



Improves lives for people suffering from mental illness and addiction disorders



**Redeye Life Science Day** - Nov 26<sup>th</sup>, 2020

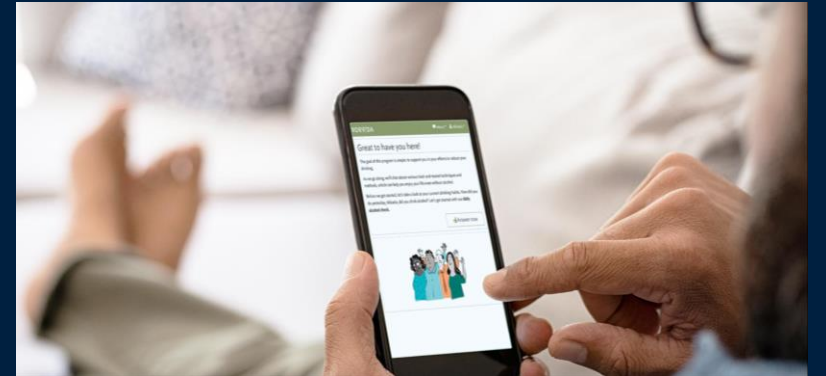
Nasdaq Stockholm: ORX, US OTC Market: ORXOY (ADR)

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# Introduction & strategic agenda

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# Orexo in brief

- New digital therapies and pharma pipeline with **significant growth potential** addressing unmet needs in mental illness and addiction disorders
- Main current product, **ZUBSOLV®** is **expected to continue as a significant profit contributor** with strong IP until 2032. The IP is validated by a federal court of appeals strengthening defense against generic competitors including current case against Sun Pharmaceuticals
- **Strong financial position** enables significant investment in 2020 and 2021 in building digital therapy business and finalize development of lead pharmaceutical project
- Negative result in Q3 is a result of the decision to invest in Digital Therapies and OX124, **ZUBSOLV® profit contribution continue with a 50% EBIT margin**



## Corporate Headquarters

(Uppsala, Sweden)  
Corporate functions and Development



## US Commercial Platform

Since 2013 direct presence in the US with a fully-owned sales force covering nearly all states

### Net revenues

LTM<sup>2</sup> Q320

SEK **742** m

### EBITDA

LTM<sup>2</sup> Q320

SEK **104** m

### Cash position

Q320

SEK **593** m

<sup>1</sup> As of October 30, 2020

<sup>2</sup> Last Twelve Months



# The profit and cash contributions from ZUBSOLV® enables continued investments in building a broader and stronger Orexo

## Broadening...

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

## Establishing...

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

## Maintaining...

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

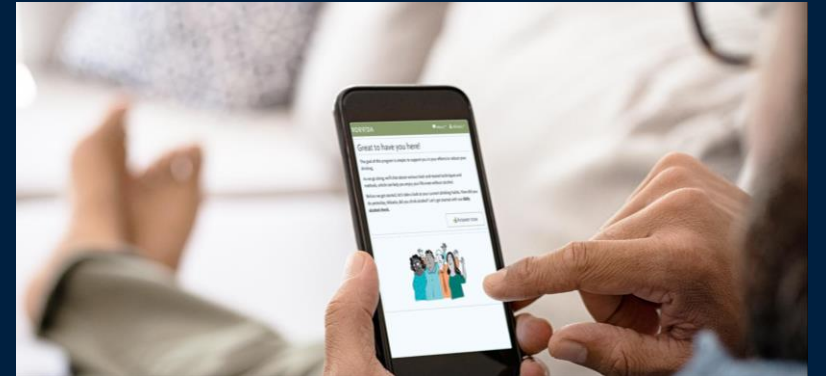
## Launching...

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



# Digital therapeutics a new frontier in treatment of mental illness

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Our ambition is become a leader in digital therapeutics, leveraging our existing commercial infrastructure and new technical platforms to scale up

## Enter DTx

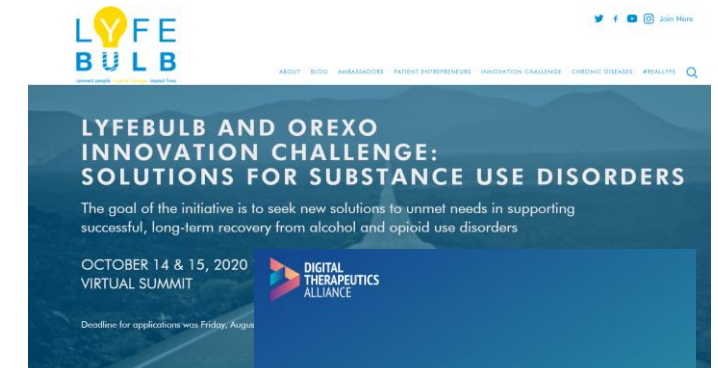
deprexis<sup>®</sup>  
VORV!DA<sup>®</sup>  
modia<sup>™</sup>

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## Establish the platform

The image displays two digital therapeutic interfaces. The top interface is for VORV!DA, featuring a green header with the text 'Here to help you get the most out of vorvida®'. Below this, there are sections for 'Get access through your insurance' and 'Get access through your employer', each with a 'Get access now' button. A 'Here to help.' section with a chat icon is also present. The bottom interface is for orexo, titled 'Program User Information (All information required.)'. It contains a form with fields for First Name, Middle Initial, Last Name, Date of Birth, Gender (Female/Male), Street Address, Other Address, City, State, Zip Code, Mobile Phone, Alternate Phone, and Email Address. Below the form is a section for 'Program User Health Insurance Information (All available information)'. The orexo interface is powered by Adobe Sign.

## Expand presence and portfolio



**Digital therapeutic quality, access, and appropriate utilization matter.**

Patients, caregivers, and clinicians should have access to DTx products that directly address patient needs, and:

- ✓ Are safe, effective, and ensure patient privacy
- ✓ Demonstrate positive clinical and economic outcomes
- ✓ Influence the delivery of healthcare in a meaningful way

# Digital therapeutics is in its infancy - while the potential is significant, several hurdles need to be addressed before the market takes off

## **Commercialization**

- Optimal pathways to commercialize and scale DTx are still uncharted

## **Pricing**

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

## **Reimbursement**

- Many payors 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

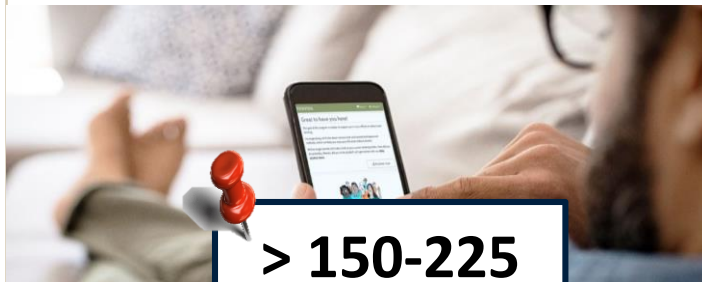
**Orexo will continue to assess the business model, the potential and the investment levels required to capture new opportunities at the appropriate time**



# With 3 digital therapies, Orexo is well positioned to take a leading role addressing unmet needs within SUD and mental health issues

## deprexis®

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

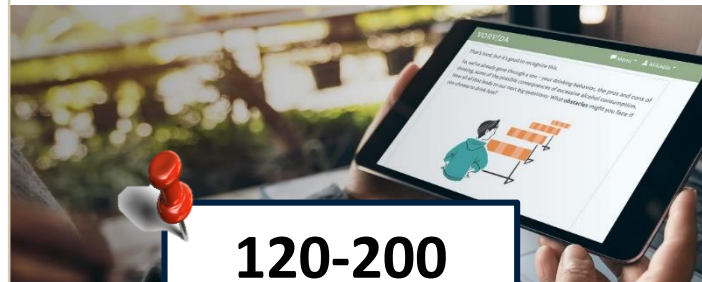


**> 150-225**

MUSD net sales potential in the US

## vorvida®

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



**120-200**

MUSD net sales potential in the US

## OXD01/modia™

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

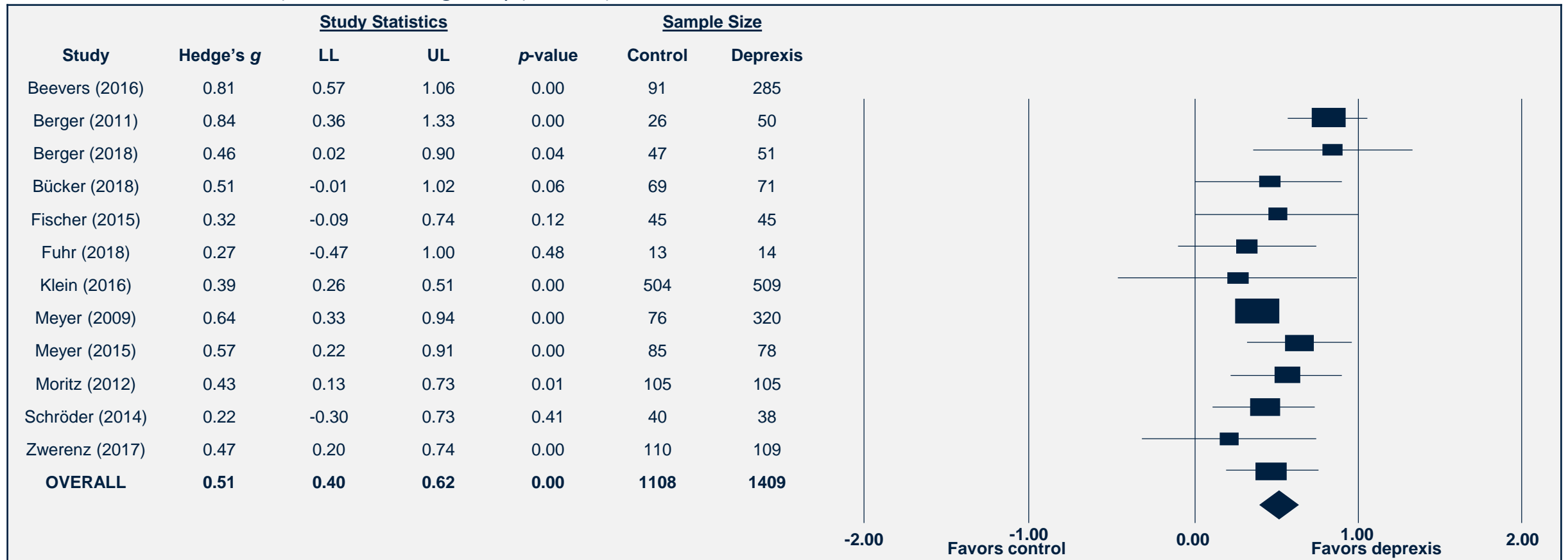


**150-225**

MUSD net sales potential in the US

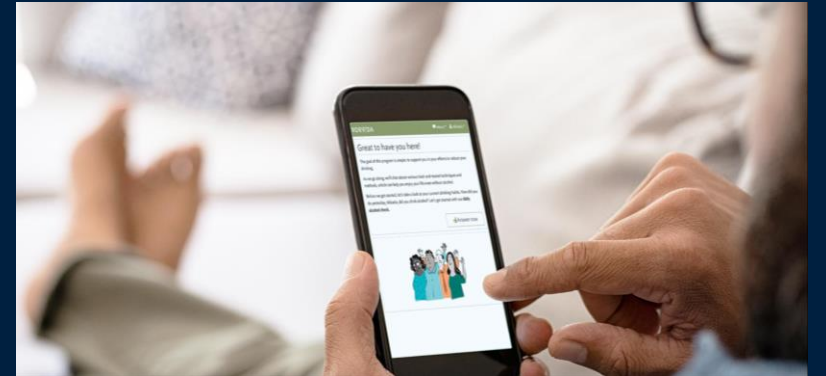
# The scientific evidence for DTx is comprehensive e.g. **deprexis<sup>®</sup>** demonstrates consistent clinical effect across multiple settings

- Meta-analysis of 12 RCTs demonstrated the effectiveness of deprexis for reducing depressive symptoms with a moderate effect size ( $g = 0.51$ , 95% CI: 0.40–0.62) and low heterogeneity ( $I^2 = 26\%$ )



# Pharma products and projects under development

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# Products approved worldwide & pipeline of potential future assets

Pharmaceuticals									
Product/ Project	Exploratory	Preclinical	Phase			Registration	Approved and/or Launched		
			1	2	3		US	EU	RoW
<b>ZUBSOLV®</b> Opioid Use Disorder									▲
<b>Abstral®</b> Breakthrough Cancer Pain Partner: Kyowa Kirin									
<b>Edluar®</b> Insomnia Partner: Mylan									
<b>OX124</b> Naloxone, Opioid Overdose									
<b>OX125</b> Nalmefene, Opioid Overdose									
<b>OX338</b> Ketorolac, Moderate to moderately severe pain									
<b>OX-MPI</b> BI1029539, Microvascular Disease Partner: Gesynta Pharma									

▲ Approved in Australia

# ZUBSOLV® resilient and strong cash contributor in a challenging market environment

## ZUBSOLV – treatment of opioid dependence

ZUBSOLV® is a product for the treatment of opioid dependence.

### Product advantages include:

- Higher bioavailability
- Fast dissolve time
- Preferred menthol flavor
- Broadest range of dose strengths



## Recent developments

- **Continued strong market growth of 13% year over year**
  - Covid-19 led to increased relapse of opioid dependent patients
  - Market growth is driven by Medicaid, while commercial segment has decreased during 2020 due to increased unemployment
- **ZUBSOLV® sales stable in “open segment” and profitability increase**
  - Overall sales declining due to increased competition in previously exclusive contracts with United Health Group and Humana
  - ZUBSOLV® sales in “open<sup>1</sup>” segment is growing YoY and has been stable during Covid-19 pandemic
  - EBIT margin above 50% expected for 2020
- **Improved market access in 2021 will support ZUBSOLV® sales:**
  - Significant market access win in ESI & CIGNA, where is ZUBSOLV® now the only preferred branded product
  - ZUBSOLV® remains the only branded product on top three US Commercial PBMs



# OX124 continues to be an attractive opportunity

## OX124 – opioid overdose

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



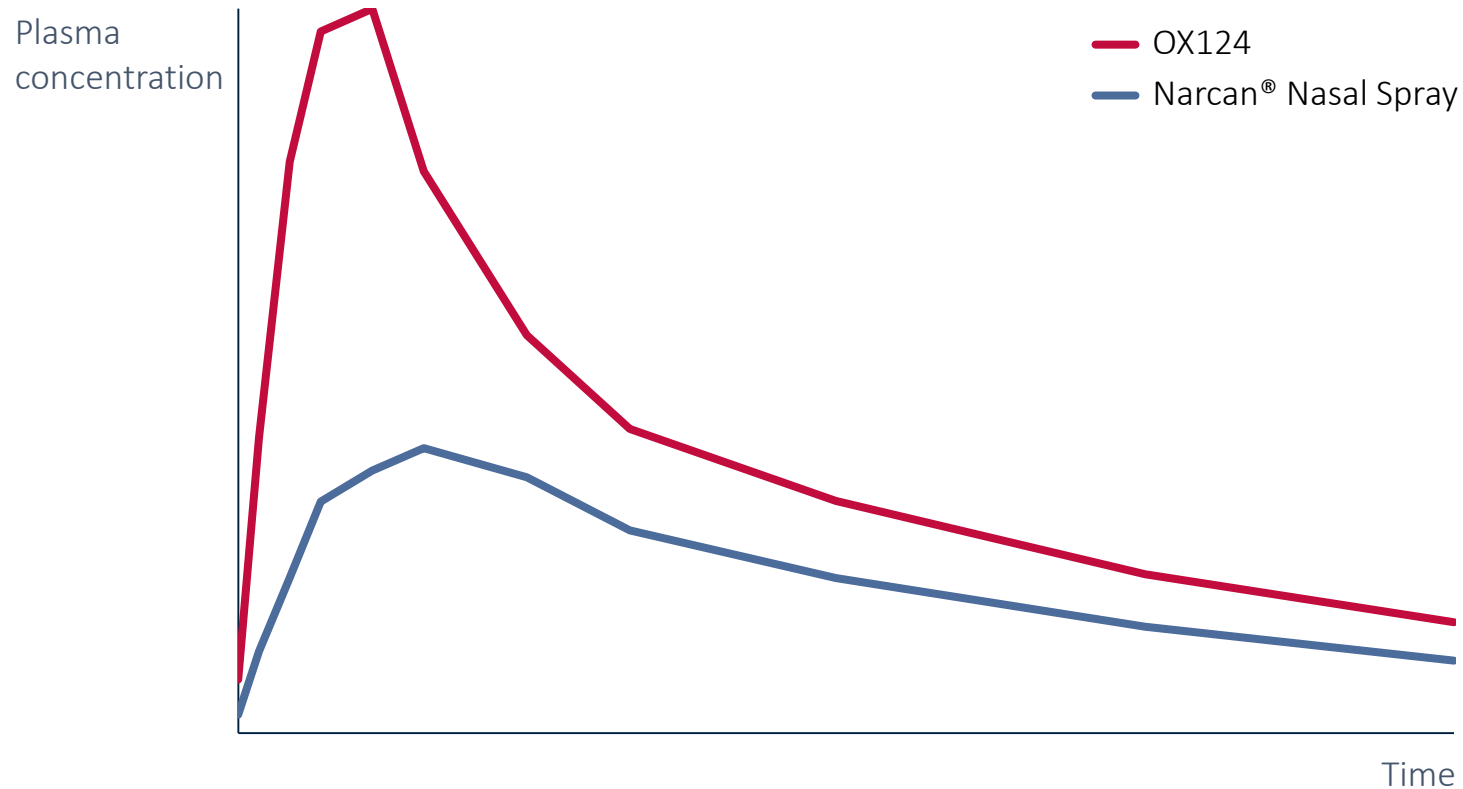
## Recent market developments

- **Covid making the unmet need even more severe:**
  - Overdose deaths in the US will reach an all-time-high this year, with a projected increase of 13%<sup>1</sup>, now trending to >76,000 deaths for 2020<sup>1</sup>
  - Synthetic opioids are now representing 76%<sup>1</sup> of opioid related deaths
  - In July, Millennium Health analyzed 500,000 urine drug tests and found a 32% increase in the national usage of non-prescribed Fentanyl<sup>2</sup>
- **US market leader Narcan® sales at record level<sup>3</sup>:**
  - USD 89 m in Q3 '20 – highest reported quarter ever (up from USD 75 m in '19)
  - USD 234 m for first nine months '20 (up from USD 214 m in '19)
  - 2020 Guidance: USD 295-315 m (up from USD 280m in '19)
- **New FDA requirements increase hurdle for new entrants:**
  - Competitor with high dose auto-injector received complete response letter and other competitors appear to be delayed

# OX124 - We have shown better PK profile than Narcan® Nasal Spray

## Faster, stronger and longer-acting vs Narcan® Nasal Spray

Results from exploratory PK study in healthy volunteers, 2019



## Expected patient benefit

- Rescue more patients with the first dose (~34% of overdose patients require more than one dose of Narcan)
- Avoid "second overdoses" thanks to longer duration (Fentanyl has a half life of 8-10 hours vs. 2 hours for naloxone)

# Thank You

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