

The logo for Oasmia, featuring the word "oasmia" in a bold, black, serif font. The letter "o" is enclosed within a yellow, hand-drawn circular scribble. The background of the slide is light gray with several thick, wavy, light green lines that create a sense of movement and depth.

**oasmia**

**OASMIA PHARMACEUTICAL**

**COMPANY PRESENTATION**

**BIO-EUROPE, HAMBURG, GERMANY**

**NOVEMBER 2019**

# FORWARD LOOKING STATEMENT

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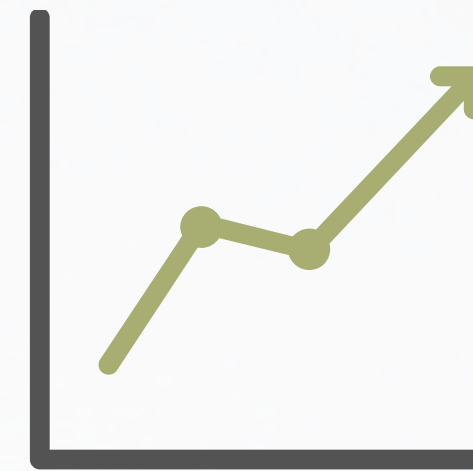
# CORPORATE OVERVIEW

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We are an innovation-focused pharmaceutical company  
**specialising in human and animal oncology**



HQ Uppsala, Sweden  
Subsidiaries in USA,  
Hong Kong and Moscow



NASDAQ Stockholm 2010  
Frankfurt Stock Exchange 2011



60 employees



FDA and EMA approved production  
facility in Sweden

# ADVANCING DRUG DELIVERY IN CANCER

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The challenge:

**Solve the insoluble**

**Many cancer APIs are not water soluble:**

- 40% of approved drugs
- 90% of developmental pipeline drugs<sup>1</sup>

Low bioavailability  
Rapid elimination



Carriers optimize  
delivery, but bring  
unpredictable  
pharmacokinetics  
and significant AEs

Managing toxicity means  
premedication and longer  
infusion times



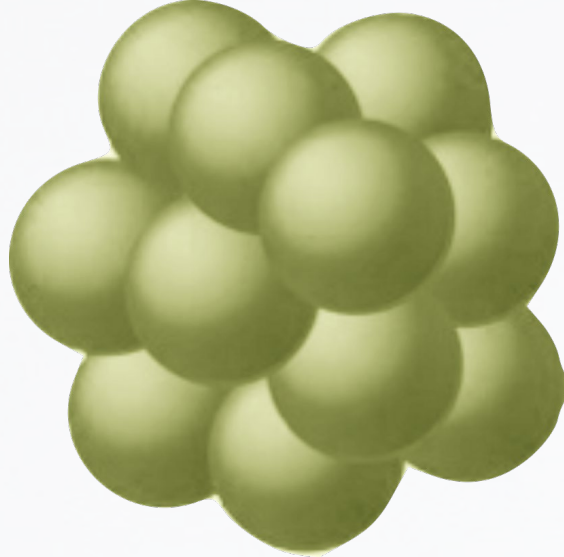
AE, adverse event; API, active pharmaceutical ingredient; PK: pharmacokinetics.

1. Kalepu S, Nekkanti V. *Acta Pharmaceutical Sinica B*; 2015: 442-453. <https://doi.org/10.1016/j.apsb.2015.07.003>

# TECHNOLOGY PLATFORM

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Active Pharmaceutical Ingredient (API)



Water-insoluble



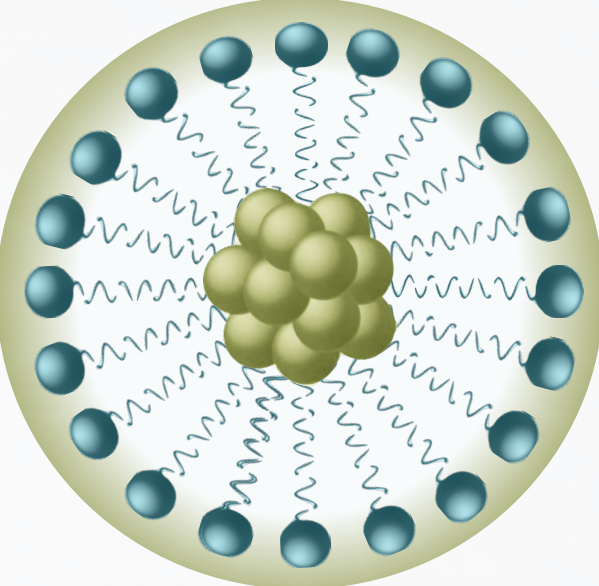
XRI7 molecule



Hydrophilic, polar head  
Hydrophobic, non polar chain



Micelle consisting of XRI7 and API



Water soluble

# XRI7 MOLECULE

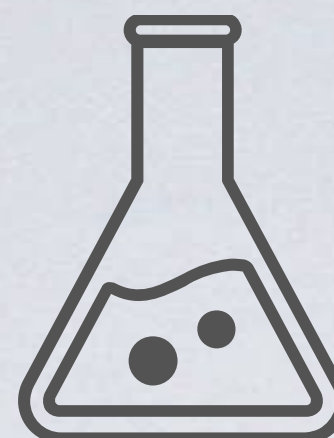
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Micellar delivery:

**A safe way to provide APIs**



In house invention  
& development



Based on novel  
vitamin A derivative



✓ Clinical studies  
✓ Toxicological studies

## Key benefits:



- Improved solubility
- Improved bioavailability
- Avoid toxic solvents



Shorter  
infusion time



No mandatory need for  
pre-medication with  
immunosuppressants

# WIDE PATENT PROTECTION TO 2036

XR17 is protected  
by the following patent families

## “Process”

Protects the manufacturing process for XR17

to: December **2036**

**PCT** application granted

**3** patents granted in US, ZA

Application pending in Eurasia, EPO, AU, CA, CN, HK, IN, ID, JP, MY, MX, NZ, KR, SG and UA

## “Water-insoluble”

Protects poorly water-soluble APIs in combination with XR17

to: December **2028**

**57** patents granted

across Eurasia, EPO, AU, CA, CN, JP, KR, MX, MY, NZ, UA, US, ZA

**SPC** applied for in the EU, pending (5-year extension)

## “Anticancer compositions”

Protects XR17 in combination with chemotherapeutic agents

to: November **2022**

**6** patents granted

In US, FR, UK, DE, CN and HK

# LAUNCH MARKET

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## Ovarian cancer:

### A strong and stable market for taxane chemotherapy

#### Prevalence of OC per year

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>22,000 [USA]; >27,000 [EU top 5]<sup>1</sup>

#### Growth of market

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- Expected value increase 12% YoY until 2025 <sup>1</sup>
- Growth driven by innovative treatments e.g. PARP inhibitors [for specific subtypes of patients only i.e. BRCA mutated – 10% of patients]<sup>2</sup>

#### Most patients treated with chemotherapy backbone

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- 1<sup>st</sup> line paclitaxel-carboplatin therapy is a standard treatment for newly diagnosed OC <sup>2</sup>
- 70% of patients relapse following 1<sup>st</sup> line paclitaxel-carboplatin therapy; re-challenging platinum-sensitive patients with carboplatin-doublet is ESMO strategy of choice <sup>2</sup>

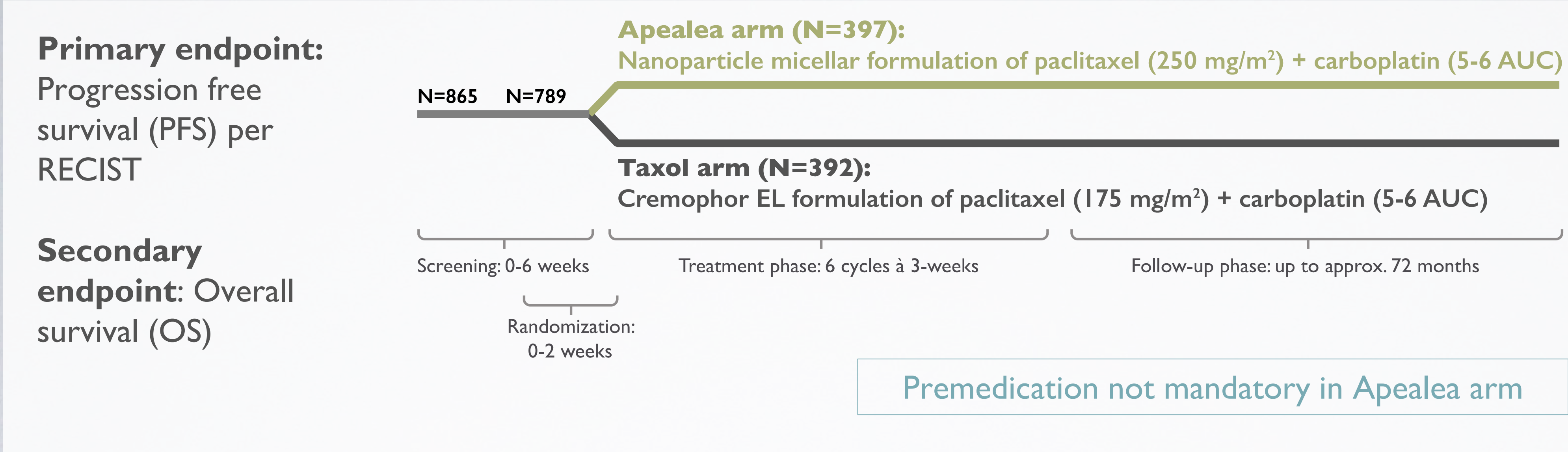
1. Grand View Research, Ovarian Cancer Drug Market 2019

2. Annals of Oncology 30: 672–705, 2019, ESMO guidelines. doi:10.1093/annonc/mdz062 Published online 2 May 2019



# PROOF OF CONCEPT

## APEALEA: Micellar formulation of paclitaxel based on XRI 7



Randomized, open label, multicenter study comparing efficacy and safety of Apealea and solvent-based paclitaxel (Taxol®). Patients had recurrent epithelial ovarian cancer, primary peritoneal cancer or fallopian tube cancer and had relapsed  $\geq 6$  months after platinum-containing treatment. Study took place at 16 countries at 81 centres in Europe including Russia (44%); Belarus (14%) and Ukraine (13%).

# PROOF OF CONCEPT

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## APEALEA: Micellar formulation of paclitaxel based on XRI7

### As effective and safe as solvent-based paclitaxel<sup>1</sup> :

- Proven non-inferiority [Apealea 10.3 months PFS vs 10.1 months]
- Apealea had a similar safety profile to solvent-based paclitaxel at significantly higher dose and numerically fewer neuropathies



#### Approvals

Central EMA approval Nov 2018, Russia  
2015, Kazakhstan 2017  
USA: Submission planned for 2020



#### Manufacturing

Apealea and XRI7 secured by in-house capacities as well  
as with a CMO agreement with Baxter Oncology,  
Germany

1. Apealea Summary of Product Characteristics. [www.ema.europa.eu](http://www.ema.europa.eu)

# WHEN THE CARRIER IS THE BARRIER

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## APEALEA:

### For women who need an alternative to solvent-based paclitaxel

#### Initial Positioning:

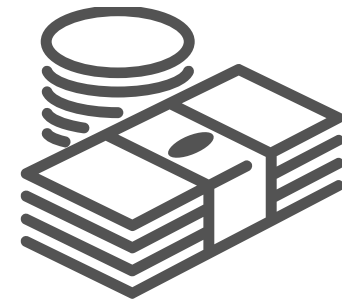
For women with first relapse of platinum-sensitive epithelial ovarian cancer, Apealea provides a **treatment alternative** to solvent-based paclitaxel **without the risk of unwanted toxicity** from cremophor-EL as well as the opportunity to avoid **excessive usage of corticosteroids** as premedication.

Indicated in combination with carboplatin for the treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer<sup>1</sup>

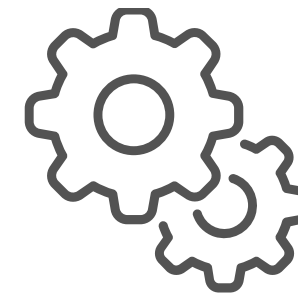
# THE WAY FORWARD

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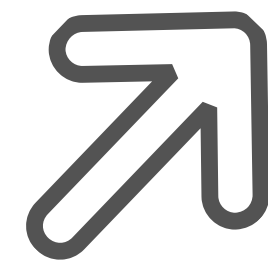
## Next steps for Apealea



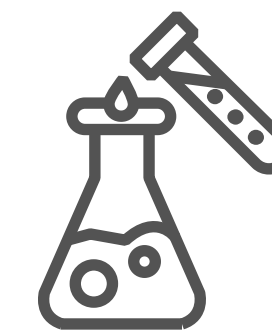
Establish commercial partnerships through licensing and/or distribution



Apply for marketing authorization in the USA and China within 2020



Launch Apealea in Europe in selective countries i.e. Nordics, through a co-promotion model



Establish scientific partnerships to further expand in oncology

# EXECUTIVE SUMMARY / INVESTMENT HIGHLIGHTS

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Our strong value proposition  
makes **Oasmia** an attractive investment opportunity

1



## Global market opportunity

Oncology market estimated to reach USD 176 billion by 2025<sup>1</sup>

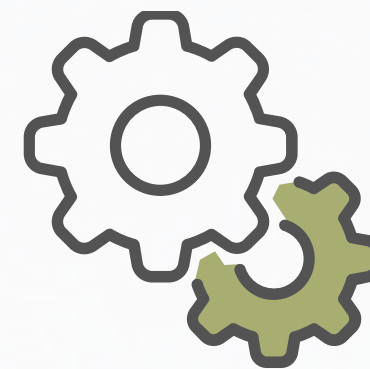
2



## Dynamic Management Team

Highly experienced BoD, Scientific and Business Advisory Boards

3



## Proprietary technology platform

XR17:  
Broad Applicable technology

4



## Proof of concept

Late-stage asset Apealea (Paclical) approved in EES & Russia

5



## Strong commercial partnerships

Global opportunities for commercialization

1. Allied Market Research. Cancer Drugs Market 2019. [www.alliedmarketresearch.com](http://www.alliedmarketresearch.com)



# **oasmia**

For more information visit

[www.oasmia.com](http://www.oasmia.com)

or send an email to

[business.development@oasmia.com](mailto:business.development@oasmia.com)