## **LIDDS** Pharma

# Addresses huge unmet medical needs in early-stage cancer treatment

Monica Wallter, CEO



### LIDDS is Addressing Key Healthcare Challenges

Short-acting drugs often require more frequent injections and hospital visits

Systemic administration routes often leads to toxicity and side effects

#### LIDDS approach with NanoZolid technology

#### **BENEFITS PATIENT & HEALTHCARE PROVIDER**

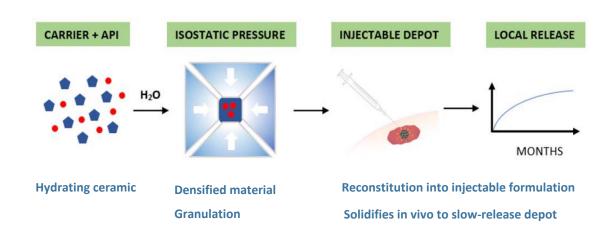
Higher efficacy could be reached Much less side-effects Fewer injections Less frequent hospital visits Improved Quality of Life

#### **BENEFITS PHARMA PARTNERS**

Prolonged patent protection to 2037 Improved compliance and patient satisfaction Re-vitalizing challenging projects using clinically validated technology

### The NanoZolid<sup>®</sup> Injectable Drug Delivery Platform Solves Challenges with Systemic Toxicity and Fast Acting Molecules

- NanoZolid<sup>®</sup> provides tailor-made and controlled releases of drugs up to 6 months or more. Side effects are avoided or significantly reduced
- The depot is injected in diseased tissue, intra-tumorally or given subcutaneously
- NanoZolid is fully biocompatible and is safely absorbed into the body allowing repeated injections
- NanoZolid<sup>®</sup> technology is clinically validated in several Phase II studies
- Provides long-term exclusivity and Life Cycle Management for drugs with expired or limited remaining patent protection
- NanoZolid<sup>®</sup> technology provides patent protection until 2037 in all major markets





### **Strong Patent Protection Until 2037**

In total, more than 130 patents have been obtained for the NanoZolid<sup>®</sup> platform

PATENT	PATENT	US	EU	REST OF THE WORLD
1 / 2004	Bioceramic compositions	Approved	Approved	Not filed
2 / 2006	Method to treat prostate cancer	Approved	Approved	Aus, Can, Chi, Jap, Mex, Russ, S Kor, Nor, Afr, Isr, Ind,
3/2007	Slow local drug release	Approved	Approved	Aus, Can, Chi, HK, Jap, Mex, Russ, S Kor, Isr, S. Afr, Ind,
4 / 2009	Mixing tool suspensions	Approved	Approved	<b>Aus, Can, Chi, Russ, Isr, Jap, Mex, S</b> Korea, Ind, S. Afr
5 / 2009	Steering of curing	Approved	Approved	<b>Aus, Can, Russ, Jap, HK, Mex, S.Kor,</b> Ind, Isr, S. Afr
6/2016	Manufacturing process	Approved	Approved	Aus, Bra, Can, China, Ind, Isr, Jap, Russ, S Afr, S Kor, Mex, Singapore
7 / 2020	NanoZolid pharmaceutical formulations	Approved	Filed	-
			-	-



### **Overview of Current Development Pipeline**

PROJECT	TARGET	FEASIBILITY	PRECLINICAL	PHASE I / II	PHASE IIb
NZ-2-HOF	Prostate cancer				
NZ-DTX	Malignant tumors				
NZ-IO-TLR9	Malignant tumors				
NZ-IO-STING	Malignant tumors				
NZ-J&J	Malignant tumors				
NZ-IO-003-004	Malignant tumors				
NZ-CHEMO	Malignant tumors		l		



### **LIDDS Main Projects**

	Liproca <sup>®</sup> Depot	Docetaxel/Chemo	NZ-TLR9	J&J Innovation
Indications	Prostate cancer	Lung cancer and other solid tumors	Head and neck cancer, prostate cancer, melanomas, lymphomas, and sarcomas	Oncology, indications undisclosed
Development phase	Phase IIb completed	Phase I ongoing	Preclinical program reported- planning Phase I study	Preclinical
Market size	Addressable market >\$3bn	Global lung cancer market worth \$37bn	More than 2 million patients diagnosed each year	Undisclosed
Partnering strategy	Out-licensed in China. Other markets partnering activities ongoing	Out-licensing after Phase I	Out-licensing after Phase I	Product license option

# Breakthrough R&D Agreement with Johnson & Johnson Enterprise Innovation Inc

- LIDDS will develop an oncology product for an undisclosed indication based on LIDDS drug delivery platform NanoZolid<sup>®</sup>
- The agreement includes an exclusive option for global product license
- This marks a breakthrough for LIDDS in terms of license the NanoZolid<sup>®</sup> technology to pharmaceutical companies

Johnson & Johnson INNOVATION



"I am pleased that we have signed this exciting collaboration. LIDDS favorable and clinically validated results using the NanoZolid® platform with different types of pharmaceutical substances, forms a bedrock for new and innovative oncology products."

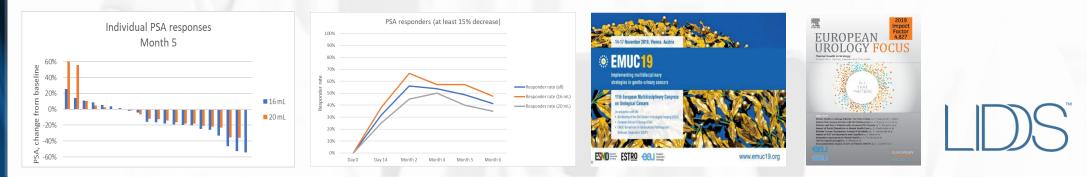
Monica Wallter, CEO of LIDDS



### Liproca Depot Phase IIb Study Indicates Prostate Cancer Control

#### Active Surveillance Patients with Low or Intermediate Risk Profile; 61 patients

- Primary objectives are successfully met and was well-tolerated and no hormonal side effects were noted :
  - Dose finding study objectives was achieved
  - Strong PSA response with 16 ml Liproca® Depot:
    - 90 % of patients had a PSA decrease
    - NanoZolid with 2-HOF delivers PSA efficacy for six months
    - 67 % of patients were responders, having more than 15% PSA decrease
- MRI analysis show that PI-RADS was unchanged or improved in all patients. In part II of the study, 7 out of 41 patients got lower PI-RADS score which indicates disease control
- Prostate volume decreased despite injection of 16-20 ml into prostate gland
- Open Label Study (OLE) indicates PSA effects for 10 months +, approx. one injection a year



### The NZ-DTX Phase I Study

#### Background

- Preclinical study shows that NZ-DTX is as efficient as systemic docetaxel in reducing tumor growth but with far less side effects
- Docetaxel is a commonly used chemotherapy: breast, head and neck, gastric, prostate and non small cell lung cancer (NSCLC)
- Severe side effects of docetaxel including anaphylaxis and systemic cytotoxicity
- How can NZ-DTX be used?
  - Monotherapy or in combination with different drugs to optimize effects
  - Neoadjuvant NZ-DTX before surgery/radiation
  - Treatment at diagnosis of tumor
  - Combination with systemic drugs, e.g. cytostatic / I-O
  - Palliative therapy
- Phase I study is ongoing
  - An open label dose-escalation and dose-expansion study well tolerated
  - Clinics include Karolinska University Hospital in Sweden, Herlev Hospital in Denmark, Kaunas University Hospital and Vilnius National Cancer Institute in Lithuania

### NZ-TRL9 Project - Planning for Phase I Study

- NanoZolid<sup>®</sup> formulated local acting TLR agonists offers greater treatment options, potentially higher efficacy and fewer injections and hospital visits while minimizing side-effects
- Also enables treatment of deep-lying cancer tumors and metastasizing tumors, e.g. head and neck cancer, prostate cancer, melanomas, lymphomas, and sarcomas
- Major commercial opportunity as NanoZolid is solving the resolving the problem with a fastacting TLR9 molecule - more than 2 million cancer patients are diagnosed each year
- Scientific Review article by a leading research group in US describes LIDDS as the only company developing an intra-tumoral TLR9 product
- Promising preclinical results using a TLR9 agonist formulated with NanoZolid<sup>®</sup>
  - Reduction of tumor growth
  - Increased survival
  - Prominent antitumoral immune response
  - At least six weeks efficacy
- LIDDS is planning a Phase I clinical trial using NanoZolid<sup>®</sup> combined with a TLR9- agonist to start in 2021, possibly together with a checkpoint inhibitor

### The Drug Delivery Market is growing

- Sweden is on the frontline of the drug delivery market
- One of the fastest growing subsegments within the life sciences industry globally
- Market driven by an increased prevalence of chronic diseases, increased demand for advanced drug administration and increased demand for immuno-oncology drugs

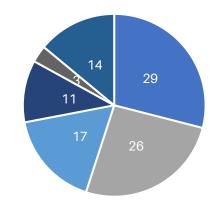
#### 50 40 **7% CAGR** 35 Growth 30 25 45 20 15 26 2019 2027

#### **Billion USD**

Swedish licensing deals in the drug delivery market 2019-2021\*:

- Upfront and milestone payments: 30-680 MUSD (average: 179 MUSD and median: 72 MUSD)
- **Royalty payments: 5-20%**

\*) Including licensors; Lipidor, Oasmia, Affibody, Calliditas, Camurus, Klaria, and Moberg Pharma



- Oncology
- Neurology
- Infections
- Ophthalmology
- Metobolism
- Other



### **LIDDS Addressable Markets**

Prostate cancerLung cancer and solid tumours*Head and neck cancer, prostate cancer, lymphomas, and sarcomasNew cases per year: 1 414 300 Deaths per year: 375 300New cases per year: 2 206 800 Deaths per year: 1 796 100Head and neck cancer New cases per year: 790 000 Deaths per year: 400 000Market value 2023: USD 8.3bn Addressable market: 420 000 patients annuallyMarket value 2025: USD 37bn Addressable market: 200 000 patients annuallyMarket value 2023: USD 8.3bn Addressable market: 200 000 patients annuallyMarket value 2023: USD 37bn Addressable market: 200 000 patients annually	Late-stage clinical development	Early-stage clinical development	Preclinical development
New cases per year: 1 414 300 Deaths per year: 375 300New cases per year: 2 206 800 Deaths per year: 1 796 100New cases per year: 790 000 Deaths per year: 400 000Market value 2023: USD 8.3bn Addressable market: 420 000 patients enpryeally.Market value 2025: USD 37bn Addressable market: 200 000 patients enpryeally.Market value 2025: USD 37bn Addressable market: 200 000Breast cancer New cases per year: 2 261 419 Deaths per year: 684 996	Prostate cancer	<u> </u>	prostate cancer, lymphomas,
Market value 2023: USD 8.3bn Addressable market: 420 000 Retients appually.		1 2	New cases per year: 790 000 Deaths per year: 400 000
Deaths per year: 155 539	Addressable market: 420 000	Addressable market: 200 000	New cases per year: 2 261 419 Deaths per year: 684 996 Lymphomas and sarcomas New cases per year: 293 761

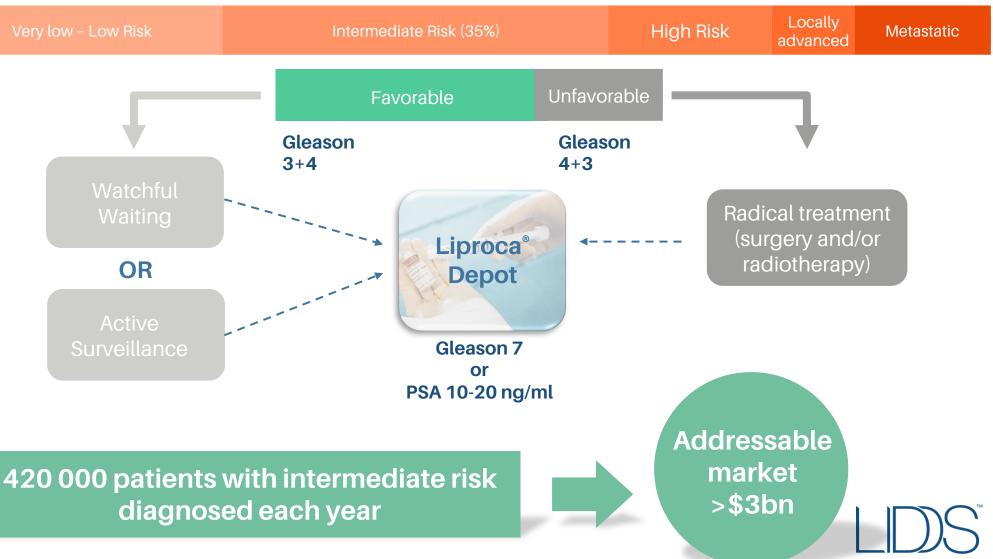
 $\star)$  Head & neck, breast and prostate cancer

Source: World Cancer Research Fund, 2018, Cancer Research UK, Prostate Smart, PharmaPoint: Prostate Cancer - Global Drug Forecast and Market Analysis to 2023.



### Liproca® Depot Targets Intermediate Risk Group





### LIDDS Has Proved its Licensing Strategy

- LIDDS out licenses the company's proprietary projects after the preclinical phase or after completing initial clinical trials
- Out-licensing after preclinical or phase I/II minimizes the own investments for LIDDS and provides a positive cash flow significantly faster than if the company on its own would take the project all the way to the market
- Pharmaceutical companies can also license the NanoZolid<sup>®</sup> technology for its own drugs

### Breakthrough R&D agreement with Johnson & Johnson Enterprise Innovation Inc.

 LIDDS will develop an oncology product based on the NanoZolid<sup>®</sup> technology. R&D agreement includes an option for an exclusive licensing agreement

### License agreement with Puheng Pharma for Liproca<sup>®</sup> Depot

- Exclusive license for Mainland China signed in 2018
- Puheng Pharma's sales network covers more than 5 700 hospitals in China
- LIDDS is together with Puheng Pharma currently preparing documentation for an international Phase III multicenter study
- Licensing of Liproca<sup>®</sup> Depot for other markets continues

### LIDDS Is in a Growth & Expansion Momentum Significant Value Inflection Points Ahead

- NZ-DTX-001 study update
- Preparations for Phase III international multicenter study
- Out-licensing of Liproca<sup>®</sup> Depot in other major markets; US, Europe, and Asia
- Main Market listing
- Initiation of Phase I study for the NZ-TLR9 project
- Update on non-disclosed NZ-IO feasibility projects
- Organization expansion



**EXPECTED MILESTONES** 



### **LIDDS Summary**

Proprietary platform technology with broad product portfolio The NanoZolid<sup>®</sup> technology constitutes a bedrock for building a broad portfolio of pharmaceutical projects, which diversifies risk and provides good prospects for future revenue

Lead candidate in late stage in prostate cancer

Phase IIb study in prostate cancer finalized in 2019 – the primary endpoints were successfully met. Licensing agreement for Liproca Depot in place with Chinese license partner, Puheng Pharma. Out-licensing to other major markets ongoing

Chemo & immunotherapy projects

LIDDS intratumoral formulations can be combined with several cytotoxic drugs and immunotherapies offering greater treatment options, potentially higher efficacy, fewer injections and less hospital visits while minimizing side-effects

**Robust patent protection** 

More than 130 national patents have so far been granted within seven patent families with comprehensive patent protection for the NanoZolid<sup>®</sup> platform in all major markets until 2037



# Thank you!

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