abstral [®]		
Technology	Sublingual (under the tongue)	
Indication	Breakthrough cancer pain	
Market approvals	E.g. US, EU, Japan, South Korea, Middle East, Israeli, Australia, Malaysia and PH	
Commercial rights	Worldwide ex-US, Kyowa Kirin	
Royalty 2020	SEK 30m ¹	
Partner GYOWA KIRIN		
Patent protection	No IP in EU & US, most other markets until 2024	



Edluar [®]		
Technology	Sublingual (under the tongue)	
Indication	Insomnia	
Market approvals	US, EU	
Commercial rights	Worldwide Mylan	
Royalty 2020	SEK 10m	
Partner	Mylan ®	
Patent protection	US until 2031, EU until 2025	



Currently 2 out of 3 Digital Therapies products launched

Digital therapies with clinically proven efficacy delivering therapeutic interventions to patients to prevent, manage, or treat a medical disorder or disease



150-225
MUSD net sales

deprexis [®]		
Technology	GAIA's proprietary artificial intelligence (AI)-expert system, broca®	
Indication	Symptoms of mild to severe depression	
Commercial rights	Orexo owns the exclusive rights to the US market	
Launch	July 1, 2020, in the US	
Partner	GAIA	
Key advantages	 Based on Cognitive Behavioral Therapy Strong clinical evidence Highly individualized Standalone treatment or as a complement to traditional pharma treatments 	



120-200
MUSD net sales potential in the US

vorvida [®]		
Technology	GAIA's proprietary artificial intelligence (AI)-expert system, broca®	
Indication	Heavy alcohol misuse, incl. alcohol use disorder(AUD)	
Commercial rights	Orexo owns the exclusive rights to the US market	
Launch	July 20, 2020	
Partner	GAIA	
Key advantages	 Based on Cognitive Behavioral Therapy Strong clinical evidence Highly individualized Standalone treatment or as a complement to traditional pharma treatments 	



150-225

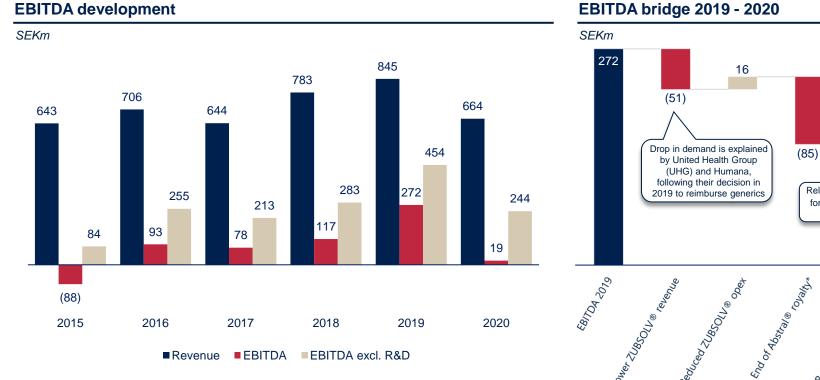
MUSD net sales potential in the US

Modia™		
Technology	GAIA's proprietary artificial intelligence (AI)-expert system, broca®	
Indication	Opioid use disorder (OUD)	
Commercial rights	Orexo owns the global rights	
Launch	H2 2021, in the US ¹	
Partner	GAIA	
Key advantages	 Based om Cognitive Behavioral Therapy Highly individualized Complement to traditional pharma treatments 	

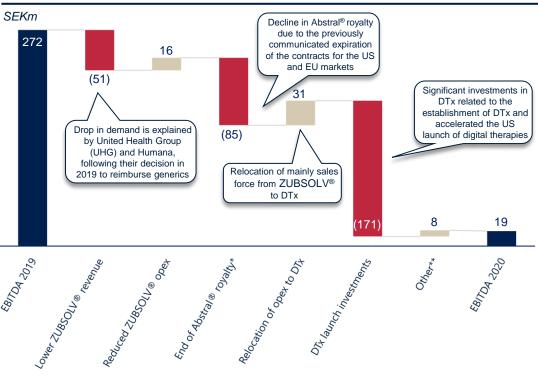


Strong EBITDA development 2015-2019

Significant investments in growth initiatives are temporarily affecting EBITDA in 2020







Orexo has a highly flexible cost base – if needed, R&D costs and investments (opex) in growth initiatives can be significantly reduced without impacting ZUBSOLV® cash generation



Strategic initiatives going forward

Focus on broadening the commercial portfolio and on products with short-time to market

1	Product portfolio addressing large and growing markets	Focusing on becoming a leader in the large and growing space of substance use disorders and mental health. In parallel, Orexo is also addressing the ongoing opioid epidemic, one of the largest health crises to take place in the US and increasingly a growing global concern
2	Entering digital therapeutics, a new evidence-based frontier in patient care	Digital therapeutics can increase access to treatment and improve treatment outcomes and are set to become an integral part of the global healthcare landscape. Substance use disorder and mental health are areas where it is most needed
3	Strong cash conversion to support growth	Lead product ZUBSOLV®, for the treatment of opioid use disorder, is a strong cash and profit contributor, enabling continued investment in launch products and R&D
4	Leveraging Orexo's US commercial excellence	Strategic focus on leveraging its commercial excellence and strong market access network in the US, by adding more products to the US commercial platform
5	Expanding pipeline targeting unmet medical needs	Continue to build on the strong experience of developing products with worldwide approval by expanding the pipeline with multiple short time to market assets based on innovative drug delivery technologies and digital therapies, addressing unmet medical needs in Orexo's key therapeutic areas



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Credit highlights

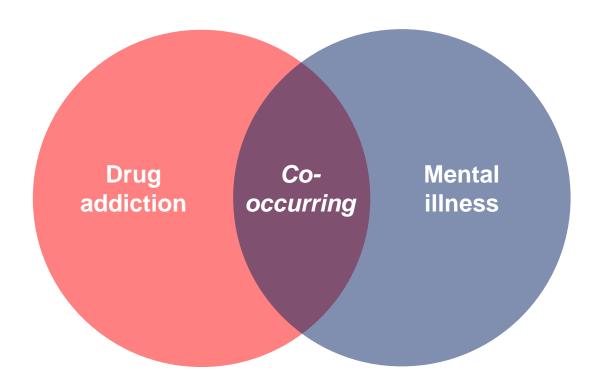
Large and growing market

- Addresses treatment of opioid use disorder treatment, alcohol misuse, mental illness and depression
- Addressable US market for opioid use disorder treatment has double digit growth and is worth c. USD 2.2 billion
- 15-20 million US citizens are heavy alcohol users and only 20% of people with alcohol use disorder receive treatment
- Increase of mental illness and depression in the overall society with expected further mental issues arising as a result of the Covid-19 pandemic
- Strong and stable market position for ZUBSOLV®
- 12 years of ZUBSOLV® patent protection remains (should ZUBSOLV® unexpectedly face generic competition, it could earliest enter the market in Q2 2023)
- Limited R&D costs for ZUBSOLV® (e.g. maintaining licenses)
- Despite increased competition from generics, Orexo increased the price for ZUBSOLV® by 3% in 2020 and 2021
- ZUBSOLV® (c. 94% of total revenues) experienced Q-o-Q EBIT growth of 30% (Q4 2020 vs. Q3 2020)
- Proven commercialization capabilities and diversified product portfolio
- Successfully developed and commercialized three products; Zubsolv®, Abstral® and Edluar®, all generated strong cash flows once commercialized
- Diversified product pipeline with four pharmaceutical products and three digital products (vorvida® and deprexis® already launched in 2020)
- Flexible cost base R&D costs and investments (opex) can be significantly reduced without impacting ZUBSOLV® cash generation
- Significant experience from prioritising and managing development costs to focus on products with strong commercialisation capabilities
- Attractive credit profile
- US Pharma (ZUBSOLV®) EBIT of SEK 331m (2020) and EBITDA excluding R&D of SEK 244m (2020)
- Strong net cash position with a cash balance of SEK 779m and a net cash position of SEK 279m post bond issue¹
- Gross debt to market capitalization of 32% and gross debt to EV (LTV) of 38% (post bond issue)
- Equity ratio of 45% (31 December 2020) and 37% (post bond issue)
- Long track-record, experienced management team and strong owners
- Long track-record in the credit market inaugural convertible bonds issued in 2010, first senior unsecured bonds issued in 2014 and second senior unsecured bonds issued in 2017
- Consistently met its commitments and fulfilled its obligations toward bondholders
- Highly qualified management with long-term sector experience
- Listed company with strong main owners consisting of prominent institutional investors such as Novo Holdings and HealthCap
- Other credit supporting factors
- Strong downside protection for bondholders from maintenance covenants (Net interest-bearing debt to EBIT for US Pharma < 2.0x & min. cash of SEK 50 million)
- Dividends only allowed if interest-bearing debt to EBITDA ≤ 2.0x and interest coverage ratio > 4.0x, historically no dividends paid out



Drug addiction - a chronic condition correlated with mental illness

Large unmet need – 50% of individuals with both mental illness and drug addiction receive treatment



- Drug addiction, also called substance use disorder, is a disease that affects a person's brain and behavior and leads to an inability to control the use of a drug
- Drug addiction is a chronic medical condition which often requires lifelong treatment
- Approximately 50 percent of the individuals suffering from drug addiction also reported having a mental health illness¹
- Only about half of individuals with co-occurring mental health ill and drug addiction received treatment in 2018¹



Opioid addiction - one of largest health crises ever in the US

ZUBSOLV® – Large addressable market as opioids addiction is common for people prescribed opiods

- Growing global concern with 53 million people using opioids worldwide¹
- Globally opioids continue to cause the most harm, accounting for two-thirds of the deaths attributed to drug use disorders¹
- The problem in the US has reached epidemic proportions where approx. 4-5 million are dependent opioid users and in 2019 approximately 72,000 died of an overdose²
- In the US two out of three overdose deaths involved an opioid like prescription opioids, heroin, or synthetic opioids (e.g. fentanyl)²
- To die from an overdose is the leading cause of injury-related death in the US

Addressed by:





USD 696 billion

Opioid epidemic cost for the US society in 2018³

8-10 %

....of people prescribed opioids for longer use develop an addiction4

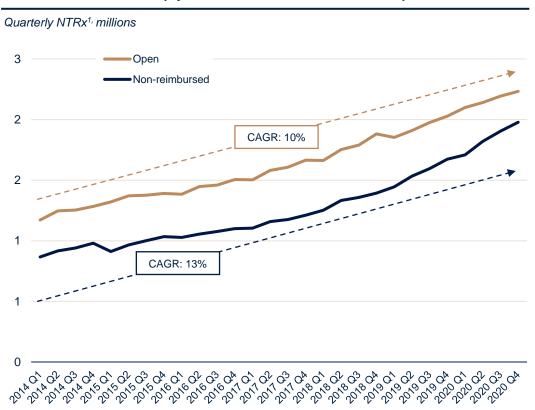


- World Drug Report
- Center of Disease Control
- White House Council of Economic Advisors

ZUBSOLV®- 2020 market grew at the strongest rate since launch

Double digit growth in a market worth approximately USD 2.2 billion³

Market volume sales (opioid use disorder treatments)



Definitions (Payers / Market Access)

- "Open"
 - Market segments where ZUBSOLV[®] is reimbursed either exclusively or nonexclusively²
- Non-Reimbursed"
 - Market segments where ZUBSOLV® is not reimbursed
- The market can also be divided by payer segments:
 - Public, where care is financed by federal/state payers such as Managed Medicaid,
 FFS Medicaid and Medicare
 - Commercial, which comprises private insurance companies
 - Cash & Vouchers, where patients themselves finance their care
- Pharmacy Benefit Managers (PBM) play an important role, as on behalf of the insurance companies and employers they are responsible for assessing which drugs are to be covered by insurance. These may enter exclusive agreements with drug suppliers or open up for the users to select within several drugs
- The market for treating opiod use disorders has grown the fastest in recent years, driven by the fact that more and more people have gained access to publicly financed healthcare and employers have become more restrictive in offering private healthcare insurance



²⁾ Open formulary business is total business where ZUBSOLV® is reimbursed and competes with other products in the market both brand and/or generics. Open formulary business excludes recent formulary changes in United Health Group and Humana, the cash segment, and payers where it is not reimbursed.

3) IMS data (before rebates to payers and wholesaler fees)



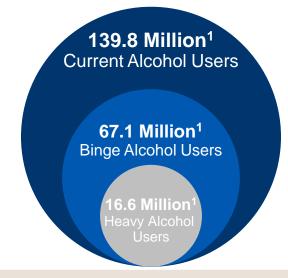
Alcohol misuse - another major health issue in the US

Unmet need with few competitors offering therapy to people with alcohol use disorder

- In the US approximately 16.6 million people are heavy alcohol users¹
- Each year, more than 88,000 people die from alcohol-related causes,² making it the third leading preventable cause of death in the country
- Alcoholism is highly stigmatized, preventing patients from seeking treatment
- Approximately 20% of those diagnosed with alcohol use disorder (AUD) received treatment, of which 60% attended Self-Help Groups³
- Abstinence is often the only goal, and current therapies require abstinence prior to initiating therapy
- Current therapy solutions are ineffective and 85% of patients do not achieve long term abstinence







USD 249 billion

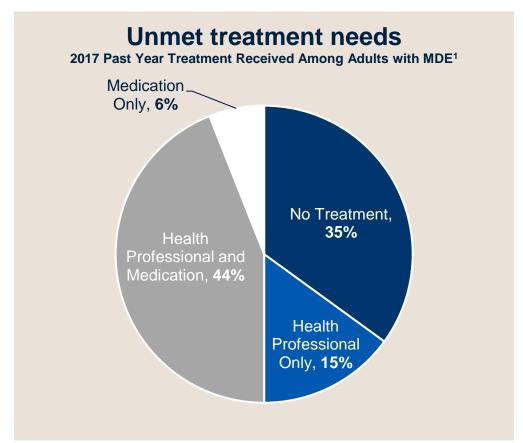
US society costs in 2010 for problematic drinking¹



- Substance Abuse and Mental Health Services Administration
- Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; Tomedi, L.E.; and Brewer, R.D. 2010 National and state costs of excessive alcohol consumption. American Journal of Preventive Medicine49(5):e73-e79, 2015.
- SAMHSA 2017 NSDUH Tables 5.2A & 5.16A, 1) SAMHSA 2017 NSDUH Table 5.19A

Depression - the leading cause of disability worldwide

Unmet need as a signficant part of people with major depression does not receive treatment



- In 2017, an estimated 17.3 million US adults (7.1% of all adults) in had at least one Major Depressive Episode (MDE)¹
- Major depression is highly recurrent: Risk of recurrence increases ~16% with each successive episode & estimated recurrence rate is ~20% over 6mo & >40% over 2 years²
- Despite the availability of effective interventions for depression, delays in initial treatment contact remain problematic³
- In 2017, approximately 35% of the 17.3 million US adults who experienced MDE did not receive treatment¹

Addressed by:

Digital Therapeutics deprexis®



- 1) National Institute of Mental Health. Major Depression. Retrieved from: https://www.nimh.nih.gov/health/statistics/major-depression.shtml
- UpToDate "Unipolar depression in adults and initial treatment: General principles & prognosis" (2018, lit review current thru Feb 2019); 3) American Psychiatric Association (APA) "Practice guideline for treatment of patients with MDD" (2010);
- 3) Yoshikawa E, et al. BMC Res Notes. 2017; 10: 673.

Covid-19 will create a tsunami of mental health issues and significantly increase the need for Orexo's products



Coronavirus Literaries U.S. map World map Recepting tracker Lives tost Your Me at from Extraordinary people

*Cries for help': Drug overdoses are soaring during the coronavirus pandemic

Suspected overdoses nationally jumped 18 percent in March, 29 percent in April and 42 percent in May, data from ambulance teams, hospitals and police shows.

Opioid misuse increases

NATIONAL*POST

Alexander Caudarella: The pandemic is making the opioid crisis worse

Escalating numbers of overdoses and deaths are being reported in many parts of the country. In Toronto in both April and May, there were more suspected opioid deaths than any month since September 2017

Alcohol misuse increases



Drug and Alcohol Use Increase During COVID-19

Our recent survey shows more people are using drugs and alcohol to cope with stress, boredom and mental health issues.

Depression increases





ZUBSOLV® for treatment of opioid use disorder

~12 years of patent protection for ZUBSOLV® remain

Historical milestones

- ZUBSOLV® was approved by the US Food and Drug Administration (FDA) in July 2013
- Launched on the US market in September 2013
- Obtained EMA approval for ZUBSOLV® in Europe in 2018
- Partnered with Accord Pharmaceutical in 2020 with expected launch in Europe Q4 2021

ZUBSOLV® in brief

- ZUBSOLV® is a product for the treatment of opioid use disorder (drug addiction)
- ZUBSOLV® was developed by improving the administration route (the path the drug is taken into the body) of existing drugs. Orexo applied its sublingual (under the tongue) tablet technology
- The broad choice of six different strengths offers the potential for finer titration and individualized dosing with potentially fewer tablets compared with existing treatments
- ZUBSOLV® should be used as part of a treatment plan, which includes counseling and psychosocial support

ZUBSOLV® short facts

Technology	Sublingual
Indication	Opioid use disorder
Market approvals	US, EU and Australia
Commercial rights	Orexo owns global rights
Net revenue in 2020	SEK 623 million
Partner	Accord Pharmaceuticals in Europe
Patent protection	In all major markets until 2032
Product advantages	 Higher bioavailability¹ Fast dissolve time² Preferred menthol flavor Broadest range of dose strengths

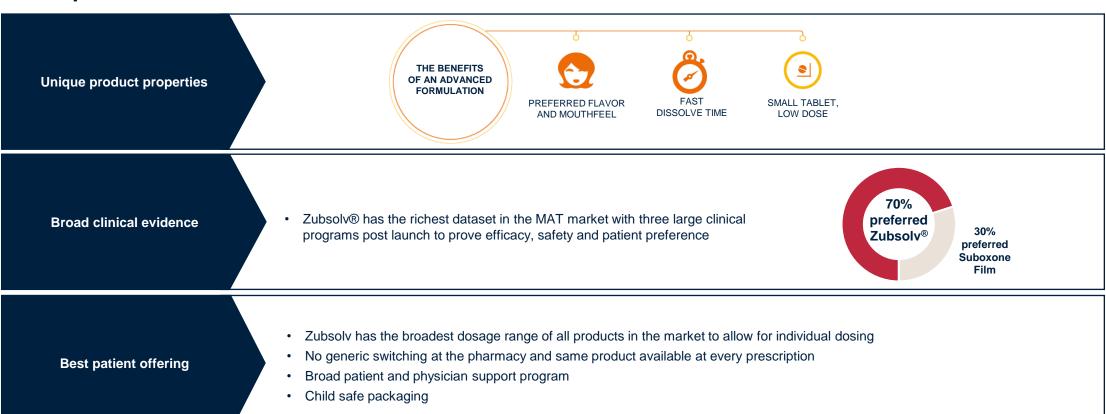






- Bioavailability refers to the extent a substance or drug becomes completely available to its intended biological destination
- 2) Time until the tablet is dissolved under the tongue

ZUBSOLV® has unique selling arguments compared to generic competitors in the market



Zubsolv (buprenorphine and naloxone) sublingual tablet (CIII) is a prescription medicine used to treat adults who are addicted to opioid drugs (either prescription or illegal) as part of a complete treatment program that also includes counseling and behavioral therapy



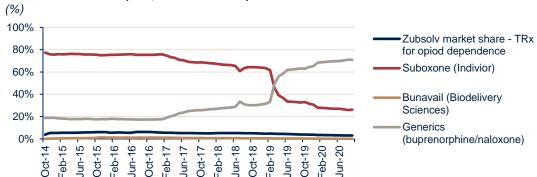
ZUBSOLV®'s market and competitive landscape

ZUBSOLV® has a competitive market position despite increased competition from generics

Strong competitive position

- In beginning of 2019, four generics on the leading competitor Suboxone film entered the market resulting in significant lower market share for Suboxone
- The trend in the market is that payers open up for more treatment options, which is negative for Orexo in the short term but has potential to be positive in the long term (reduces rebates and opens up for more listings)
- The number of exclusive positions (plans) for ZUBSOLV® has reduced and only a few minor exclusive positions are left, making ZUBSOLV® less dependent on exclusive positions
- Despite the increased presence of generics, the list price of generics has been on a par with or a little higher than that of the drugs sold under patent-protected brand names i.e. no significant price pressure impact
- Increase in ZUBSOLV® prices of 3% since 1 January, 2020 despite generic competition illustrating ZUBSOLV®'s competitive price point in the market1
- From January 1, 2021, ZUBSOLV[®] will be the only preferred branded product on the top three Commercial Pharmacy Benefit Manager ("PBM") (ESI, Caremark & Optum) national formularies which totals 59 percent of the commercial buprenorphine/naloxone market²

US MARKET SHARE (TRx, Retail channels)



ZUBSOLV® GM AND # OF GENERIC COMPETITORS





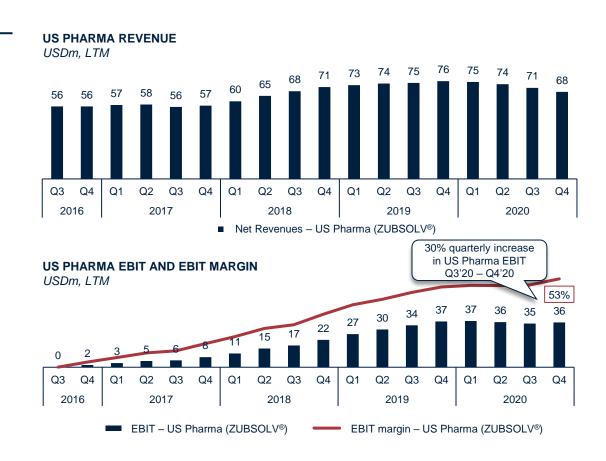
- Gross to net rate improvement due to price increase and more favorable payer mix
- Responsible for management of costs associated with prescription pharmaceuticals and recommendations on behalf of insurance companies and employers in the US Source: Symphony Health Data; Management

ZUBSOLV®'s financial development since commercialization

Strong historical growth and profitability – maintained profitability despite challenging market in 2020

US Pharma (ZUBSOLV®)

- ZUBSOLV® is highly profitable and cash generative
- US Pharma (today effectively only ZUBSOLV[®]¹) has stably grown in recent years due to strong market growth and better market access
- The decrease in revenue in 2020 is mainly driven by lower volumes from previously exclusive plans (e.g. UHG & Humana) and declining Commercial segment due to increased unemployment as a result if Covid-19
- The revenue downside risk has come down as there are less dependence on exclusice positions (plans)
- US Pharma's (ZUBSOLV®) gross margins exceeded 90% in 2020
- LTM EBIT in Q4 2020 was higher than previous quarter as a result of lower COGS (efficiencies in the supply chain) and lower operating expenses
- All-time high EBIT margin (US Pharma) of 53% for full year 2020





27

Two legal processes emerging during July and August 2020

Indian generic company intends to file for approval of generic versions of ZUBSOLV® and a subpoena

Claiming generic version of ZUBSOLV®

- On August 10, 2020, Orexo received an Abbreviated New Drug Application ("ANDA") notification from the Indian company Sun Pharmaceuticals ("Sun"), claiming they have developed a generic version of ZUBSOLV®
- After Orexo filed a complaint (within 45 days following the notification), Orexo will be granted a "30-Month Stay" to solve the legal matters
- If the generic producer Sun prevails it can launch a generic version, if Orexo prevails it can block Sun's generic product
- Orexo is now looking into the filing and product and is developing potential claims that Sun Pharma is infringing on the patents
- Should Orexo unexpectedly face generic competition on ZUBSOLV®, the generic could earliest enter the market in Q2 2023

Subpoena

On July 14, 2020 Orexo US received subpoenas to provide US Authorities with certain information with regards to ZUBSOLV® and other buprenorphine products. Orexo has no knowledge of the background to the requests, but has engaged a US counsel to advice the company and prepare for any further requests or actions from the authorities

Experience from similar situations

- Orexo has been in this situation once before with ZUBSOLV®
- Orexo however won last time (early 2019) against the company Actavis, it went all the way to the federal circuit, where ZUBSOLV[®]'s main patent lasting until 2032 was found valid i.e. validated by the Federal Circuit
- The patent is described as a "gold plated patent" i.e. a patent which is very difficult for a generic company to overturn due to the validation by the federal court
- Most of the cases are solved before it goes to court (9 out of 10)¹ and are settled in one
 way or another, usually through a license agreement for the generic to enter before
 patent expiry
- Orexo announced new Zubsolv patent on December 30 2020 further strengthening the patent protection
- Orexo are very confident in the strength and breadth in its patent families (lasting until 2028 and 2032)



Product pipeline addressing large and untapped markets

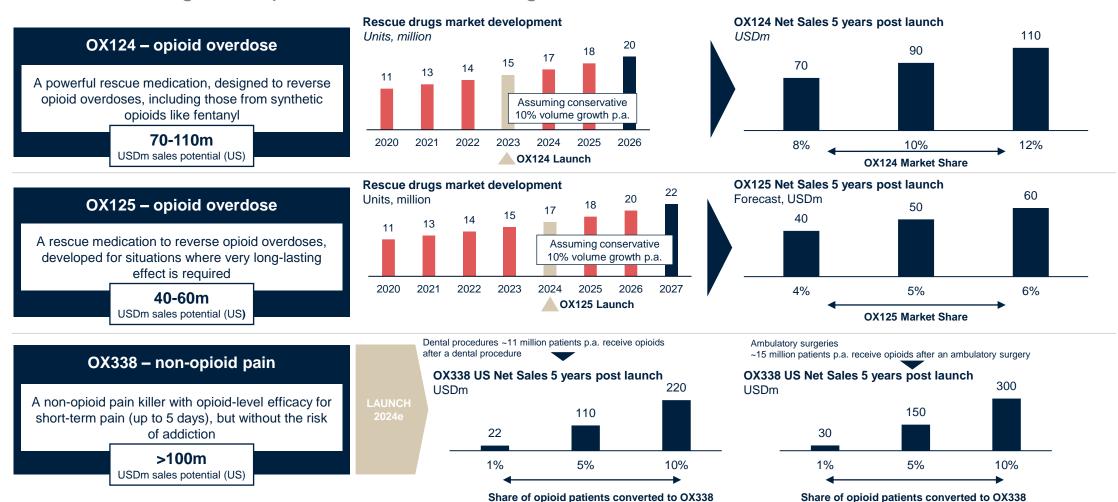






Pharma pipeline; USD 162-600m sales potential 5y post launch

Three convincing development assets addressing unmet needs





Digital Therapeutics (DTx) – 2 of 3 products launched in 2020

Orexo is well positioned to be market leader within treatment of substance use disorder and mental health issues with total sales potential of USD 420-650m 5 years post launch

deprexis®

deprexis® is a fully automated digital therapy to help patients manage their symptoms of mild to severe depression with extensive clinical evidence



vorvida®

A fully automated digital therapy scientifically proven to reduce troublesome drinking patterns in adults suffering from alcohol misuse inclusive alcohol use disorder (AUD)



modia™ (OXD01)

"Digitizing" counselling at bundle offer with ZUBSOLV®, a full medication assisted therapy (MAT) solution for opioid use disorder (OUD) patients in need





Digital Therapeutics (DTx) – Partnership with global leader

Orexo and its partner GAIA are leading the next disruption in healthcare: Digital therapy (DTx)

GAIA – Partner for digital therapeutics

- GAIA is a global leader in digital therapeutics and successfully launched its first digital health product in 2001
 - GAIA' technology platform, broca®, has been the backbone of over 70 products and tested on more than 10,000 patients in clinical trials
 - Based on artificial intelligence (AI), and engages users in individualized, simulated 1-1 interactions, guiding patients stepby-step towards specific goals and therapeutic targets
 - Developed and implemented digital therapeutic projects with many partners, such as Abbvie, J&J, E. Lilly, Lundbeck, Merck and Orexo
- Orexo has acquired rights to commercialize new digital therapies from GAIA for the below treatments:
 - deprexis® depression (US)
 - vorvida® alcohol use disorder (US).
 - modiaTM opioid use disorder (globally)

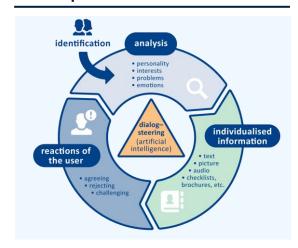


Why Orexo and GAIA will succeed

Three reasons why Orexo and GAIA will succeed:

- 1) Orexo has gained experience and established the needed infrastructure (e.g. sales force and regulatory connections) through the commercialization of **ZUBSOLV®**
- 2) The digital therapy platform from GAIA is clinically validated, which will increase pricing power and regulatory status
- 3) For modiaTM: Counselling and psychosocial support is a compulsory part of OUD therapy – those resources are scarce today

broca® platform overview



Highlights of the platform:

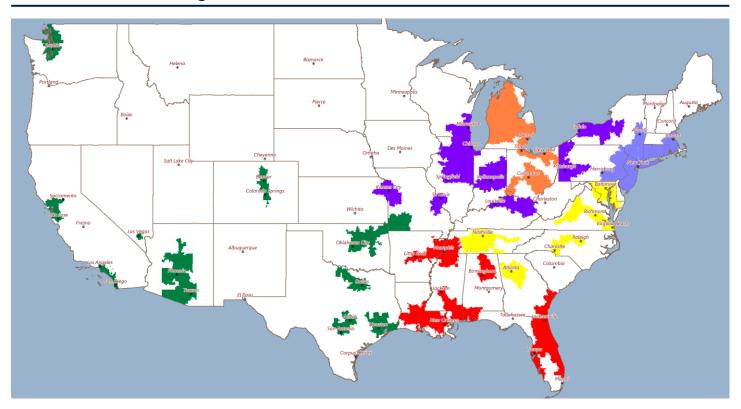
- 100% mobile and cloud-based ensures availability on any mobile device
- Complex cognitive-functional interventions to modulate brain functions and thought processes
- Individualized tailored for each individual based on interaction
- In-depth collection of individual patient data to trigger further research and patient interaction
- Input from variables used to drive further content and user interaction



Own commercial platform (sales force) in the US

Possibility to swiftly leverage the sales force by adding new commercialized products

Orexo's US sales coverage*



US commercial platform

- Direct presence in the US since 2013
- Strong market access network and capabilities
- Fully-owned field force covering most relevant geographies in the US
- · Currently 51 sales territories organized in various regions
- Only player with presence in opioid addiction treatment clinics
- Able to swiftly leverage the sales force by adding new commercialized products
- Strong synergies between ZUBSOLV® and new digital therapies



Expenses management and development

Continously tracking of progress to ensure that opex are allocated to most commercial products

Prudent expense management has been central to Orexo during the current leadership

- Management is continuously looking to reduce expenses e.g. COGS of ZUBSOLV® has been reduced by more than 35% in 2017-2020
- Key to maintain a high degree of flexibility in opex during launch of products to ensure opex can be adjusted to synchronise with revenue development

Continuous investment will be based on a continuous opportunity assessment using e.g. "toll gates"

- Continued investments in launch of Digital Therapies in 2021 (the launch of the third digital therapy, modiaTM) and increased selling activities for all digital therapies as reimbursement are secured
- Orexo focus R&D on OX124 and will increase investments during 2021 to finalize the clinical trial and set-up of commercial manufacturing process and preparation of commercial launch
- "Toll gates" are established for both Digital Therapies and OX124. It enables the company to have control of the progress versus expectations as well as when to increase or decrease investments. For example, Digital Therapies agreements with larger health insurance companies will trigger additional investments

Opex for Digital Therapies in 2020 of SEK 175m to establish new business area and scalable platform

- Opex has been evenly split between marketing, infrastructure (on-line e-commerce platform), payer management system and processes
- Overall infrastructure to manage payment, reimbursement and customer service is a scalable platform with mainly non-recurring expenses and limited opex to add additional products
- Increase in opex due to modiaTM commercialization will be limited in 2021 since product has a 100% commercial overlap with existing ZUBSOLV[®] field force, existing opex will be allocated between the products

Opex for R&D of c. SEK 160m in 2020 is expected to increase in 2021 with the final development investments in OX124

- OX124 largest R&D investment in 2020 (also a sizable investment in OX125 was taken)
- The high R&D opex level is expected to continue in 2021
- Year following 2021 expected to require less R&D investments
- All investments in OX124 are included as opex (with exception of some capex in machinery and inventory)



Equity ratio and interest coverage ratio

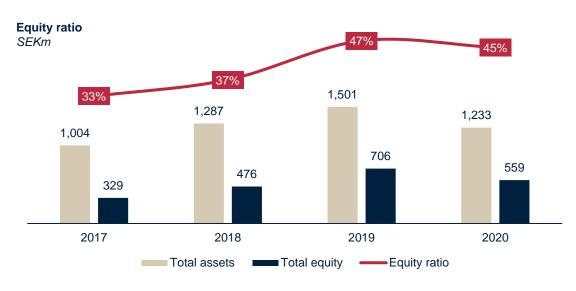
Strong equity position and debt service capacity

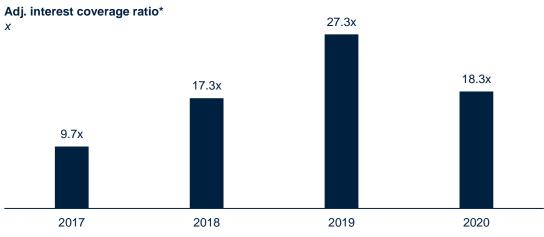
Equity and interest coverage ratio

SEKm	2017	2018	2019	2020
Equity ratio				
Equity	329.1	476.1	706.4	558.5
Total assets	1,003.9	1,286.7	1,501.1	1,232.9
Equity ratio (%)	33%	37%	47%	45%
Interest coverage ratio				
EBITDA	78.2	116.6	272.1	19.0
Bond payments (LTM)	(21.9)	(16.4)	(16.6)	(13.3)
Adj. EBITDA (excl. R&D)	212.4	283.4	453.3	243.9
Adi. ICR	9.7x	17.3x	27.3x	18.3x

Comments

- Orexo has a solid equity position of SEK 559m
- Orexo has strong debt service capacity with an increasing ICR
- As R&D expenses are reported under operating costs in the P&L, the adjusted ICR illustrates if R&D expenses were capitalised or postponed, which further strengthens the ICR







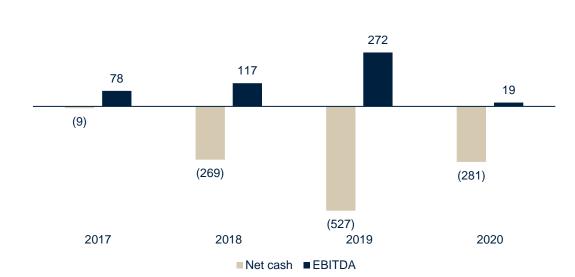
Solid financial position

Net cash and low gross debt in relation to enterprise value

Net cash / EBITDA and LTV

SEKm	2017	2018	2019	2020
Gross debt	319.1	320.6	289.6	224.5
Cash	327.9	589.8	816.8	505.3
Net cash	(8.8)	(269.2)	(527.2)	(280.8)
EBITDA	78.2	116.6	272.1	19.0
Net debt / EBITDA	n.q.*	n.q.*	n.q.*	n.q.*

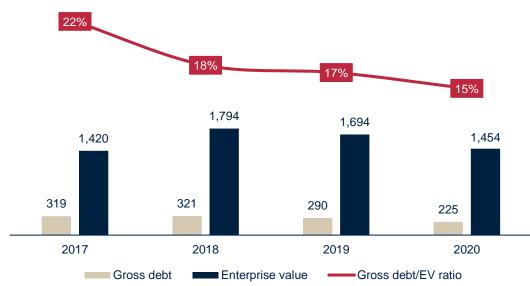
Net cash and EBITDA SEKm



Comments

 Orexo has a solid financial position with low leverage (i.e., a net cash position) and high liquidity, enabling the company to pursue its strategy to invest in the digital therapies and to continue the development of the pharmaceutical pipeline

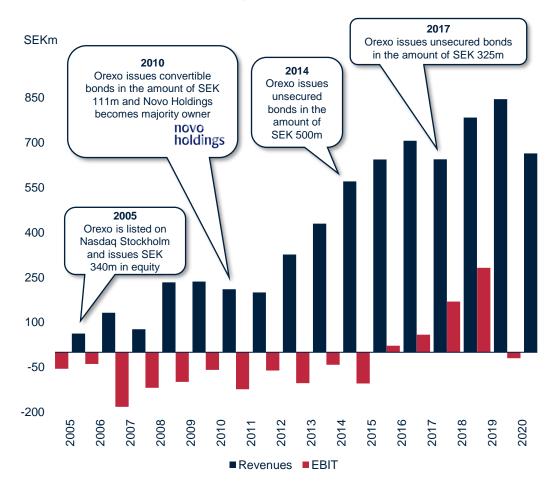
Gross debt/EV ratio SEKm





Long track record from the capital markets

Orexo has consistently met its commitments and fulfilled its obligations toward bondholders



Long track record from both the equity and debt capital markets

- Orexo has been active in the capital markets since 2005 when the Company was listed on Nasdaq Stockholm raising SEK 340 million in its initial public offering
- In 2010 Orexo completed its first debt issue, a convertible bond in the amount of SEK 111 million
- In 2014 Orexo issued its first senior unsecured bonds in the amount of SEK 500 million
- In 2017 the Company issued its second senior unsecured bonds in the amount of SEK 325 million
- Orexo has consistently met its commitments and fulfilled its obligations toward bondholders and other stakeholders
- Largest shareholder since 2010 is Novo Holding with approx. 28% of the shares
 - Novo Holding is the holding company of Novo Group which is a global healthcare company with more than 90 years of innovation and leadership in diabetes care
- Shareholder since 2005 and second largest holder is Healthcap with approx. 10% of the shares
 - HealthCap is one of the largest specialized providers of venture capital within life sciences in Europe



Highly qualified management building a strong team



Nikolaj Sørensen President and CEO, since 2013, employed since 2011

B.Sc., and M.Sc., Copenhagen Business School, Denmark

Other appointments:

Member of the Board. Bioservo Technologies AB

Previous appointments:

Senior management positions at Pfizer Inc. with a focus on commercialization in Europe and Chairman of the Board and Managing Director at Pfizer AB. Prior to Pfizer Nikolaj Sørensen served as a management consultant at Boston Consulting Group (BCG), leading several projects within M&A, commercial transformation, and turnarounds



Robert A. DeLuca President Orexo US, since 2013

R.Ph, Registered Pharmacist

Other appointments:

Member of the St. John's College of Pharmacy Dean's Advisory Board, American Society of Addiction Medicine, Academy of Managed Care Pharmacy and the American and New Jersev Pharmacists Associations

Previous appointments:

Experience establishing commercial operations in the US with a combined background in market access, marketing, and sales. Has held leadership positions at multinational pharmaceutical companies including Sanofi-Aventis, ScheringPlough, Berlex and Pharmacia, and most recently served as CCO at Archimedes **Pharmaceuticals**



Joseph DeFeo EVP and CFO, since 2018

Joined Orexo US Inc. in 2013 as VP. Finance & Adm

Bachelor degree in accounting from Clarion University, US, and a MBA in finance from St. Joseph's University, US

Previous appointments:

Joseph DeFeo has worked in several senior finance positions among others establishing of a US operations for a large Italian pharmaceutical company, Head of International Treasury and led finance for the commercial operations in the US for two major pharmaceutical companies



Johannes Doll **EVP and Chief Commercial** Officer, since 2016

MBA, University of Texas,

and Dipl. Kaufmann, WHU Otto Beisheim School of Management, Germany

Johannes Doll worked as an advisor to Orexo during the period 2013-2016 when he was recruited as the EVP and Head of Corporate Development. Since October 2019, Johannes Doll is the company's Chief Commercial Officer

Previous appointments:

Johannes Doll has worked with McKinsey & Company from 2004 to 2013, advising clients in the global pharmaceutical and private equity industry



Dennis Urbaniak EVP Digital Therapeutics

since 2019

Monmouth University, US, BS Business Administration/ Marketing/English

Other appointments: Member of HIMSS

Previous appointments: Chief Digital Officer, Havas

Health & You. Chief Executive Officer, Havas Health Plus. Prior to Havas Health & You, Managing Director Accenture Digital Life Sciences Analytics and Janssen Client Account Lead. Before joining Accenture, twenty years at Sanofi in various sales and marketing roles. Previous volunteer experience as Board Member and Board Chair in different foundations



Michael Sumner Chief Medical Officer.

since 2013

MB BS, MRCP (UK), MBA

Other appointments: Scientific Advisory Board

FirstString Research Inc

Previous appointments:

Extensive experience within the pharmaceutical industry from Novartis Pharmaceuticals, Aventis Behring and Novo Nordisk and most recently held the position of Vice President Clinical and Medical Affairs at Shire



Cecilia Coupland

VP and Head of Operations, since 2019, employed since 2006

MSc in Chemical Engineering, Uppsala University, Sweden

Previous appointments:

Head of Supply Chain & Planning at Orexo since 2014 and prior to that extensive experience of global pharmaceutical manufacturing and supply chain management, as well as drug development and project management, from various key positions at AstraZeneca and Orexo AB



Robert Rönn

VP and Head of R&D, since 2019, employed since 2007

MSc in Chemical Engineering and PhD in Medicinal Chemistry, Uppsala University, Sweden

Previous appointments:

Head of Pharmaceutical Development & IP at Orexo AB since 2016 and prior to that extensive experience of drug discovery and development, as well as patent prosecution and litigation, from various key positions at Biolipox AB and Orexo AB



Board of directors



James Noble Chairman since 2020

M.A. from the University of Oxford

Other appointments:

Board member of Adaptimmune since 2019. Board member and Deputy Chairman of GW Pharmaceuticals since 2007

Previous appointments:

Brings more than 30 years of industry experience from both the private and the public sector, which includes: being co-founder of Adaptimmune and founder and CEO of Immunocore. Has also been Chairman and CEO of Avidex. James has held several positions as board member at companies including, among others, Medigene, PowderJect Pharmaceuticals and CuraGen Corporation



Charlotte Hansson Board Member since 2020

MSc. in Business Administration from Handelshögskolan at the University of Gothenburg

Other appointments:

CFO at Systembolget AB, since 2015

Previous appointments:

Has been Group CFO & Executive VO at Cision AB. Charlotte has also been Group CFO at Addici AB. Before this she had an extensive career within business controlling, with many year at, for instance, Modern Times Group (MTG)



Henrik Kjaer Hansen Board Member since 2018

BSc. In Business Administration and MSc. In Applied Economic and Finance at Copenhagen **Business School**

Other appointments:

Senior Director, Principal Investments, Novo Holdings A/S. Board member of Xellia **Pharmaceutical**

Previous appointments: Prior to joining Novo Holdings A/S. Kiaer Hansen was employed as a Senior Vice President in Moelis & Co. in London, focusing on healthcare M&A transactions. Other previous employments include Deutsche Bank and ABN AMRO, all in London. Does not hold any shares in Orexo



Mary Pat Christie Board Member since 2019

MBA

Other appointments: Board member of

Hackensack Meridian Health's Carrier Clinic and Restaurant Technologies

Previous appointments:

Managing Director at Angelo Gordon & Co., where she focused on business development of new fund strategies and new strategic alliances Prior to that Mrs. Christie worked at Cantor Fitzgerald as an Institutional Salesperson and was an original partner at the Seaport Group. Mary Pat was also the founder of Mendham Capital Management. Her career also includes high level roles at JP Morgan, Donaldson, Lufkin & Jenrette, and Fleet Bank



Staffan Lindstrand Board Member since 2002

M.Sc. In Engineering

Other appointments:

Partner of HealthCap since 1997. Board member of HealthCap AB. PulmonX Inc. Doctrin AB and The Swedish Association of Exchangelisted Companies

Previous appointments: Ten years in investment

banking



David Colpman Board member since 2015

B.Sc. Pharmacv.

Other appointments:

Director of Colpman Consulting Ltd since 2014. Member of the Royal Pharmaceutical Society. Board member of HRA Pharma and Forendo Pharma Ltd.

Previous appointments:

Former Head of Global Business Development 2012-2014. Senior VP of Business Development at Shire plc 1999–2012. Various business development & commercial positions at Glaxo Wellcome, Novo Nordisk and Boots **Pharmaceuticals**



Kirsten Detrick Board member since 2016

MBA

Other appointments:

Managing Director at Takeda Austria GmbH and Takeda Osteuropa Holding GmbH since July, 2016

Previous appointments:

VP Global Marketing.

Therapeutic Area Commercial Lead - GI at Takeda Pharmaceuticals, Executive Director positions within US as well as Global Marketing and Commercialization at Amgen Inc. 2004-2013, Various marketing and commercial positions at Bristol-Myers Squibb 1991-2004. Former member of the Board of Southern California Biomedical Council and member of Healthcare Businesswomen's Association



Fred Wilkinson Board Member since 2019

MDA., B.Sc. Pharmacv

Other appointments:

Board member of Alter Pharma Group

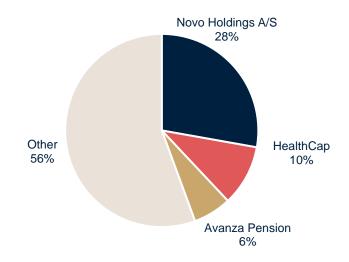
Previous appointments:

Has served as President and CEO of-Impax Laboratories, Inc. from 2014 until Dec 2016. Prior to that. Fred held the position of President of the Specialty business at Watson Pharmaceuticals, Inc. (currently Allergan) from 2009 through 2014. Other previous employments include among others President of Duramed Pharmaceuticals, Inc., CEO of Columbia Laboratories. and multiple positions at Sandoz Pharmaceutical Corp. Fred has previously served as board member of several different Pharma companies



Strong owners

Prominent institutional investors



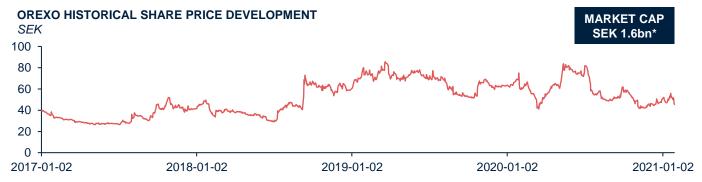


Novo Holdings is a Danish private limited liability company wholly owned by the **Novo Nordisk** Foundation. Novo Holdings is the holding company of the Novo Group and manages the Foundation's investment assets



HealthCap is a family of venture capital funds investing globally in life sciences. With more than EUR 1 billion raised since the start in 1996, HealthCap is one of the largest specialized providers of venture capital within life sciences in Europe

#	Owner	# Shares (k)	Value (SEKm)	Capital	Votes	Country
1	Novo Holdings A/S	9,643	482.2	27.8%	27.8%	Danmark
2	HealthCap	3,556	177.8	10.2%	10.2%	Sverige
3	Avanza Pension	2,221	111.0	6.4%	6.4%	Sverige
4	Arbejdsmarkedets Tillægspension (ATP)	2,041	102.0	5.9%	5.9%	Danmark
5	Anders Walldov	1,600	80.0	4.6%	4.6%	Sverige
6	Lancelot Asset Management AB	625	31.3	1.8%	1.8%	Sverige
7	Orexo AB	416	20.8	1.2%	1.2%	Sverige
8	Nordnet Pensionsförsäkring	361	18.0	1.0%	1.0%	Sverige
9	Swedbank Försäkring	347	17.4	1.0%	1.0%	Sverige
10	Evli Fonder	336	16.8	1.0%	1.0%	Finland
	Top 10 shareholders	21,146		61%	61%	
	Total other shareholders	13,565		39%	39%	
	Total shares outstanding	34,711		100%	100%	





Agenda

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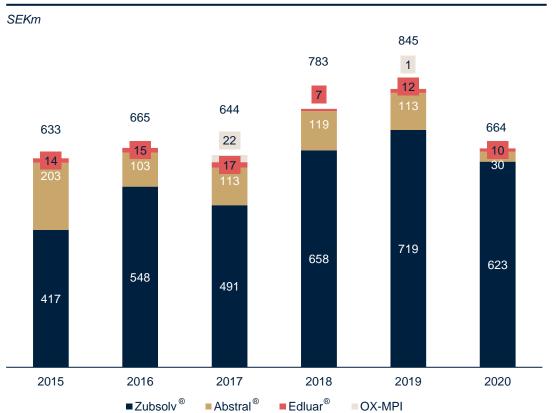




Revenue development

ZUBSOLV® is the main revenue contributor and has shown resilience despite the Covid-19 pandemic

Revenue split by pharmaceutical 2017 – 2020



Comments

- The decrease in ZUBSOLV® revenues during 2020 is driven by lower demand due to competition in previously exclusive plans, declining commercial segment due to increased unemployment as a result of Covid-19, lower adjustments of accrued product returns and by unfavourable exchange-rates, this is partly offset by increased wholesaler stocking levels and improved pricing
 - ZUBSOLV® dropped in demand in 2020 is mainly explained by decline in United Health Group (UHG) and Humana, following their decision in 2019 to reimburse generics). After the formulary change impact at UHG and Humana, the number of exclusive positions (plans) for ZUBSOLV® has reduced and only a few minor exclusive positions are left, making ZUBSOLV® less dependent on exclusive positions
- Abstral® revenues decreased, explained by the previously communicated expiration of the contracts for the US and European markets. For most markets, patents expire in 2024 and Orexo will not receive further royalties from the US market from Abstral® since they were withdrawn from the market by Orexo's commercial partner in 2019
- Edluar® revenues consist of royalties from a partnership with Mylan and have remained constant since launch, except for a decrease in 2018 due to delivery problems



Group and (US Pharma) ZUBSOLV® profitability

ZUBSOLV® is highly cash generative, but group profitability is impacted from significant investments

Group profitability

- The delta between Group and ZUBSOLV® EBIT is mainly explained by investments in opex for growth initiatives. The largest items are related to investments in research and development and selling expenses, which are both expensed over the P&L
- Orexo's profitability development during 2020 reflects COVID-19's impact on ZUBSOLV® and FX headwind, but is mainly explained by significant investments in digital therapeutics (SEK 175m in 2020) and product pipeline (OX124 and OX125)

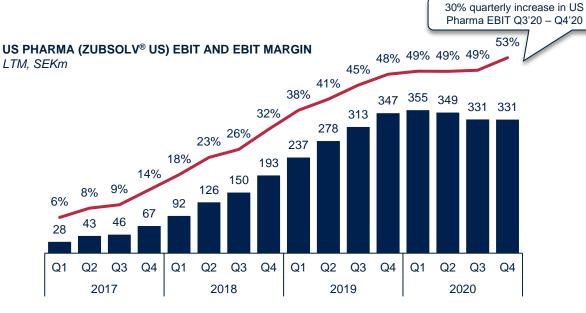
 Most investments are expensed over the P&L, but in 2020 investments related to digital therapeutics were capitalised on the balance sheet



ZUBSOLV® profitability

- US Pharma (currently only ZUBSOLV®) EBIT has increased due to i) improved EBIT margin, which has been mainly driven by lower COGS and ii) increased revenue
- The Commercial segment (private insurance companies), remains the most important for ZUBSOLV® due to excellent reimbursement and less rebates than Public segment

 LTM EBIT in Q4 2020 was in line with previous quarter as a result of lower COGS (efficiencies in the supply chain) and lower operating expenses

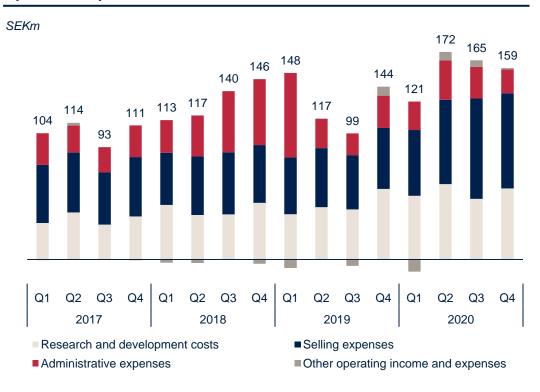




Historical opex

Increased opex driven by costs for developing and launching new products

Opex development 2017 Q1 - 2020 Q4



Comments

- Orexo has historically treated all investments in developing and launching of new products as opex, i.e. low historical levels of capex
 - Nearly all expenses in Digital Therapies is recorded as opex, only milestones and investments in hardware are accounted as capex. Future investments in clinical trials for modiaTM will be assessed based on IFRS and could be capitalized
- Increase in total opex in 2020 is mainly driven by increased selling expenses due to launch of Digital Therapies and investments in OX124
 - Two new digital therapies launched in Q3 2020
 - Opex related to US Pharma/ZUBSOLV® has been reduced in 2020
- The volatility in administrative expenses is explained by legal expenses
 - Orexo has successfully defended patent challenge on ZUBSOLV® leading to substantial investments in legal expenses in 2018-2019
- The increase in research and development costs in Q4'2019 Q4'2020 is explained by advancement of pipeline projects
 - Orexo has three on-going projects OX124, OX125, OX338
 - OX124 has been prioritized in 2020 and last stages of development is associated with increased R&D opex



P&L

05//	0047	0040	0040	0000
SEKm	2017	2018	2019	2020
Royalties and revenues from launched products	622	752	843	664
One-time payments and revenues from non-launched products	22	31	1	-
Total revenues	644	783	845	664
Cost of goods sold	(164)	(172)	(106)	(66)
Gross profit	479	611	739	598
Selling expenses	(191)	(191)	(192)	(287)
Administrative expenses	(96)	(167)	(140)	(103)
Research and development costs	(134)	(167)	(181)	(225)
Other operating income and expenses	(1)	9	5	(4)
Operating earnings	57	96	231	(20)
Financial income	0	35	46	2
Financial expenses	(28)	(39)	(50)	(21)
Net financial items	(28)	(4)	(3)	(18)
Earnings before tax	30	92	228	(38)
Тах	(7)	46	(9)	(46)
Net earnings for the period	23	138	219	(84)
Gross margin %	74%	78%	88%	90%
EBITDA	78	117	272	19
EBITDA margin	12%	15%	32%	3%

Comments

- Cost of goods sold consists of costs related to ZUBSOLV® for the US market, as well as technical infrastructure costs for deprexis® and vorvida®
- Operating expenses consist of selling expenses, administrative expenses, R&D expenses and other operating expenses:
 - Selling expenses consists of manufacturing expenses related to the US sales offices
 - Legal expenses are booked under administrative expenses
 - Research and development costs are expensed over the P&L and relates to expenses on development projects
 - Other income and expenses relates to exchange-rate gains/losses derived from revaluation of operating receivables and payables in foreign currency and income/expenses from activities outside the scope of normal business operations



Source: Orexo financial reports 45

Condensed balance sheet

SEKm	2017	2018	2019	2020
ASSETS				
Fixed assets				
Tangible fixed assets	20	20	22	47
Intangible fixed assets	121	104	114	253
Right-of-use assets	-	-	57	68
Deferred tax assets	28	93	86	33
Other financial assets	7	10	1	1_
Total fixed assets	177	227	280	401
Current assets				
Inventories	250	174	132	108
Accounts receivable	218	265	234	165
Other receivables	7	6	20	26
Prepayment and accrued income	24	26	18	27
Cash and cash equivalents	328	590	817	505
Total current assets	827	1,060	1,221	832
TOTAL ASSETS	1,004	1,287	1,501	1,233
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity	329	476	706	559
Long-term liabilities				
Provisions	6	7	11	26
Long-term liabilities, interest bearing	319	321	290	-
Lease liabilities, long-term	-	-	33	47
Total long-term liabilities	325	327	334	73
Current liabilities and provisions				
Provisions	201	266	269	197
Current liabilities, interest bearing	-	-	-	225
Current liabilities, non-interest bearing	149	218	170	160
Lease liabilities, current	-	-	21	19
Total current liabilities and provisions	350	483	461	601
TOTAL EQUITY AND LIABILITIES	1,004	1,287	1,501	1,233

Comments

- Development expenses are capitalised under intangible assets and intangible fixed assets for the Group consist of:
 - Acquired research and development which consists of acquired individual project and the surplus values arising in conjunction with business combinations
 - Patents and rights
 - Proprietary intangible assets which consist of clinical studies and registration expenses for these that are considered to contribute to future economic advantages for the Group. These studies are linked to products that have already been approved and commercialized
- Interest-bearing liabilities are associated with Orexo's corporate bond
- Orexo has office related leases e.g., premises, cars and other equipment used in the business. Leases also consists of machines and motor vehicles
- Provisions refer to a legal or informal undertaking as a result of an event that has
 occurred and when it is probable that an outflow of resources will be required to
 settle the undertaking, recognized in the amount expected to be required in to
 settle the undertaking



Source: Orexo financial reports 46

Cash flow statement

SEKm	2017	2018	2019	2020
Operating earnings	57	96	231	(20)
Adjustment for non-cash items	88	62	41	(7)
Interest received	0	3	10	3
Interest paid	(16)	(15)	(18)	(12)
Tax paid	(20)	(18)	(12)	1
Cash flow from operating activities before changes in	110	128	253	(35)
working capital	110	120	233	(33)
Changes in working capital	36	115	34	52
Change in inventories	83	84	43	10
Change in receivables	(71)	(22)	45	25
Change in current liabilities	24	`53	(54)	17
Cash flow after operating activities	147	242	287	17
. •				
Investing activities				
Acquisition of tangible fixed assets	(1)	(3)	(5)	(29)
Acquisition of intangible assets	(1)	(1)	(27)	(160)
Acquisition of financial assets	-	(3)	· ·	-
Disposal of financial assets	-		10	1
Cash flow from investing activities	(2)	(6)	(22)	(189)
Financing activities				
New share issue	0	0	2	-
Buyback shares	-	(0)	-	(27)
Issuance of corporate bonds	319	-	-	-
Buyback of corporate bonds	(405)	-	-	-
Repayment of loans	-	-	(56)	(84)
Cash from financing activities	(85)	0.0	(54)	(111)
Cash flow for the period	60	236	211	(284)
Cash and cash equivalents at the beginning of the period	282	328	590	817
Exchange-rate differences in cash and cash equivalents	(14)	26	16	(28)
Changes in liquidity	46	262	227	(312)
Cash & cash equivalents at the end of the year	328	590	817	505

Comments

- Adjustments for items not included in cash flow comprise depreciation and impairment, change in provision, share based payments and exchange rate income and expense
- Most of Orexo's investments are expensed as operating expenses over the P&L, rather than capitalized
- The increase in investments during 2020 is mainly related to the acquisition of exclusive US rights from GAIA AG (i.e., a world-leading digital therapy to help patients manage the symptoms of depression) to commercialize deprexis[®], where Orexo paid a non-refundable milestone to its partner during the second quarter
- Increase in investments are also explained by the purchase of equipment for the development organization

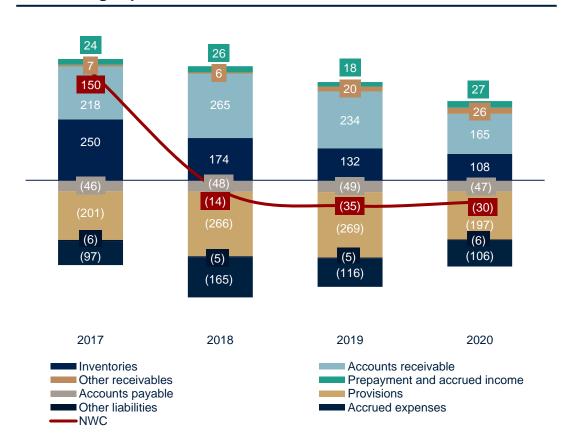


Source: Orexo financial reports 47

Net working capital

Orexo operates with negative net working capital

Net working capital



Comments

- Orexo ties up cash from mainly accounts receivable and inventories. As the Company has R&D inhouse, the number of suppliers and also the level of accounts payable are limited and significantly lower than the level of accounts receivable
- The main item releasing cash from NWC is provisions. Since the transaction price
 for sale of goods is usually not known, a cumulative discount deduction is reported
 in provisions as an estimate for an expected future return which might then be
 reversed from previous periods
- The decline in net working capital from 2018 is primarily related to the lower levels of inventories and accounts receivable



Appendix









Orexo's pharma business model

Orexo's pharma business is associated with lower cost, shorter development times and lower risk

Business model

- Orexo develops improved products by combining well-known and well-documented substances with in-house innovative drug delivery technologies
- By combining known pharmaceutical substances with its patented proprietary drug delivery technologies, Orexo develops pharmaceuticals at a lower cost, in a shorter period of time and at a lower risk
- Orexo is acknowledged as the world leader for sublingual (under the tongue) formulation platforms. The sublingual formulation technology is to be found in all of Orexo's current pharmaceutical products
- Development of products in the pipeline is evaluated by medical need and commercial potential
- All manufacturing is managed by Orexo, but performed by external partners

"Orexo develops pharmaceuticals at a lower cost, in a shorter period of time and at a lower risk"

Orexo's value creation

Input

- Innovation
- Proprietary drug delivery technologies developed inhouse

Value creation

Create value by development and commercialization of new drugs based on existing and well-known substances, either in-house or together with partners, that:

- offer medical advantages
- meet unmet needs
- have commercial potential

Input

- Commercialization of in-house and/or licensed products, either in-house or with partners
- Milestone payments related to development projects and launched products through partners



Orexo's DTx strategic business model

Orexo's ambition is to become a leader in digital therapeutics, leveraging its existing commercial infrastructure and new technical platforms to scale up

Acquire digital therapies

- Acquire innovative digital therapies with clear synergies with existing commercial footprint
- Scientifically validated products
- Reduced development risk through partnering with established companies



Establish "the Platform"

Develop proprietary scalable reimbursement, payment and distribution platform to solve main hurdle in the market today





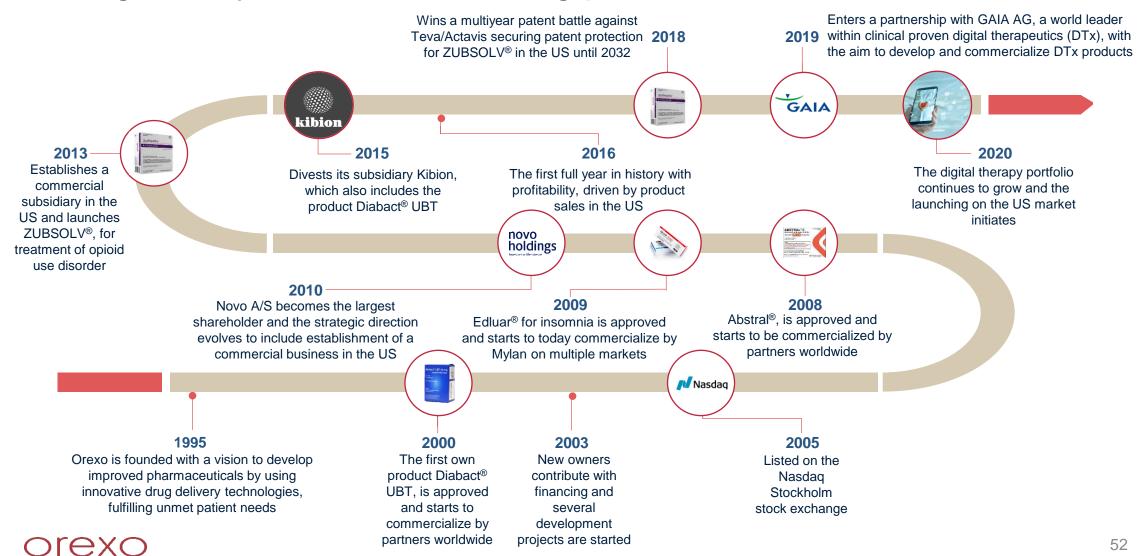
Expand presence and portfolio

 Leverage the platform to attract new partners providing access to either Orexo commercial capabilities and/or "The Platform"





Strong history of commercializing pharmaceuticals



Orexo's sustainability agenda

Since 2018, Orexo supports the ten principles of the UN Global Compact in the areas of:







At Orexo, the sustainability work contributes to several of the UN's Sustainable Development Goals (SDGs) with a primary focus on SDG3 "Good health and well-being". This target is of especial importance as it is closely aligned with Orexo's ambition to strengthen the prevention and treatment of substance abuse.



Glossary (1/3)

ANDA - An Abbreviated New Drug Application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug

Artificial Intelligence - Artificial intelligence (AI) is the simulation of human intelligence processes by machines, especially computer systems

Breakthrough pain - A short, intensive period of pain that occurs in addition to chronic levels of long-term pain even though these are treated by regular painkillers

Broca® - GAIA's proprietary intelligence system, based on artificial intelligence, underpins the development of digital therapies targeting multiple therapy areas

Buprenorphine/naloxone - In combination with counseling, it is used to treat opioid use disorder. It decreases withdrawal symptoms for about 24 hours. Buprenorphine/naloxone is available for use in two different forms, under the tongue or in the cheek

Cash segment - One of the three distinct payer segments in the US market for treatment of opioid dependence. In this segment, the patient is paying for the prescriptions out of pocket

Clinical Studies - Studies of the safety and efficacy of a drug in human beings

Commercial segment - One of the three distinct payer segments in the US market for treatment of opioid dependence. The commercial segment is funded by private insurances or employers

Digital health - Digital health is the convergence of digital technologies with health and healthcare to enhance the efficiency of healthcare delivery and make medicine more personalized and precise

Digital therapeutics (DTx) - Digital therapeutics, a subset of digital health, are evidence- based therapeutic interventions driven by high quality software programs to prevent, manage, or treat a medical disorder or disease

Drug delivery - The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended



Glossary (2/3)

EMA - The European Medicine Agency

FDA - The US Food and Drug Administration

Fentanyl - An opioid with a similar effect on human patients as morphine. Used mainly within anesthesia and analgesia

Generic drugs - *copies* of brand-name drugs that have exactly the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the original drug. In other words, their effects are exactly the same as those of their brand-name counterparts

IP - Intellectual Properties

LTM - Last Twelve Months

Naloxone - An opioid antagonist used to counter the effects of opioids

NTRx - Tablets per prescription divided by 30

Opioids - Collective term for compounds that act via opioid receptors on nerve cells, mainly in the central nervous system

PBM (Pharmacy Benefit Manager) - Responsible for management of costs associated with prescription pharmaceuticals and recommendations on behalf of insurance companies and employers in the US

Phase I studies - Studies mainly of the safety of a drug. Performed on healthy human volunteers

Phase II studies - Studies of the safety and efficacy of a drug in appropriate doses. Performed on a limited number of patients

Phase III studies - Studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients



Glossary (3/3)

Preclinical development/Preclinical studies - Studies of the safety and efficacy of a drug prior to evaluation in humans. Can be performed on animals and in various cell systems

Public segment - One of three distinct payer segments in the US market for treatment of opioid dependence. The public segment covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D

Reimbursement - Healthcare reimbursement describes the payment that your hospital, doctor, diagnostic facility, or other healthcare providers receive for giving you a medical service. Healthcare providers are paid by insurance or government payers through a system of reimbursement. After you receive a medical service, your provider sends a bill to whomever is responsible for covering your medical costs

Sublingual - Under the tongue

Total Prescriptions (TRx) - Total number of prescriptions written by doctors for a particular drug over a specific period

30-Month Stay - If the patent holder files an infringement suit against the generic applicant within 45 days of the ANDA notification, FDA approval to market the generic drug is generally postponed for 30 months unless the patent expires or is judged to be invalid or not infringed before that time. This 30-month postponement, commonly referred to as the "30-month stay," gives the brand product sponsor and patent holder a prescribed amount of time to assert patent rights in court before a generic competitor is approved and can market the drug



Risk factors









Risk factors (1/11)

The purpose of this section is to enable a potential investor to assess the relevant risks related to their potential investment in the Bonds in order to make an informed investment decision. The below risk factors are therefore limited to risks that, in the meaning of Regulation (EU) 2017/1129, are material and specific to Orexo AB (publ) (the "Issuer" and together with its direct and indirect operating subsidiaries, the "Group") and the Bonds.

The manner in which the Issuer and the Bonds are affected by each risk factor is illustrated by way of an evaluation of the materiality of the relevant risk factor based on the probability of it occurring and the expected magnitude of its negative impact, for the purpose of which the probability is estimated as "low", "medium" or "high" and the magnitude of negative impact if it would occur as "low", "medium" or "high". The most material risk factor in a category is presented first under that category, whereas subsequent risk factors in the same category are not ranked in order of materiality.

Risk factors specific and material to the Issuer and the Group

I. Risks related to the Group's business activities and industry

Risks due to the outbreak of the coronavirus

The outbreak of the coronavirus disease, COVID-19, is generally deemed a global pandemic. The spread of COVID-19 has had severe disruptive effects on the Swedish, US and global economies and has caused increased volatility and declines on financial markets. In the US, where COVID-19 has caused lock-downs, the Group's sales force accessibility to healthcare providers has been limited. Such access is important in order for the Group to be able to market its branded pharmaceuticals as an alternative over generic substances. The spread of COVID-19 has also caused increased unemployment, which has negatively affected, and may, going forward, negatively affect the development of the commercial segment. Due to the commercial segments being crucial for the sales and profitability relating to the Group's main product ZUBSOLV® ("Zubsolv"), there is a risk that the Group's sales decline and that growth opportunities are impaired, which would negatively affect the Group's results of operation. Furthermore, COVID-19 may result in delays within the development chain which can result in unexpected delays in the pharmaceutical projects. The Group may also experience disruption to the Group's supplier chains of services and increased unavailability of staff, which in turn could lead to the Group breaching delivery obligations or incur increased costs, which will have a negative effect on the Group's results of operation.

If the pandemic continues over a prolonged period of time, the adverse impact on the global economy could deepen and result in material adverse effects on the Group's business, financial position as well as overall future prospects

The Issuer considers that the probability of the above risks occurring is *high* in short term but *medium* in the long term. If the risks would materialise the Issuer considers the potential negative impact to be *medium*.

Risks related to eligibility for reimbursement and formularies

In order for the Group to maintain successful level of sales of its pharmaceuticals in general, and Zubsolv in particular, it is crucial that the pharmaceuticals have access to patients and reimbursement to the same extent as competitors. The Group's products are eligible for reimbursement both through private and government sponsored healthcare payment system. The Group's products are commercialised in three different payer segments; the public segment, with public sector payers such as Managed Medicaid, FFS Medicaid and Medicare Part D; the commercial segment, with private insurance company payers and the cash segment, where patients themselves finance their care. The public segment has been the fastest growing segments in the past years due to increased access to publicly financed healthcare through the Affordable Care Act, and the public segment now represents more than half of the total market volume.

The public segment is stringently controlled by insurance companies with regard to what drugs may be prescribed and which physician a patient can choose. In order to be reimbursed within the public and commercial segment the Group typically needs to have its pharmaceuticals or therapies taken up at formulary lists covering the pharmaceuticals and/or treatments that can be reimbursed within the scope of publicly financed health plans and/or insurance. Having its pharmaceuticals enlisted in the formularies consequently makes the Group's pharmaceuticals eligible for reimbursements under such programmes.



Risk factors (2/11)

The pharmaceutical market is greatly affected by political policy that may affect, for example, reimbursement levels for pharmaceutical expenses and limits for the prescription of products. Especially the market for controlled substances is under tight surveillance and control by authorities who can change the market conditions with new policies, legislation and price control tools. There is a risk that policy changes influence or restrict spending under Medicare, Medicaid or other publicly funded or subsidised health programmes in the US, impose price transparency requirements as well as policies aimed at generally reducing formulary list prices and limiting pricing flexibility for pharmaceutical manufacturers. Political policy may also result in that formularies are made exclusionary for certain branded pharmaceuticals or are opened up for generic versions for cost efficacy reasons (see further risk factor "Risks relating to price control and price pressure"). In addition, except for price-pressure imposed by policy changes, payers may challenge the price and cost-efficacy of medical products and services. Certain formularies or insurance companies may deploy strategies to automatically favour generics before branded pharmaceutics, which methods could be utilised by payers to limit the use of branded products and put pressure on manufacturers to reduce net prices.

In addition, the Group is to a certain extent dependent on Pharmacy Benefit Managers ("PBM"), such as CVS Caremark and Express Script (ESI), being responsible for assessing, on behalf of insurance companies and employers, which drugs are to be covered by insurances. Even where such assessment is based on the prevailing public policy, the PBMs are constantly reviewing their formularies and historically, the Group has been subject to the risk that generics have been added to the lists whereby reimbursement have been reduced. Even if the Group only has a small volume left in exclusive contracts, there can be no assurance that the Group becomes more dependent on being on exclusionary lists in the future. This may lead to significant changes in market access in relation to the Group's products.

There is a risk that political policy is changed or the PBMs act in a manner that the market conditions for the Group's products are negatively affected or that sales are otherwise restricted. Furthermore, should the Group fail to have its products included in relevant formularies, or the relevant PBMs otherwise treat the Group's products less favourably, it could lead to the Group's products not being reimbursed. Declining reimbursement levels, due to failure to list the Group's products in relevant formularies, policy changes, increased competition from generic substances, or otherwise, would lead to decreased revenues and impaired market access as well as reduced profitability for the Group's products. This will in turn have an adverse negative effect on the Company's business, results of operation as well as, in the longer perspective, financial position.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise the Issuer considers the potential negative impact to be medium.

Risks relating to price control and price pressure

The revenues and profit margin in relation to the sales of the Group's products depend on any pricing approvals by government authorities and the availability of payment or reimbursement from payers in the Group's market segments (see further risk factor "Risks related to eligibility for reimbursement and formularies"). The outcome of pricing approval processes and the payment or reimbursement status of newly approved pharmaceutical products are inherently uncertain. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve the Group's proposed products for marketing and could further limit pricing approvals for, and reimbursement of, the Group's products from government authorities and payers. For the Issuer, the ability to close collaborations with new potential partners on the EU market will be dependent on the outcome of pricing discussions, which are ongoing with authorities in multiple European countries. A governmental or payer decision to disapprove pricing for, or provide adequate coverage and reimbursements of, the Group's products, would limit market acceptance and commercialisation opportunities of such products, which in turn would cause revenues to decrease, and will negatively affect the Group's business and results of operation.

Furthermore, increased generic presence may lead to increased price pressure. The Group's position on the market for opioid addiction treatment market has historically seen several generics of mainly Subutex® ("Subutex") and Suboxone® ("Suboxone") tablets. For example, during 2019, the Group noted increased generic presence, as four generic versions challenging the market leading Suboxone film entered the market, which negatively affected net sales of the branded Suboxone film products. Similarly, the sales of Zubsolv may be negatively impacted as payers open up for more alternative treatments and generic options to the Group's branded alternatives. There is a risk that generics come at lower list prices than the Group's products sold under patent-protected brand names, and the Group has seen examples of campaigns from individual generic companies that have offered discounts to pharmaccies which have then reduced the price in certain segments. Where generics are favoured by insurance companies in the public segment, by way of prioritising generics over branded pharmaceuticals, it may also lead to indirect pressure on companies with new products to lower the price. As a result, increased generic presence and such potential price pressure could force the Group to lower its prices or reduce the sales volume, which may negatively affect profitability and revenues. This would in turn negatively affect the Group's results of operation and financial position.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise, the Issuer considers the potential negative impact to be medium.



Risk factors (3/11)

Dependence on research and development of new products

Business activities involving development of pharmaceutical product candidates is a complex, risky and lengthy process and requires financial investments and other resources as well as successful research and development. As the Group is a relatively small organization, it is necessary to focus on a small number of prioritized projects with high market potential. There is a risk of failure at several stages in the process, which may be due to factors such as failure to obtain the required regulatory or marketing approvals, unfavourable clinical efficacy data, failure to reach adequate cost-efficacy and demonstrate it to relevant payers, risk of new competitors entering the market during development, as well as the risk of changes in the requirements of the regulatory authorities. Furthermore, due to the pharmaceutical industry being highly influenced by digitalization, there is a risk that the Group fails to keep pace with rapid technological development and changes in customer demand, which could result in the Group being unable to make profit on its development projects, especially within digital therapies.

Since the Group's business is built around the development and subsequent commercialisation of improved pharmaceuticals and digital therapies, the Group is dependent upon its research and development activities in order to remain profitable and further future growth. The Group's research and development pipeline currently comprise four pharmaceutical product candidates, whereof the development of one is fully managed and financed by an external partner, Gesynta AB, as well as one digital therapy product candidate which are pending for registration. The Group has made significant investments in its research and development projects over time, and may pursue additional investments going forward. In order to remain profitable and further future growth the Group needs to continuously expand its product portfolio or improve existing products, especially upon expiration of existing product patents.

As a result, should any of the above factors lead to that the Group fails in its product development, or that the Group otherwise is unable to successfully pursue its research and development activities, it could lead to the Group being unable to profit on its investment in such area and lead to decreased future sales. This would in turn have a material adverse effect on the Group's results of operations, financial position and future prospects.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise, the Issuer considers the potential negative impact to be medium.

Commercialisation and launch of product candidates and clinical trials

The Issuer is subject to strict controls on the commercialisation processes for its pharmaceutical products, and the criteria for establishing safe, efficient and qualitative products are essential to meet in order to obtain marketing approvals. In order to obtain necessary approvals for the commercial sale of its products, the Group and its collaborating partners will need to complete clinical and pre-clinical trials to demonstrate the safety and efficacy of its product candidates. Regulators may refuse to grant approval or may require additional data before approval is granted. There is also a risk of that the trial data prove that the Group's product candidates are not sufficiently safe and effective to the extent necessary to obtain necessary approvals or that regulatory policy change in such way that the trial data becomes useless or appears more unfavorable than expected.

Negative or inconclusive clinical trial data or results may force the Issuer to conduct further trials, narrow down the anticipated indication or even suspend the development of the relevant product candidate and delays in regulatory review and approval could in turn delay the Group's launch process of product candidates. This could in turn result in increased costs, significant delay in filings for approval or force the Issuer and its collaboration partners to abandon the commercialisation of the product candidate.

Should any of the above risks materialise, the Group may be unable to commercialise and profit on its product development and incur additional or unexpected costs, which in turn would decrease profit and limit the Group's access to future revenue. This would in turn have a material adverse effect on the Group's business, results of operation and financial position as well as future prospects.

The Group has made significant investment towards a new infrastructure in order to launch the Group's digital therapies. There is a risk that the market for digital therapies will not be as favorable as anticipated. Furthermore, the Issuer has recently conducted a strategic review of the Group's business and decided to prioritize the launch of the Group's digital therapies resulting in the Group's re-allocation of resources from the Zubsolv commercial team to digital therapeutics. In the pharmaceutical pipeline, the Group has also shifted resources towards certain product candidates as a result of such new strategy. There can be no assurance that this change of strategy will be successful or that the market reception of digital therapies will be favorable. Furthermore, there is a risk that shifting of commercial focus and allocation of resources away from the Zubsolv commercial team will prove unsuccessful. If the Group's revenues and profitability, which in turn would have an adverse effect on the Group's results of operation and financial position.

The Issuer considers that the probability of the above risks occurring is low. If the risks would materialise, the Issuer considers the potential negative impact to be medium.



Risk factors (4/11)

Competition

Many potential competitors of the Group have greater financial resources and expertise in research and development, clinical trials, obtaining regulatory approvals and marketing than the Group. The Issuer competes with several companies and institutions, including pharmaceutical companies, biotechnology companies, academic institutions and research organisations in marketing and development of drugs. Competitors may develop more efficient, more affordable or more practical products or may achieve earlier patent protection or commercialisation of their products than the Issuer. Also, such competitors may have greater access to hospitals, physicians, patients or the medical community in general for purposes of marketing a competing product. In addition, some competitors have made attempts to settle ongoing litigations initiated by US authorities, by offering free products for treatment of opioid addiction, these settlement discussion have not made any progress, but the litigation cases are ongoing. These competing products may render the Issuer's products obsolete or may limit the ability of the Issuer to generate revenue, which could have a negative effect on the Group's business, operating results and financial position.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise, the Issuer considers the potential negative impact to be medium.

Dependency on personnel and key executives

The Group relies on recruiting and retaining talented and skilled employees with a diverse range of know-how, expertise and capabilities, in order to maintain growth. Consequently, the Group is dependent on the ability to attract and retain highly qualified personnel within the fields of research and development, sales, and production, as well as personnel with particular expertise in clinical trials and governmental regulation. Furthermore, in order to pursue strategic objectives, the Group is dependent on its executive management.

Loss of key personnel could delay or obstruct the Issuer's research and development, sales of existing products and product manufacturing. The Group is subject to competition in recruiting and retaining personnel from other companies, universities, public and private research institutions, government entities and other organisations. Should the Group be unsuccessful in its recruitment and retention efforts, the development of the Group's products or future growth potential may be impaired, which, in the long term would negatively affect the Group's business and results of operation.

The Issuer considers that the probability of the above risks occurring is low. If the risks would materialise, the Issuer considers the potential negative impact to be medium.

Dependency on third party contractors

The commercialisation rights in relation to Zubsolv are held by the Group's various commercialisation partners, including, amongst others GoGo Meds and Gesynta Pharma. The Group is therefore dependent on maintaining relevant distribution and commercialisation arrangements in order to commercialise its products. There is a risk of such commercialisation arrangements are terminated and that the Group is unable to replace such partnership in a timely manner, or at all, which could lead to lost business opportunities, delayed deliveries or increased costs.

Furthermore, the Group relies on third party partnerships to market and distribute its products, conduct clinical trials and develop and manufacture certain products utilizing the Issue's innovative drug-delivery platforms. Should such third parties fail to fulfil its contractual obligations vis-á-vis the Group, whether of financial or operational nature, fail to meet deadlines or expected levels of quality or accuracy, the Group's marketing activities and clinical trials may be extended, delayed or terminated. Any failure by such partners would negatively affect the Group's ability to develop, commercialise and license its products, which would have a negative effect on the Issuer's business and results of operations.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise, the Issuer considers the potential negative impact to be low.



Risk factors (5/11)

Risks related to supply chains and production process

The entire production and packing of the Group's products is carried out by external partners. Zubsolv is manufactured by third party contractors located in the US and packed by third party contractors in the US for the US market and in Romania for the European market. The manufacturing and packing facilities as well as methods and processes must meet applicable Good Manufacturing Practice standards ("GMP") overseen by relevant authorities in several countries, including in the US, where the GMP are overseen and administered by the US Food and Drug Administration ("FDA"). The group is therefore dependent on its continuous monitoring and evaluation of the fulfilment of GMP both internally and by all strategic sub-suppliers, as the Group and its sub-suppliers may be inspected by different authorities that have the power to grant approvals. The Group's production comprises highly potent controlled substances and there are strict rules and regulations regarding manufacturing, storage, handling, freight, import and export, and waste management for such products. Failure to comply with manufacturing regulations may lead to regulatory inspection findings that could cause cessation of certain manufacturing procedures, product seizure, debarment or recalls, all of which could have a material adverse effect on the Group's business as well as lead to reputational harm.

The Issuer also relies on third-parties for the timely supply of goods, such as the active pharmaceutical ingredients, equipment and packaging. Access to pharmaceutical ingredients may be uncertain and entail long delivery times, and certain goods may be difficult to substitute in a timely manner or at all. Consequently, the Group must ensure that it can gain access to any required substances at an early stage. To ensure an adequate and safe supply of Zubsolv in the US market, the Group must hold a certain inventory level raw materials, semi-finished products and finished products. Carrying a high inventory level creates a risk of depreciation of finished products or chemical compounds where the products or compounds cannot be used or sold within the estimated shelf-life of expiration time. Failure of making correct estimations and assumptions could lead to improper valuations of inventories, which could have a negative effect on the Group's valuation of assets.

Difficulties with manufacturing and supply, forecasting, distribution or third-party suppliers may result in product shortages or excess, which would result in product sales losses and reputational harm in relation to partners and customers. This could in turn result in decreased sales and increased costs, which would adversely affect the Group's results of operation.

The Issuer considers that the probability of the above risks occurring is low. If the risks would materialise, the Issuer considers the potential negative impact to be medium.

Acquisitions

The Issuer continuously evaluates opportunities to acquire products and businesses as part of its day-to-day business activities. A successful acquisition and integration process creates increased value. The acquisition and integration of new products and business units is associated with uncertainty, for example the risk that costs related to an acquisition become higher than expected or that future results and synergy effects do not correspond with expectations. There is also a risk that any contractual arrangements made with the sellers of such products or business units prove to be ineffective, which could cause problems or unforeseen risks following the acquisition. Moreover, transactions can lead to costs which may be significant and which may not be recovered or compensated for in the event of, for example, a transaction not being completed. Any such unforeseen events in connection with acquisitions of products and businesses could have a negative effect on the Group's business and financial position.

The Issuer considers that the probability of the above risks occurring is low in the short term and medium in the long term. If the risks would materialise, the Issuer considers the potential negative impact to be medium.

Risks related to intellectual property

The Group's product portfolio, and hence its assets, consist of patent-protected products and technologies. The ability to obtain and maintain patents and other intellectual property rights protecting the Group's technologies and products is therefore crucial in order to protect the value of the Group's assets. Furthermore, patent rights are typically acquired at the very start of the product development and since the research and trial phase preceding the commercial approval and launch may take significant time, there may only be a few years to earn an adequate return on investments made. As a consequence, the Group is dependent, at all stages of product development, to obtain, maintain, defend and enforce patents and other intellectual property rights to protect and recoup investment in research and development and maintain its cash flow.



Risk factors (6/11)

Should the Issuer fail to obtain necessary patent protection, as well as to defend and enforce its patent rights it could allow entry of generic or competitor products earlier than anticipated. This could have a material adverse effect on the pricing and sales of the Group's products and materially adversely affect revenues.

Obtaining patents related to pharmaceuticals is a complex process that involves both scientific and legal expertise. Even if a patent has been granted, it may later be challenged legally, declared invalid or bypassed, which may limit the Group's ability to commercialise its new products. There is a risk that pending patent applications may not result in issued patents. Since certain patent applications are confidential until patents are issued, third parties may have filed patent applications for technology covered by the Issuer's pending applications without the Issuer being aware thereof, whereby the Issuer's patent applications may not have priority over the applications of others. There is a risk that the Group's efforts to protect its rights are insufficient and unauthorised parties may be able to obtain and use information that the Issuer regards as proprietary. Moreover, the mere issuance of a patent does not guarantee that it is valid or enforceable against third parties. The patent position of pharmaceutical or biotechnology companies, including the Issuer, is generally uncertain and comprises complex factual and legal assessments. The rules applied by patent offices in various countries for the granting of patents are not always applied in a predictable or uniform manner and may be subject to change.

The Issuer further relies on unpatented trade secrets, know-how and continuing technological innovation to develop and maintain its competitive position. The Issuer's failure to protect its trade secrets, know-how and technologies may undermine its competitive position and adversely affect the value of the Issuer's commercialised products, technologies and product candidates.

There is also a risk that the Group's own products are found to infringe patents owned or licensed by third parties, including research-based and generic pharmaceutical companies and individuals. Such third-parties may seek remedies for patent infringement, including injunctions (for example, preventing the marketing of one of the Group's products) as well as damages.

Any inability for the Group to protect and enforce its patent protection and other intellectual property rights, or any infringements of the rights of others, could result in a decrease in cash flow generated by intellectual property transferred onto partners or third parties, which, in turn, could have a negative effect on the Issuer's business operating results and financial position.

The Issuer considers that the probability of the above risks occurring is *medium*. If the risks would materialise, the Issuer considers the potential negative impact to be *high*.

Product safety and product liability

The Group's business of manufacturing, testing, and marketing of pharmaceuticals involves an inherent risk related to product safety and product liability to accurately assess, prior to launch, the expected safety or efficacy of a new product once in broader clinical use can only be based on available pre-launch data, which is inherently limited due to the relatively short periods of product testing and inherent limitations in clinical study patient samples. Safety concerns or adverse events relating to the Group's products could lead to product recalls, seizures, loss of product approvals, declining sales and interruption of supply and could materially adversely affect market and patient access and impair brand reputation. Such safety concerns or adverse events, whether due to the Group or the patient not adhering to relevant warnings for risks related to use of the Group's products, could also result in injuries or even fatalities, which could expose the Issuer to material product liability damages claims, settlements and awards, particularly in the US. Adverse publicity relating to the safety of a product or of other competing products may also itself increase the risk of further product liability claims.

Any claims directed at the Group, whether unfounded or not, could have a material adverse effect on the Group's business and financial position, and may also lead to significant reputational harm, thus jeopardizing market access and access to clinical trials.

Furthermore, there is a risk that safety risks are non-insurable in any market where the Group may operate from time to time. Moreover, any insurance that the Issuer does obtain may not provide adequate protection against potential liability or claims. Should any insurance prove inadequate to cover losses incurred by the factors described above, it could lead to unexpected losses and thereby negatively affect the Group's results of operation and financial position.

The Issuer considers that the probability of the above risks occurring is low. If the risks would materialise, the Issuer considers the potential negative impact to be medium.



Risk factors (7/11)

II. Legal and regulatory risk

Disputes with third parties or regulatory and administrative authorities

The nature of the Group's business, including the protection of intellectual property rights and distribution of pharmaceutical products to consumers, subjects the Issuer to risks related to claims and litigation. The Group may, for example, be involved in disputes relating to product liability, consumer complaints, commercial contracts, anti-trust claims, environmental damages claims, employment related claims or tax proceedings or investigations. Litigation, particularly in the US, is inherently unpredictable and adverse outcomes of such proceedings may result in unexpectedly high awards for damages.

On 14 September 2020 the Issuer announced by way of press release that it had filed a patent infringement action in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries Limited, Sun Pharma Global, Inc., and Sun Pharmaceutical Industries, Inc. (collectively "Sun"). Sun seeks to market and sell generic versions of Zubsolv. The outcome of the dispute is still uncertain but may prove costly and may result in the Group losing markets shares. This legal dispute, as well as any future legal disputes and proceedings may be time consuming, disrupt operations and come at high cost. There is a risk that certain of the Group's competitors may be able to sustain the costs of complex patent litigation more effectively than the Group, due to having substantially greater resources. In some proceedings, the counterparties may also seek damages and other remedies, which, if imposed or charged, could cause the Group to be liable for significant amounts, which outcome may be difficult to predict. If any of the abovementioned risks materialise, it could have a materially adverse effect on the Group's business, results of operation as well as, in turn, financial position.

The Issuer considers that the probability of the above risks occurring is *medium*. If the risks would materialise, the Issuer considers the potential negative impact to be *high*.

Risks related to compliance and regulatory challenges

The Group's business operations are subject to a wide range of laws, rules and regulations from governmental and non-governmental bodies around the geographies where the Group operates. Such statutes, rules and regulations include for instance, GMP, national and international environmental and occupational health and safety laws, trade control laws, embargoes, trade and economic sanctions and anti-boycott requirements, competition laws, financial regulations including, but not limited to, external financial reporting, taxation, employment practices as well as numerous particular healthcare related US rules and regulations.

Furthermore, the Group handles and process personal data and is thus obligated to follow the EU's General Data Protection Regulation (EU) 2016/679 ("GDPR") concerning rules and regulations for personal data processing as well as any equivalent data protection regulations in other countries. The Group is also subject to various regulations on handling of patient data. The Group is subject to risks that personal data is used erroneously, lost, disclosed or processed in violation of the applicable rules concerning data protection and privacy by the Group or by a third party contracted by the Group. Sanctions pursuant to such data protection laws, including the GDPR, could be significant.

In addition, changes in legislation may result in increased costs for regulatory compliance and administration costs for the Group.

If the Group fails to comply with applicable laws, rules and regulations as well as to adequately anticipate or proactively manage emerging policy and legal developments, the Issuer may be liable to pay damages or fines and/or be subject to suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and prosecution. Such failure may also adversely affect the Group's reputation; cause harm to persons or the environment, and/or lead to significant fines or other penalties. Should any such risks materialise, it could have a material adverse effect on the Group's business, results of operation and financial position.

On 14 July 2020 the Issuer's US subsidiary received subpoenas for the purpose of enabling US authorities to obtain certain information in relation to sales and marketing of Zubsolv and other buprenorphine products. The background for such requests is still unclear and the Issuer is collaborating with the US authorities to ensure that the necessary information is submitted and the scope of the investigations is clarified. It cannot be ruled out that such requests may result in an indictment and material fines, which could result in unexpected costs or reputational damage, or that management's attention will be diverted from the day-to-day operations.

The Issuer considers that the probability of the above risks occurring is *medium*. If the risks would materialise, the Issuer considers the potential negative impact to be *high*.



Risk factors (8/11)

Risks related to illegal trade of pharmaceuticals

The illegal trade in pharmaceutical products is widely recognised as an increasing issue in the pharmaceutical industry. Illegal trade includes counterfeiting, theft and unauthorised use in markets where the relevant pharmaceutical is not approved. Illegally traded products entering the supply chain pose risks to public health, and the Group is expected to mitigate risks of illegal trade of its products by monitoring its supply chains. There is also a risk that the Group's products are accessed by individuals that have not obtained the adequate prescription or that otherwise shall not have access to the Group's products. Any illicit trade or use of the Group's products may cause public confidence to decline, which could adversely affect the Issuer's reputation and business. In addition, undue or misplaced concern about this issue may cause some patients to stop taking their medicines, with consequential risks to their health. There is also a direct financial loss when, for example, counterfeit products replace sales of genuine products in a market or genuine products are recalled following discovery of counterfeit products.

The Issuer considers that the probability of the above risks occurring is low. If the risks would materialise, the Issuer considers the potential negative impact to be medium.

Environmental regulation

Because of the chemical ingredients used in pharmaceutical products and the nature of their manufacturing process, the pharmaceutical industry is subject to stringent environmental regulations and to the risk of incurring liability for damages or costs of remedying, decontaminating or investigating environmental problems. If the Issuer fails to comply with environmental regulations relating to the proper use, discharge or disposal of hazardous materials or otherwise fails to comply with conditions attached to operating permits, such permits could be revoked and the Issuer could be subject to criminal sanctions and incur substantial liability and costs, and could thus be required to suspend or modify its operations. Should any of the abovementioned risks materialise, it could have a negative effect on the Issuer's business and reputation, which may affect its financial position negatively.

The Issuer considers that the probability of the above risks occurring is low. If the risks would materialise, the Issuer considers the potential negative impact to be low.

III. Risks related to the Group's financial situation

Macro-economic factors

The Group operates globally and is subject to political, socio-economic and financial factors (including foreign exchange movements) both globally and in individual countries.

The pricing and the demand of pharmaceutical products may be adversely affected by a downturn in the general economy in the US and/or in the EU, as well as on other major pharmaceutical markets. An economic downturn could, among other things, put pressure on healthcare payers, including authorities, insurance companies and hospitals, resulting in a lower willingness to pay for pharmaceutical products which, together with, *inter alia*, other changes in aforementioned payers' budgets, could result in reduced reimbursement for the Group's present and potential future products. Furthermore, it may be future initiatives to curb rising pharmaceutical costs in the US and EU, as well as on other major pharmaceutical markets, which could affect future sales margins and product sales for pharmaceutical companies, including the Issuer. Such measures could result in fewer reimbursement possibilities and/or lower reimbursement levels in certain markets. Trade conflicts between the US and Europe could cause disruption to the groups supply chain and result in increased cost of manufacturing from import taxes and increased cost securing a sufficient inventory. Accordingly, deteriorated macro-economic conditions and changes to rules regarding the pricing of pharmaceutical products could have a negative effect on the Group's results of operation and therefore its financial position.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise the Issuer considers the potential negative impact to be medium.



Risk factors (9/11)

Currency risk

The Issuer's consolidated financial statements are prepared in SEK, which thus is the reporting currency but also the functional currency of the Issuer. The earnings and financial position of Group companies that use a functional currency other than the reporting currency (SEK) are restated in SEK in the consolidated financial reports. The Issuer markets and distributes its products in countries other than SEK. Receiving revenues and expenses in foreign currency give rise to currency transaction exposure. Furthermore, having assets in form of accounts receivable and liquid funds as well as liabilities, in form of accounts payable, in foreign currencies, results in currency translation exposure. The major part of the Group's currency risk exposure is attributable to the sale and manufacturing of Zubsolv in the US as well as royalty income in currencies other than SEK, as license agreements are primarily denominated in USD and EUR.

A weakening of the SEK against other currencies increases the Issuer's reported assets, liabilities, income and expenses, while a strengthening of the SEK against other currencies reduces these items. As of 31 December 2019, a change in the value of USD against SEK of 10 per cent. and with balance sheet exposure at such closing date would have entailed a change in other operating income and expenses of approximately SEK 13.1 million. The Issuer's financial policy permits the use of exchange-rate hedging instruments, but no such arrangements are used as at the date of this material. Major currency fluctuations between SEK and other currencies could thus have material negative effects of the Group's balance sheet, which could have an adverse effect on the Issuer's financial position.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise the Issuer considers the potential negative impact to be low.

Incentive programs

The Issuer has introduced a number of share-based incentive programs with the aim of motivating and rewarding key employees through partial ownership of the Group's shares, thereby promoting the Issuer's long-term interests. Such programmes will be paid in cash or treasury shares will be used for employees who wish to receive shares. There is a risk that such goals or targets will not be achieved resulting in employee dissatisfaction or that the incentivizing objectives do not result in increased or enhanced performance by the Group's employees. Furthermore, share-based incentive programs entail tax related risks as well as risks for breaches of regulatory requirements imposed by, for instance, relevant stock markets. There is a risk that the Issuer's assessments of applicable tax laws and other regulations are inaccurate or that the group otherwise fail to comply with any applicable rules and regulations, which may lead to a future increased tax burden and/or fines or costs, which in turn could negatively affect the Group's results of operation and financial position.

The Issuer considers that the probability of the above risks occurring is *medium*. If the risks would materialise the Issuer considers the potential negative impact to be *low*.

Risk factors specific and material to the Bonds

I. Risks related to the nature of the Bonds

Ability to service debt

The Issuer's ability to service its debt obligations under the Bonds depends on the Group's ability to meet its payment obligations, which in turn is dependent on the Group's future financial and operating performance. The Issuer's and the Group's financial position is affected by several factors, a number of which have been discussed above. If the Group's operating income is not sufficient to service its current or future indebtedness, the Group may be forced to take actions such as reducing or delaying its business activities, acquisitions, investments or capital expenditures, selling assets, restructuring or refinancing its debt or seeking additional equity capital.

The risk that the Group cannot service its debt obligations under the Bonds also implies a credit risk for investors in the Bonds. An increased credit risk may cause the market to charge the Bonds a higher risk premium, which would affect the Bonds' market value negatively, which in turn could affect any secondary trading in the Bonds. Another aspect of the credit risk is that a deteriorating financial position could negatively impact the Group's access to financing and thereby reduce the Group's ability to repay the Bonds at maturity, as set out below under "Refinancing risk".

The Issuer considers that the probability of the above risks occurring is low. If the risks would materialise, the Issuer considers the potential negative impact to be medium.



Risk factors (10/11)

Refinancing risk

The Group may be required to refinance certain or all of its outstanding debt, including the Bonds. As at 30 September 2020, the Group's long-term interest-bearing debt amounted to SEK 224.1 million. The Group's ability to refinance the Bonds or other debt as such obligations fall due may be restricted due to the Group's financial position at the time of such refinancing. Furthermore, according to the terms and conditions for the Bonds (the "Terms and Conditions"), certain additional indebtedness could only be incurred if the Issuer meets the requirements under the Incurrence Test (as defined in the Terms and Conditions), stipulating that a minimum Net interest Bearing Debt to EBITDA level and a maximum Interest Coverage Ratio (all as defined in the Terms and Conditions). In addition, the Issuer must ensure that the Maintenance Test (as defined in the Terms and Conditions) is met as long as any Bond is outstanding, which is tested quarterly and requires the Issuer to maintain certain levels of Cash and Cash Equivalents as well as a certain ratio of Net Interest Bearing Debt in relation to earnings before income and tax in the US Pharma segment. There can be no assurance that the Issuer meets the stipulated requirements if needed in order to refinance its outstanding debt obligations.

Such restrictions as well as adverse developments in the credit markets and other future adverse developments, such as the further deterioration of the overall financial markets or a worsening of general economic conditions, could have a material adverse effect on the Group's ability to borrow funds as well as the cost and other terms of funding. There can be no assurance that such funds will be available at a commercially reasonable cost, or at all and consequently, there can be no assurance that the Group will be able to refinance the Bonds when they mature.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise, the Issuer considers the potential negative impact to be medium.

Interest rate risks and benchmarks

The Bonds' value depends on several factors, one of the more significant over time being the level of market interest. The Bonds will bear a floating rate interest of STIBOR plus a certain margin and the interest rate is therefore adjusted for changes in the level of the general interest rate. Hence, there is a risk that increased general interest rate levels significantly affect the market value of the Bonds.

The determining interest rate benchmarks, such as STIBOR have been subject to regulatory changes such as the Benchmarks Regulation (Regulation (EU) 2016/1011 on indices used as benchmarks in financial and contracts or to measure the performance of investment funds) (the "BMR"). The implementation of the BMR will lead to that certain previously used benchmarks, such as LIBOR, will be discontinued There is a risk that also STIBOR will be discontinued, or that alternative benchmark rates will dominate market practice, leading to uncertainties in relation to the interest rate payable in relation to the Bonds. There is a risk that developments in relation to STIBOR cause volatility in STIBOR, which would affect the interest rate for the Bonds.

The Issuer considers that the probability of the above risks occurring is medium. If the risks would materialise, the Issuer considers the potential negative impact to be medium.

Currency risk

The Bonds will be denominated and payable in SEK. If investors in the Bonds measure their investment return by reference to a currency other than SEK, an investment in the Bonds will entail foreign exchange-related risks. For example, possible significant changes in the value of the SEK relative to the currency by reference to which investors measure the return on their investments could cause a decrease in the effective yield of the Bonds below their stated coupon rates and could result in a loss to investors when the return on the Bonds is translated into the currency by reference to which the investors measure the return on their investments. Government and monetary authorities may impose (as some have done in the past) exchange controls that could adversely affect an applicable exchange rate or the ability of the Issuer to make payments in respect of the Bonds. As a result, there is a risk that investors may receive less interest or principal than expected, or no interest or principal at all.

The Issuer considers that the probability of the risks described above is low. If the effects would materialise, the Issuer considers the potential negative impact as low.



Risk factors (11/11)

II. Risks related to the Bondholders' rights and representation

Risks related to admission to trading

The Issuer has undertaken to ensure that the Bonds are listed on the corporate bond list of Nasdaq Stockholm or, if such admission to trading is not possible to obtain or maintain, admitted to trading on any other Regulated Market within certain stipulated time periods, as defined in the Terms and Conditions, and the failure to do so provides each Bondholder with a right of prepayment (put option) of its Bonds. Furthermore, the Issuer has an intention to have the Bonds admitted to trading within thirty (30) calendar days after the any relevant Issue Date (as defined in the Terms and Conditions). There is a risk that the Bonds will not be admitted to trading on the relevant market place within the intended time frames or at all. If the Issuer fails to admit the Bonds to trading within the intended period of thirty (30) calendar days, investors holding Bonds on an investment savings account (Sv. ISK or IS-konto) will no longer be able to hold the Bonds on such account, thus affecting such investor's tax situation.

The Issuer considers that the probability of the risks described above is low. If the effects would materialise, the Issuer considers the potential negative impact as high.

Financing, structural subordination and priority rights

In the event of insolvency, liquidation or a similar event relating to one of the Company's subsidiaries, all creditors of such subsidiary would be entitled to payment in full out of the assets of such subsidiary before the Company, as a shareholder, would be entitled to any payments. Thus, the Bonds are structurally subordinated to the liabilities of such subsidiaries. Defaults by, or the insolvency of, certain subsidiaries may result in the obligation of the Company to make payments under financial or performance guarantees in respect of such subsidiaries' obligations or the occurrence of cross defaults on certain borrowings of the Group. There is a risk that the Company and its assets would not be protected from any actions by the creditors of a subsidiary, whether under bankruptcy law, by contract or otherwise.

Furthermore, the Group may, subject to certain limitations, incur additional financial indebtedness including providing security and/or guarantees for such indebtedness. Consequently, an enforcement of material security provided under any such secured obligations would have a material negative effect on the value of the Group's assets, the Group's operations and the Bondholders' possibility to claim recovery under the Bonds. In addition, in the event of bankruptcy, restructuring or winding-up of the Company, the Bondholders will be subordinated in right of payment out of the assets being subject to security.

Each investor should therefore be aware that by investing in the Bonds, there is a risk that the investor loses all or part of its investment if the Company becomes liquidated, bankrupt, insolvent, carries out a restructuring or is wound-up.

The Issuer considers that the probability of the above risks occurring is low. If the risks would materialise, the Issuer considers the potential negative impact as medium.



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