

## Investor meeting October 9<sup>th</sup>, 2023



### **Experienced Team in Pharmaceutical and Business Development**





#### **David Westberg**

**CEO** 

Education: MSc KTH Royal Institute of Technology













Co-founder and head of IP/Patent Education: PhD University of Uppsala

Co-founder and Head of Production

Education: PhD University of Uppsala





**Björn Svanström** 

**CFO** 

Education: MBA Stockholm School of

Economics







**Bengt Gustavsson** 

Medical director

Education: PhD University of Uppsala











Mårten Rooth

and ALD R&D

Head of Quality Assurance

Education: MSc KTH Royal Institute of Technology





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#### **Otto Skolling**

**Director Business Development** 

Education: MSc KTH Royal Institute of Technology



SEB





#### **Sven Undeland**

**Director Strategic Market Analysis** Education: MSc University of Karlstad





#### Marie Gårdmark

**Director Regulatory Affairs** Education: PhD M Sci Pharm







#### Kristine Bäck

Senior project leader

Education: BSc in pharmacy University of Uppsala





**Joel Hellrup** 

Head of Pharmaceutical R&D

Education: PhD M University of Uppsala





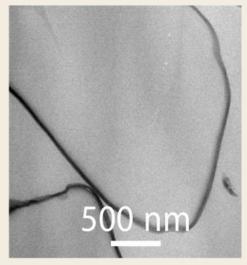


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### **PharmaShell®**



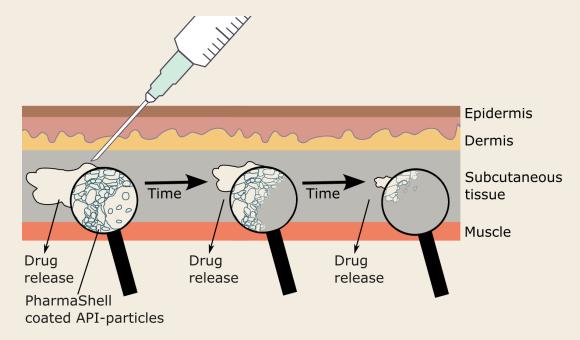
The high drug load delivery system enabling the next generation long-acting injectables through atomic layer precision



TEM image of PharmaShell® coated API particle



Illustration of PharmaShell®'s nanometer thick coatings



- $\rightarrow$  Drug delivery system encasing active substance microparticles (Dv50 5-15 µm) with extremely thin coatings (10 50 nm).
- → System based on Atomic Layer Deposition (ALD) technology, enabling Nanexa to control the thickness of the drug's shell with high precision and determine the rate of release of the drug in advance

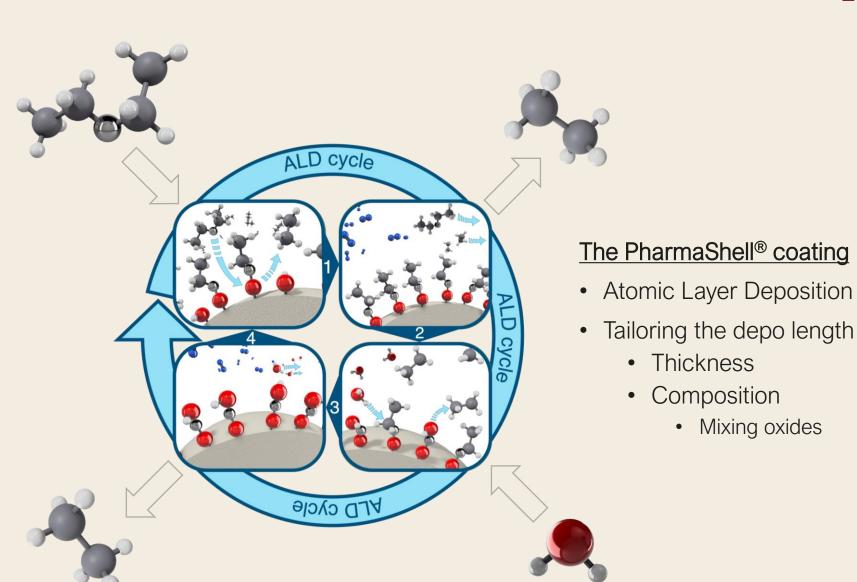
- → Release rate determined by dissolution of the inorganic oxide coatings into its ions
- → Controlled drug release with PK profiles providing high exposure
- → About 20 small molecules successfully coated as well as peptides and monoclonal antibodies.

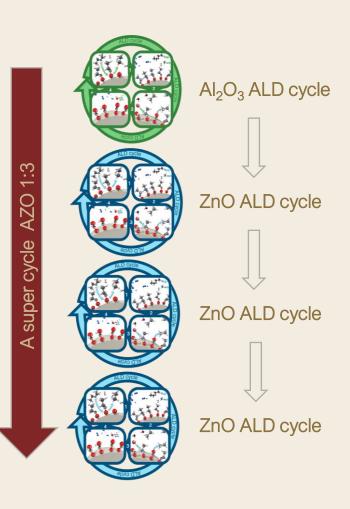
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CONFIDENTIAL

## PharmaShell® - Technique

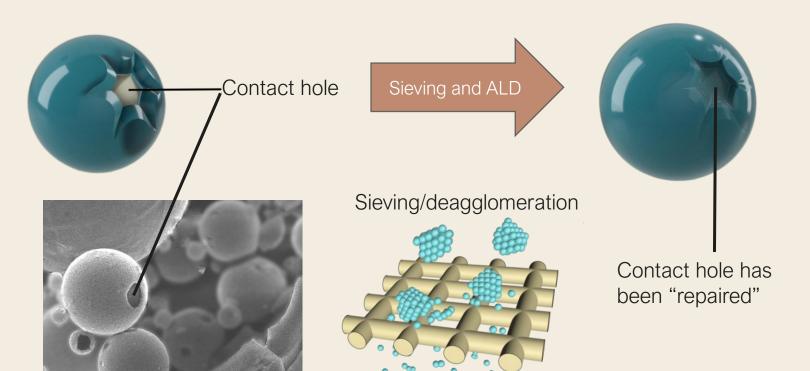






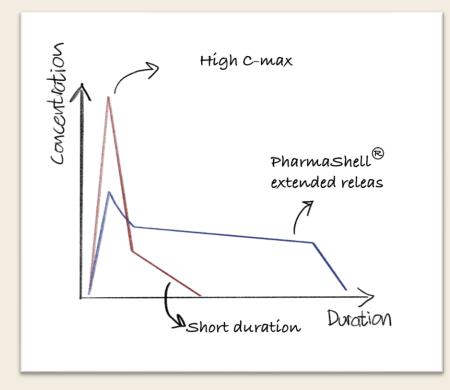


## PharmaShell® – technique



#### To get the desired depo

- Low defect density
- Right composition





### **Formulation**

- PharmaShell® formulations consist of
  - Coated particles <u>and</u> vehicle
- Optimal vehicle
  - Easily suspends particles
  - Maintain high stability of suspension
  - Easy to administer
  - High tissue tolerability





## **Preclinical investigations**

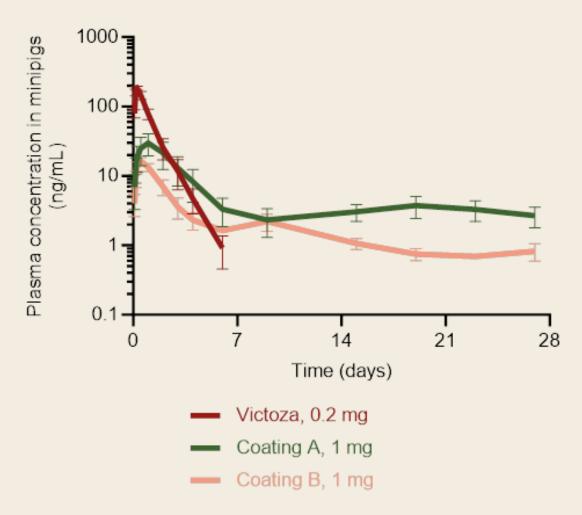
- Animal models give understanding of how formulations work with regards to:
  - Pharmacokinetics
    - Plasma samples are collected and analysed with regards to API
  - Tolerability
    - Injection sites are studied visually and with histopathology
- Preclinical studies are performed at CROs
  - Charles River Laboratories, UK
  - Scantox, Denmark



## Preclinical example

Controlled release of liraglutide with PharmaShell® showed in the first preclinical study in mini-pigs

- Single doses of two different NEX-22 formulations in different doses with plasma exposure over 28 days for NEX-22, compared to a few days for a formulation with liraglutide without the PharmaShell<sup>®</sup> coating
- Overall low variability in release from NEX-22 between animals



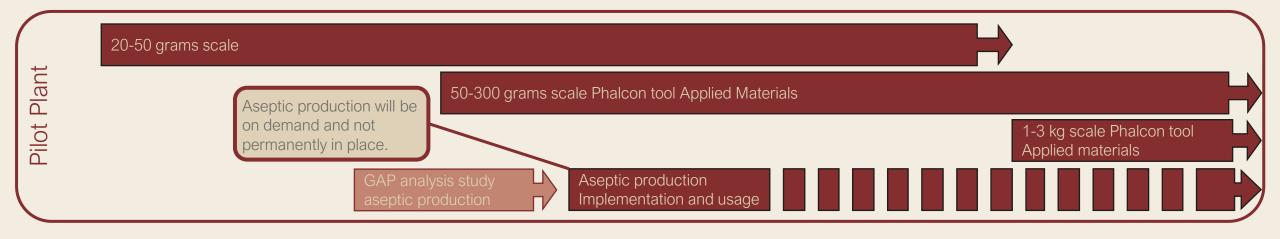
### PharmaShell® system achievements



	Small molecule	Peptide	mAbs	NEX-22	NEX-20	NEX-18	Partner projects
PharmaShell in combination wi allows for limited requirements compounds → Lower risk, proj	for clinical progr	ams compared	d to new	<b>✓</b>		<b>✓</b>	
Prolonged release confirmed in vitro			/	-	/	/	
1-week release confirmed in animals						1	
1-month or longer release confirmed in animals				<b>✓</b>	<b>/</b>		
Controlled burst release confirmed in animals	<b>/</b>	/		<b>✓</b>	/	/	
1-week release profile confirmed in clinical study						/	
1-month release profile confirmed in clinical study					<b>/</b>		
Receptor affinity after PharmaShell process Confirmed Invitro							



## **Pilot Plant Scaleup**



3-50 grams scale is continuously available as R&D material





#### Pilot Plant – Production of CTM

- Flexible design, grade of rooms and isolators determined by project demand.
  - Terminally sterilized product
  - Aseptic production (not implemented)

#### QC – Release testing of CTM

- In-house capabilities
  - Analysis of raw materials
  - Analysis of coated materials
  - Analysis of biologics
  - Assay and impurities, coating composition, drug release testing, particle size, surface area/morphology





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#### **ACHIEVEMENTS**

- Readout from preclinical studies confirming extended PK profile
- CRO selection

#### **MILESTONES GOING FORWARD**

- Final selection of clinical formulation
- Clinical Protocol finalised
- CTA submission
- GMP batch manufacturing
- Phase 1 study readout
- FDA meeting
- Start Phase 2 study

### **NEX-22** project: Type-2 diabetes



One single injection of NEX-22 with Nanexa's unique PharmaShell® technology can replace daily injections with liraglutide



- Currently in pre-clinical phase
- Clinical Trial Application for first NEX-22 clinical study to be submitted in Q4 2023
- Phase 1 PK study to start in Q1 2024 in patients
- CRO Profil in Germany specialized in Type-2 diabetes studies



#### **ACHIEVEMENTS**

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#### **ACHIEVEMENTS**

- GLP tox for subcutaneous administration
- GMP manufacturing and stability studies of CTM
- CTA approval
- Phase 1 study readout in healthy volunteers

#### **ACHIEVEMENTS**

- Preclinical PK studies
- GMP manufacturing and stability studies of CTM
- CTA approval
- Phase 1 study in MDS patients
- Identification of preclinical model for efficacy superiority



#### **ACHIEVEMENTS**

- GLP tox for subcutaneous administration
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- Phase 1 study readout in healthy volunteers

#### **MILESTONES GOING FORWARD**

- Successful formulation optimization confirmed in preclinical studies
- Preparation of Phase 1b study
- Initiation of Phase 1b study in patients

#### **NEX-20** project: Multiple Myeloma



One single injection of NEX-20 controlled-release, long-acting lenalidomide can replace daily dosing over a 28-day treatment cycle



- Phase 1 study NEX-20-01 completed September 2023
- Available results
  - The formulation studied shows a controlled release pharmacokinetic profile close to that required for once-monthly dosing
  - Local reactions observed with redness and/or swelling corresponding to the area of injection ranging from mild to moderate from lower to higher doses with the given formulation of. All reactions subsided during the study period.

### NEX-18



## **NEX-18 project: Myelodysplastic syndrome (MDS)**

fait fait fait fait fait fait fait fait



NEX-18 will offer a single monthly injection – replacing the seven daily doses per treatment cycle currently needed

#### **ACHIEVEMENTS**

- Preclinical PK studies
- GMP manufacturing and stability studies of CTM
- CTA approval
- Phase 1 study in MDS patients
- Identification of preclinical model for efficacy superiority

#### MILESTONES GOING FORWARD

- Preclinical efficacy superiority study
- Formulation development with preclinical studies
- Preparation Phase 1b

**NEX-22** 

NEX-20

**NEX-18** 



#### **ACHIEVEMENTS**

- Readout from preclinical studies confirming extended PK profile
- CRO selection

#### **MILESTONES GOING FORWARD**

- Final selection of clinical formulation
- Clinical Protocol finalised
- CTA submission
- GMP batch manufacturing
- Phase 1 study readout
- FDA meeting

75 MSEK

Start Phase 2 study

**121 MSEK** 

#### **ACHIEVEMENTS**

- GLP tox for subcutaneous administration
- GMP manufacturing and stability studies
- Stability study of CTM
- CTA approval
- Phase 1 study readout in healthy volunteers

#### MILESTONES GOING FORWARD

- Successful formulation optimization confirmed in preclinical studies
- Preparation of Phase 1b study
- Initiation of Phase 1b study in patients

#### **ACHIEVEMENTS**

- Preclinical PK studies
- GMP manufacturing and stability studies of CTM
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#### **MILESTONES GOING FORWARD**

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**121 MSEK** 

 Preclinical efficacy superiority study

- Formulation development with preclinical studies
- Preparation Phase 1b





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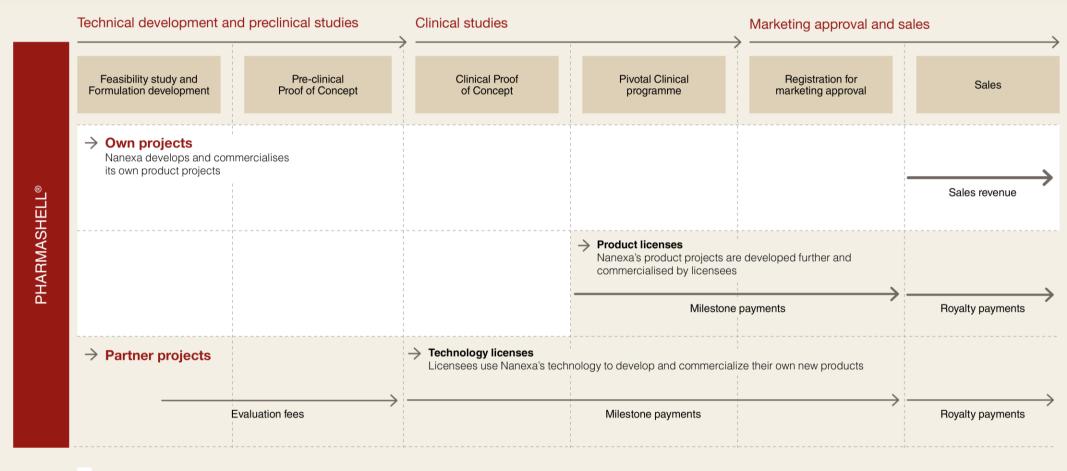
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"Nanexa will be a world-leading drug development company for Long-Acting-Injectables, developing a new generation of innovative drug products enabled by our PharmaShell® ALD technology"



## Revenue model: Driving progress towards commercialisation





In-house development

### Depot drugs can deliver smarter treatments





#### **PATIENTS**

- → Make it easier for the patient
- → Reduce sideeffects associated with immediate release administration



#### **HEALTHCARE**

- → Greater adherence
- → Greater efficacy for the treatment



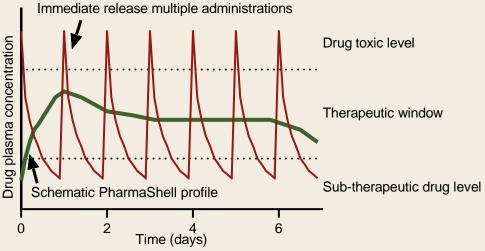
#### **PAYERS**

- → Fewer patient visits to clinics save money for society
- → More costeffective treatment



#### SUSTAINABILITY

- → Reduced risk of medication mishandling
- → Reduces negative environmental impact and manufacturing cost by minimizing use of injection device components



Concept data illustrating the avoidance of high and low plasma concentrations by using PharmaShell®

- Immediate release formulations are converted into long-acting injectables with enhanced properties
- Drug concentrations are kept within the therapeutic window to achieve the maximum benefit

# Investment highlights – low risk development model based on technology with significant benefits for patients and society





#### Unique technology with significant benefits

- PharmaShell® enabling controlled release of drug substances over days, weeks, or even months
- Long-acting drug delivery system with significant benefits for patients and society improving e.g. compliance and quality of life



#### Low risk model despite early-stage development...

- Nanexa is focusing on new drugs based on already approved substances where the patent has expired
- PharmaShell drug delivery system taken into clinical studies in two oncology indications



#### ...with huge potential upside

- Successfully commercialised substances using PharmaShell® will be protected by patents
- Focuses on markets with huge potential e.g. diabetes, obesity and multiple myeloma currently three own projects ongoing



#### Novo Nordisk agreement – huge potential upside - highlight additional upside from partnerships

- Licensing PharmaShell® technology potential to cost-efficiently capture additional areas, e.g. types of substances and indication areas
- License agreements usually includes signing fees, milestone payments and royalties



#### State-of-the-art GMP<sup>1)</sup> production plant in place

- Possible to source clinical trial material for phase I-III to own and partner projects
- Ability to rapidly scale up drug manufacturing



#### Experienced management and board of directors

- Management with extensive expertise in pharma development, ALD<sup>2)</sup>, and business development
- BoD with significant experience in pharma and business development, and exceptional international networks
- World class scientific boards for each internal project

## PharmaShell® patent portfolio



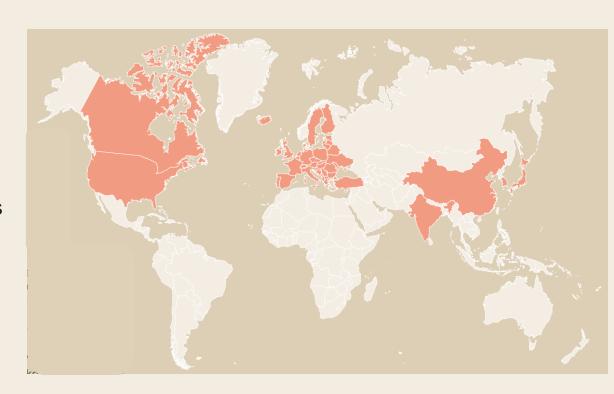


Long term strategy to build strong patent portfolio to enable consistent value growth



Patent strategy covering all major markets

- →At present 14 patent families with granted patents from two of those
- →Patent strategy will enable multiple licenses to partners in addition to inhouse projects.
- →Covering particle generation, ALD processing and product formulations
- →R&D focused on making patented inventions
- →Several patent applications pending with potential patent protection beyond 2040
- →Patent strategy to enable patent listings in Orange book for own & partner projects



## PharmaShell® – Product candidates in multiple indications – huge potential





Strong internal pipeline of projects with significant benefits for patients, enabled by innovative technologies

Addressing major markets and with potential for peak sales well over USD 1bn<sup>3)</sup>

NEX-22 has potential to reach peak sales of multibillion USD

Multiple myeloma

<sup>2)</sup> Myelodysplastic syndrome

<sup>3)</sup> Xplico report commissioned by Nanexa

## GLP-1 & GLP-1/GIP market forecast 9MM in type 2 diabetes

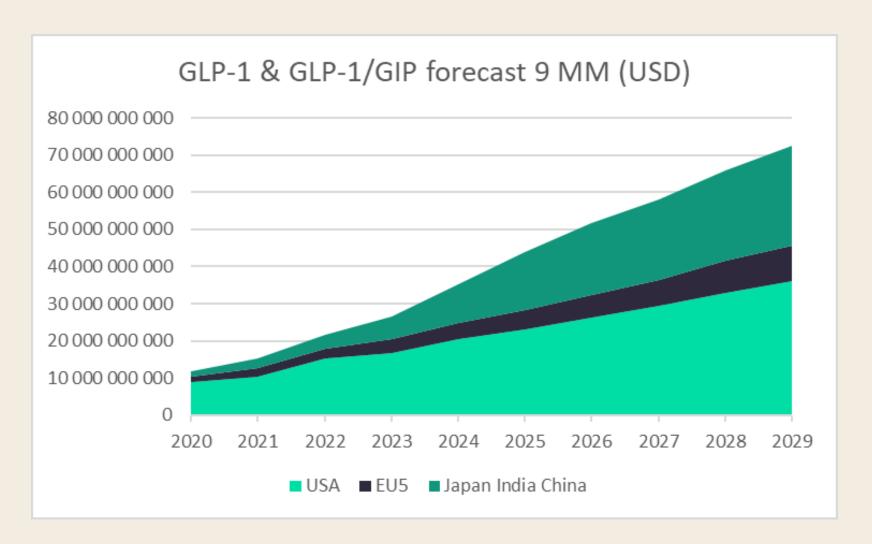


#### USD >130bn

sales of drugs for T2D expected by 2029

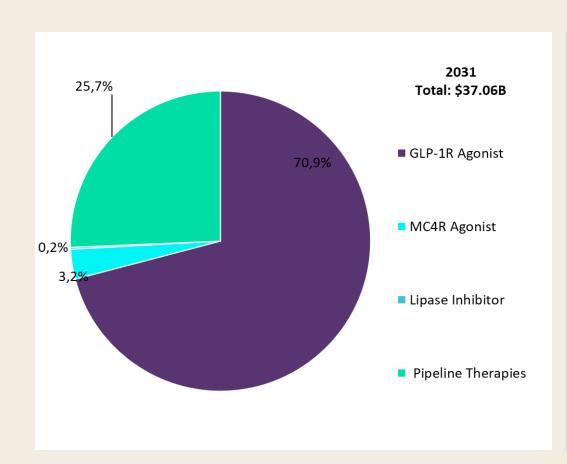
#### USD >70bn

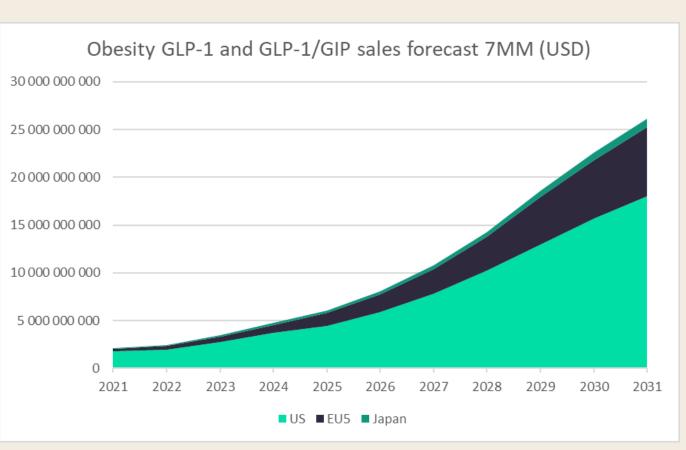
sales of GLP-1 analogues expected by 2029



## **GLP-1 & GLP-1/GIP market forecast 7MM in obesity**







Source: Global Data Type 2 Diabetes forecast Dec 2022

## **Exclusivity and evaluation agreement with directed share issue to Novo Nordisk**



#### **Exclusivity and evaluation agreement**



Evaluation Agreement signed in Dec 2022, under which Novo Nordisk will provide Nanexa with its products and Nanexa will develop a long-acting injectable using PharmaShell®. The new formulation will be evaluated in preclinical studies by Novo Nordisk



Nanexa will receive payments of SEK ~46.1m for providing Novo Nordisk exclusivity and performing work under the Evaluation Agreement, whereof SEK ~41.7m was paid upfront

#### **Directed share issue**



Novo Nordisk invested SEK 17.2m in Nanexa in a directed share issue at a premium of 33 percent versus the Company's closing price prior to the signing



Following the directed share issue, Novo Nordisk is the largest shareholder in Nanexa, with 16.5 percent of the Company's shares



## Experienced BoD in Pharma and Business Development, with an exceptional international network

#### **Board of directors**



**Göran Ando Chairman of the Board**Education: MD University of Linköping







Magnus Westgren Board director Education: MD PhD Karolinska University Hospital





Richard Davis
Board director
Education:
PhD University of Leicester













Birgit Stattin Norinder
Board director
Education:
MSc University of Uppsala







Jakob Dynnes Hansen
Board director
Education: MSc in Economics
from University of
Copenhagen and an MBA
from INSEAD.



### Transaction structure and timetable



#### **Terms**

- Existing shareholders in Nanexa have preferential rights to subscribe for two (2) new common share per one (1) existing share, an issue ratio of 2:1.
  - The rights issue comprises of up to 121,318,524 new common shares.
- The subscription price has been set to SEK 1 per new common share, resulting in total proceeds of approximately SEK 121 million, before issue costs.

#### **Subscription undertakings and guarantees**

- The rights issue is covered to SEK 75m with subscription undertakings with or without preferential rights and by external guarantors.
  - Novo Nordisk has undertaken to subscribe shares for SEK 20m, provided they not own more than 19.9% post issue.
  - Subscription undertakings from Novo Nordisk, Board and Management and existing shareholders amount to SEK 24m.
  - The remaining part up to SEK 75 m is covered by external guarantee commitments

#### Indicative timetable for rights issue

21 September	Announcement
6 October	Last day of trading in Nanaxa's shares including the right to receive subscription rights
9 October	First day of trading in Nanexa's shares excluding the right to receive subscription rights
11 October	Date for publication of the prospectus
12 October - 23 October	Trading in subscription rights
12 October - 26 October	Subscription period
30 October	Announcement of the final outcome of the rights issue

## Nanexa in a position for commercialisation and substantial revenues in a one to two-year perspective



#### Use of proceeds 75 MSEK

- NEX-22
  - Read-out Phase I PK study
  - Pre-IND FDA
- NEX-20
  - Formulation optimization NEX-20 ready
  - Preparation of Phase Ib PK study NEX-20
- PharmaShell formulation development
  - Broaden its use in biologics, e.g. peptides, proteins and monoclonal antibodies
  - Ensure minimal and acceptable tissue impact at injection site
- Novo Nordisk preclinical data available
- Partner project converted to development/license agreement

#### Use of proceeds 121 MSEK

(Additional milestones to 75 MSEK financing)

- Novo Nordisk evaluation completed
- NEX-22
  - Initiation of Phase II
- NEX-20
  - Initiation of Phase Ib PK study NEX-20
- NEX-18 preclinical superior efficacy study and formulation development completed
- Preparation, selection and start of NEX-24 project





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## Regulatory strategy - market approval

- Short-cut to regulatory approval using:
  - US: Section 505(b)(2)
  - EU: Art 10(3) or Art 8(3) mixed market
- Approval build on:
  - Bridge to Agency's benefit/risk decision for Reference Drug
  - Nanexas own clinical data supporting any difference to the Reference Drug
- Potential for 3-year (US) and 8 (+2) years (EU) data exclusivity



## Regulatory strategy before approval

- Ensure feed-back from FDA and EMA before major decisions
  - FDA meetings Nanexa in collaboration with US regulatory consultant with long experience from 505(b)(2) submissions
  - Meeting with EU authorities as needed
- Clinical trial applications approved by Swedish MPA for NEX-18 and NEX-20
  - No major objections on IMPD
- Nanexa GMP-facility approved by MPA 2022





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### Clinical Development, Medical **Affairs & HEOR**



#### **Economic value**

#### Clinical efficacy/ effectiveness

#### **Optimize** evidence aeneration

- Early payer Ad Board
- Input to CTs and US EAP RWD studies
- PRO strategy
- Publications

#### Translate clinical value into monetary terms

- Literature review
- Budget Impact Model
- Cost-Effectiveness Model

#### Value communication

#### Communicate clinical and economic value

- Value propositions
- GVD
- Publications

#### **Patient access**

#### **Optimize** patient access

- Pre AMCP dossier
- Early HTA interactions (NICE/GB-A)
- Pricing study

#### Disease state

#### Establish disease burden

- Literature review
- US RWD
- Publications

need

**Identify unmet** 

- Literature review
- US RWD

**Unmet need** 

Publications

- Preclin Collaboration
- Global KOL Ad Boards
- Patient Advocacy Groups
- Scientific Communication Plan
- National KOL Ad Boards
- Medical Information Plan
- Field-based Medical Affairs
- Academic Collaboration
- Global KOL Ad Boards
- RWD studies

Scientific Messaging Platform

Global KOL Ad Boards

Preclinical and Phase I

Phase II

Phase III/Registration

Phase IV New Indications





## **NEX-22** project: Type-2 diabetes

- A new long-acting formulation of Liraglutide enabling monthly injections
- Currently in pre-clinical phase
- CTA for first clinical PK study to be submitted Q4-23
- Phase I PK study read out 2024 Specialist CRO (Profil GmbH)
- Relatively short efficacy studies, with accepted surrogate marker (HbA1c) for measurement of long-time blood sugar levels Can be used in both Phase II and Phase III

## **Option:**

To expand long-acting liraglutide into obesity treatment
To formulate other GLP-1's with PharmaShell for these indications

## **NEX-22** – Improved treatment of type-2 diabetes



#### Project description

- Monthly depot of the peptide liraglutide
- Patients with low adherence to treatment will be main target group, but the majority of all patients will see this as an attractive product
- Less than 50% of patients with diabetes achieve the glycemic goals recommended by the American Diabetes Association<sup>1</sup>
- Improved treatment efficacy and therefore significant savings for healthcare and society, and most importantly healthier patients
- Strong interest in developing long-acting GLP-1 products from the major pharmaceutical companies

#### Benefit to patients



One single injection of NEX-22 with Nanexa's unique PharmaShell® technology can replace daily injections with **liraglutide** 



#### Expert Advice – Key opinion leaders

Prof. John Buse - University of North Carolina, Chapel Hill, NC, USA

**Prof. Jan Bolinder** – Karolinska Institute, Sweden

Prof. Deepak L Bhatt - Harvard Medical School, Boston, MA, USA

Evaluation of substance	Formulation development	Preclinical development	Phase I	Phase Ib/II	Phase II	Approval

■ Completed In progress About to happen

## **NEX-20**



## **NEX-20** project: Multiple Myeloma

- Once monthly injection formulation of Lenalidomide
- First Phase I study just completed preparation of Phase Ib-study
- Activities together with global patient advocacy group, the International Myeloma Foundation (IMF), started during 2023
- Systematic Literature Review (SLR) accepted at ISPOR EU in Copenhagen, November 2023, as oral poster presentation

## **Option:**

To expand indication to treatment of Newly Diagnosed Multiple Myeloma (NDMM)

## **NEX-20** – Improved adherence for patients with multiple myeloma



#### Project description

- Monthly depot of Lenalidomide
- Patients with low adherence to maintenance treatment will be main target group, but expansion possible, as Lenalidomide is a backbone agent in several lines
- Adherence to treatment with Lenalidomide might be as low as 38%1
- Improved treatment efficacy and therefore significant savings for healthcare and society, and most importantly healthier patients

#### Benefit to patients



One single injection of NEX-20 with Nanexa's unique PharmaShell® technology can replace daily oral capsules



#### Expert Advice – Key opinion leaders

Prof. Xavier Leleu – CHU Poitiers, Poitiers, France

Prof. Karthik Ramamsamy – Oxford University Hospitals NHS Trust, Oxford, UK

**Prof. Marie von Lilienfeld-Toal** – Universitätsklinikum Jena, Jena, Germany

Dr. Christopher Maisel - Baylor University Medical Center, Dallas, TX, USA

Prof. Axel Glasmacher - University of Bonn, Bonn, Germany

Evaluation of substance	Formulation development	Preclinical development	Phase I	Phase lb/ll	Phase II	Approval

■ Completed In progress About to happen

<sup>40</sup> 





## **NEX-18** project: Myelodysplastic Syndrome (MDS)

- A new long-acting formulation of Azacitidine enabling weekly injection
- Currently in pre-clinical phase
- Advice from global Ad Board to generate preclinical data on the likelihood of NEX-18 being more efficacious than existing formulations of Azacitidine Epigenetic effect likely better with continuous dosing
- Discussions with leading academic research group

## **Option:**

To expand length of depo formulation

To expand indication to patients with precious failure on HMA-treatment

## **NEX-18 – Improved treatment of MDS**



#### Project description

■ Completed In progress

- A single monthly injection of Azacitidine
- All patients in need of Azacitidine will be main target group
- Improved health resource utilization (and possibly treatment efficacy). and therefore significant savings for healthcare and society, and most importantly healthier patients
- Discussing/designing preclinical studies to show superior efficacy as compared to marketed azacitidine

About to happen

#### Benefit to patients



One single injection of NEX-18 with Nanexa's unique PharmaShell® technology can replace seven daily injections



#### Expert Advice – Key opinion leaders

Prof. Robert Peter Gale - Imperial College London, London, UK

Prof. Axel Glasmacher – University of Bonn, Bonn, Germany

**Prof. Kirsten Grønbæk** - Copenhagen University Hospital, Copenhagen, Denmark.

**Prof. Uwe Platzbecker** - Leipzig University Hospital, Leipzig, Germany.

Dr. Magnus Tobiasson - Karolinska Institute, Stockholm, Sweden.

Dr. José Miguel Torregrosa Diaz - University Hospital of Poitiers, Poitiers, France.

Evaluation of substance	Process development	Formulation development	Preclinical development	Phase I	Phase lb/II	Phase II	Approval





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## Partnering & presentations 2023 X

 $Q_1 - 23$ 

 $Q_2$ -23

 $Q_3 - 23$ 

 $Q_{4}$ -23

BioEurope Spring Mar. 20-22 Basel

Barrier Lugano

- PODD: Oral presentation and booth
- DDF: Presentation

14th Global Drug delivery & Formulation May.31 – June 2 Berlin

Bio International Jun. 5-8 June Boston

Controlled release society July. 24 - 28 Las Vegas

Partnering opportunities in drug delivery Oct. 16-17 Boston

BioEurope Nov. 6-8 Munich

CHPI Oct. 24 - 26 Barcelona

# Process to agreements, example X of feasibility program

- Each conferance generates 10-20 meetings and 3-5 leads that generates new agreements
- Nanexa have ongoing discussions-feasibility studies or finalized feasibility studies with 8 of 10 top Pharma companies

Estimated Timelines: Gant chart	Months after start														
Study item	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1: Method transfer and development	х	X	X	X											
2: Coating feasibility		Х	Х												
3: Powder formulation				х	X	X	X								
4: Suspension formulation						х	х								
5: Stability of suspension						Х	Х								
6: Stability of powder formulation						х	х								
7: Rodent in vivo studies								х	х	Х					
8: Manufacturing for pig in vivo											Х	х			
9: Stability of lead candidates												x	X	x	
10: Pig in vivo studies													Х	Х	Х

## PharmaShell – Benchmark Deals



## Similar technology deals benchmark our deal assumptions

Licensor	Licensee	Deal Headline	Therapeutic Modality	Year	Adjusted Total Deal Value	Adjusted Upfront Cash	Total Milestone Payments	Royalty
Camurus AB	Ra Pharmaceuticals Inc.	Camurus grants Ra Pharma exclusive, w orldw ide rights to FluidCrystal extended release formulation of Zilucoplan to treat complement-mediated disorders	Macrocyclic peptides; Sustained release formulation	2019	71,500,000	2,000,000	69,500,000	Tiered single digit royalties
Lyndra Inc.	Allergan plc	Allergan partners with Lyndra to develop once- weekly, oral formulations of Allergan's treatments to treat Alzheimer's disease using Lyndra's sustained-release technology	Sustained release formulation	2017	52,500,000	7,500,000	90,000,000	No/Undisclosed
Marina Biotech Inc.	LipoMedics Inc.	Marina Biotech grants LipoMedics rights to its SMARTICLES liposomal-based delivery technology to deliver nanoparticles	Liposomal delivery	2017	45,000,000	Undisclosed	90,000,000	No/Undisclosed
MannKind Corp.	Receptor Life Sciences Inc.	MannKind grants new co Receptor Life Sciences a license to formulation and delivery technology to develop multiple inhaled products	Inhalational delivery	2016	51,150,000	Undisclosed	102,300,000	Mid-single to low double-digit royalties
Camurus AB	Rhythm Holding Co. LLC	Camurus grants Rhythm worldwide rights to develop and commercialize Camurus' FluidCrystal sustained duration technology in combination with Rhythm's setmelanotide	The state of the s	2016	65,000,000	Undisclosed	Undisclosed	Mid- to mid-high single-digit royalties
Durect Corp	Santen Inc.	Durect granted Santen an exclusive, worldwide license to Durect's SABER formulation platform to develop and commercialize a sustained release ophthalmology therapeutic	Sustained release formulation	2014	78,000,000	2,000,000	76,000,000	Single - to low double- digit tiered royalties
Ascendis Pharma A/S	Genentech Inc.	Ascendis grants Genentech w orldw ide rights to its TransCon technology to develop and commercialize products for ophthalmic indications	Other formulation or delivery	2013	10,000,000	10,000,000	180,000,000	No/Undisclosed
Tris Pharma Inc.	Vernalis plc	Tris grants Vernalis exclusive, North American rights to commercialize six cough and cold products reformulated by Tris using its OralXR+ extended release formulation technology	Oral delivery; Sustained release formulation	2012	14,833,333	833,333	84,000,000	Eligble, undisclosed
Ligand Pharmaceuticals Inc.	Bi Lilly and Co.	Ligand and Eli Lilly partnered to formulate Eli Lilly's products with Ligand's Captisol modified beta- cyclodextrin reformulation technology	Other formulation or delivery	2012	500,000	500,000	Undisclosed	No/Undisclosed
Median					51.150.000	2,000,000		

## NEX-22 – Potential Term Sheet GLP-1 Case



Proposed term sheet for NEX-22 in line with similar deals taken development stage, indications and target patient population into account. Term sheet for NEX-22 is in the low end as line extension and not a new compound competing with biosimilars and new treatments.

	Value	Notes / Supporting data page
Deal value - out-licensing after phase I/II based on a 50:50 split:	USD 300M	Equal today value of USD 60M taken discount rate, risk, costs tax into account (rNPV for NEX-22).
Signing fee	USD 40M	
Development & regulatory milestones	USD 160M	
Sales milestones up to	USD 100M	
Tiered-up royalty rates	10-15%	
Exit value at deal in (before tax) based on the above terms:	USD 140M	Equal today value of USD 60M taken discount rate, risk, costs tax into account (rNPV for NEX-22).

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## NEX-22, Novo Nordisk and other evaluation projects with substantial near-term revenues



## Potential major deals to target within 1-2 years

## **Priority targets**

- NEX-22 project after PoC in Phase I
  - Product license Type-2 diabetes and potentially also Obesity
    - Revenue: Signing & milestone fee, fee for development work/CTM manufacturing as well as royalty
- Novo Nordisk after completion of pre-clinical evaluation
  - Technology license PharmaShell in combination with Novo Nordisk compound class
    - Revenue: Signing & milestone fee, fee for development work/CTM manufacturing as well as royalty
- Other Partner companies currently evaluating the PharmaShell system, after completion of pre-clinical evaluation
  - Technology license PharmaShell in combination with partner compound
    - Revenue: Signing & milestone fee, fee for development work/CTM manufacturing as well as royalty

## Other possible options

- NEX-18, NEX-20 projects before or after clinical PoC
  - Co-developments / License agreements





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# Investment highlights – low risk development model based on technology with significant benefits for patients and society





#### Unique technology with significant benefits

- PharmaShell® enabling controlled release of drug substances over days, weeks, or even months
- Long-acting drug delivery system with significant benefits for patients and society improving e.g. compliance and quality of life



## Low risk model despite early-stage development...

- Nanexa is focusing on new drugs based on already approved substances where the patent has expired
- PharmaShell drug delivery system taken into clinical studies in two oncology indications



### ...with huge potential upside

- Successfully commercialised substances using PharmaShell® will be protected by patents
- Focuses on markets with huge potential e.g. diabetes, obesity and multiple myeloma currently three own projects ongoing



## Novo Nordisk agreement – huge potential upside - highlight additional upside from partnerships

- Licensing PharmaShell® technology potential to cost-efficiently capture additional areas, e.g. types of substances and indication areas
- License agreements usually includes signing fees, milestone payments and royalties



## State-of-the-art GMP<sup>1)</sup> production plant in place

- Possible to source clinical trial material for phase I-III to own and partner projects
- Ability to rapidly scale up drug manufacturing



## Experienced management and board of directors

- Management with extensive expertise in pharma development, ALD<sup>2)</sup>, and business development
- BoD with significant experience in pharma and business development, and exceptional international networks
- World class scientific boards for each internal project

## Transaction structure and timetable



#### **Terms**

- Existing shareholders in Nanexa have preferential rights to subscribe for two (2) new common share per one (1) existing share, an issue ratio of 2:1.
  - The rights issue comprises of up to 121,318,524 new common shares.
- The subscription price has been set to SEK 1 per new common share, resulting in total proceeds of approximately SEK 121 million, before issue costs.

### **Subscription undertakings and guarantees**

- The rights issue is covered to SEK 75m with subscription undertakings with or without preferential rights and by external guarantors.
  - Novo Nordisk has undertaken to subscribe shares for SEK 20m, provided they not own more than 19.9% post issue.
  - Subscription undertakings from Novo Nordisk, Board and Management and existing shareholders amount to SEK 24m.
  - The remaining part up to SEK 75 m is covered by external guarantee commitments

## Indicative timetable for rights issue

21 September	Announcement
6 October	Last day of trading in Nanaxa's shares including the right to receive subscription rights
9 October	First day of trading in Nanexa's shares excluding the right to receive subscription rights
11 October	Date for publication of the prospectus
12 October - 23 October	Trading in subscription rights
12 October - 26 October	Subscription period
30 October	Announcement of the final outcome of the rights issue





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