R&D Day March 24 2026

amorphOX®

Management team leading a streamlined organization with presence in Sweden and the US

Nikolaj Sørensen
President and CEO

Employees after Zubsolv® US transition:
~55
5

Fredrik Järrsten
EVP CFO & Business Development

- Staff functions
- Finance
- Business and Corporate Development

Robert Rönn
SVP Head of R&D

- Pharmaceutical and analytical development
- IP
- Exploratory work with new substances

Cecilia Coupland
SVP Head of Operations

- Project Management
- QA
- Supply
- Procurement

Ed Kim
Chief Medical Officer

- OX390 and BARDA interface
- Medical and clinical strategies development programs

Lisa Moore
SVP Product & Portfolio Strategy

- Commercial assessment of projects and portfolio strategy
- Commercial planning
- US Government Affairs

Agenda

9.30-9.45	Strategy & value creation	Nikolaj Sørensen, President and CEO
9.45-10.00	AmorphOX® platform insights	Robert Rönn, SVP Head of R&D/ Cecilia Coupland, SVP Head of Operations
10.00-10.15	AmorphOX® expansion & partnerships	Lisa Moore, SVP Product and Portfolio Strategy/ Robert Rönn
10.15-10.30	OX640: Best-in-class epinephrine	Lisa Moore/ Cecilia Coupland
10.30-10.45	Break	
10.45-11.00	OX390: Medical countermeasure program	Edward Kim, Chief Medical Officer
11.00-11.15	Emerging overdose threats – expert view	Mark A. Smith, PhD Davidson College, NC, US. [1]
11.15-11.30	Business development & value model	Fredrik Järrsten, EVP and CFO, Head of Business Development
11.30-12.00	Q&A, incl. closing remarks	

9.00-9.30
Registration & Breakfast

12.00
Lunch to be served

1 Dr Smith will attend through a prerecorded video

R&D Day website: https://orexo.com/investors/calendar/2026-03-24-orexo-rd-day-2026/ -

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Shaping Orexo's future:
Strategic priorities and value creation

Nikolaj Sørensen
President and CEO

Rooted in science, proven in market

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Sale of Zubsolv enables a transformation of Orexo

Divestment of Zubsolv® US rights

Zubsolv US rights sold to Dexcel

- USD 91 m
- Up to USD 16.8 m in earn-out
- Majority of US employees to join Dexcel

Streamlining the operations

Restructure organization

- Stepwise restructuring as service obligations to Dexcel conclude
- Severance and LTIP vesting
- Exit supplier contracts

Restructure balance sheet

- Corporate bond redemption
- Zubsolv rebates and return reserves

Resolve DOJ investigation

- Seek settlement resolution

Transformation

Drive global leadership in amorphous powder for drug delivery

Advance projects to value inflection.

Expand partnerships for the AmorphOX® technology

Building a new company on a strong heritage…

Heritage in numbers

4 drugs developed from idea to market[1]

Markets with approval

> 25

Long experience from partnering

accord Make it better · abera BIOSCIENCE · sobi rare strength · Dexcel pharma · VIATRIS · J&J · GESYNTA PHARMA AB · GRÜNENTHAL · AstraZeneca · KYOWA KIRIN

1. Of which three are develop based on the first-generation drug dilivery platform – the sublingual

Innovation by numbers

amorphOX®

8	> 500	5	>100
Years of experience with AmorphOX technology	AmorphOX-based formulations under research	Clinical trials conducted with AmorphOX	Patents granted and submitted

30 yrs of experience developing improved pharmaceuticals based on proprietary drug delivery technologies.

novo holdings — Investing to benefit people and the planet — **- largest shareholder at 26 %**

SEK 912 m
Cash position Dec. 31 2025

...and a promising development pipeline and established commercial products

Development program		Technology	Partnership	Preclinical	Clinical	Registration	Approved
Exploratory/ Large molecules	OX472 GLP-1 agonist, semaglutide	amorphOX®					
	Vaccine, influenza	amorphOX®					
Own projects/ Small molecules	OX390, atipamezole, overdose caused by adulterated drugs	amorphOX®	BARDA				
	OX640, epinephrine, incl. anaphylaxis	amorphOX®					
	Izipry™, naloxone, overdose caused by opioids	amorphOX®					
Launched products							
Approved products developed by Orexo	Zubsolv® US, opioid dependence	Sublingual platform	Dexcel Pharma				US
	Zubsolv EU, opioid dependence	Sublingual platform	accord Make it better				EU
	Abstral®, breakthrough cancer pain	Sublingual platform	GRÜNENTHAL				EU, US, RoW
	Edluar®, insomnia	Sublingual platform	VIATRIS™				EU, US, RoW

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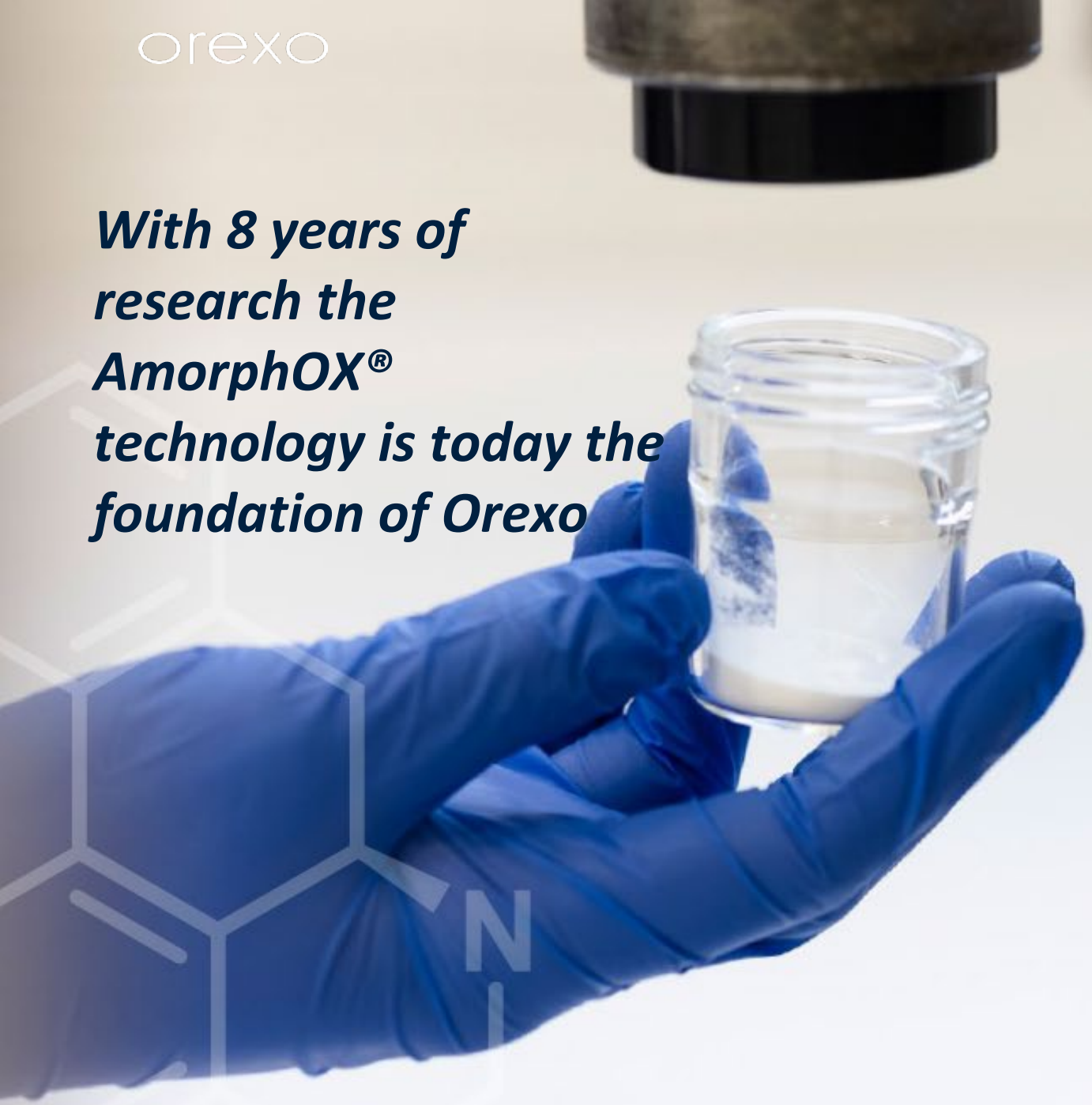
With 8 years of research the AmorphOX® technology is today the foundation of Orexo



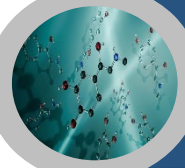
amorphOX®

AmorphOX® is a powder-based formulation technology that enables new and more effective solutions for the administration, manufacturing, and distribution of pharmaceuticals.

- ✓ **Versatile applications**
- ✓ **Superior bioavailability**
- ✓ **Stabilizes peptides and biologics**
- ✓ **Needle-free delivery**

3 strategic focus areas to maximize value of the AmorphOX technology

amorphOX®



EXPLORE

New applications of the AmorphOX® technology are key to unlocking substantial future value creation

DEVELOP

Proprietary projects drive greater value capture and renewed commercialization opportunities

PARTNER

The AmorphOX technology has potential beyond Orexo's capacity and access to molecules

New applications of AmorphOX key to unlock substantial future value

Explore new AmorphOX® applications

- From incremental gains to transformative drug delivery
- New applications driving projects, partnerships, and proof-of-concept
- Platform optimization to expand capabilities and IP

Current focus

- GLP-1 agonists/peptides – improving bioavailability
- Vaccines/proteins – expanding partner and academic collaboration

Status: promising start

✓ **Positive first in-vivo results**

– Higher nasal absorption of semaglutide vs. Rybelsus®

– Positive immune response (Abera collaboration)

✓ **Further in-vivo studies with optimized formulations**

✓ **New patents expanding AmorphOX beyond nasal delivery**

Note: Rybelsus® is a registered trademark of Novo Nordisk A/S

Proprietary projects with greater value capture and renewed commercialization opportunities

Zubsolv® transaction supports funding to key value inflection points

- Izipry™ progressed to approval to remove FDA uncertainty
- OX640 de-risked by strong data and manufacturing synergies, with significant upside in pivotal trials
- OX390 awaits nasal uptake proof-of-concept from in vivo and clinical trials.

Partnering to enable global presence and financing

- Commercial partners for global reach and co-financing
- Potential for US commercialization role for Orexo

Status: Approaching FDA filings in 2026 & 2028

- ✓ **Izipry on track for FDA refiling in Q3 2026**
- ✓ **OX640 on track to initiate its first pivotal trial in Q4 2026**
- ✓ **OX390 with ongoing first in-vivo studies evaluating the initial formulation and nasal uptake of atipamezole.**

AmorphOX with potential beyond Orexo's capacity and access to molecules

Partner the AmorphOX® technology

- Rapid feasibility testing enabled by a broad, validated molecule library
- Applicable to both proprietary partner APIs and well-known APIs outside Orexo's priorities
- Reduces development risk and contributes to cover costs

Partnership model

- Partnerships typically start with low-resource feasibility studies
- Provides access to new APIs, new data, and additional proof of concept before full development decisions.

Status: expanding the reach

✓ **Multiple feasibility studies ongoing and completed with potential partners**

✓ **Studies using AmorphOX alone or combined with new APIs and other technologies**

✓ **Orexo plans to strengthen business development to expand reach and the partnering pipeline.**

Several value opportunities short, medium and long term

	2026	2027	2028	2029 and beyond
Launched	• Zubsolv® EU	• Zubsolv US earn-out	• Zubsolv US earn-out	
Izipry™	• Q3 FDA filing	• Q1 FDA approval • Partnering		
OX640	• Q4 pivotal trial start	• H1 trial results • Start final pivotal trials	• Outcome final pivotal trials • FDA/EMA submission	• 2029 FDA/EMA approval
OX390	• Q2 in-vivo study results	• BARDA financing stage 2	• First clinical study	• Continued clinical studies, FDA review process, submission and approval
Explore GLP-1 agonist / vaccines	• Additional in-vivo studies	• First human studies (if in-vivo are successful)	• Development plan	• Continued clinical studies, FDA review process, submission and approval

Partnering is a continuous process for all projects without specific target dates

Global leadership and growth

Company key objectives

Building global leadership in amorphous drug delivery

Strategic pillars to reach key objectives

Drive global leadership in amorphous powder for drug delivery

- Accelerate R&D and internal expertise in amorphous powder drug delivery
- Expand biomolecule research in peptides and proteins
- Strengthen academic and KOL partnerships

Advance projects to value inflection

- Fund proprietary projects to value inflection
- Enforce go/no-go decisions to optimize speed and resources
- Drive proactive out-licensing with pharma partners

Expand partnerships for the AmorphOX technology

- Partner to unlock AmorphOX value
- Lower risk and cost through partner funding
- Capture upside via royalties and milestones

AmorphOX: A unique opportunity to transform drug delivery of biomolecules in an established scalable commercial supply chain.

Robert Rönn
SVP Head of R&D

Cecilia Coupland
SVP Head of Operations

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From product idea to next-generation drug delivery technology – AmorphOX

Technology development

Medical need:
Naloxone rescue product with rapid onset and high bioavailability

Hypothesis:
Nasal Naloxone powder

Evaluation of different formulation principles

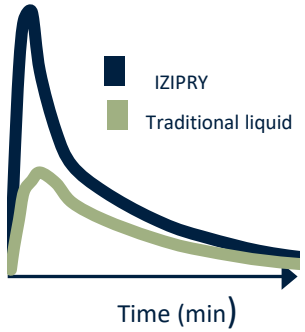
Spray-dried amorphous composite powder

AmorphOX®

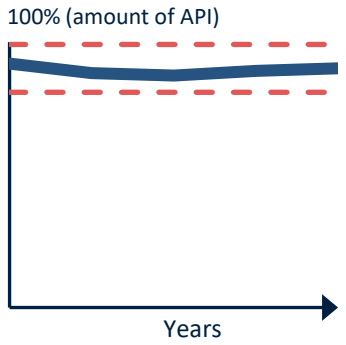
IZIPRY™

naloxone rescue medication

Rapid onset and high bioavailability

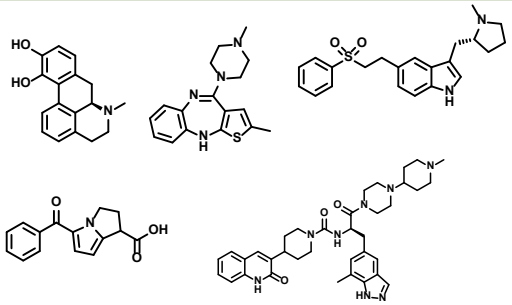


Highly stable formulation

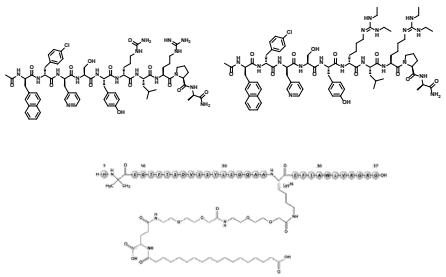


Versatile technology

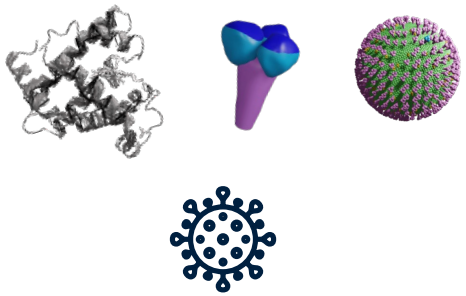
Other small molecules



Peptides



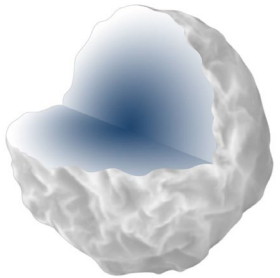
Biologics



The foundation of AmorphOX: Structure, process and IP

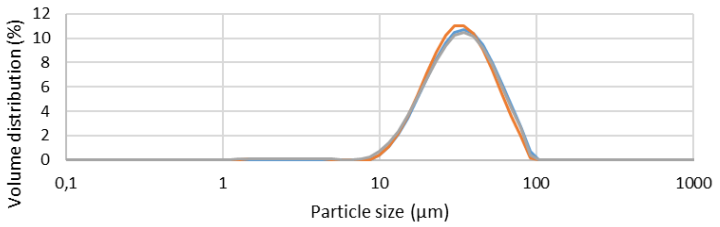
Powder consisting of amorphous composite particles

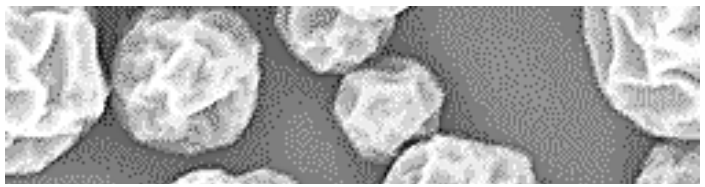
- Unique combination of drug and excipients
  - Disaccharide
  - Polymer
  - Permeability enhancer (optional)
  - Other excipients (optional)
- Amorphous
- Monoparticulate



Manufactured by spray-drying

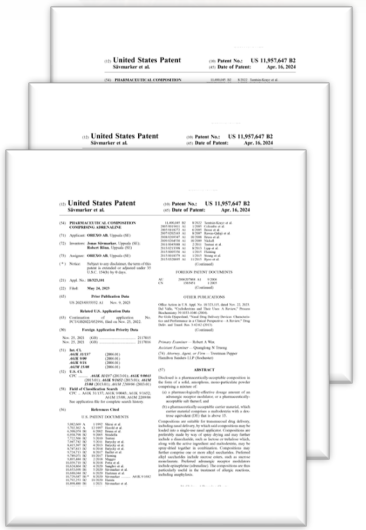
- Control of particle size
- Continuous, scalable process





Extensive IP protection

- Numerous patents and patent applications
- Still evolving
- Current protection ranging from 2039 to 2047
- Know-how



Differentiating attributes of the AmorphOX® platform

A versatile, modality-agnostic drug delivery platform

- Small molecules, peptides, proteins and vaccines
- Nasal, oral, sublingual, parenteral
- Powder, tablet, capsule, powder for reconstitution

Chemical and physical stability

- Long shelf-life and flexible storage conditions
- Elimination of cold chain requirements
- No need for antioxidants, chelating agents or unfavorable pH adjustments

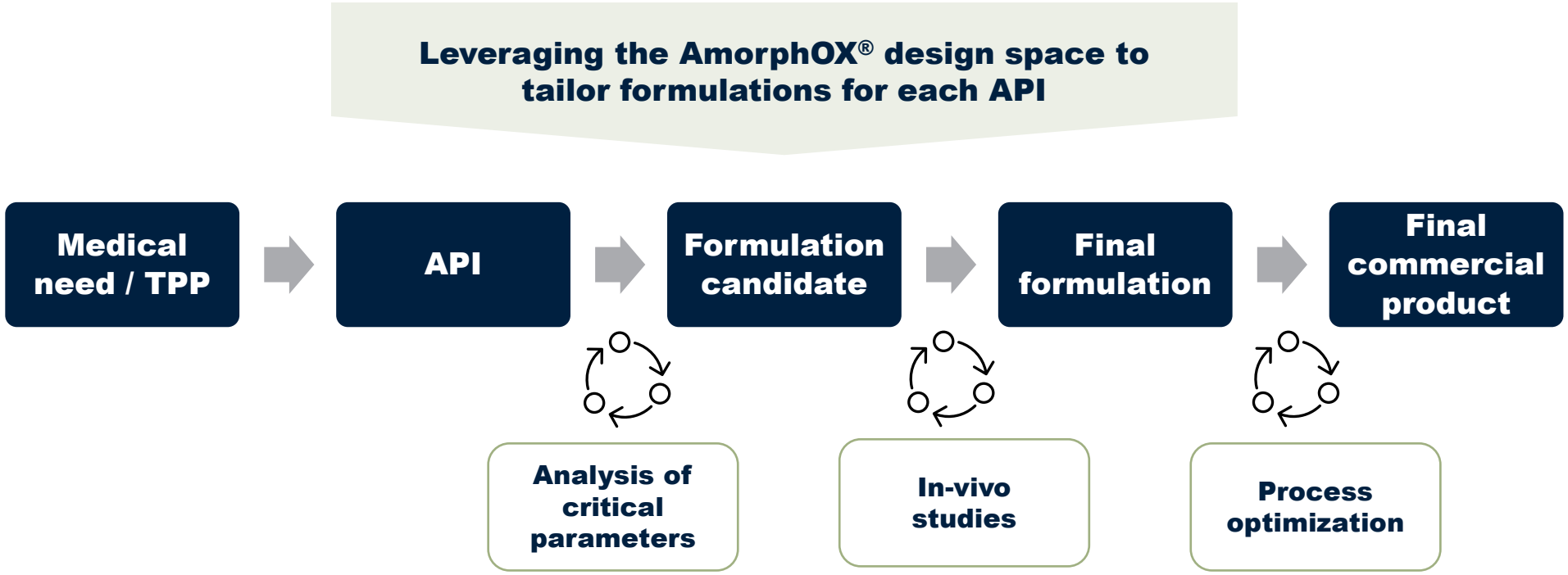
Rapid absorption and high bioavailablity

- Supersaturation at site of absorption
- Nose-to-brain opportunity (nasal)
- Reduced food-effect (nasal or oral)

Free-flowing, high-density composite powder

- No segregation, de-risking commercial manufacturing
- Co-localization of critical formulation components

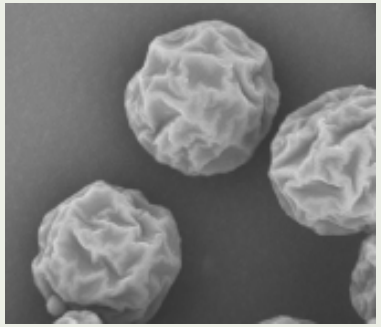
Enabling tailored formulation and product development with AmorphOX



Note: TPP: Target Product Profile. API: Active Pharmaceutical Ingredient

Spray-drying manufacturing built for scale

- ✓ **Rapid early development enabled by in-house lab-scale spray-drying for clinical materials**
- ✓ **Robust, scalable spray-drying process with established commercial design space at Orexo's CMO**
- ✓ **Proprietary Orexo know-how used to design platform-specific spray-drying processes**
- ✓ **Proven manufacturability at scale, with multiple commercial-scale batches across project**
- ✓ **Stable, free-flowing powders simplify downstream manufacturing across modalities**
- ✓ **Sterile powder capability enables reconstitution and distribution without cold chain**



AmorphOX: Moving beyond nasal delivery in GLP-1s and expanding into new areas with significant market needs through preclinical innovation, and strategic partnerships.

Lisa Moore
SVP Product and Portfolio Strategy

Robert Rönn
SVP Head of R&D

Rooted in science, proven in market

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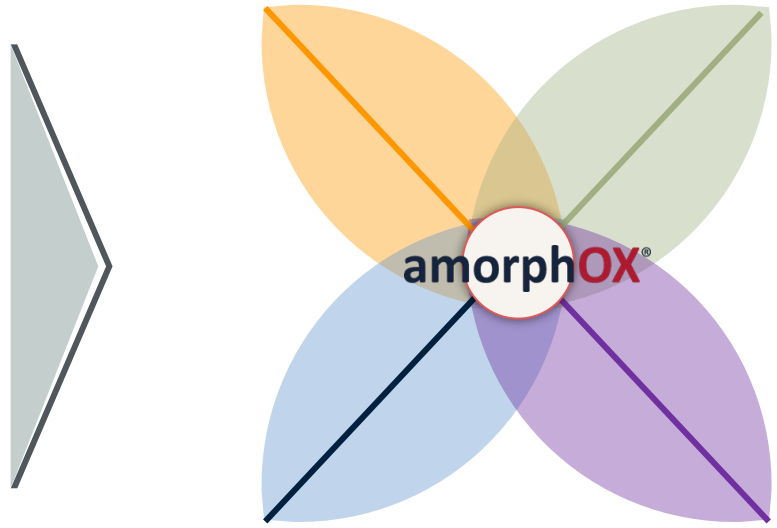
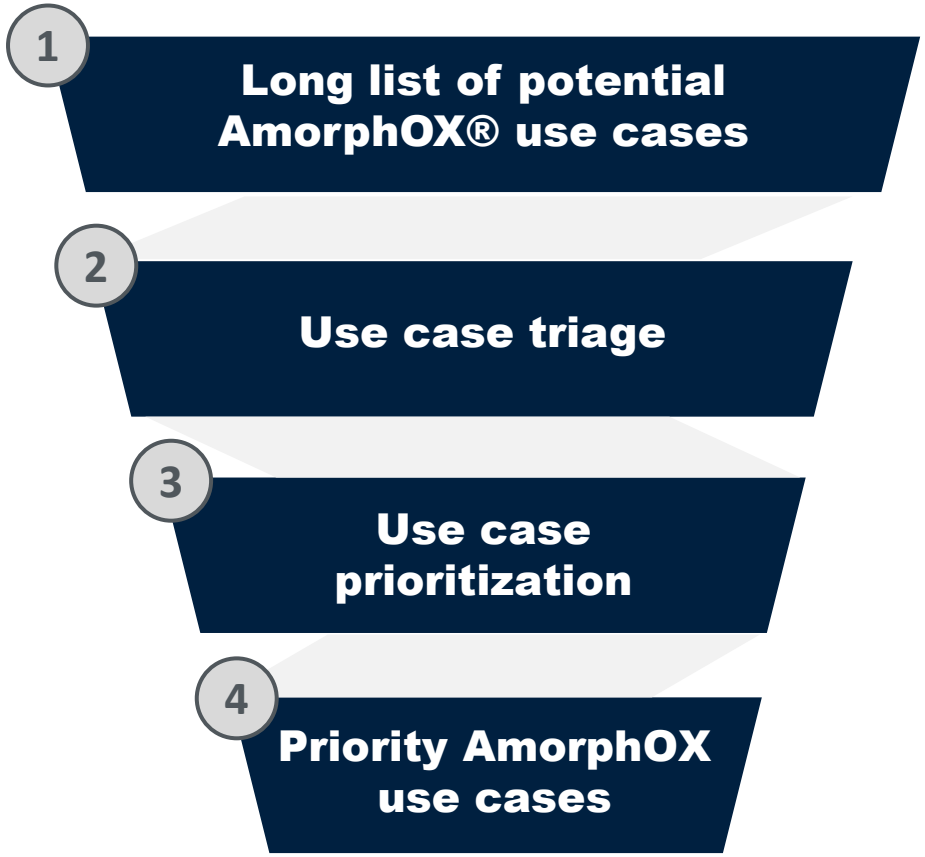
AmorphOX® technology applications advance when four key requirements are met

- Fulfill a **commercial imperative** for a manufacturer
- Fulfill a strong **unmet need** for a patient, healthcare professional, or payer
- Allow for **differentiated enablement** by Orexo
- Allow Orexo to share in the **value** generated or captured by the asset formulated



A disciplined triage engine drives identification of top priority AmorphOX use cases

Use cases tested in interviews with experts and industry representatives



Use case prioritization approach

- Examine major therapeutic areas, modalities, and route of administration to inform list of use cases
- Assess use case feasibility in the near-term versus long term, considering degree of technical fit
- Prioritize use cases that represent a material opportunity with significant unmet need addressable by AmorphOX

Large molecules: GLP-1s/peptides and vaccines

GLP-1: Glucagon-like peptide 1

AmorphOX-formulated GLP-1s unlock new possibilities for patients and customers

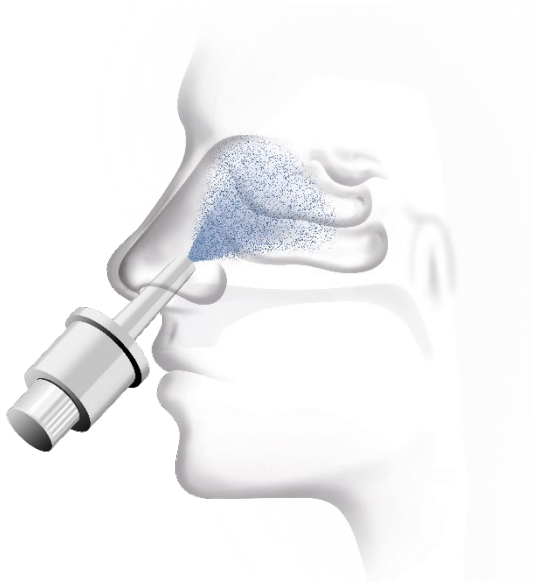
- Provides a more convenient RoA than injectables with potentially less frequency than daily orals
- Eliminates the need for the cold chain
- Bypasses first-pass metabolism, avoiding food and water restrictions with administration
- Enables a unique powder formulation that may use less API
- Creates value for patients, providers, and manufacturers

~2.5 b	Adults globally who are overweight[1]
~890 m	Adults globally living with obesity[1]
~USD 25.9 b	Size of global anti-obesity medication market in 2025, growing to ~USD 82.55 b by 2032[2]

1. WHO. 2. Coherent Market Insights. RoA: Route of Administration. API: Active Pharmaceutical Ingredient

Promising first data on Orexo's nasal semaglutide formulation

- Data shared with industry experts and companies active in the field
- Good feedback with regards to bioavailability required to make future products commercially attractive
- New formulations to be tested in new in-vivo studies



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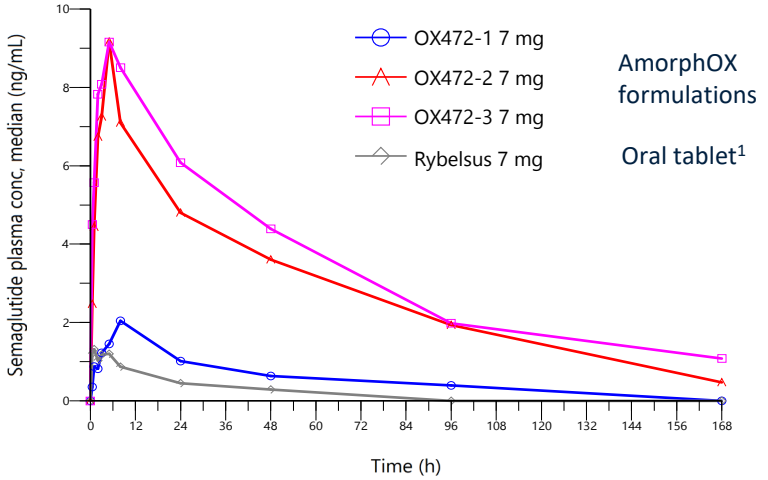
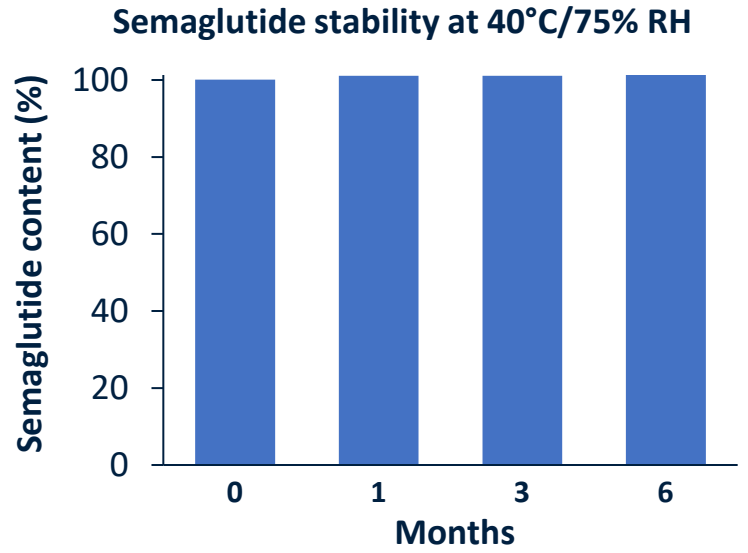
Preclinical PK study: Intranasal semaglutide formulated by AmorphOX vs oral formulation





Note: Rybelsus® is a registered trademark of Novo Nordisk A/S

1. Exposure of AmorphOX formulations were lower than injectable reference.

Moving beyond nasal GLP-1: Exploring the potential of AmorphOX in oral peptide delivery

Scientific rationale for AmorphOX®

- Amorphous → supersaturation at site of absorption
- Disintegration/dissolution properties
- Co-localization of drug and excipients
  - Avoid peptide aggregation
  - Critical formulation components released and available at the same site and time

Potential benefits and value

- Higher bioavailability → reduced dose → reduced cost and supply risks
- Reduced food effect → more flexible and convenient dosing
- Improved stability and shelf-life

Status

- **Formulation development of semaglutide tablets ongoing**
- **New IP filed**

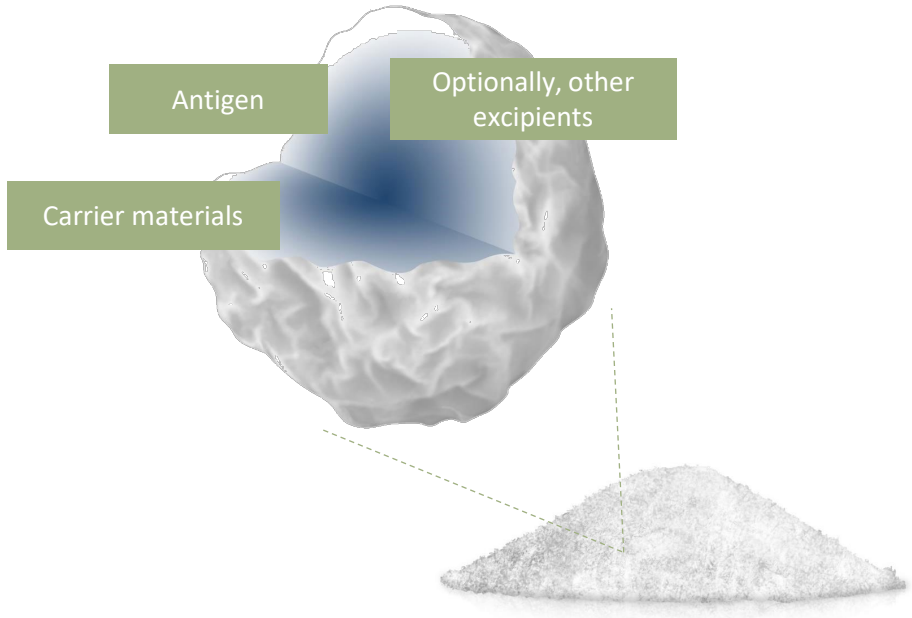
Next steps

- **Pre-clinical in-vivo pharmacokinetic Proof-of-Concept study H2 26**

AmorphOX-formulated thermostable vaccines create new opportunities to transform care

- Creates a thermostable vaccine for administration as a nasal powder or powder for reconstitution
- Eliminates the need for the cold chain, broadening patient access and global reach and reducing transportation and storage costs
- Stimulates mucosal immunity, which may prevent the spread of infection
- Creates value for patients, providers, and manufacturers

AmorphOX vaccine:
Nasal powder or powder for reconstitution

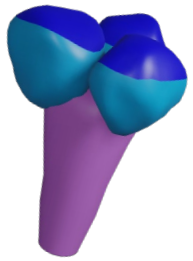


Advancing a new generation of vaccines

- **AmorphOX® is a highly stable delivery platform enabling formulation of sensitive APIs, including vaccines**
- **Eliminating cold chain requirements may improve accessibility and reduce COGS**

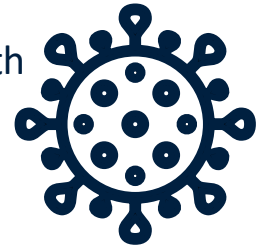
1 SARS-CoV-2 Spike Protein in AmorphOX

- ✓ Successfully formulated on the AmorphOX platform
- ✓ Free-flowing powder
- ✓ Retained activity after formulation and manufacturing, confirmed by binding assay and **stability at 40 °C for 3 months**



2 Live Attenuated Virus in AmorphOX

- ✓ Successful formulation of a live attenuated virus on the AmorphOX powder platform with retained activity
- ✓ Data generated supporting a thermostable powder

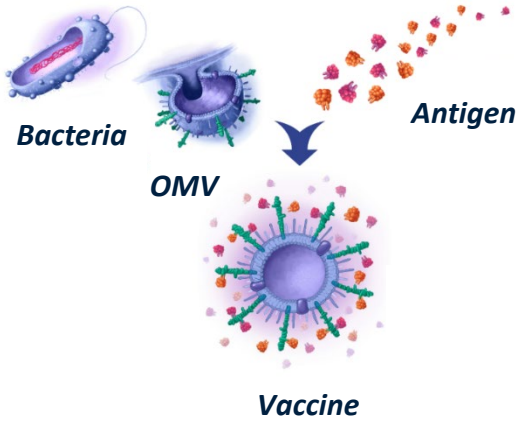


3 OMV Vaccine: Nasal powder vaccine demonstrates potential advantages over liquid nasal spray

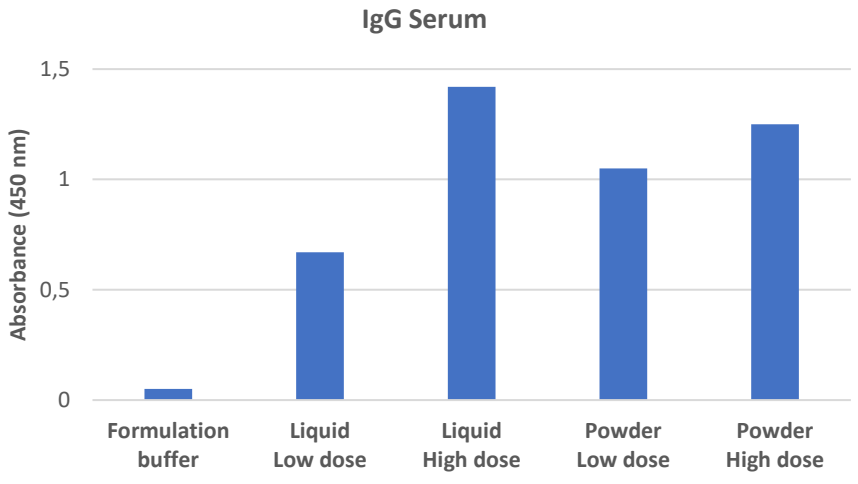
- Collaboration between Abera and Orexo to develop nasal powder vaccines combining the AmorphOX® and BERA™ platforms
- In-vivo study comparing Abera's influenza vaccine as a liquid nasal spray versus an AmorphOX nasal powder formulation

Note: Outer Membrane Vesicle (OMV) vaccine

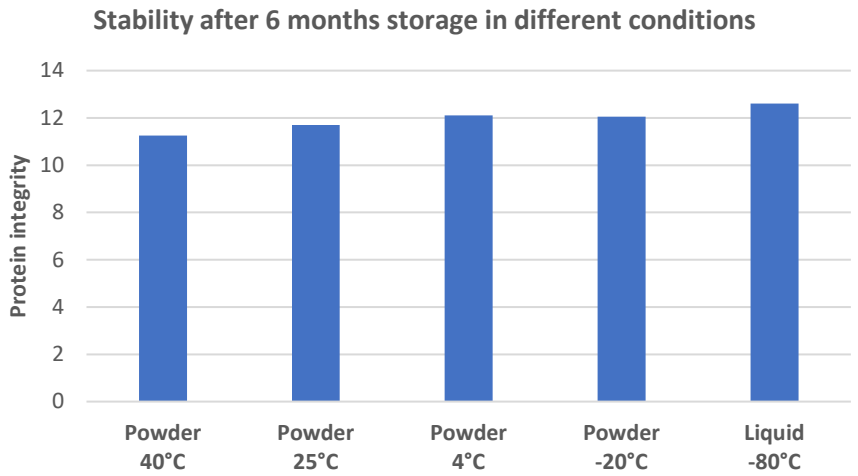
BERA™ vaccine platform



Systemic immune response



Stability study of the OMV particles



Building the evidence base to advance vaccine partnerships

Data generated so far

- Succesful formulation of three different vaccine types in the AmorphOX platform
- Thermostable powders generated for all three vaccine types
- In-vivo proof-of-concept shown with nasal AmorphOX powder

Next steps

- Advance ongoing collaboration with Abera
- Initiate new collaborations with industry and academic partners (discussions ongoing)
- Generate more data to gain better traction in partnership discussions

OX640: Advancing a best-in-class nasal epinephrine product with improved stability, bioavailability, and patient convenience, supported by accelerated development and scalable manufacturing to meet the needs of severe allergy patients.

Lisa Moore
SVP Product and Portfolio Strategy

Cecilia Coupland
SVP Head of Operations

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Large global epinephrine market, growing steadily; strong momentum for needle-free delivery systems

- **200M+ people globally** have life-threatening food allergies[1]
- **~40M people in US** experience Type I allergic reactions[2]
- **Global epinephrine market to reach ~USD 6 b by 2033**, up from ~USD 3 b in 2025[3]
- **Epinephrine market dominated by autoinjectors**; cumbersome to carry; painful needle injections can deter rapid use in an emergency[4]
- **EMA: Some patients/caregivers delay or fail to administer epinephrine** due to needle fear, lack of portability, or fear of giving injection without medical training[5]
- **A nasal spray option has gained strong US commercial traction**; multiple country/region regulatory approvals and rollout confirm global expansion potential[6,7]

1. Fiocchi A, et al. The World Allergy Organization journal, 2021. 2. Raymond James Research, Cantor Fitzgerald Research, 2025. 3. Grand View Research, Epinephrine Market, 2025-2033. 4. Leerink Partners, 2026. 5. pharmaphorum News, March 12, 2026. 6. Market Growth Reports, February 2026. 7. Seeking Alpha, March 2026. EMA: European Medicines Agency

First nasal alternative with promising start and high expectations

- **Strong sales development** in first year with USD 72.2 m net sales revenues in US[1]
- **Ongoing rollout in several countries**. Germany market share of close to 18% after 6 months[2]
- **Well-received by payers**, with price premium relative to autoinjectors in US and Europe[2]
- **High expectations** of global sales potential; analysts forecast USD 500 m peak US sales and USD 500 m ex-US.[3]

"90% of patients favor epinephrine nasal spray over auto-injectors." [4]

1. Company A Q4 FY2025 Earnings. 2. Company B Annual Report 2025. 3. Seeking Alpha April 2025.
4. SnackSafely.com, Market Research Study, HCPLive: Douglas Mack MD March 17, 2026

OX640 aiming for best-in-class nasal epinephrine emergency treatment of severe allergic reactions

Differentiated OX640 target product profile vis-à-vis nasal competitors[1]:

- **Highly stable**: Maintains potency at very low and high temperatures and does not freeze when exposed to freezing temperatures
- **Rapid onset**: Rapidly dissolving nasal powder epinephrine; high plasma levels within minutes
- **Extensive absorption**: High plasma levels for extended period after single dose under allergic rhinitis conditions
- **Long shelf life**: Long dating that results in less need for frequent prescription refills.

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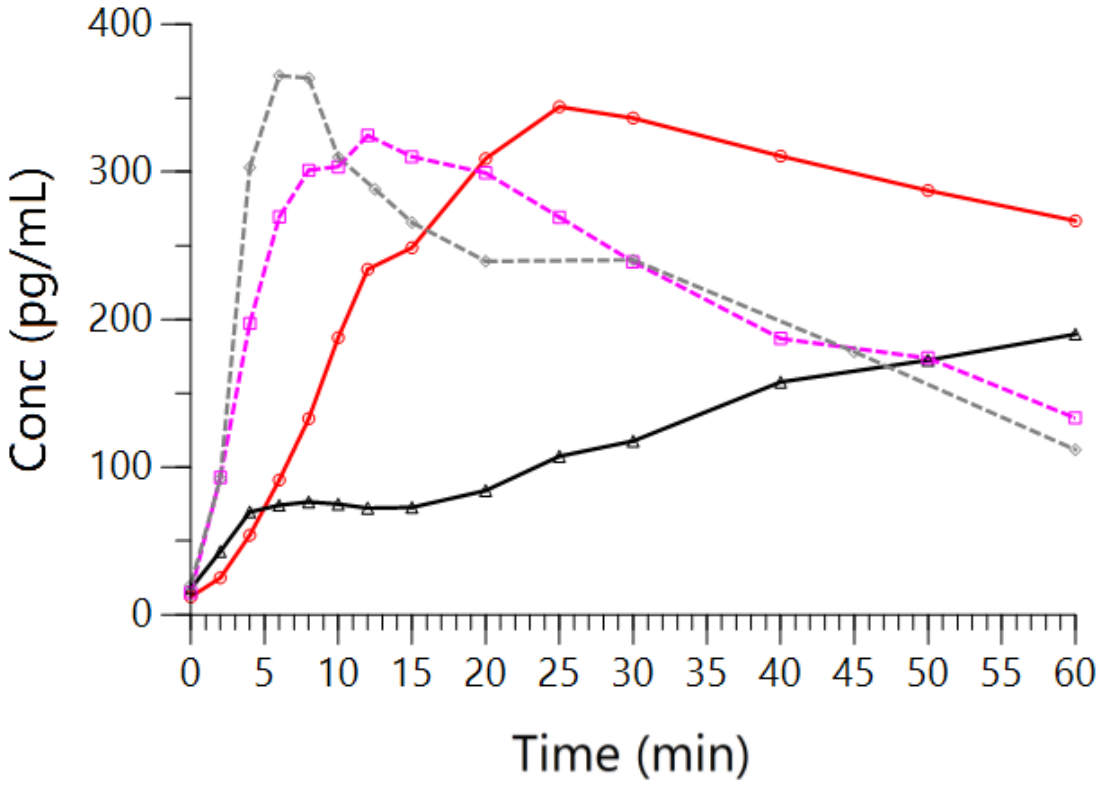
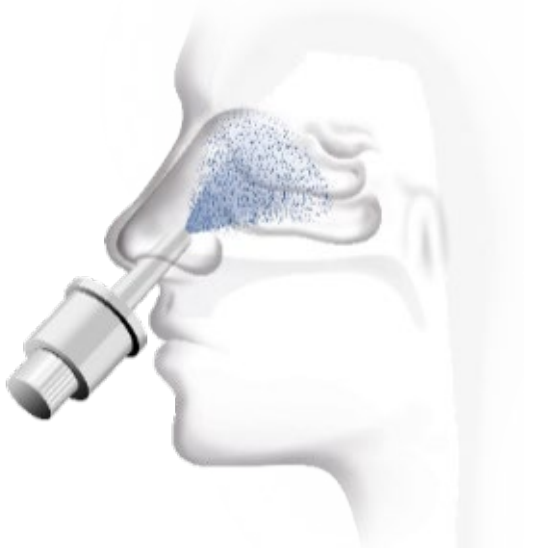
1. Orexo Data on File. OX640 is investigational and is not approved by any regulatory agency. Stability, performance, and shelf life need to be confirmed with final commercial dose.

Solid preliminary PK data[1] from cross-study comparison



OX640 2mg
IM 0.3mg
OX640 2mg NAC (dose-scaled)
Autoinjector 0.3mg (cross-study comparison)



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1. Orexo Data on File. OX640 is investigational and is not approved by any regulatory agency. Stability, performance, and shelf life need to be confirmed with final commercial dose. Cross-study comparison. PK: pharmacokinetic. NAC: Nasal allergen challenge

OX640 powered to transform anaphylactic rescue

Going from this…

… to this

Images are for illustrative purposes only.

OX640 uptake will be greatest with those who prioritize portability and reducing patient burden

Attribute	Enthusiasm	Perspectives
Route of Administration		*"I hate needles; they give me so much anxiety. If there was another option, I'd be interested."* – *Patient*
Product Size		*"If the device is less bulky, patients would probably be more likely to carry the device with them."* – *Allergist*
Temperature Stability		*"Temperature stability is important if you live in a climate with seasons, which is the majority of people in the U.S."* – *PCP*
Shelf Life		*"A stable dose over a longer shelf life means fewer unpleasant surprises when the product is needed."* – *Allergist*

1. OX640 Qualitative Market Research, October 2025. OX640 is investigational and not approved by any regulatory agency.

Physician Patient

Next steps: Getting ready to start pivotal program

Earlier stages CMC and clinical work has been performed using earlier formulations and pilot scale manufacturing.

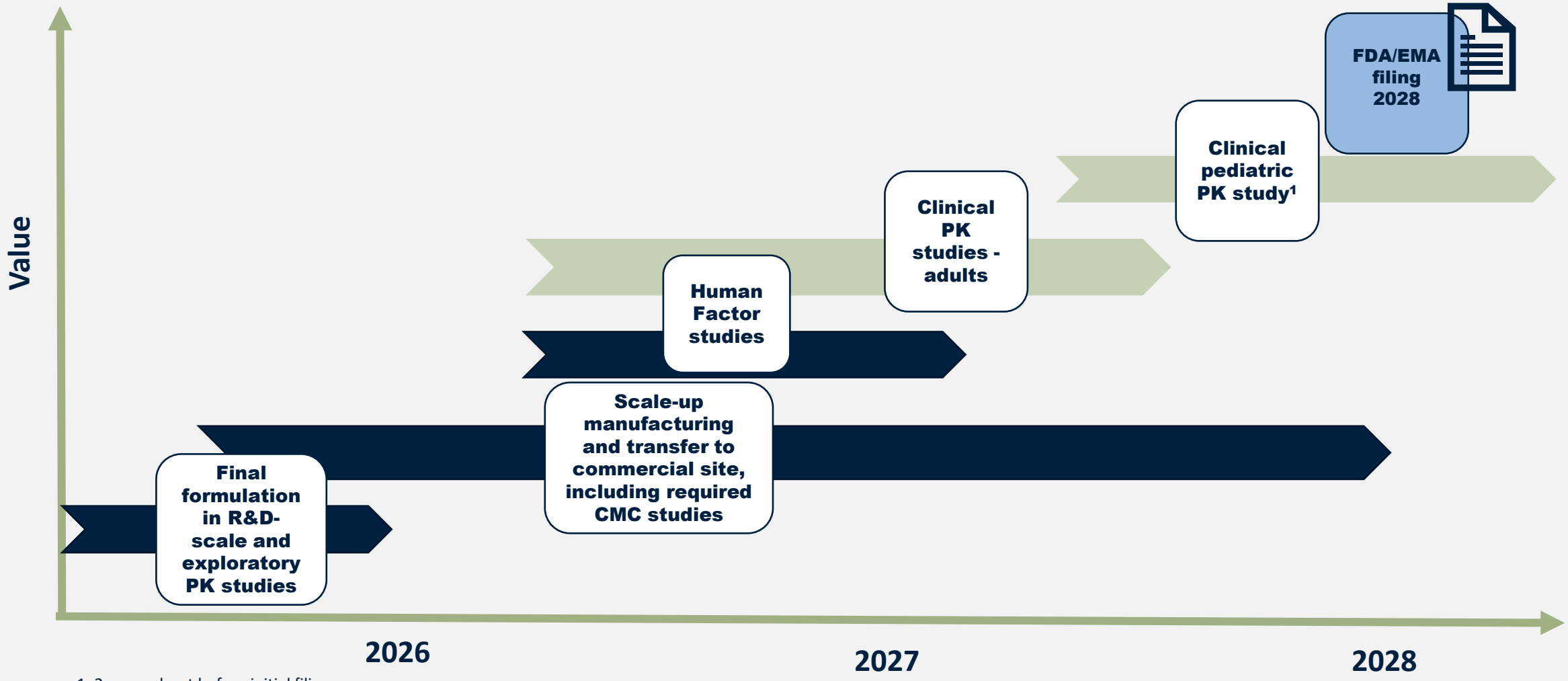
- Finalize scale-up of manufacturing to commercial scale
- Test product (incl Instruction for Use) in Human Factor Studies
- Final FDA interaction on development program before start of pivotal program
- Initiate OX640 pivotal clinical trial and reach value inflection point – first patient dosed

De-risking OX640 through proven learnings

- Final commercial product (FCP) produced on commercial lines for reliability and verification studies
- Importance of performing human factor work early and using the right vendor
- Inputs from FDA/EMA on clinical program for OX640 and first nasal epinephrine

- Izipry™ manufacturing platform reused for OX640
- Izipry™ human factors inform OX640 intruction for use (IFU) and labeling
- OX640 clinical program aligned with FDA/EMA feedback and product profile

FDA/EMA market approval timeline for OX640



1. 2mg read-out before initial filing

Orexo´s own manufacturing capabilities create a competitive edge in nasal epinephrine

- ✓ Rescue products require **99.999% reliability** (<1 failure per 100,000)
- ✓ Izipry™ FDA interactions, manufacturing and supply chain leveraged for OX640
- ✓ Product and manufacturing designed end-to-end to minimize device failure
- ✓ Extensive sensors and controls prevent faulty devices reaching the market

Images: Filling equipment used in Orexo's FDA-inspected nasal powder production site. ▶

Break

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OX390: Developing the world's first medical countermeasure (MCM) to

the rising threat from xylazine and medetomidine in collaboration with BARDA, a center within the US Department of Health and Human Services.

Edward Kim
Chief Medical Officer

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Xylazine – an emerging public health threat

APRIL 12, 2023

Biden-Harris Administration Designates Fentanyl Combined with Xylazine as an Emerging Threat to the United States

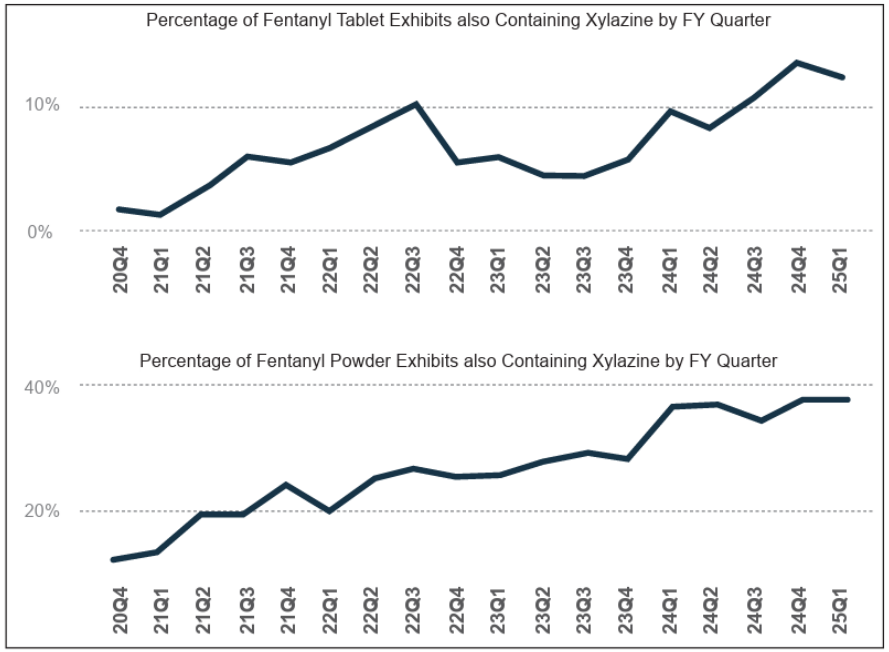
DEA Reports Widespread Threat of Fentanyl Mixed with Xylazine

- Veterinary sedative known as "**Tranq**", alpha-2 agonist added to illicit opioids:
  - Produces profound sedation, "zombie-like" behavior, severe necrotic sores on skin
  - Increases brain hypoxia when co-administered with fentanyl
    - ***NOT*** *reversed by naloxone*[4]
  - From 2015 to 2020, overdose deaths involving xylazine increased from 2% to 26% in Philadelphia[1]
- **No α2-antagonist is approved for human use**

1. Frieman et al Drug Alcohol Depend 2022;233:109380 2. E Viscusi, personal communication 3. Choi et al (2023) Neuropsychopharmacology 2023 Dec 20 4. US DEA Public Safety Alert 2023 5. Gummin et al (2022) 2021 Annual Report for the National Poison Data System.

Xylazine adulteration of fentanyl is spreading across the US

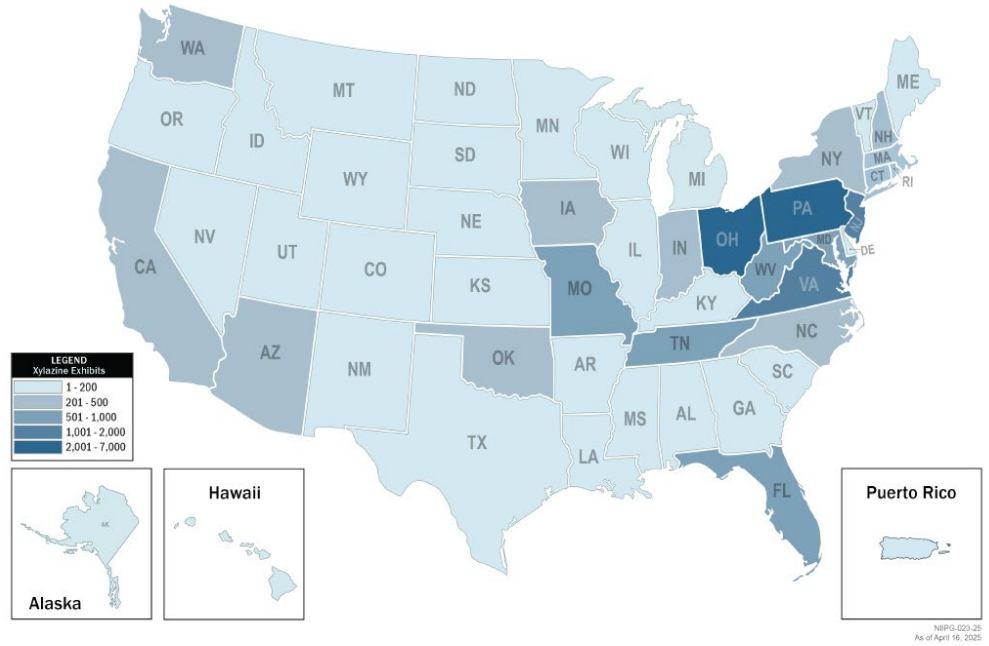
Figure 12. Percentage of Fentanyl Pills (top) and Powder (bottom) Containing Xylazine, 2020-2024



Source: DEA

The percentage of fake powder fentanyl and fake fentanyl pills containing xylazine has steadily risen since 2020. Fentanyl powder samples containing xylazine exceeded **35%** in the beginning of 2025.

Figure 21. States with Reported Seizures of Xylazine, 2024



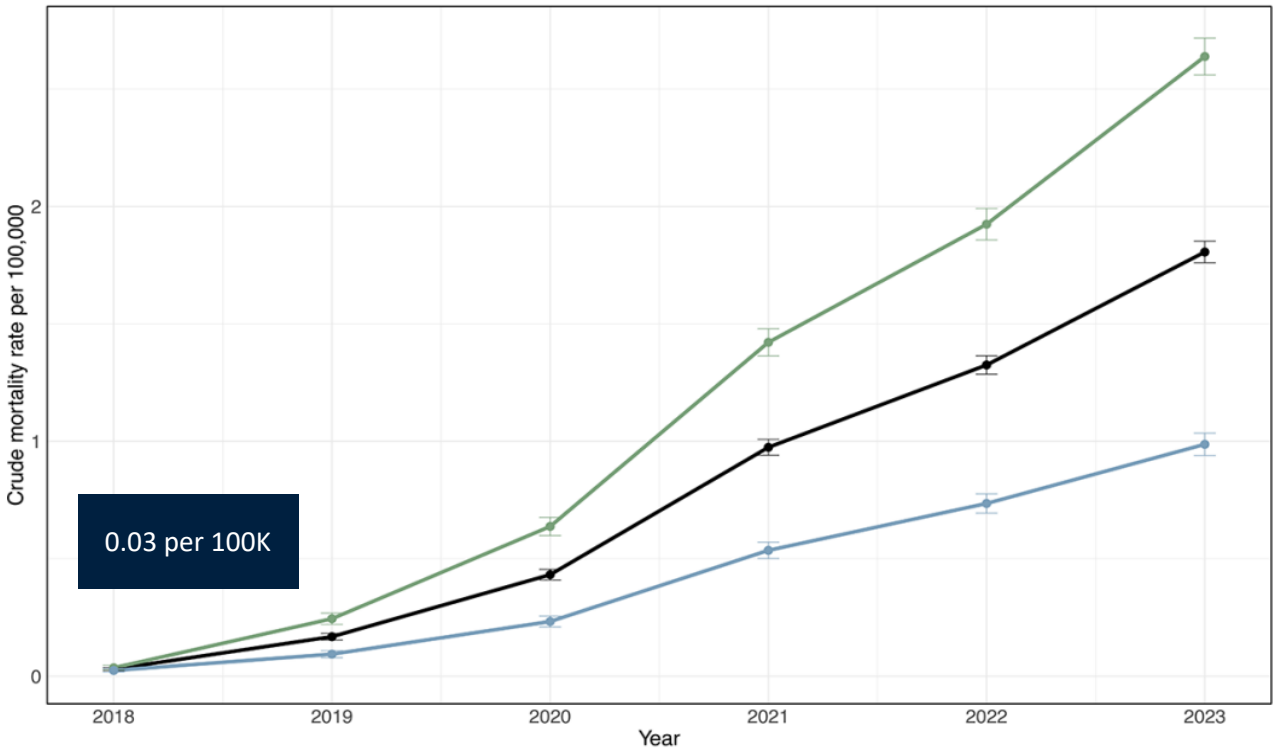
Source: National Forensic Laboratory Information System, data retrieved April 16, 2025

Xylazine has been identified in seized drug samples in every U.S. state, plus the District of Columbia and Puerto Rico.

It is most prevalent in drug samples seized in New Jersey, Virginia, Ohio, Maryland, Pennsylvania, and Florida.

Source: 2025 National Drug Threat Assessment (NDTA), data from DEA forensic laboratories

The number of fentanyl-involved deaths with xylazine detected is increasing yearly



Mortality rate per 100K for IMF-xylazine increased **60x** between 2018-2023

Zhu DT, Cano M. *Inj Prev* doi:10.1136/ip-2024-045596

Medetomidine (i.e., “rhino tranq”) is increasingly being found mixed with fentanyl and xylazine

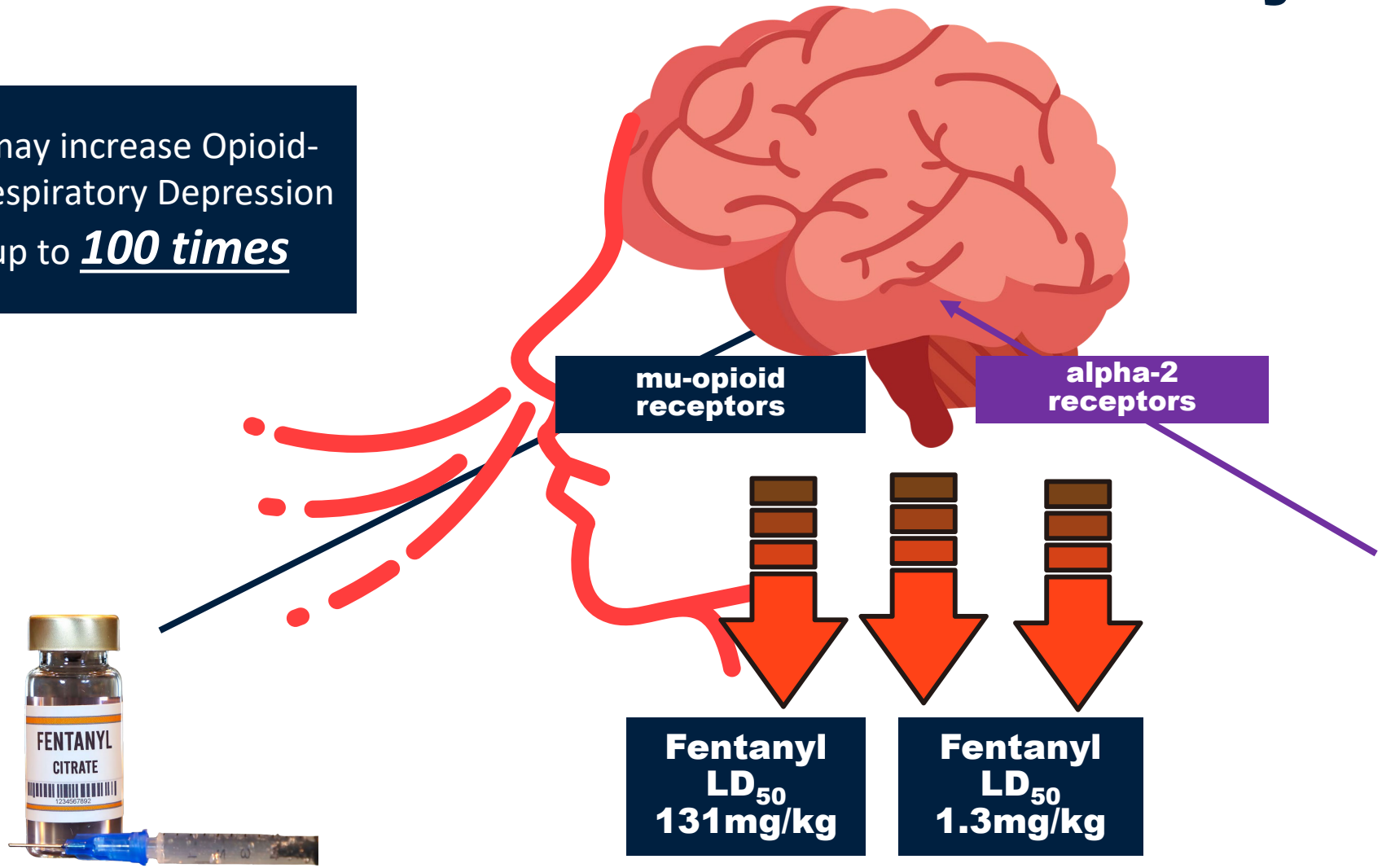
CDC to Clinicians: Look Out for Medetomidine in Opioid Overdose
— Often mixed with fentanyl, medetomidine is showing up in more illicit street drugs
by Joedy McCreary, Enterprise & Investigative Writer, MedPage Today
August 7, 2025 • 3 min read

Source: Open Source

- **Medetomidine’s potency is 200-300 times greater** than that of xylazine
- According to DEA Office of Forensic Sciences, xylazine remains the number one adulterant found in fentanyl powder, but the **emergence of medetomidine is a dangerous development**
- This further exacerbates the emerging threat declared in 2023

Potential Reason for Increased Lethality

Xylazine may increase Opioid-Induced Respiratory Depression (OIRD) up to ***100 times***



Mark Smith 2023

The lack of targeted antidotes for alpha-2 agonist exposure is an unmet need

› Reg Anesth Pain Med. 2025 Jan 7;50(1):55-58. doi: 10.1136/rapm-2023-105190.

Emergence of xylazine as a public health threat: what does the anesthesiologist need to know for perioperative care?

Pawan K Solanki [1], Samir Yellapragada [2], Brendan Lynch [2], Maria Eibel [2], Eugene R Viscusi [3], Trent Emerick [2]

Affiliations + expand

PMID: 38242642 DOI: 10.1136/rapm-2023-105190

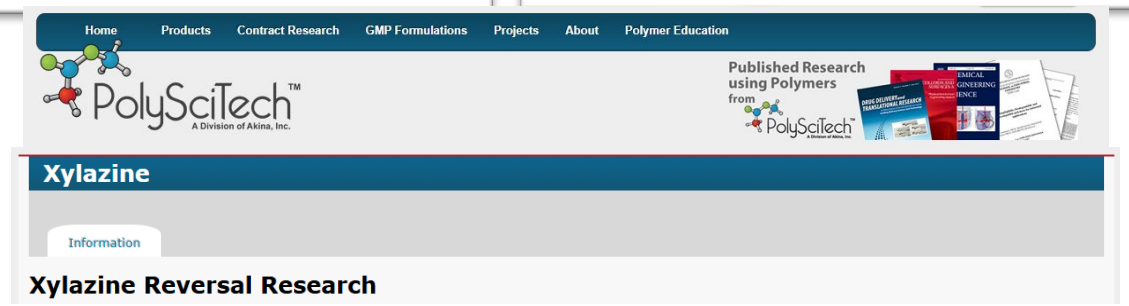
Comment › Reg Anesth Pain Med. 2025 May 6;50(5):452-453. doi: 10.1136/rapm-2024-105471.

Alpha-2 antagonists should be developed as xylazine antidotes in humans

William Oles [1], Janet O Adeola [2], Alexander B Stone [3]

Affiliations + expand

PMID: 38772636 DOI: 10.1136/rapm-2024-105471



"Further work toward developing xylazine overdose and blocking treatments is warranted."

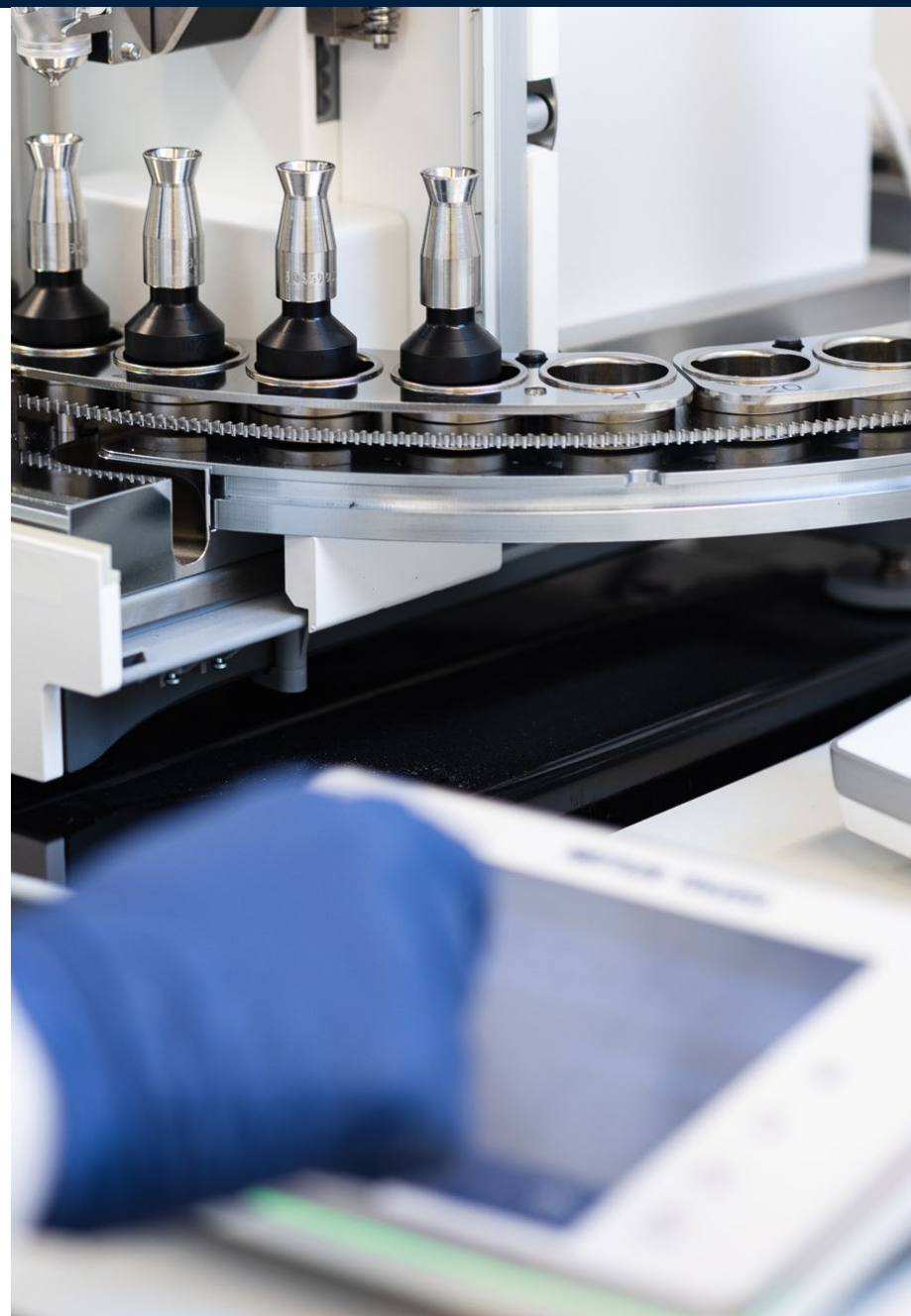
Future research should focus on developing targeted antidotes, refining overdose management protocols, and improving surveillance systems to combat this growing public health emergency effectively.

The solution – OX390 (atipamezole) intranasal powder

Single use device

Sealed storage tube

amorphOX®



OX390 (atipamezole) – a de-risked human NCE

α2 antagonist approved as Antisedan® for veterinary use in the US since 1996

- Reverses sedation due to xylazine, medetomidine in animals
- Human development
  - Clinical studies by **Orion Corporation** in 1990's demonstrated efficacy to reverse sedation from dexmedetomidine (α2 agonist approved for human use)
  - Well-tolerated when administered intravenously
  - Development discontinued due to lack of commercial opportunity in anesthesia

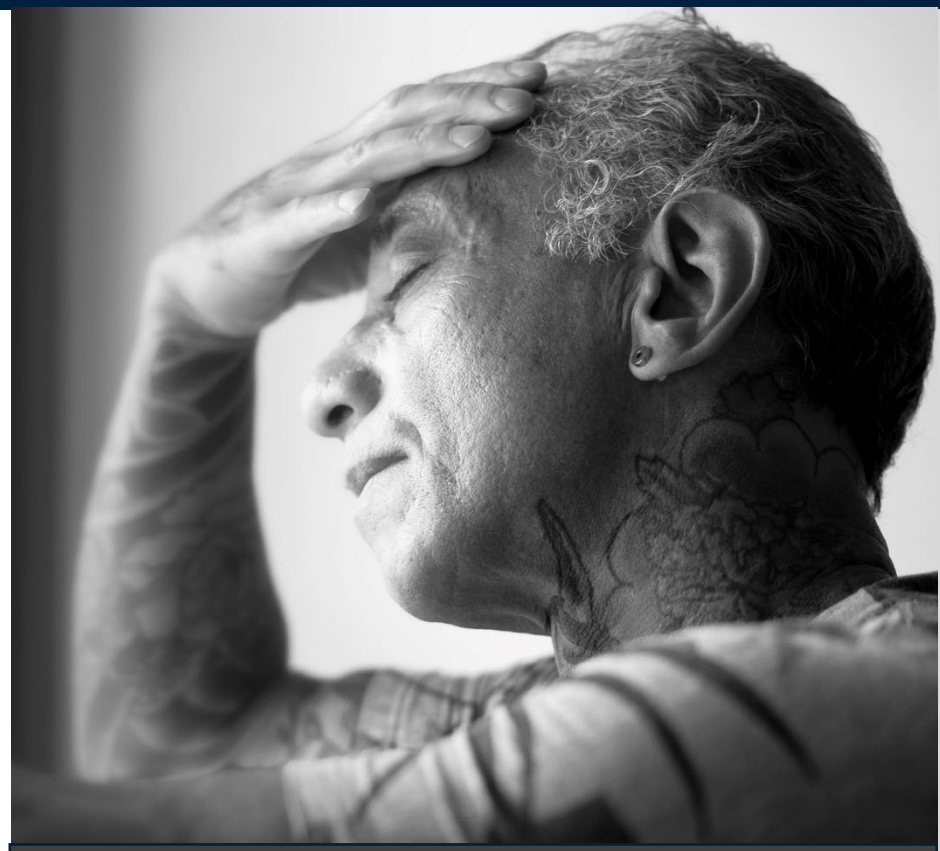
Orexo held a pre-IND meeting May 22, 2024 with FDA highly productive

- FDA agreed with unmet medical need due to xylazine adulteration of illicit opioid supply

BARDA contract summary – a public-private collaboration to address a public health threat

Contract awarded for base period of September 2025 - March 2027

- Cost-sharing contract valued at USD 8.5 m to cover pre-IND requirements
- Four additional option periods to support NDA approval – total project value USD 51 m
- Work started Q4 2025



NEWS: Orexo US to partnering with BARDA for development of OX390 for adulterated opioid overdoses.

Where we are today

- In-vitro studies completed to optimize formulation
- Four formulations selected for preclinical in-vivo PK study (Q2 2026)
- Planning the nonclinical program needed for first in human PK study
- Storage tube optimization to increase shelf life and temperature excursions
- Preparing FDA guidance meeting request (Q2 2026)

Expert perspectives: Why countermeasures are needed

for the emerging threats from xylazine, medetomidine, and fentanyl combinations.

Mark A. Smith
PhD Davidson College, NC, US[1]

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1. Recorded interview

Building a viable business model
through business development.

Fredrik Järrsten,
EVP and CFO,
Head of Business Development

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Business Development is a fundamental element of a viable business model

Strategic Transformation

- Sale of Zubsolv® strengthens financial flexibility and allows Orexo to transition into a platform- and development driven company
- Investments redirected into three fundamental pillars of platform development, proprietary pipeline projects and partnerships.

Business Development (BD) role

- BD plays an integral part in the business model
  - **market insights** needed to scale AmorphOX® and guide Orexo's R&D priorities.
  - **partnerships**
  - **funding**

Explore AmorphOX® technology

Develop proprietary projects

Partner AmorphOX technology

➢ **Our goal is a capital-efficient business with scalable revenue streams tied to technology, partnerships and milestone economics resulting in value creation.**

Building on a long track record of partnering experience, providing additional funding

A long history of partnerships…

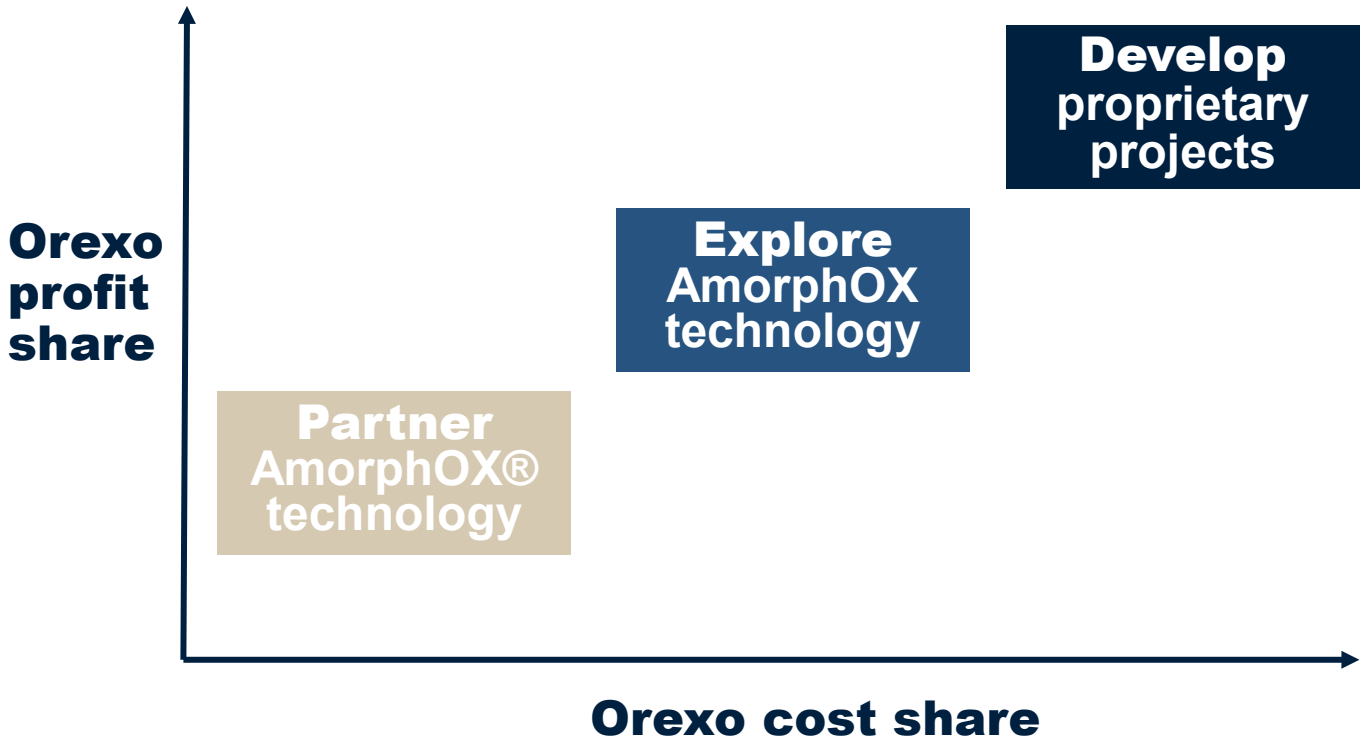
Examples:

accord Make it better
abera BIOSCIENCE
GESYNTA PHARMA AB
VIATRIS
J&J
Kyowa Kirin
GRÜNENTHAL
AstraZeneca
sobi rare strength
Dexcel pharma
MEDA
BARDA
mundipharma
ProStrakan

…incl. transactions with significant financial impact

2012	Abstral® EU royalties sold for SEK 610 m
2013	Abstral US sold for USD 15 m
2015	Abstral EU milestone of GBP 5 m
2016	Zubsolv® ex US rights sold for EUR 7 m
2025	OX390 BARDA financing of up to USD 51 m
2025	Zubsolv US sold for USD 91 m plus earn-out

Three strategic focus areas diversify Orexo's risk-reward profile



- Orexo owns projects to be partnered at **value inflection** and Orexo can take an active role in **commercialization**
- New areas with **transformative potential** to be partnered when **proof-of-concept data** is established
- Partner financed projects, where **partners takes most expenses in development** and Orexo profits comes from **royalty at commercialization**

Partnering at value inflection is a critical source of financing and de-risking

Proof-of-concept based on strong in-vivo and first human data

- Access to API, know-how, scientific methods
- Cost share
- Royalties & milestones

Izipry™ after FDA approval
OX640 clinical data from pivotal trial(s)
OX390 clinical data from humans

- Upfront payments, royalty and milestones

Postive outcome of feasibility studies

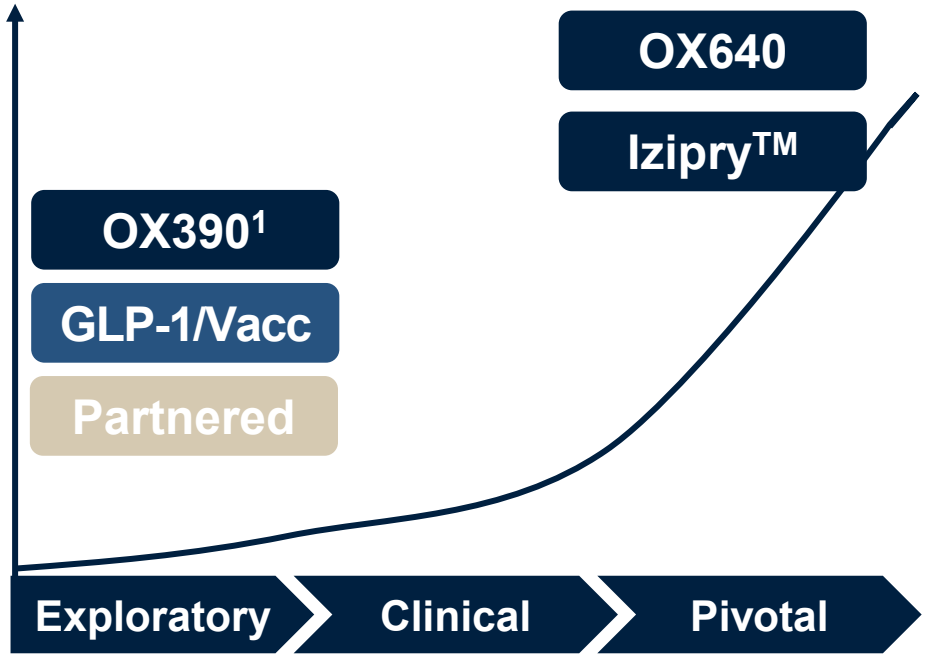
- Cost coverage
- Co-development
- Access to API
- Royalties and milestones

Short term business development and investment focus on OX640 and Izipry

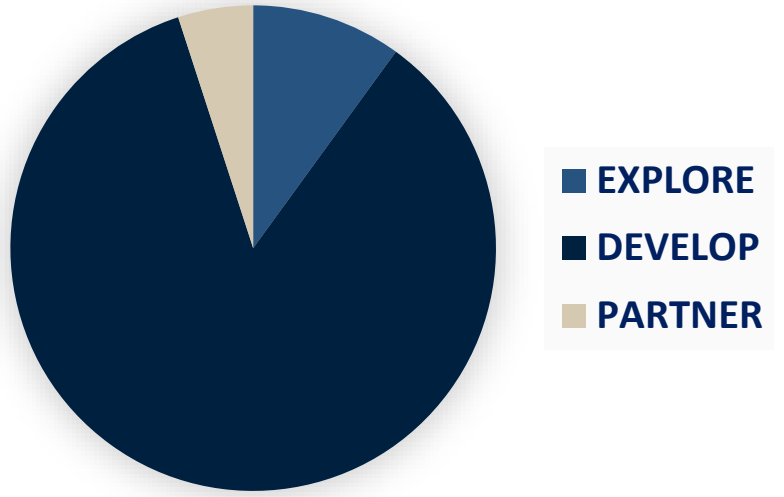
OX640 and Izipry™ are in pivotal development stage…

… leading to significant investments in 2026-2028

R&D cost level



Allocation of R&D investments



OX640 is the main planned investment with ~SEK 210 m external expenses remaining

1. Majority of costs are financed by BARDA

Business development is the main source of financing

Financing

1. Zubsolv® divestment of USD 91 m plus earn-out
2. Research contribution from BARDA of up to USD 51 m
3. Royalties from commercial products Zubsolv, Abstral® and Edluar®
4. Future milestones and royalties from development programs
5. Partner-funded R&D for AmorphOX-enabled projects

The above-mentioned funding sources are central to Orexo's financing. In parallel, opportunities for long-term financing through the capital markets are continuously evaluated, depending on the company's performance and prevailing market conditions.

Q&A

..including closing remarks by CEO Nikolaj Sørensen

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Global leadership and growth

Company key objectives

Building global leadership in amorphous drug delivery

Strategic pillars to reach key objectives

Drive global leadership in amorphous powder for drug delivery

- Accelerate R&D and internal expertise in amorphous powder drug delivery
- Expand biomolecule research in peptides and proteins
- Strengthen academic and KOL partnerships

Advance projects to value inflection

- Fund proprietary projects to value inflection
- Enforce go/no-go decisions to optimize speed and resources
- Drive proactive out-licensing with pharma partners.

Expand partnerships for the AmorphOX technology

- Partner to unlock AmorphOX value
- Lower risk and cost through partner funding
- Capture upside via royalties and milestones

Thanks

lunch

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