

# OASMIA PHARMACEUTICAL AB

**COMPANY PRESENTATION** 

NON-CONFIDENTIAL

F. R. Martelet, M.D. CEO June 2020



## **Forward looking statement**

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## Oasmia – an innovation-focused specialty pharmaceutical company



Founded in 1999 HQ Uppsala, Sweden 27 employees



NASDAQ Stockholm 2010 Market Cap approx. SEK 3,1 B



XR17<sup>™</sup> technology platform, allowing nano-sized particle formulations of APIs, to be soluble in water – broad applications in oncology, human and animal health



GMP-certified Production Facility and R&D, in Uppsala, Sweden



Lead product Apealea® approved in EU/EEA in ovarian cancer, in discussions with FDA; global commercial deal worth up to \$698m + royalties



New CEO in place since March 2020



## New CEO and experienced management team and Board taking Oasmia to next level



FRANCOIS MARTELET, M.D., **Master's Degree Business** Chief Executive Officer

#### **Previous experience:**

CEO in Biotechnology/BioPharma in UK, DNK, US and senior executive global roles at Novartis Oncology, Merck & Co., Inc with large P&L responsibility

MICHAEL AF WINKLERFELT Chief Finance Officer

**ELIN TRAMPE**, Chief Technical Officer

REINHARD KOENIG, M.D. Acting Chief Medical Officer

**TBD** Chief Business Officer



ANDERS HÄRFSTRAND, M.D., PhD.

Non executive Chairman

**Previous experience**: Experienced Pharma BoD, M&A experience, former executive positions in Pfizer, Pharmacia. Pharmacia & Upjohn

**SVEN ROHMANN,** M.D., PhD. **Board Member** 

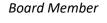
Ex- Oasmia Interim CEO

B.A. **Board Member** 

HEGE HELLSTRÖM,

PETER ZONABEND, LL.M, EMLE **Board Member** 

**BIRGIT STATTIN** NORINDER, MSc.





## **Encapsulation technologies as drug delivery systems**

### Advantages of 3 clinically established encapsulation technologies

- Improving the **stability** of hydrophobic drugs, making them suitable for administration
- Improving biodistribution and pharmacokinetics leading to better efficacy
- Improving patient safety by reducing instances of adverse effects



Liposomes nanoparticles

Self-assembled artificial vesicles consisting of a spherical bilayer structure surrounding an aqueous core domain

Limitations

Need to enhance stability and structural integrity with surface modification (e.g. Pegylation)

faif

janssen **T** 

Bristol Myers Squibb



2 Micelles

Formed when amphiphilic surfactants or polymeric molecules spontaneously associate to form core—shell structures

Limitations

Ability to entrap only insoluble hydrophobic drugs

oasmia

\*samyang\*\*



Protein-based nanoparticles

Utilizes the natural properties of albumin to reversibly bind API and transport it across the endothelial cell

Limitations

Ability to bind only hydrophobic drugs

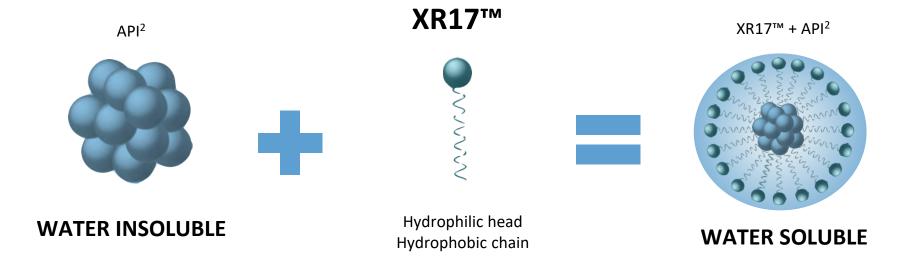




# Oasmia's XR17™ increases solubility and potentially improves safety of new formulations

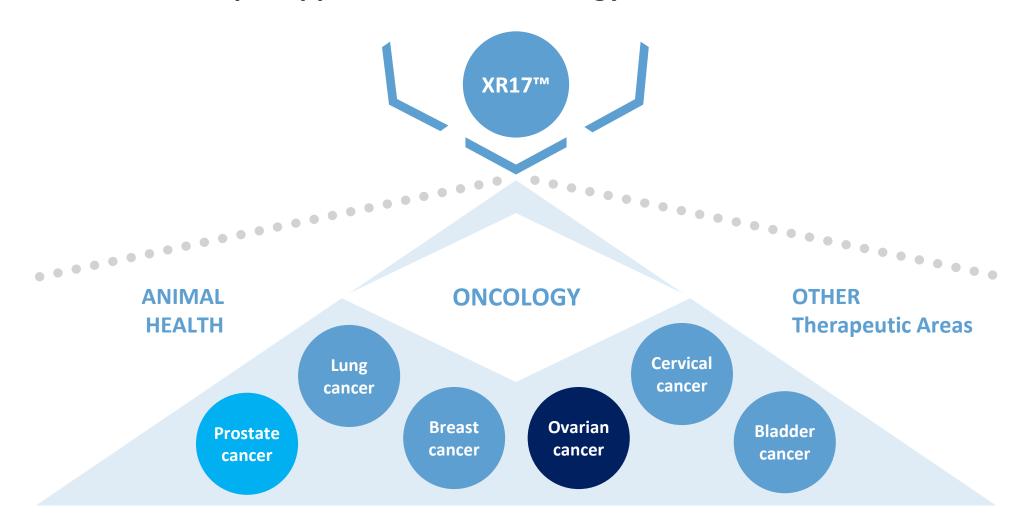
LOW WATER SOLUBILITY AFFECTS
C.40% OF APPROVED DRUGS AND
C.90% OF PIPELINE DRUGS<sup>1</sup>

SOLUBILITY ENHANCERS CAN CAUSE SERIOUS ADVERSE SIDE EFFECTS OR REQUIRE USE OF ADDITIONAL DRUGS<sup>1</sup>





# XR17<sup>TM</sup> – multiple opportunities in oncology, human and animal health





## **XR17™ – Key platform benefits**

Strong solubilization capacity

 Superior solubility compared to other nanoparticle platforms and technologies

Strong & validated safety profile

Clinically validated

Drug load capacity

Significantly reduce the need for premedication

Codelivery

- Drug load capacity (API to cosolvent ratio and high dose potential)
- Co-delivery potential



## **XR17™** – clear benefits for patients

### **NOVEL XR17<sup>TM</sup> PLATFORM**



Based on vitamin A derivatives Forms micelles, 10 – 60 nm size



High API-to-carrier ratio potentially reduces risk of unwanted carrier biological effect



Remarkable solubilizing properties Enhances bioavailability of API



Alcohol-free formulations Free from substances of animal or human origin

### **PROVEN CLINICAL ADVANTAGES**



Demonstrated safety in cancer indication<sup>1</sup>



Shorter infusion time<sup>1,2</sup>



No mandatory need for pre-medication<sup>1</sup>



Free from Cremophor EL and Polysorbate-80



## XR17<sup>™</sup> – broad IP protection worldwide up to 2036

#### **PROCESS**

Protects the manufacturing process for XR17™

pct application granted

patents granted
In USA, ZAF

Application pending in Eurasia, European Patent Office, AUS, CAN, CHN, HKG, IND, IDN, JPN, MYS, MEX, NZL, KOR, SGP and UKR

### **WATER-INSOLUBLE**

Protects poorly water-soluble
APIs¹ in combination with XR17™

patents granted across Eurasia, European Patent Office, AUS, CAN, CHN, JPN, KOR, MEX, MYS, NZL, UKR, USA, ZAF

**SPC** applied for in the EU, pending

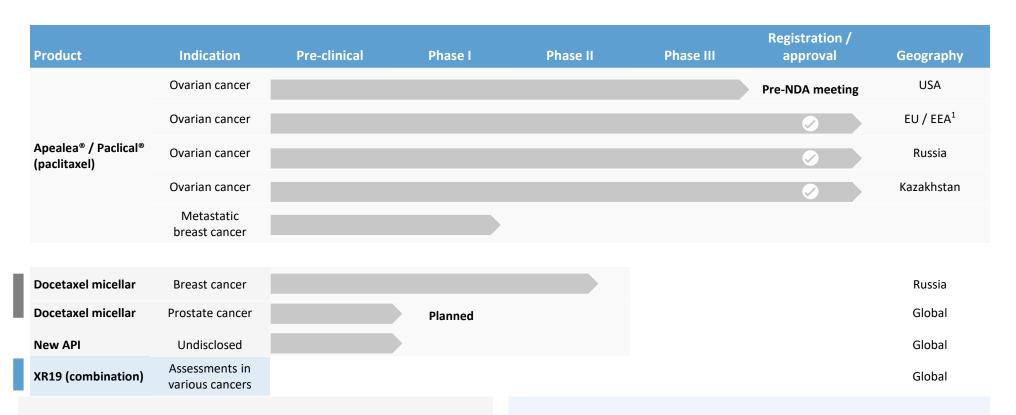
### **ANTICANCER COMPOSITIONS**

Protects XR17™ in combination with chemotherapeutic agents

patents granted
In USA, FRA, GBR,
DEU, CHN and HKG



# Building a diverse human health portfolio based on XR17™ platform technology



### **Docetaxel micellar**

- New solvent-free formulation of docetaxel
- Docetaxel (Taxotere\*) extensively used, including in the treatment of breast cancer, head and neck cancer, stomach cancer, prostate cancer and non-smallcell lung cancer

### **XR19**

- Potential combination of XR17™ and two frequently used cytostatic substances
- Combination therapies are standard treatment for many forms of cancer such as ovarian cancer, first-line breast cancer, prostate cancer and lung cancer



## Oasmia Pharmaceutical AB Animal Health Portfolio

Product	Indication	Pre-clinical	Clinical	Registration / approval	Geography
Paccal vet (paclitaxel)	Mammary Carcinoma (Canines)			No	US
Doxophos vet (doxorubicin)	Lymphoma (Canines)			No	US

### **Doxophos vet**

### **Potential next steps**

- Reapply for MUMS designation (expired 2018)
- Concurrence Field study protocol
- Application for Conditional Approval & field study

### **Paccal vet**

### **Potential Next steps**

- Concurrence Field study protocol
- Field study
- Application for full approval



# **Apealea® – offering improved treatment options**



**Approved in EU/EEA** for treatment of first relapse ovarian cancer<sup>l</sup> and in Russia for first line and relapsed ovarian cancer<sup>2</sup>

Current standard of care in Ovarian cancer is carboplatin + paclitaxel

Subset of patients cannot tolerate solvent-based paclitaxel

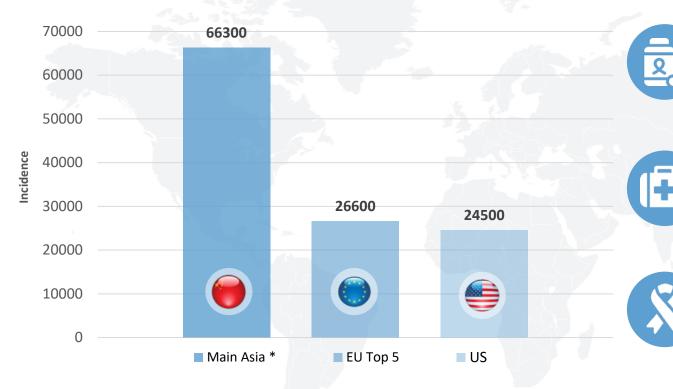
Apealea® is an IV injectable formulation using XR17<sup>TM</sup> which facilitates solubility of paclitaxel





# Apealea® – meeting unmet medical needs in selected ovarian cancer patients

### OVARIAN CANCER INCIDENCE<sup>1</sup>



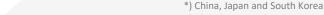




Approximately **70%** of women have a returning disease within three years after being diagnosed<sup>2</sup>. 5 year survival 47%<sup>3</sup>

The most used therapeutic agents against ovarian cancer are platinum analogs alone or in combination with paclitaxel<sup>4</sup>

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<sup>1)</sup> Global Cancer Observatory



<sup>2) &</sup>lt;u>Springerplus</u>. 2016; 5(1): 1197. Published online 2016 Jul 28. doi: <u>10.1186/s40064-016-2660-0</u>

<sup>3)</sup> J Natl Cancer Inst. 2019 Jan; 111(1): 60–68. Published online 2018 Apr 28. doi: 10.1093/jnci/djv071

<sup>4)</sup> ESMO guidelines: Annals of Oncology 30: 672-705, 2019 doi:10.1093/annonc/mdz062 Published online 2 May 2019

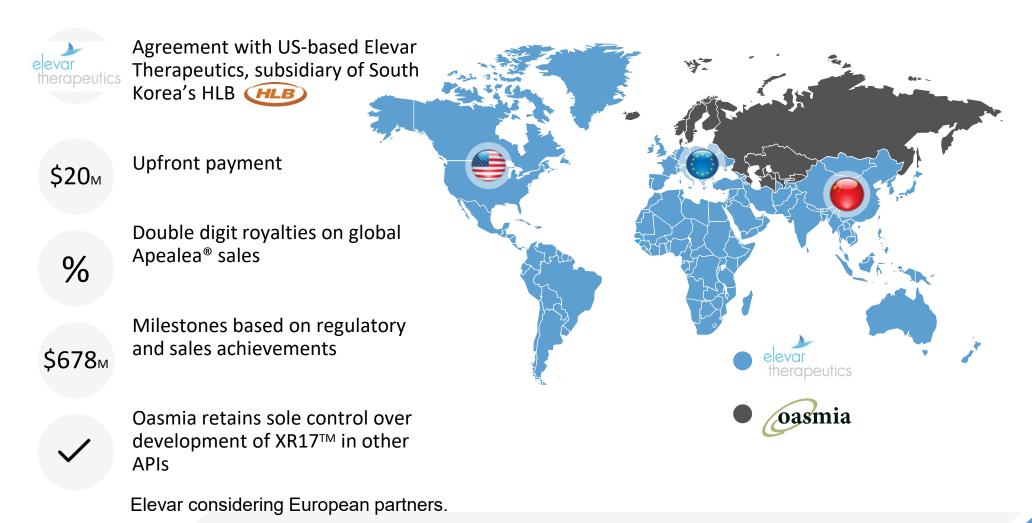
## Differentiation vs Abraxane and other paclitaxel products

Apealea® is the only non-cremophor drug approved for use in advanced stage ovarian cancer in the EU

Product	Apealea®	Taxol®	Abraxane®	Lipusu®	Genexol-PM® Korea
Company	Oasmia	BMS	Celgene	Luye	Samyang
Indication	Ovarian Cancer	Ovarian Cancer Breast Cancer NSCLC	Breast Cancer	Ovarian Cancer Breast Cancer NSCLC	Ovarian Cancer Breast Cancer NSCLC
Infusion Solution	Micellar Solution	Emulsion	Colloidal Suspension	Liposome	Micellar Solution
Particle Size	25nm	10-22nm	I30nm	400nm	~25nm
Excipient	XRI7	Cremophor EL	Human Albumin	Lecithin/Cholest erol	PEG-PDLLA
Dose	250mg/m <sup>2</sup>	175mg/m²	260mg/m <sup>2</sup>	175mg/m²	260mg/m <sup>2</sup>
Ratio (Excipient : API)	1.3:1.0	88.0:1.0	9.0:1.0	-	5.0:1.0
Infusion Time	lh	3h	<ih< th=""><th>3h</th><th>0.5h</th></ih<>	3h	0.5h
Pre-medication	Not mandatory	Yes	No	Yes	No
Hypersensitivity	No	Yes	No	Yes	No



# Apealea® – global partnership worth up to \$698m + royalties





## **Key value drivers**

### **Short Term 12 months**

- Docetaxel micellar clinical development plan
  - Phase 1 Study Initiation
- Review of Animal Health Business assets
- XR-17 Technology Platform Partnering
- M&A opportunities
- XR-19 Value Assessment

### Mid Term 12-24 months

- Apealea Royalties
- Docetaxel micellar Phase 1 Study Results
- Realisation of cost control measures
- M&A opportunities
- Transition to Speciality Pharma Company



## Strategic vision: Oasmia to become a significant speciality pharma Co.

- Proven ability to register an oncology drug
- Expand pipeline, including XR17™ technology
- Strong cash position
- Proven ability to negotiate substantial partnering deal
- Potential divestment of non-core assets
- New CEO & experienced board team

Platform to build a Sweden-based cash-flow positive specialty pharma leader

Well placed for M&A

Attractive in-licensing partner

