orexo

Develops and commercializes improved pharmaceuticals and digital therapies – with the aim of becoming a leader within the treatment of addiction



Life Science Virtual Investor Conference,
Nikolaj Sørensen, President and CEO, March 26, 2020

Nasdaq Stockholm: ORX US OTC Market: ORXOY (ADR)

Legal Disclaimer

- This presentation, which is personal to the recipient, has been prepared and produced by Orexo AB (publ) ("Orexo") solely for the benefit of investment
 analysis and may not be used for any purpose other than assessment of investments concerning Orexo. Unless otherwise stated, Orexo is the source for all
 data contained in this presentation. Such data is provided as at the date of this presentation and is subject to change without notice.
- This presentation does not constitute or form part of, and should not be construed as, an offer or invitation for the sale of or the subscription of, or a solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it or the fact of its distribution form the basis of, or be relied on in connection with, any offer, contract, commitment or investment decision relating thereto, nor does it constitute a recommendation regarding the securities of Orexo
- The shares of Orexo have not been registered under the U.S. Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold in the United States (as such term is defined in Regulation S under the Securities Act) except pursuant to an exemption from, or a transaction not subject to, the registration requirements of the Securities Act or unless registered under the Securities Act.
- The information in this presentation has not been independently verified. No representation or warranty, express or implied, is made as to, and no reliance should be placed on, the fairness, accuracy or completeness of the information or opinions contained herein. None of Orexo, any of its shareholders, or any of their respective subsidiary undertakings or affiliates or any of such person's directors, officers or employees, advisers or other representatives, accepts any liability whatsoever (whether in negligence or otherwise) arising, directly or indirectly, from the use of this presentation or otherwise arising in connection therewith.
- This presentation includes forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, achievements or industry results to be materially different from those expressed or implied by these forward-looking statements. Forward-looking statements speak only as of the date of this presentation and Orexo expressly disclaim any obligation or undertaking to release any update of, or revisions to, any forward-looking statements in this presentation as a result of any change in our expectations or any change in events, conditions or circumstances on which these forward-looking statements are based.
- This presentation is not a prospectus in accordance with the Swedish Financial Instruments Trading Act (Sw. lagen (1991:981) om handel med finansiella instrument) or any other Swedish laws or regulations. Neither the Swedish Financial Supervisory Authority (Sw. Finansinspektionen) nor any other Swedish regulatory body has examined, approved or registered this presentation.

Orexo develops and commercializes pharmaceuticals and digital therapies

- Focuses on treatment of addiction in all phases, from prevention to treatment
- Broad pipeline with multiple assets based on innovative drug delivery technologies or digital therapeutics (DTx)
- Developed four commercial products with worldwide approval
- Direct presence in the **US opioid dependence market**, one of the largest health crises in US history, with lead asset **Zubsolv**®
- Strategic focus on **portfolio expansion** through development and licensing/M&A
- **Profitable** company with **strong financial position** to support future growth
- Top two largest shareholders¹: **Novo Holdings** (27.7%) and **HealthCap** (10.2%)



Corporate Headquarters (Uppsala, Sweden)
Corporate functions and Development



US Headquarters
(Morristown, New Jersey)
Commercial subsidiary incl.
fully owned field force

Net revenues SEK, 2019

SEK, 2019

EBITDA

272 m

Cash position

SEK, Dec. 31, 2019

817 n

¹ As of January 31, 2020



2019 delivered the strongest financial results ever

Group net revenues SEK 845 m 85% from Zubsolv®	Growth 8% (Zubsolv® 16%)
Group EBITDA SEK 272 m	Growth 133%
SEK 351 m	Growth 77%
Cash position SEK 817 m	Positive net cash position SEK 527 m



The profit contributions from Zubsolv® enables investments in building a broader and stronger Orexo

Orexo objectives

Broaden...

..the portfolio of commercial products to be promoted by our existing US organization in 2020

Maintain

.. Zubsolv® profit contribution in 2020 and ensure it is sustainable and growing over time

Establish

..a new revenue generating business area within Digital Therapeutics (DTx) and launch first new product in 2020

Launch

..a new pharmaceutical product from Orexo's development pipeline within the next two years



Growing the Zubsolv® franchise



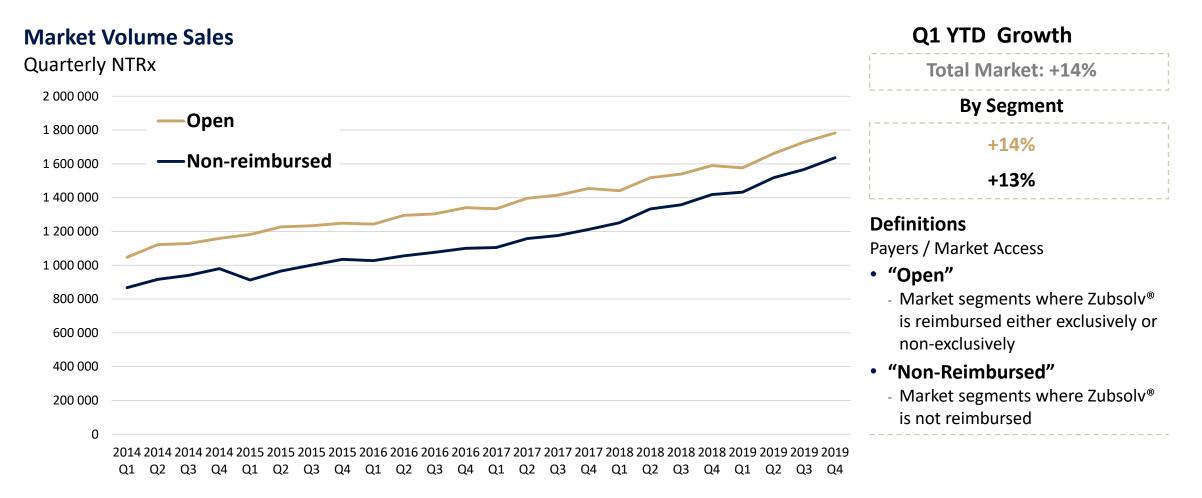






Full year market growth of 14% 2019 vs 2018 continues in Q1

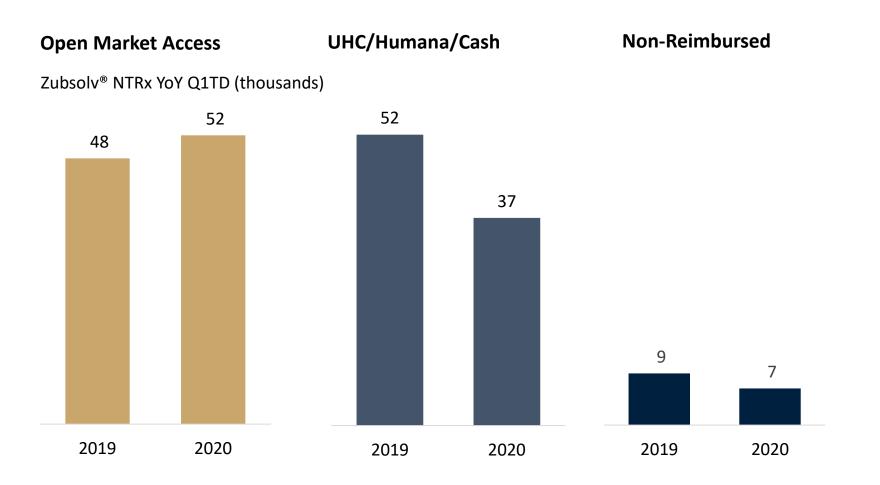
New market definitions to be applied by Orexo







Zubsolv® growing in the open business, but overall volume declining from competition in former exclusive contracts



Market Changes

From year 2019 to 2020

- Generic film introduced late Feb 2019
 - UHC/Humana add generics
- 2020 Public access lower by
 3 %-point vs 2019
- 2020 Commercial access increased 1 %-point vs 2019

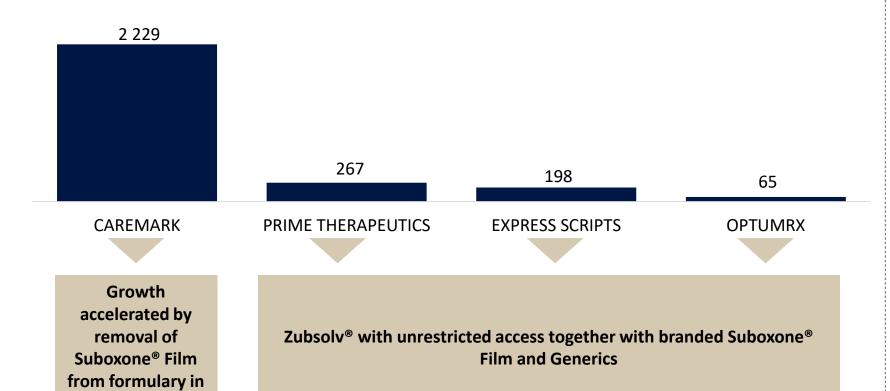
Note: NTRx =Total prescriptions adjusted to 30 tablet/film scripts Source: IQVIA XPO



Zubsolv® growth in open business explained by unrestricted access to all large national commercial PBMs

Prescription incremental growth to major national PBMs

Zubsolv® NTRx YoY Q1TD (thousands)



Total increase of 2,759 NTRx year-to-date

Opportunity to continue to grow business and to translate successes to other payers as well

Additional removal of Suboxone® Film from formularies likely to drive additional growth

Growth in commercial formularies expected to increase after Q1 due to declining deductibles

Note: NTRx =Total prescriptions adjusted to 30 tablet/film scripts Source: IQVIA XPO



Oct. 2019

Several possible triggers for Zubsolv® growth in 2020 and beyond



Continued improved market access

- ...Orexo continues to aggressively pursue expanding market access in Medicare and Medicaid
- ...Largest branded competitor likely to lose reimbursement over time

Competition from "the preferred" authorized generic of Suboxone® Film will end

- ...Supply of authorized generic has ceased from the manufacturer (Indivior) and product will disappear when inventories are depleted
- ... Market share of authorized generic has dropped from >50% to 28% last week

Orexo will be the only pharmaceutical company promoting a Buprenorphine product to most prescribers

- ...Sublocade® and other depot formulations primarily promoted to larger institutions
- ...Orexo has an expanding pipeline addressing the most urgent concerns in the industry



A pipeline with significant future potential

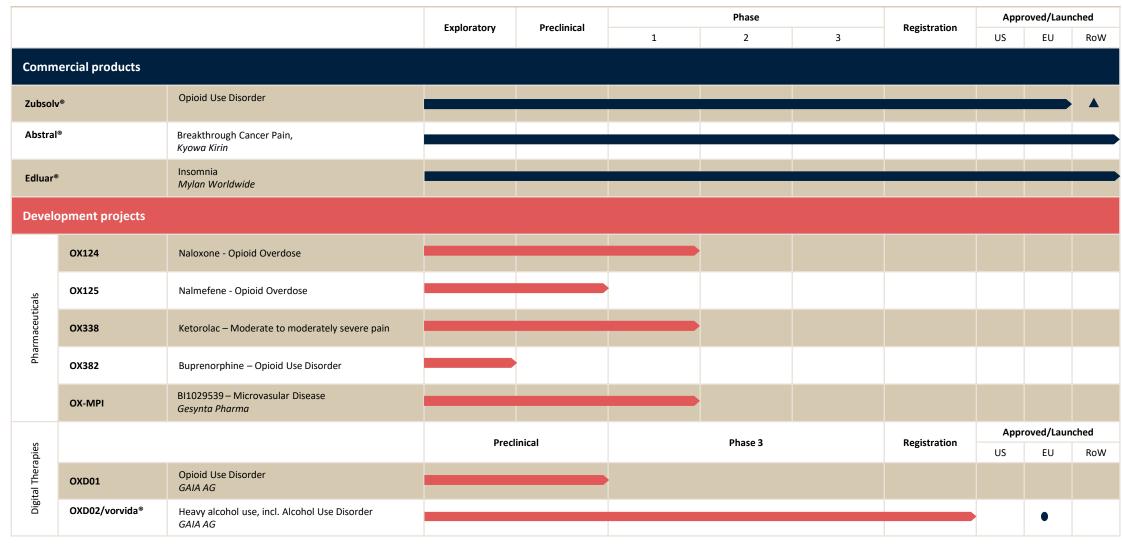








Pipeline addressing large markets with significant patient needs





3 convincing development assets addressing critical unmet needs

OX124 – opioid overdose

A powerful rescue medication, designed to reverse opioid overdoses, including those from synthetic opioids like fentanyl



OX125 – opioid overdose

A rescue medication to reverse opioid overdoses, developed for situations where very long-lasting effect is required



OX338 – non-opioid pain

A non-opioid pain killer with opioid-level efficacy for short-term pain (up to 5 days), but without the risk of addiction





DTx – new frontiers in patient care









In a few months....

Patients

...suffering from alcohol misuse will have access to a new digital therapy, vorvida®, which replaces the need for frequent visits to a counsellor during treatment

....will get their digital therapy reimbursed by their insurance company, just like any other medical intervention

....will have access to gold standard behavioral therapy with consistent quality, when they have time and in their own privacy

Healthcare Professionals

....will have access to a treatment with strong clinical evidence and will be able to prescribe **vorvida®** like any other treatment available

....will be able to treat more patients with less efforts

Orexo

.... will expand into a new adjacent disease area with significant unmet patient need and with a completely new type of products





The regulatory and payer landscape is starting to adopt digital therapy ...

Significant movement in both US and Europe

The two largest PBMs are reducing barriers for DTx



The Digital Health Software Pre-certification (**Pre-Cert) Program** is part of an effort by the FDA to develop a future regulatory model that will provide more streamlined and efficient regulatory oversight of software-based medical devices.²



Express Scripts is placing companies, offering cutting-edge treatments, into a "formulary" of recommendations for insurance plans and doctors in order to ease commercial traction.³



The Bundestag recently passed the German Digital Care Act (DVG), which requires public health insurance companies to cover the costs of certain health technology applications.¹



CVS Caremark has launched a platform for digital therapies, enabling payers to formalize the reimbursement and distribution and allowing CVS to capitalize on booming interest in digital health treatments.⁴

Source: 1. Frontiers https://www.frontiers.health/german-digital-healthcare-act/ 2. https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program 3. CNBC https://www-cnbc-com.cdn.ampproject.org/c/s/www.cnbc.com/amp/2019/12/12/express-scripts-to-add-digital-health-treatments-like-livongo-omada.html 4. Business Insider https://www.businessinsider.com/cvs-caremark-launches-digital-therapeutics-platform-2019-6?r=US&IR=T



... but digital therapy is in its infancy

Commercialization

 Optimal pathways to commercialize and scale DTx are still unchartered

Pricing

• Entry barriers are low for offerings without clinical evidence, and thus payers need to establish appropriate assessment criteria to enable price differentiation

Reimbursement

 Many payers still to establish payment and reimbursement processes

Disruptive technology

 While digital therapies have been proven clinically, speed of adoption is still unknown as for any new therapeutic approach





The pricing of digital therapy is scattered, with significant differences driven by sophistication and clinical evidence



Pricing of Orexo DTx expected in the range of USD 600-1,000 per treatment



Two digital therapies with the potential to disrupt the current treatment of substance use disorder in the US

vorvida®

A fully automated digital therapy scientifically proven to reduce trouble-some drinking patterns in adults with AUD



"Digitizing" counselling at scale to offer with Zubsolv®, a full medication assisted therapy (MAT) solution for so many opioid use disorder (OUD) patients in need.

150-225

MUSD net sales potential in the US



Outlook









Limited impact from the COVID-19 virus currently¹

Development

Supply

Sales

Finance

OX125 - Preparations for first clinical trial progress as planned in the UK

OX124 - Orexo works with several partners in different geographies, so far no impact, but delays cannot be excluded

Digital Therapies - No impact and no need for FDA inspections which should limit risk of delays from FDA

Zubsolv® - Manufacturing of Zubsolv® is solely done in the US and significant inventory exist to secure uninterrupted supply

Supply to wholesalers and pharmacies is a part of existing pharmaceutical logistics network and unlikely to be affected

Zubsolv® and vorvida® -Sales calls have been redirected to digital channels and in person only upon request

Zubsolv® is well established and experience from unstaffed sales territories shows no impact short term from no sales calls

Sales training of vorvida® will start immediately to leverage the time

Orexo has SEK 817m in cash and a profitable operations from Zubsolv®

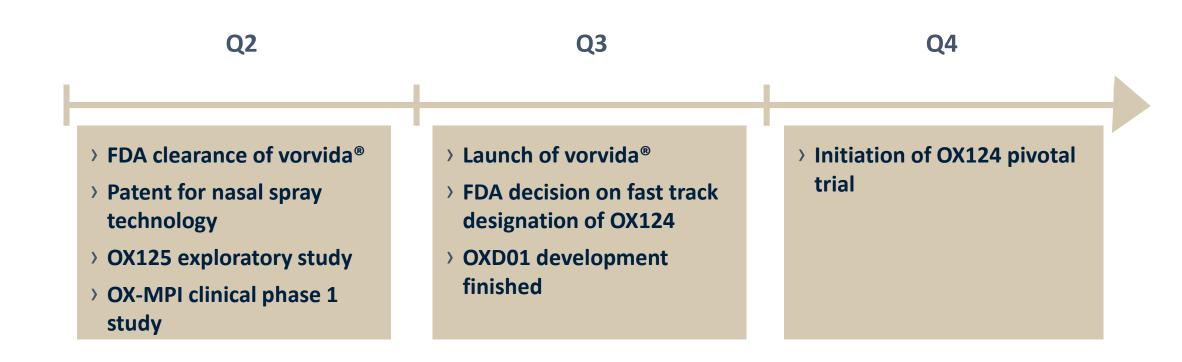
Short term we expect limited to no impact on financial results

No financing risk exist in the company

¹ This analysis assumes impact from COVID-19 is limited to H1 2020



2020 a year with a steady news flow expected





Strong value drivers for long-term growth

Investment thesis

1. Addressing large markets with significant patient needs

Focusing on becoming a leader within the large and growing space of addiction, alongside addressing the opioid epidemic, one of the largest health crises ever in America and a growing global concern

2. Strong financial position and profitability

Fueled by the sales of the lead product Zubsolv® which will continue to be an important cash and profitability contributor

3. Leverage the US commercial platform

Strategic focus on product portfolio expansion, through M&A and business development, to leverage the US commercial infrastructure

4. Expanding pipeline

Continues to build on the strong track record of developing products with worldwide approval by expanding the pipeline with multiple assets based on innovative drug delivery technologies and digital therapeutics addressing unmet medical need in addiction

5. Entering DTx, the new megatrend in life science

Digital therapeutics (DTx) will become an integral part of the healthcare landscape and addiction is one of the therapeutic areas where it is most needed



Thank You!