nanoform
small is powerful®

# Nanoform Management Presentation

DNB Healthcare Conference
Oslo

November 26, 2024

# Disclaimer

## Forward-Looking Statements

This presentation contains forward-looking statements, including, without limitation, statements regarding Nanoform's strategy, business plans and focus. The words may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this presentation are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, any related to Nanoform's business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other companies, and other risks described in the Report of the Board of Directors and Financial Statements for the year ended December 31, 2023 as well as our other past disclosures. Nanoform cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Nanoform disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this presentation represent Nanoform's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

# Business and Strategy

# Key strategy

**All active pharmaceutical ingredients (API's) should be Starmapped**

**Nanoform work with customers/partners to enable both novel & existing molecules to become new and improved medicines**

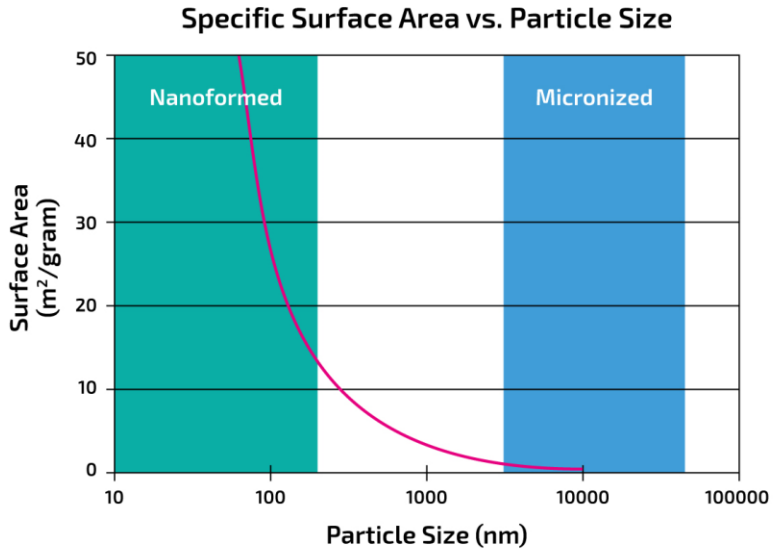
**In parallel, to show a conservative industry the power of nanoforming, we create up to a dozen 'product kernels'**

# Proprietary technology platforms

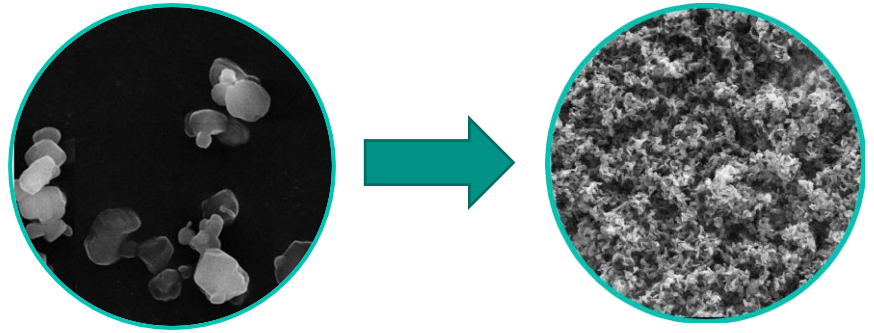
| ***Small molecules*** | ***Large molecules*** | ***Formulation*** | ***AI*** |
|---|---|---|---|
| **Proven CESS®* nanotechnology enables new medicines through *improved bioavailability*, *higher drug load* & *novel formulations*** | **Unique BIO nanoparticles enable improved routes of administration with *high drug load* and *long-acting delivery*** | **Highly differentiated *novel formulations* and *unique drug delivery opportunities* drive optimized therapeutic potential & patient convenience** | **STARMAP® 2.0 online *picks best candidates* and *accelerates development* by integrating deep expertise with sparse data AI** |

# Particle size is key

## Smaller particle size can improve a drug's bioavailability




- The surface area increases 30-fold from a 10 micron[1] sized particle once the particle size is reduced to 100nm
- Reduction of particle size down to 50nm increases the surface area by 1,000-fold



Pre-nanoforming | Post-nanoforming

- Smaller particles have a larger surface area
- Larger surface area of particles enables improved bioavailability of a drug
- Improved bioavailability implies increased absorption of a drug by the body's circular system
- CESS® can produce API with large surface areas which can significantly improve the bioavailability of drugs

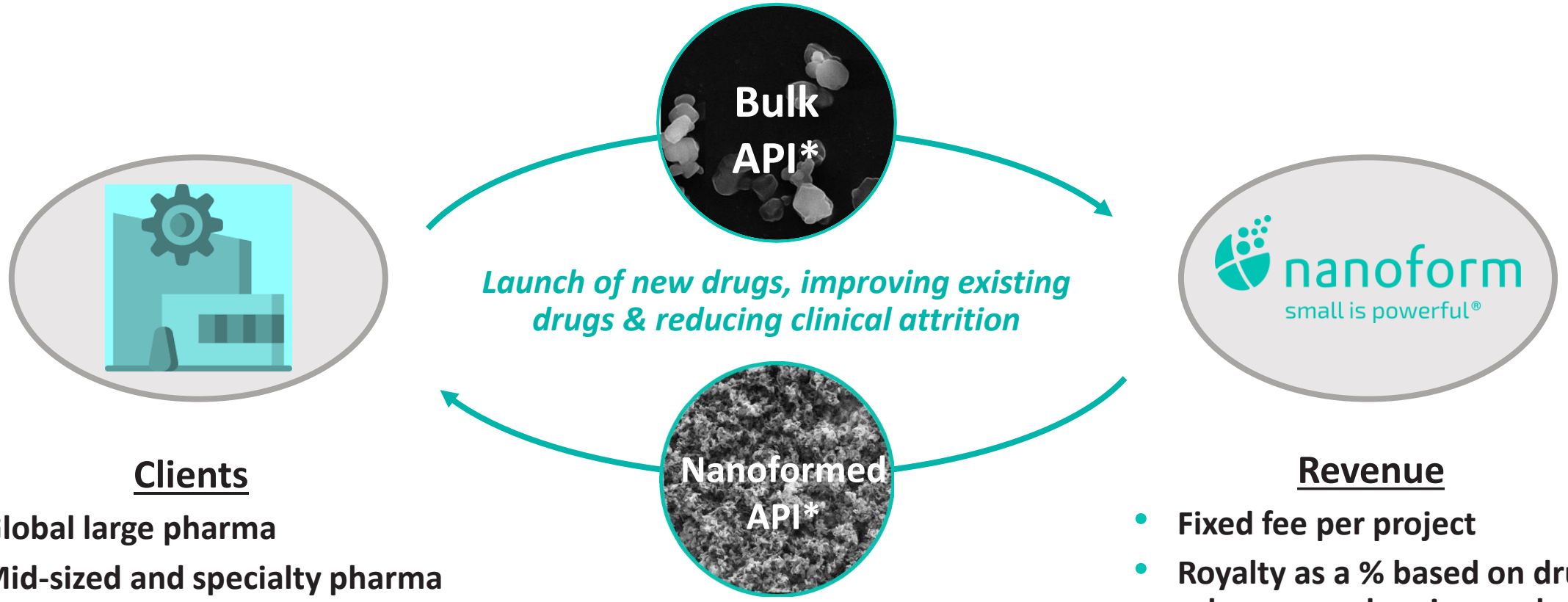
➢ CESS® produced nanoparticles have a larger surface area and as such improved bioavailability.



Source: Company information
1) 1 micron = 1,000nm

# Simplified value chain

***High level overview of Nanoform's value chain and business model***




## Clients

- Global large pharma
- Mid-sized and specialty pharma
- Biotech

## Revenue

- Fixed fee per project
- Royalty as a % based on drug sales or supply price per kg

**API = Active Pharmaceutical Ingredient*

# Growth since IPO 2020

| | *IPO June 2020* | *September 2024* | *Growth* |
|---|---|---|---|
| **Employees** | **50** | **177** | **~3x** |
| **Manufacturing lines** | **5** | **20** | **~4x** |
| **Customers enrolled** | **5** | **49** | **~9x** |
| **Customer projects started** | **5** | **88** | **~18x** |
| **Patents granted** | **5** | **42** | **~8x** |

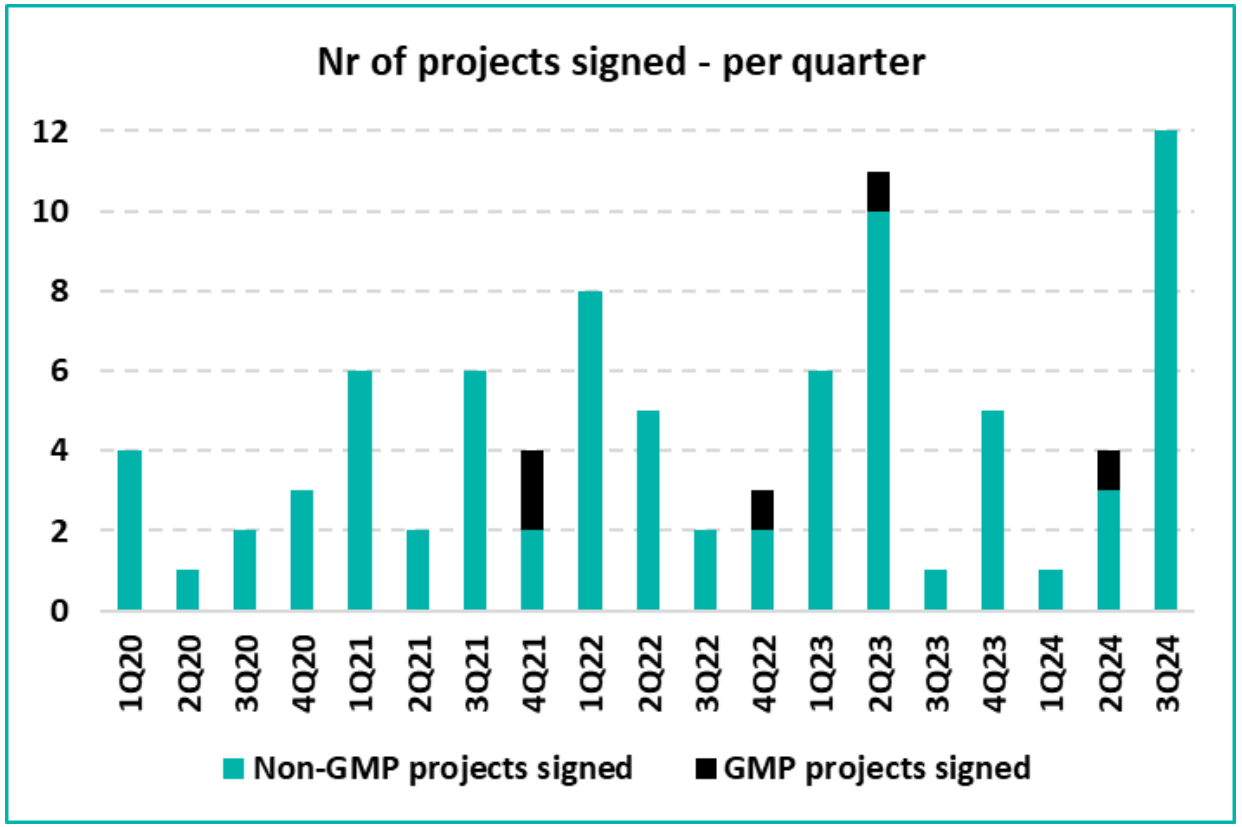
*Nanoform headquarters in Helsinki, Finland*

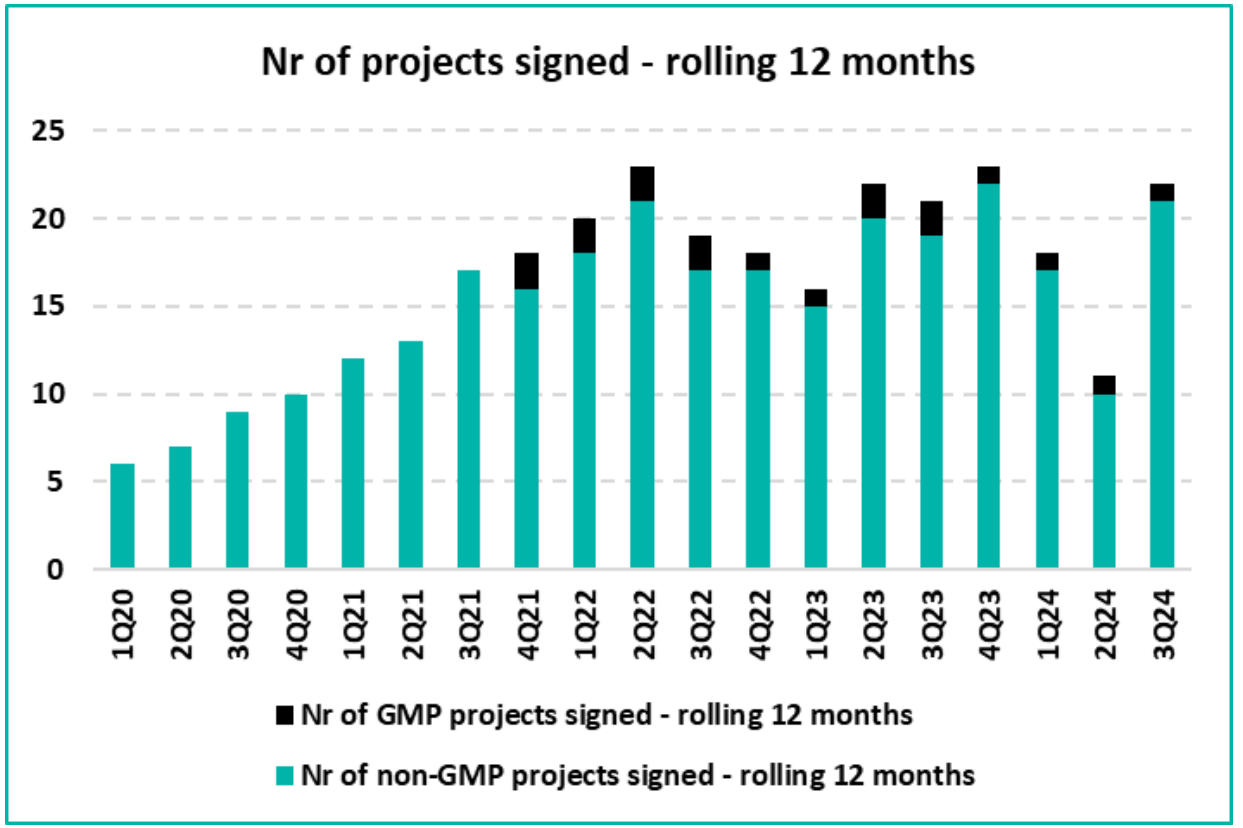
# Nanoform business highlights Q3 2024

| | |
|---|---|
| 1 | **New quarterly record on customer non-GMP projects signed.** |
| 2 | **Revenue growth is back and is expected to accelerate in coming quarters and years.** |
| 3 | **Following completion of in vitro proof of concept studies of a novel plasma-derived therapy formulation with Takeda, Nanoform will provide non-GMP nanomaterial to Takeda for in vivo studies. The first results of these studies are expected in early 2025.** |
| 4 | **Manufacturing of GMP material for pivotal studies and registration batches in Project Nanoenzalutamide continues, pivotal studies to start in 1Q25, with first read-out in 2Q25.** |
| 5 | **Further progress on dealmaking around our product kernels; half a dozen term sheets received, first letter of intent signed and several license/commercial supply agreements on multiple product kernels expected to be signed in coming quarters.** |

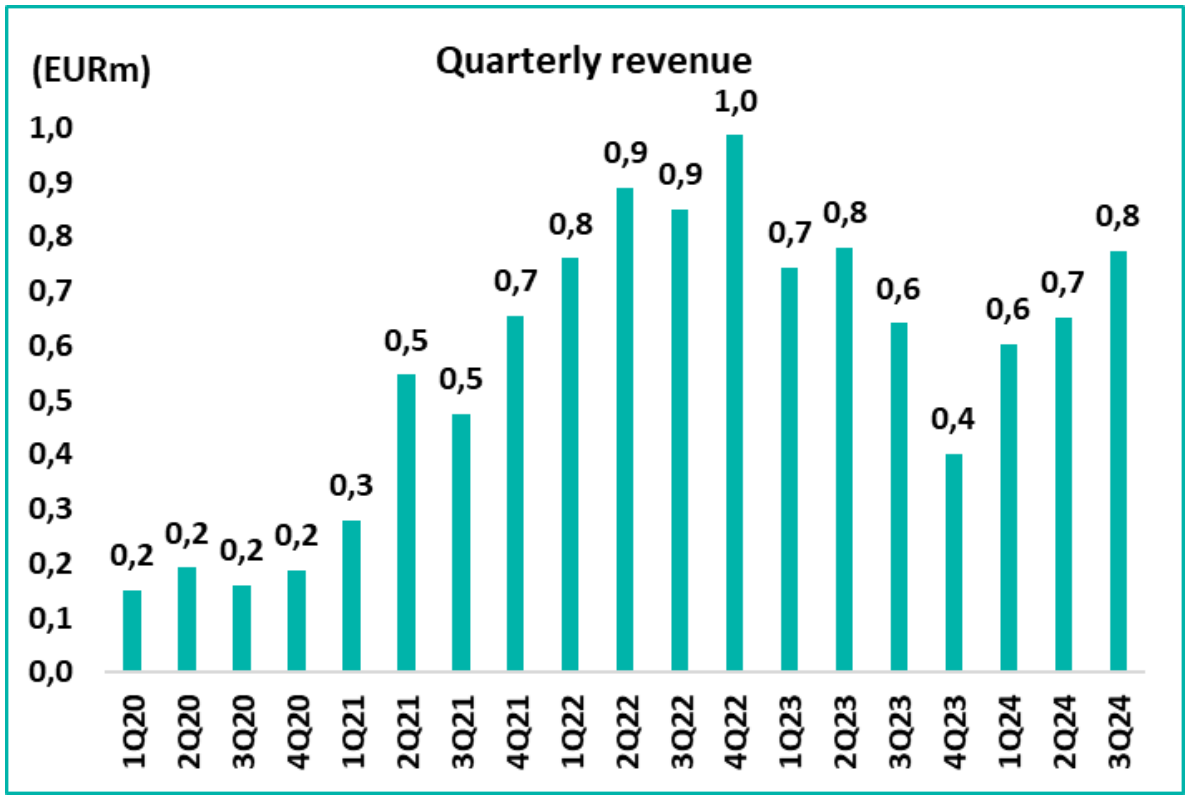
# Financials

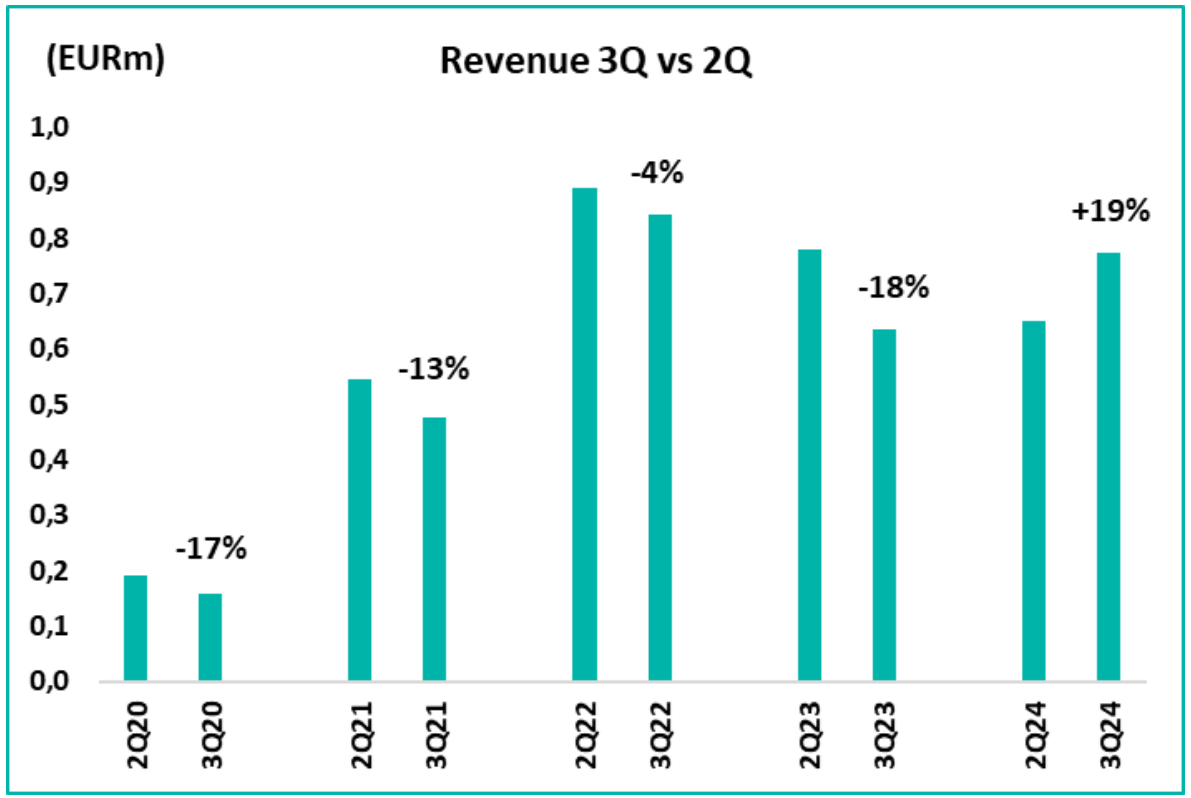
# Number of customer projects signed – new record in a quarter



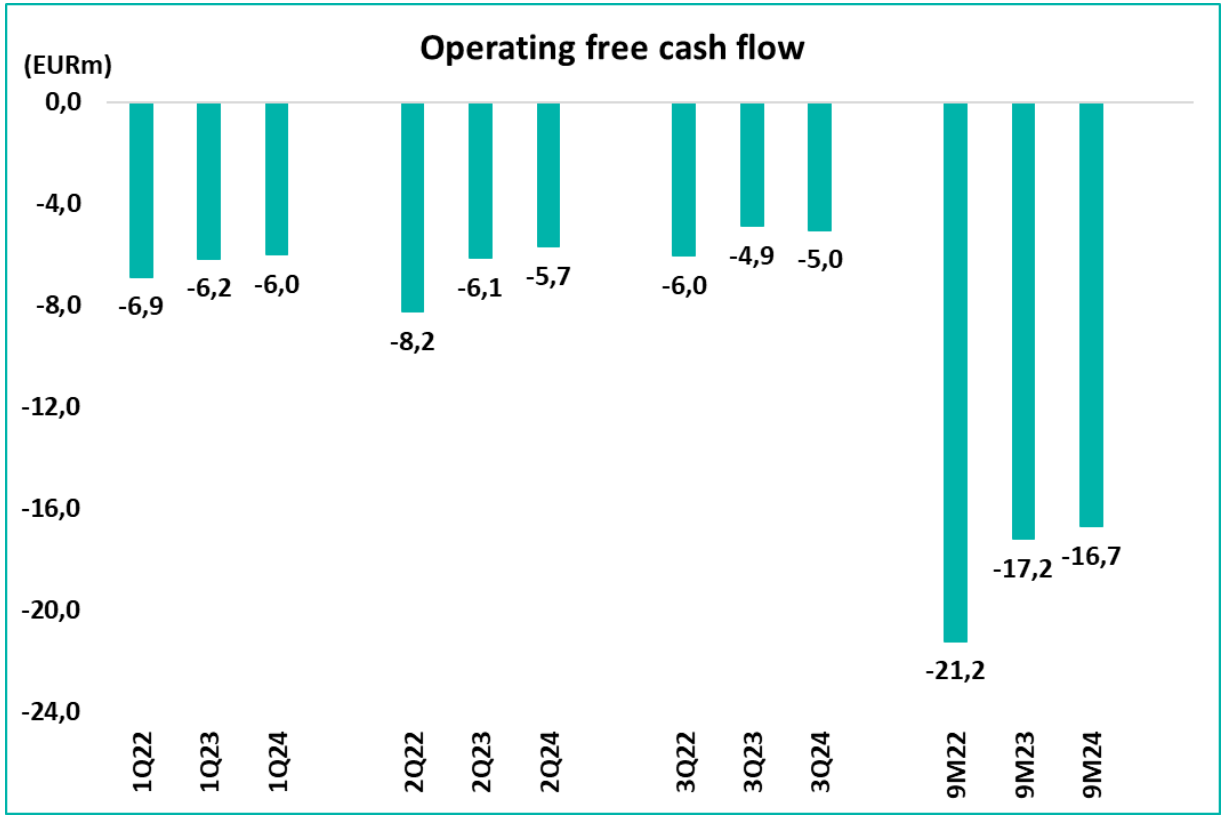
# Revenue +21% y/y in 3Q, and +19% q/q despite summer period*

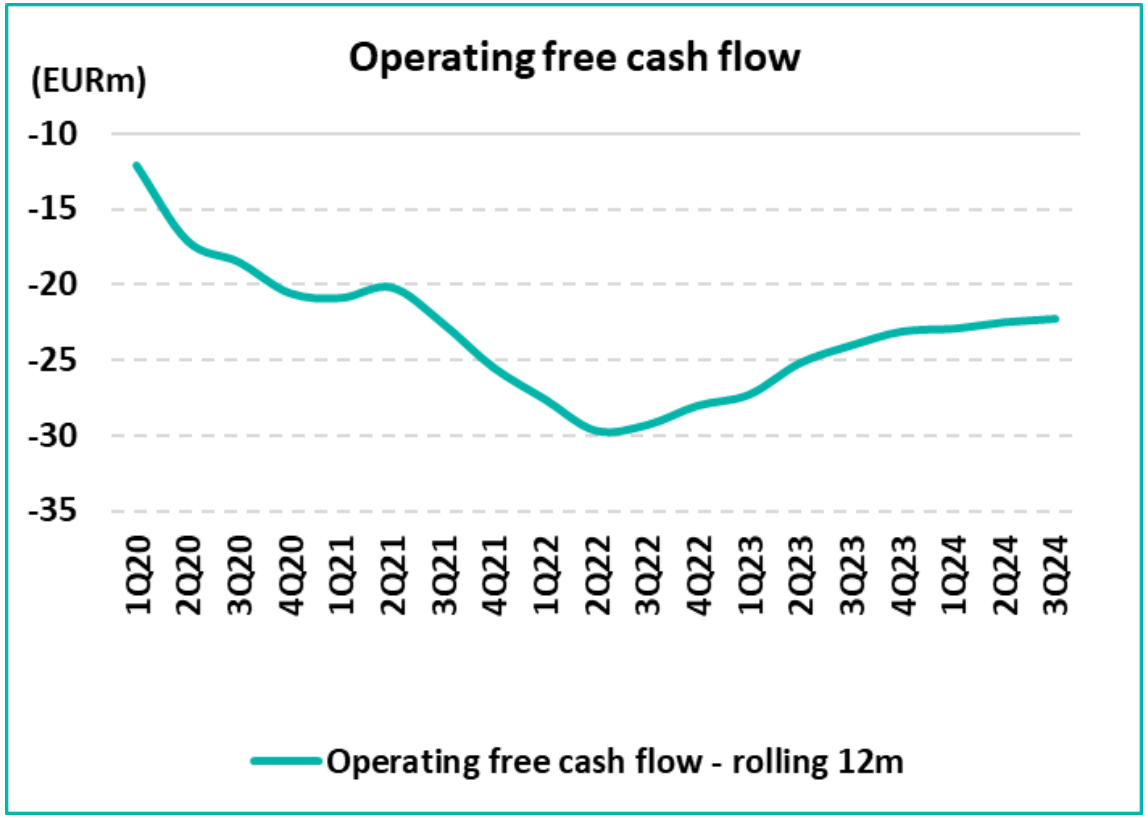



*3Q has historically had lower revenue recognized than 2Q as the hours worked are lower due to summer holiday period

# Improvement in operating free cash flow to continue



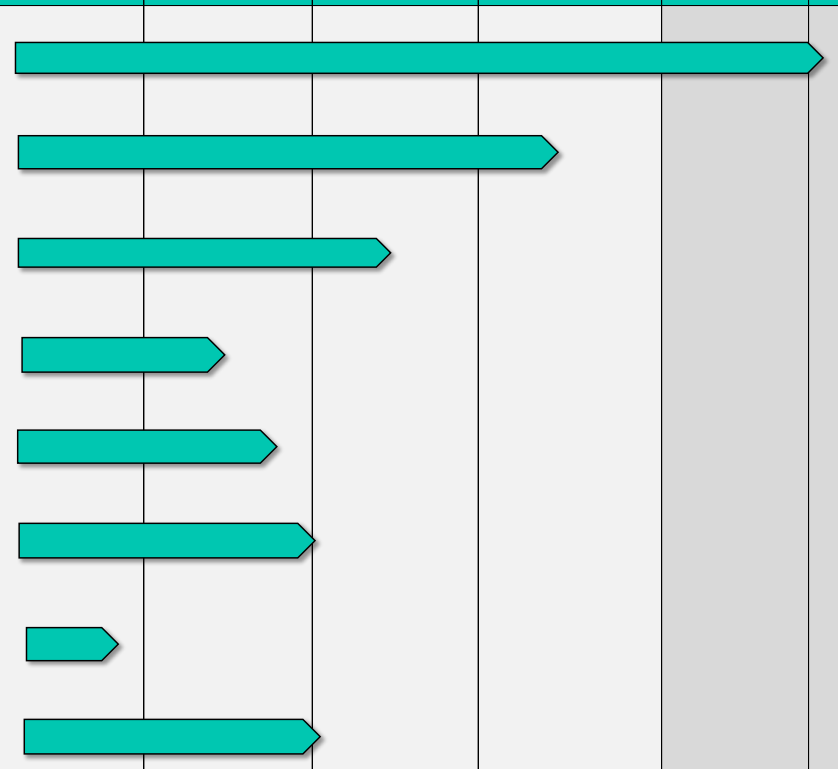




**At the end of 3Q24, Nanoform had some than EUR 46m in cash & short-term government bonds and no debt**

# Product Kernels

# Product Kernels*

| Nanoform 'product kernel' project data | | | | | Preclinical (Nanoform) | | | | Clinical (Nanoform) | | Commercial (Nanoform) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Project | Originator | API | Indication | Delivery route / dosage form | PoC | Pre-formulation + in-vitro | Dosage form development + in vivo | PoP* / Dosage form development | Phase 1 / Pilot | Pivotal | Commercial partnering window | Targeted market launch | Expected originator peak sales* |
| OnConcept (Development partner) | Astellas/ Pfizer | Nanoenzalutamide | Prostate cancer | Oral/ tablet | | | | | | | 2024-25 | 2027 | >$5bln |
| NAN024 | Johnson & Johnson | Nanoapalutamide | Prostate cancer | Oral/ tablet | | | | | | | 2024-25 | 2032 | >$5bln |
| NAN030 | Undisclosed | Undisclosed | Oncology | Oral/ tablet | | | | | | | 2025-26 | | |
| NAN027 | Undisclosed | Undisclosed | Oncology | Oral/ tablet | | | | | | | 2025-26 | | |
| Undisclosed (Development partner) | Undisclosed | Undisclosed | Inflammation | Oral/ tablet | | | | | | | 2025 | | |
| NANxxx/LAI | Undisclosed | Undisclosed | Prostate cancer | Long Acting | | | | | | | 2026 | | |
| Undisclosed (Development partner) | Undisclosed | Undisclosed | Oncology | Long Acting | | | | | | | 2026 | | |
| NBN008 | Undisclosed | Undisclosed | Oncology | High Concentration SC Bio | | | | | | | 2026 - 27 | | |



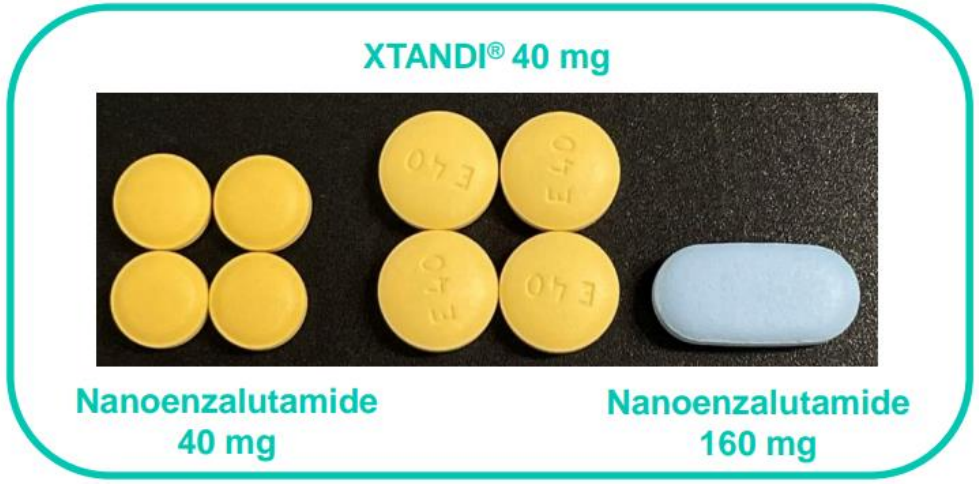
*Only Product Kernel pipeline, i.e. not including customer projects
*Sources: Pharmacircle and Decision Resources, Inc.

*PoC = Proof of Concept
*PoP = Proof of Process

# Nanoenzalutamide and Nanoapalutamide

| | XTANDI® | Nanoenzalutamide |
|---|---|---|
| Formulation | ASD | Crystalline Nanoparticle |
| Drug load 160mg (x1) | - | 40 % |
| Drug load 40mg (x 4) | 12 % | 40 % |
| Size 160mg (x1) | - | 18.1 x 8.6mm |
| Size 40mg (x4) | 10.1mm | 8.0mm |

| | ERLEADA® | Nanoapalutamide |
|---|---|---|
| Formulation | ASD | Crystalline Nanoparticle |
| Drug load 240mg (x 1) | 21 % | 42 % |
| Drug load 60mg (x4) | 7 % | 42 % |
| Size 240mg (x1) | 21 x 10mm | 15 x 7mm |
| Sixe 60mg (x4) | 17 x 9mm | 8mm |





Nanoformed and nanocrystalline medicines offer an attractive alternative to ASD medicines* (and other) with the following benefits: green manufacturing process, significantly higher drug load, more patient centric medicines (pill burden), extended IP, potential for earlier market entry and the possibility to do fixed dose combinations



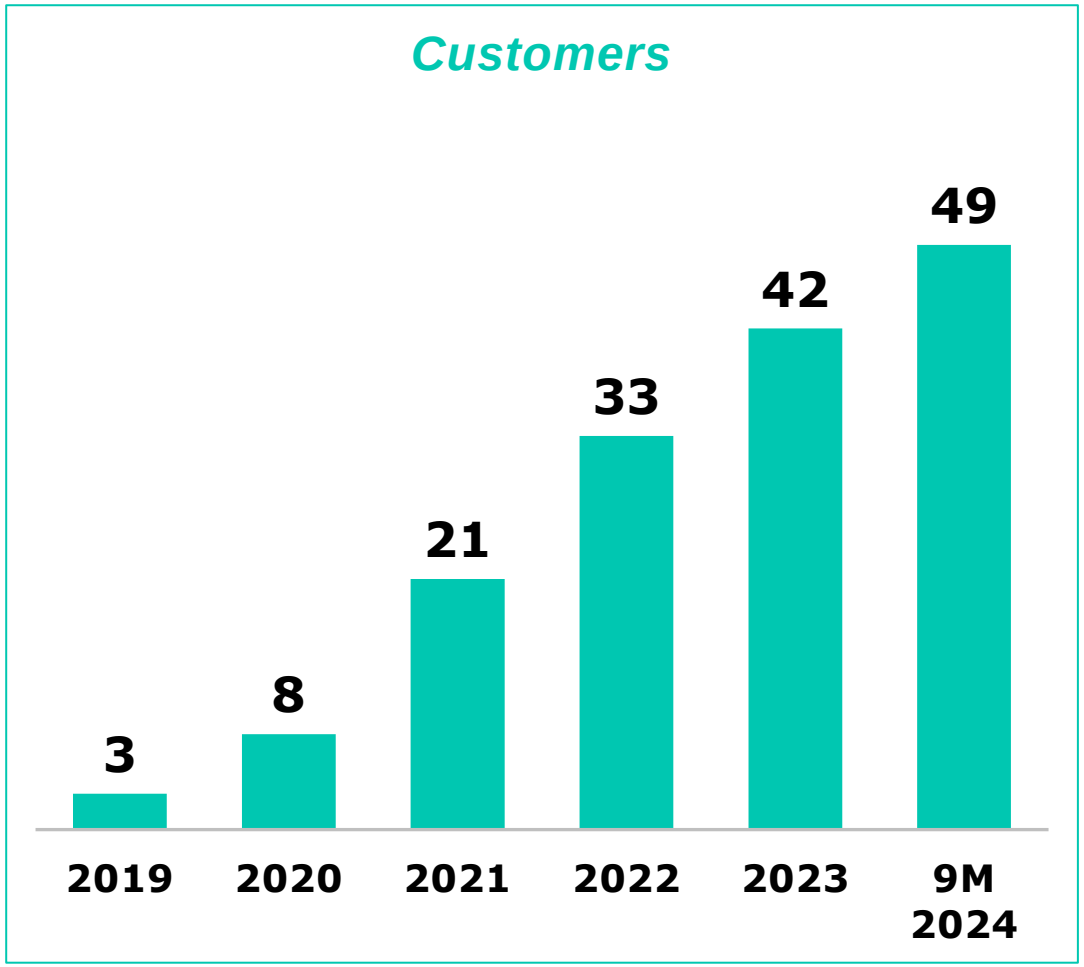
*There are ~50 marketed amorphous solid dispersion (ASD) medicines globally that sell for ~$50bln annually

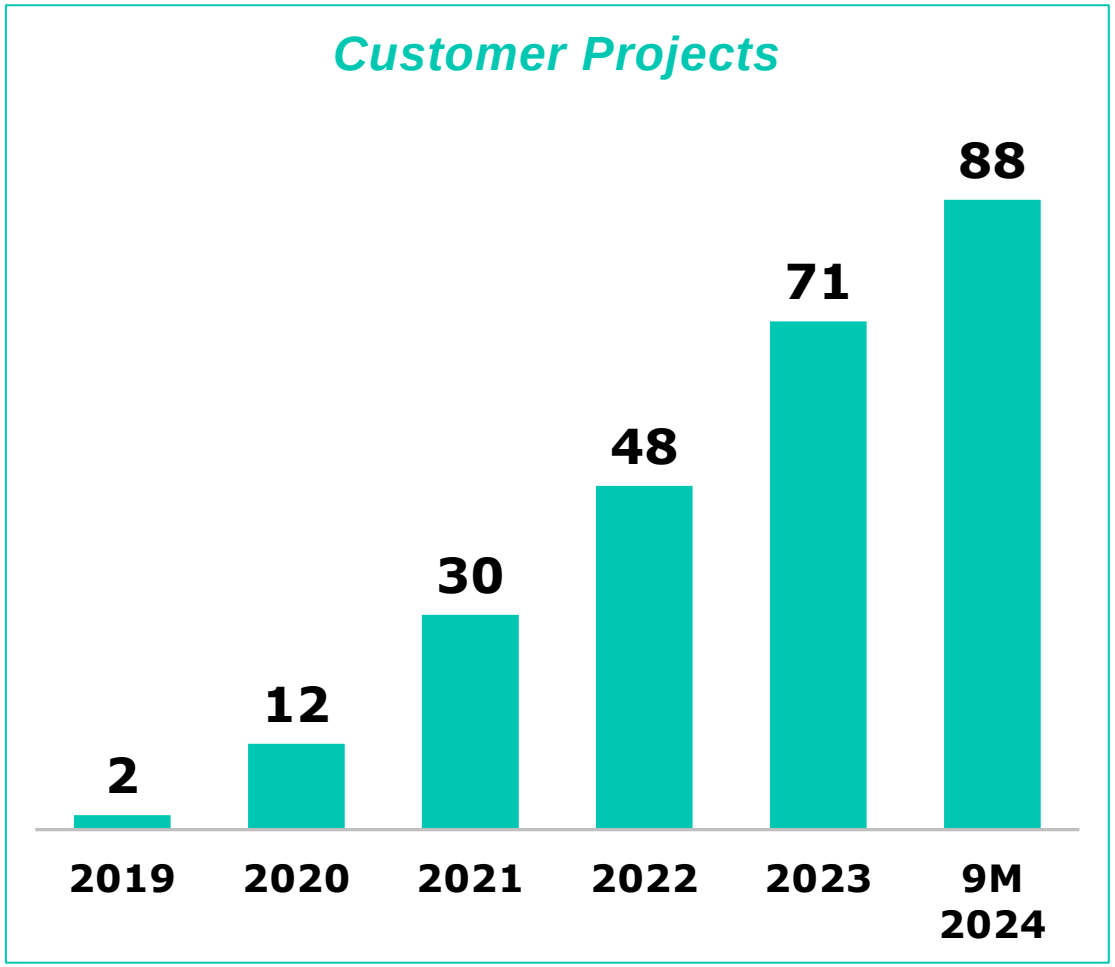

Commercial

# Experienced global sales team driving commercialization
## – Locations and previous experiences


gsk
janssen
Bristol Myers Squibb
AstraZeneca
MERCK
JM Johnson Matthey
Inspiring science, enhancing life
Siegfried
Dr.Reddy's
Biocon
Lonza
Hovione
SIGMA-ALDRICH
PORTON
Prosonix
Revolutionising Respiratory Medicine
PROVEPHARM
bioenvision
CAMBRIDGE MAJOR LABORATORIES
Hoechst
AZGARDABIO
Dishman Carbogen Amcis

# Cumulative number of customers and projects signed



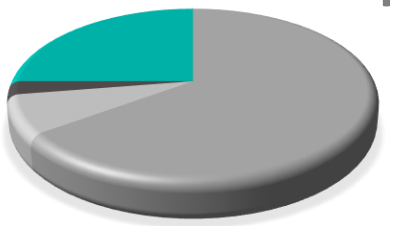
# Commercial Relationships 2019 – Q3 2024

## Customer mix

**11 major pharma**

**36** mid-sized, specialty pharma & biotech companies

**2** co-developments



**3** collaborations

## Selection of partners

Takeda

SANOFI

GSK

Boehringer Ingelheim

AstraZeneca

Celanese

BILL & MELINDA GATES foundation

TARGTEX
TARGETED THERAPEUTICS

# Commercial Activities

Dr Ajit Shetty, former Chairman of Janssen, and Dr Makarand Jawadekar, former Pfizer global R&D executive, visit Nanoform HQ in Helsinki

Director Sophie Janbon and Director Geof Wolfenden, AstraZeneca Plc, visit Nanoform HQ in Helsinki

Nanoform visit Bluepharma in Portugal, ONConcept® consortium partners for Nanoenzalutamide

Tomoyasu Nakamura and Shigerau Yokohama, CBC, present Nanoform partnership and Nanoform's technologies at 41st Symposium on Formulation and Particle Design in Okayama, Japan


Andreas Liebminger, Ph.D., Global Head of Plasma-derived Therapies Pharmaceutical Sciences, Takeda, present Nanoform's Biologics technology


Christian Schneider, Celanese Inc, present Nanoform collabortion and Nanoform's small molecule technology




# Nanoform customer projects – therapy area overview*

| Pre-Clinical | Phase I | Phase II & III | Marketed/505b2 |
|---|---|---|---|
| Cardiology (e.g. Anemia) | Immunology/Inflammation (e.g. Cystic Fibrosis) | Metabolism and Endocrinology (e.g. Adrenal Hyperplasia) | Infectious Disease (e.g. HIV) |
| Gastroenterology (e.g. Microbiome) | Dermatology/Oncology (e.g. Basal Cell Carcinoma) | Neurology (e.g. Schizophrenia) | Immunology/Inflammation (e.g. HEP B) |
| Immunology/Inflammation (e.g. Psoriasis) | Neurology (e.g. Parkinsons) | Oncology (e.g. lung cancer) | Immunology/Inflammation ) (e.g. Cystic Fibrosis) |
| Infectious Disease (e.g. HIV) | Oncology (e.g. Solid Tumors) | | Oncology (e.g. Prostate Cancer) |
| Metabolism and Endocrinology (e.g. Diabetes) | Ophthamology (e.g. Cataract) | | Ophthamology (e.g. Glaucoma) |
| Neurology (e.g. Parkinsons) | Pain (e.g. Post Operative Pain) | | |
| Oncology (e.g. Multiple Myeloma) | Infectious Disease (e.g. HIV) | | |
| Ophthamology (e.g. Glaucoma) | | | |
| Respiratory (e.g. COPD) | | | |

*Shows the stage of customer molecule, not in which phase the project is at Nanoform (non-GMP, GMP, at market)

# Q & A

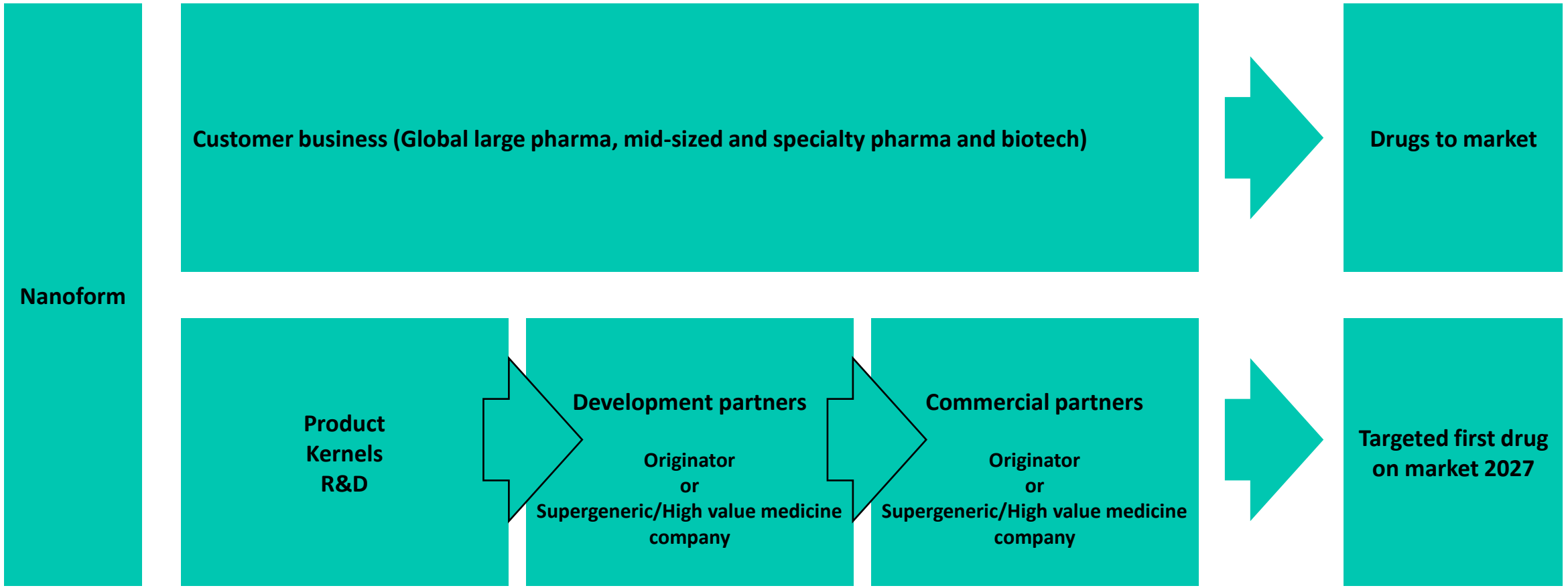
*Nanoform headquarters in Helsinki, Finland*

*www.nanoform.com*

*San Diego - Chicago - New York - Lisbon - Manchester - Oxford - London - Cambridge - Bordeaux - Stockholm - Budapest - Helsinki*


APPENDIX

# Nanoform Technology – route to market



# Nanoenzalutamide clinical trials

**2023-2024**

**Phase 1/Pilot clinical trial in North America.**

**Relative bioavailability study of nanocrystalline-enabled enzalutamide (nanoenzalutamide) tablet formulation, an alternative to the amorphous solid dispersion (ASD) used in Xtandi®.**

**The single-dose, randomized, comparative bioavailability study, which was performed by a contract research organization (CRO) in North America and completed on January 25, 2024, compared enzalutamide 160mg filmcoated tablets (Bluepharma) and Xtandi® 4×40 mg film-coated tablets (Astellas Pharma Europe B.V.).**

**The clinical trial demonstrated promising results.**

**2025**

**Pivotal bioequivalence clinical trials in EU and US are expected to start in Q1 2025, with first read-outs in 2Q 2025.**

**Bioequivalence means 80% - 125% of the Cmax and AUC in a large cohort study in fed and fasted states with a 90% confidence interval.**

**Nanoenzalutamide is expected to progress via the ANDA (Abbreviated New Drug Application)/Hybrid generic pathway and as such will need to show bioequivalence vs the originator product, Xtandi®.**

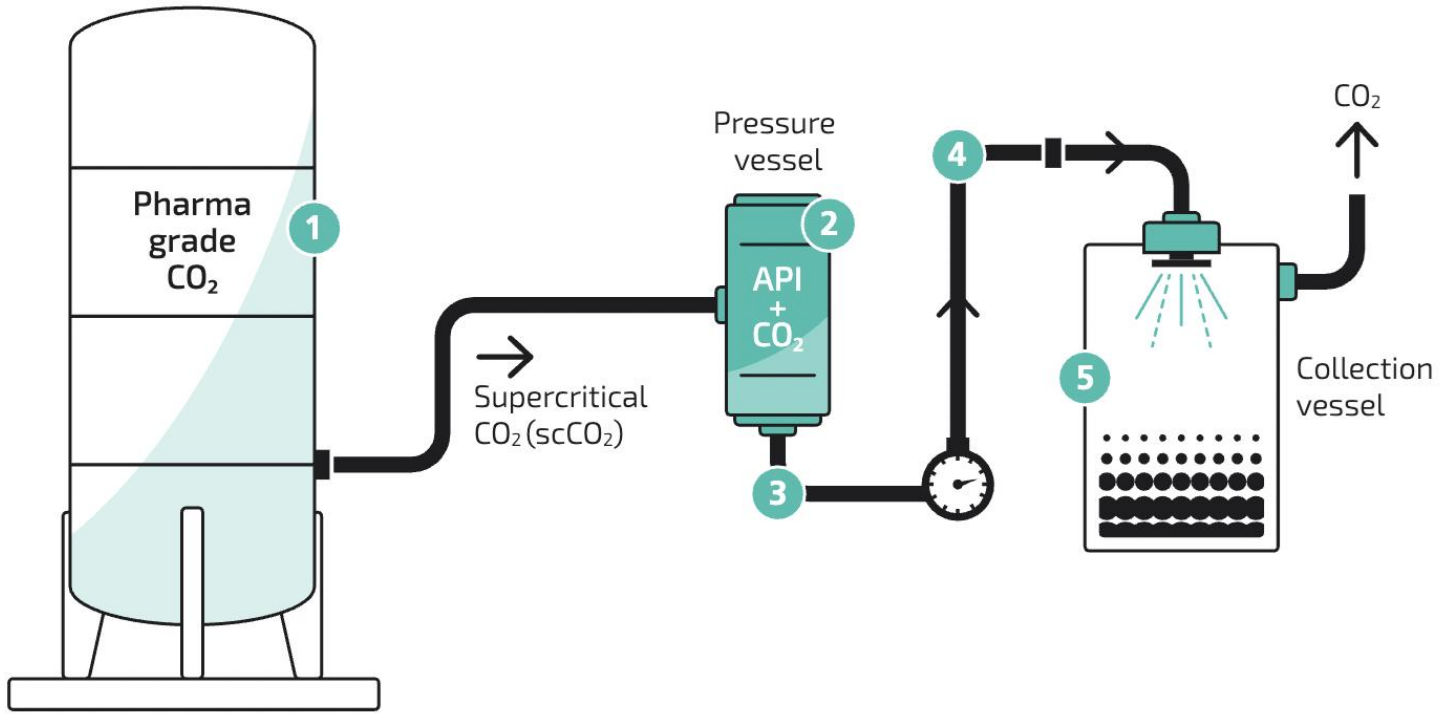
**License and commercial supply agreements are expected to be signed in coming quarters.**

**We plan nanoenzalutamide to take a meaningful share of this market through its highly patient centric product differentiation (1 tablets 4 tablets) and unique IP position (different technology, crystalline product, different excipients), while not forgetting its green attributes.**

# Small Molecules - Proprietary technology

**Green technology**

## Controlled Expansion of Supercritical Solutions - CESS®




1. Supercritical $CO_2$ is guided into a pressure vessel loaded with API
2. Increasing the pressure and temperature in the vessel dissolves the API in supercritical $CO_2$
3. The $CO_2$ and the API are released from the pressure vessel and the flow, pressure and temperature profiles are accurately controlled
4. The pressure and temperature is controlled to achieve a stable nucleation phase and formation of nanoparticles
5. In a collection vessel the $CO_2$ is sublimated resulting in final nanoparticles ready for collection and formulation

➢ **Relatively simple process developed through combining deep knowledge in physics, chemistry, and pharma**

# CESS® Superior to Existing Technologies

| | Controlled Expansion of Supercritical Solutions (CESS®) | Solid dispersion (e.g. spray drying) | Jet milling | Nanomilling |
|---|---|---|---|---|
| Description | Extracts API from supercritical $CO_2$ by applying controlled reduction in pressure | API is dispersed into a solid material, which dissolves when exposed to an aqueous media | Application of energy to physically break down API particles to finer ones | API particle size is reduced in a liquid vehicle via grinding |
| Particle size | Down to 10nm | 300nm-25µm | 800nm-10µm | >150nm |
| Particle formation | Controlled crystalline or amorphous and stable | Amorphous (unstable without excipients) | Unstable (crystalline and amorphous structures) | Unstable (crystalline and amorphous – needs excipient to stabilise) |
| Ease of formulation | ✓ | ✗ | ✗ | ✗ |
| Reproducibility | ✓ | ✓ | ✗ | ✗ |
| Free from excipients and solvents | ✓ | ✗ | ✓ | ✗ |
| Yield | High | Low | High | Low |
| Investment | Low | High | Low | Low |

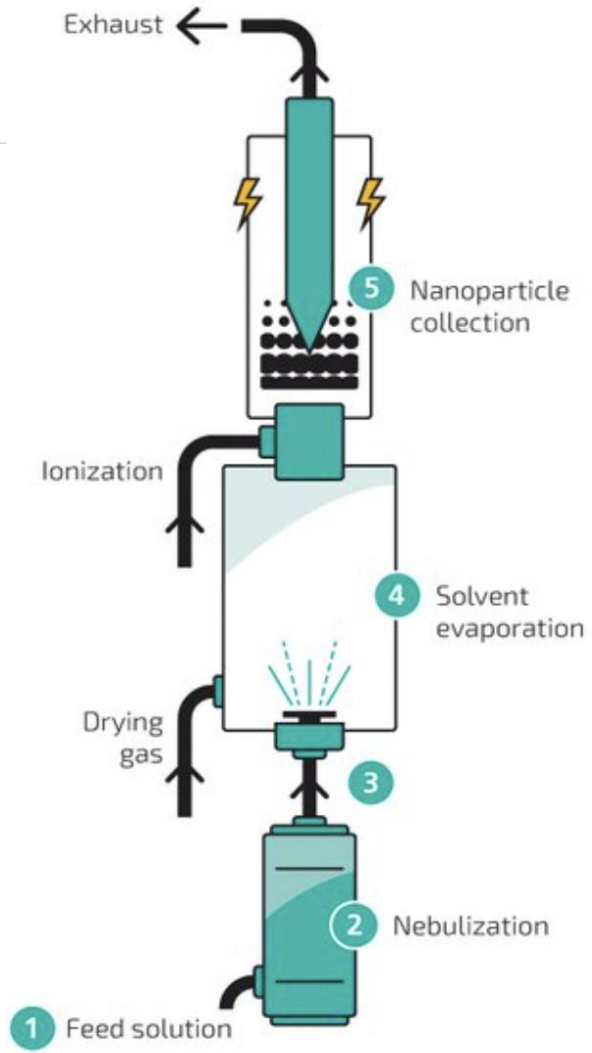
Source: Company information; Chimica Oggi: Chemistry Today; Roots Analysis, Pharmaceutical Spray Drying Market, 2014-2024

# Large molecules - Proprietary technology

Green technology

## Nanoforming process for biologics

1. API containing feed solution is pumped into the nebulizer
2. Feed solution is nebulized into a carrier gas
3. Mist is transported into the drying chamber via a connection pipe
4. Mist is dried using low-temperature drying gas
5. Dried particles are charged by the ionizer and collected using electrostatic precipitation

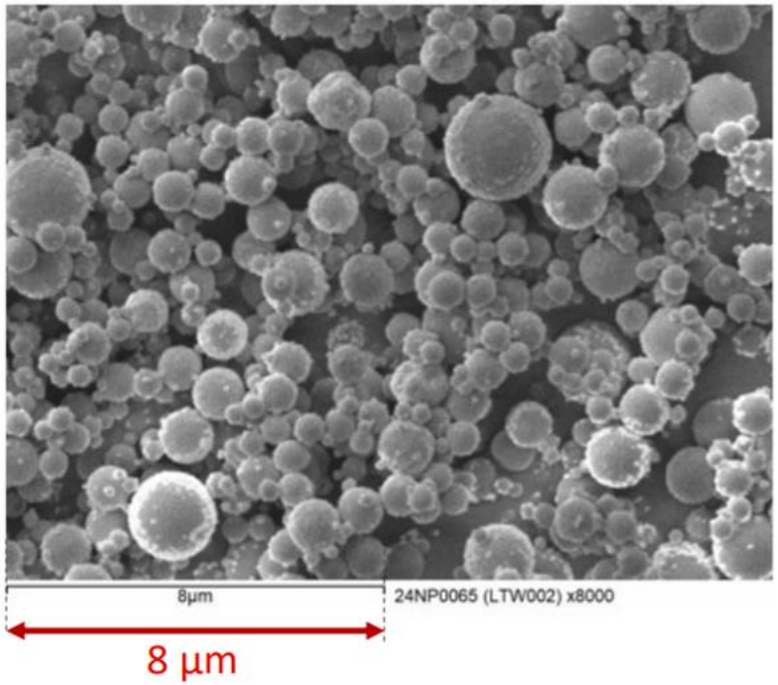



**API = active pharmaceutical ingredient**
**Nebulization = turns liquid into mist**
**Ionization = particles electrically charged**

# Comparison of Nanoform's proprietary biologics technology vs existing technologies

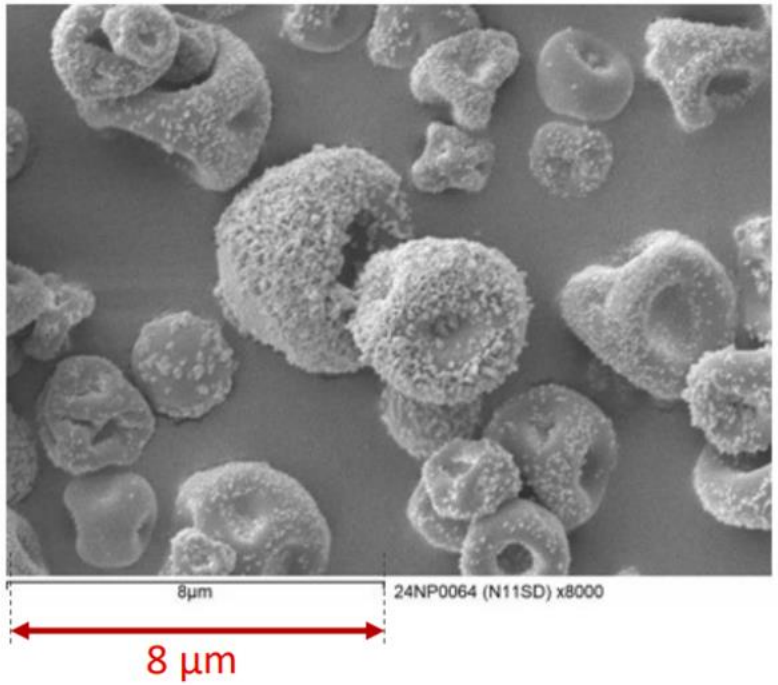
## Nanoformed

**Perfect spheres, highly flowable and aerodynamic, great packing and injection properties**



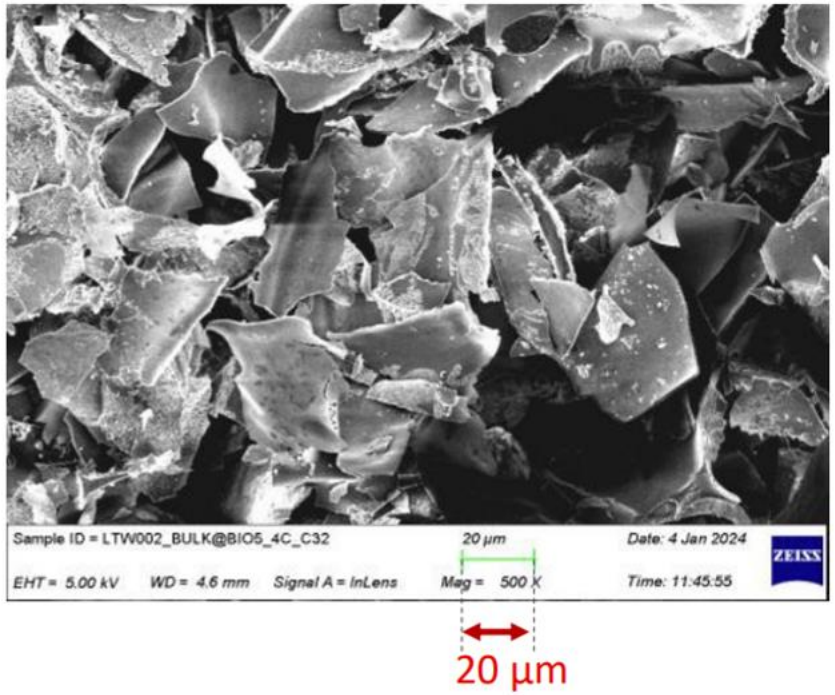

## Spray dried

**Sticky, poor flowability, raisin shaped**




## Lyophilized / freeze dried

**Flaky morphology, dry cake, no flowability**




**Nanoforming biologics: Superior flowability, aerodynamic performance, high density packing, lower injection force properties, improved material quality and stability properties vs spray drying and lyophilization**

# 4 cases

## TargTex

**Biotech customer**

**Glioblastoma Multiforme**

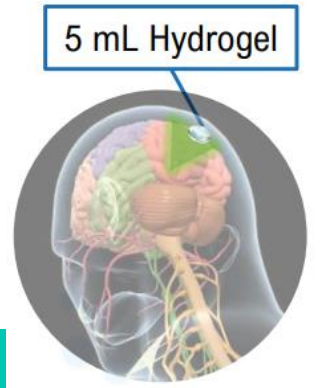
**Small molecule**

**New medicine/s**

**200x higher drug load with Nanoformed API**

**Promising animal data**

**GMP manufacture and then clinic (Phase 1/2a)**




## Takeda

**Major pharma customer**

**Rare diseases**

**Large molecule (Plasma Derived Therapy)**

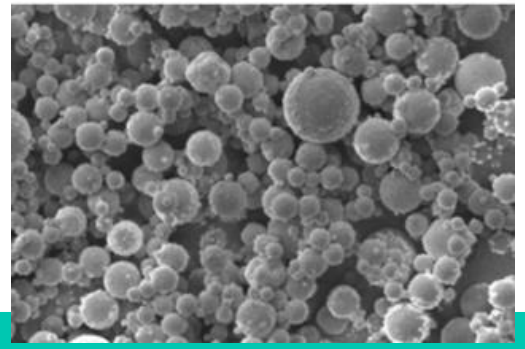
**New medicine/s**

**Innovative Drug Delivery**

**In-vivo results due end of Q1 2025**

**Nanoformed**

Perfect spheres, highly flowable and aerodynamic, great packing and injection properties



## Nanoenzalutamide

**Product Kernel**

**Prostate Cancer**

**Small molecule**

**Reformulated existing ASD marketed product (Xtandi)**

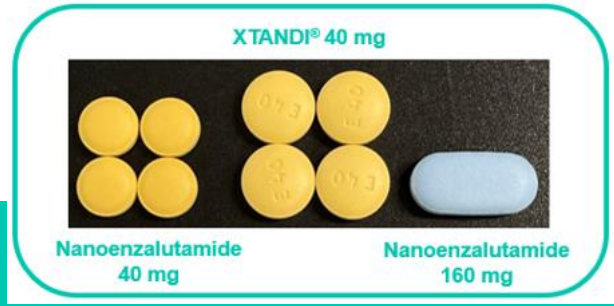
**Promising clinical data**

**Pivotal bioequivelance clinical trial Q1 2025**

**Development partners in place**

**Commercial partnering discussions ongoing**

**Target launch 2027 US and 2028 EU**




## Nanoapalutamide

**Product Kernel**

**Prostate Cancer**

**Small molecule**

**Reformulated existing ASD marketed product (Erleada)**

**Promising animal data**

**Partnering discussions ongoing**

# Upcoming events

| | |
|---|---|
| November 26 | DNB 15th Annual Nordic Healthcare Conference, Oslo |
| November 26-27 | BOS, Manchester |
| November 28 | Stora Aktiedagarna - Aktierspararna, Stockholm |
| December 11-13 | DDL 2024, Edinburgh |
| December 16 | Nordea Growth Day, Helsinki |
| January 13-16 | JPM Healthcare Conference 2025, San Franciso |
| February 25-26 | BIO Asia 2025, Hyderabad |
| February 27 | Nanoform Financial Report 2024 |
| March 11 | Danske Bank Small & Mid Cap Seminar, Stockholm |
| March 16-20 | DCAT, New York |
| March 26-27 | DNB/Back Bay Nordic-American Healthcare Conference, New York |
| June 2-4 | DDF, Berlin |
| June 12 | Danske Bank Healthcare Seminar, Helsinki |
| September 15-16 | DDF American Summit, Boston |
| October 27-28 | PODD, Boston |
| October 28-30 | CPHI, Frankfurt |

# Nanoform near-term business targets 2024

| Topic | Target | Status |
|---|---|---|
| Customer Projects | *Increased number of non-GMP and GMP projects signed in 2024 vs 2023 ** | *16+1 in 9M2024 vs 17+1 in 9M2023* |
| Operating Free Cashflow | *Improved operating free cashflow in 2024 vs 2023 *** | *EUR -16.7m 9M2024 vs EUR -17.2m in 9M2023* |
| Commercialization | *To sign one or several license/commercial supply agreements during 2024* | *Half a dozen term sheets received, one LOI signed* |

*GMP = Good Manufacturing Practice*
** 22 non-GMP and 1 GMP projects signed in 2023*
*** Operating free cash flow EUR -23.0m in 2023*

# Nanoform mid-term business targets 2025

**>70**
**new APIs per year**

**35 lines of which 7-14 are GMP compliant**

**200-250**
**employees**

**>90%**
**gross margin**

**Cash flow positive**

# Nanoform commercial highlights Jan-Sep 2024

| | |
|---|---|
| *NOV* | New quarterly record in customer project intake |
| *SEP* | Nanoform and Celanese expand collaboration into long-acting biologics delivery through small implants |
| *AUG* | Nanoform initiates collaboration with Takeda on their plasma-derived therapy development (biologics) |
| *JUL* | New US major pharma signed multi-API contract |
| *MAY* | Nanoformed high-concentration biologics formulation for subcutaneous delivery results presented by Takeda at DDF summit in Berlin |
| | Celanese showcases Nanoform's technology for long-acting small molecule drug release at DDF summit in Berlin |
| *APRIL* | Global top 5 animal health company signed new multi-API contract |
| | Nanoform enters sales partnership with CBC to bring best-in-class nanomedicine technology to Japan |
| | Nanoform and PlusVitech partner to repurpose aprepitant as a treatment for lung cancer |
| *FEB* | Nanoapalutamide study demonstrates the advantages of Nanoforming over traditional cancer treatment formulations |
| *JAN* | Nanoform announces important milestone with promising clinical results for patient-centric Nanotechnology-enhanced Nanoenzalutamide |

# Customer projects and customer's formulation challenge

| | Company Type | Therapeutic Area | Customer Formulation Challenge | Pre-Clinical | Phase 1 | Phase 2 | Phase 3 | Marketed |
|---|---|---|---|---|---|---|---|---|
| Small Molecules | Mid-Size Pharma/Biotech | Oncology | Drug Load | | | | | |
| | Mid-Size Pharma/Biotech | Autoimmune | Food Effect/Dose Reduction | | | | | |
| | Large Pharma | Immunology | Dissolution | | | | | |
| | Mid-Size Pharma/Biotech | CNS | Drug Load | | | | | |
| | Large Pharma | Autoimmune | Drug Load | | | | | |
| | Mid-Size Pharma/Biotech | Oncology | Pill Burden | | | | | |
| | Mid-Size Pharma/Biotech | Glioblastoma | Drug Load/Stability | | | | | |
| | Mid-Size Pharma/Biotech | Respiratory | FPF | | | | | |
| | Large Pharma | Oncology | Solubility/Bioavalability | | | | | |
| | Mid-Size Pharma/Biotech | Infectious Disease | Bioavalability/Release Profile | | | | | |
| | Mid-Size Pharma/Biotech | Infectious Disease | Solubility/Bioavalability | | | | | |
| | Large Pharma | Infectious Disease | LAI/Release Profile | | | | | |
| | Large Pharma | Infectious Disease | LAI/Release Profile | | | | | |
| | Large Pharma | Infectious Disease | LAI/Release Profile | | | | | |
| | Mid-Size Pharma/Biotech | Infectious Disease | LAI/Release Profile | | | | | |
| Large Molecule | Large Pharma | Respiratory | FPF | | | | | |
| | Mid-Size Pharma/Biotech | Autoimmune/Oncology | Release Profile | | | | | |
| | Mid-Size Pharma/Biotech | Autoimmune/Oncology | Release Profile | | | | | |
| | Large Pharma | Respiratory | FPF/Drying | | | | | |
| | Large Pharma | Respiratory | FPF/Drying | | | | | |
| | Mid-Size Pharma/Biotech | Endocrinology | High Conc. SuBQ | | | | | |

*LAI = Long Acting Injectable*
*FPF = Fine Particle Fraction*

# Nanoform has made substantial progress in Nanoforming solutions with in-vitro, in-vivo, and clinical study results

**Oncology:** **Replaced amorphous solid dispersion (ASD) formulations with nanocrystalline high drug load formulations**, matching bioequivalence for Enzalutamide and Apalutamide where life cycle management **opportunities to reduce tablet burden to a single, smaller, easier-to-swallow tablet** as well as working on Aprepitant in partnership with PlusVitech for lung cancer to develop a regimen with substantially fewer tablets.

**Inhalation:** **Engineering nanoformulations of both small and large molecules** with excellent fine-particle dose (FPD) and fine-particle fraction (FPF) performance in comparison to spray drying technologies. In biologics, Nanoform has shown FPF >95% vs 50% with spray drying for delivering **high drug load** to the lungs.

**Biologics:** Demonstrated in partnership, with Takeda and other companies, **ultra-high concentrations for subcutaneous drug delivery** with acceptable viscosity for injection (Takeda – Plasma Derived Therapies).

**Ophthalmic:** **Multiple projects where nanoparticles have shown improved delivery potential. High drug load** to the eye enabling smaller implants with no requirement for mesh membranes, eye drop suspensions and ophthalmic inserts.

**Hydrogels:** **Shown high drug load** applications (5 x more than nanomilling) for post-surgical glioblastoma drug delivery and deep penetration across the brain parenchyma **enabling non-recurrence of glioblastoma** where other formulations failed.

**IP:** **Novel technologies, processes and formulations** can enable market opportunities, lifecycle management and strong launch strategies

# Business case Amorphous Solid Dispersions (ASDs)

**Amorphous solid dispersion (ASD) medicines are currently the leading formulation strategy for poorly soluble APIs and there are ~50 marketed medicines globally that are ASDs and sell for ~$50bln annually**

**Nanoformed and nanocrystalline medicines (e.g. nanoenzalutamide and nanoapalutamide etc) offer an attractive alternative to ASD medicines (and other) with the following benefits:**

- ***substantially higher drug load in the final drug product***
- ***reduced pill burden for the patient***
- ***opportunity to extend IP protection for the reformulated and improved product***
- ***opportunity for earlier market entry***

⇨ ***Several opportunities for Nanoform to replicate early successes with project kernels nanoenzalutamide and nanoapalutamide***

# Project Nanoenzalutamide (oral tablet for prostate cancer)

**Clinical results 26.1.2024:** Very promising relative bioavailability study of nanocrystalline-enabled enzalutamide* (nanoenzalutamide) tablet formulation.

**Nanoforming benefits: 1)** Opportunity for an improved and differentiated finished product, **2)** Development of a 160mg, single tablet per day regimen may be preferable for patients in need of reducing their total number of daily pills **3)** Unique IP position may allow the nanoenzalutamide product to enter the market prior to other generic competition based on the ASD formulation, which is currently patent protected in the US and Europe until 2033

**Next steps:** Manufacture Nanoformed material for registration batches and EU/US pivotal bioequivalence clinical trials that are expected to start in 1Q 2025, with first read-outs in 2Q 2025. License and commercial supply agreements are expected to be signed in coming quarters.

**Target launch:** Submissions of dossiers 1H 2026, launch after expiry of the enzalutamide substance patent in USA 2027 & in Europe in 2028. Nanoenzalutamide is expected to progress via the ANDA (Abbreviated New Drug Application)/Hybrid generic pathway and as such will need to show bioequivalence vs the originator product, Xtandi®. In the eyes of the regulators, bioequivalence typically means 80% - 125% of the Cmax and AUC in a large cohort study in fed and fasted states with a 90% confidence interval. The global annual sales of Xtandi® is presently USD 6bn and growing. We plan nanoenzalutamide to take a meaningful share of this market through its highly patient centric product differentiation (1 tablets 4 tablets) and unique IP position (different technology, crystalline product, different excipients), while not forgetting its green attributes. We expect nanoenzalutamide to be the first nanoformed medicine to reach the market.

**Value added medicine companies vs originators**: We see the program to be attractive to value added medicine companies as a uniquely differentiated and high value supergeneric product that can enable a product launch before market entry by other generic products based on the ASD formulation, for which the originator currently holds patents in both Europe and the US (with expiry dates in 2033). For the originator company we believe that the nanocrystalline single tablet product offers a patient centric life cycle extension opportunity with compelling sustainability advantages that would be difficult for generic competitors to match. Avoiding the inherent stability challenges associated with amorphous materials is also a clear benefit for any company considering alternative formulation approaches.

# Project Nanoapalutamide (oral tablet for prostate cancer)

**FEBRUARY 19, 2024 – APALUTAMIDE STUDY AGAIN DEMONSTRATES THE ADVANTAGES OF NANOFORMING OVER TRADITIONAL CANCER TREATMENT FORMULATIONS**

**Positive results from own pre-clinical, in-vivo study of a nanocrystalline-enabled apalutamide oral formulation, which shows potential to enable a much smaller tablet than Erleada®, (Erleada is a registered trademark for Apalutamide owned by Johnson & Johnson / Janssen Biotech, Inc.) a nonsteroidal antiandrogen (NSAA) blockbuster amorphous solid dispersion (ASD) medicine used to treat prostate cancer. The nanocrystalline-enabled formulation provided high serum concentration (Cmax), fast time to peak drug concentration (Tmax), and 100% absolute bioavailability.**

**Nanoform's nanocrystalline formulations enable significantly higher drug loading, allowing for smaller pills and a reduced pill burden. Its technology is free from organic hydrocarbon solvents, offering an environmentally sustainable alternative.**

**NOVEMBER 18, 2024 – PROJECT NANOAPALUTAMIDE PROGRESSING ACCORDING TO PLAN**

**We were pleased with the positive results from a recent in vivo study comparing Nanoform's tablet prototypes with the currently marketed product. The results provide confidence in our choice of the lead tablet prototypes and are expected to further accelerate interest among potential partners. Based on earlier experience with Nanoenzalutamide, we expect that following further optimization of the formulation, the next major development milestone for this project is a pilot PK study in humans during 2H2025.**

# Takeda (plasma-derived formulations for rare conditions)

**MAY 7, 2024 - NANOFORMED HIGH-CONCENTARION BIOLOGICS FORMULATION FOR SUBCUTANEOUS DELIVERY RESULTS TO BE PRESENTED BY TAKEDA AD DDF SUMMIT**

**The proof-of-concept study data support the potential of Nanoform's patented biologics platform to achieve high protein concentrations in suspension formulations that are suitable for subcutaneous injection, as shown by results of syringeability and injectability studies.**

**Controlling the viscosity and aggregation of protein-based solutions is important for pharmaceutical formulators. Because injection volume is limited by the device, therapeutic protein formulations which are to be delivered via intramuscular or intravenous injection need to be highly concentrated. At protein concentrations greater than 200 mg*mL$^{-1}$ however, viscosity increases to significantly higher than 20 cP (centipoise) to quickly exceed the maximum 40 cP viscosity deemed acceptable for a conventional subcutaneous injection.**

**AUG 15, 2024 - NANOFORM COLLABORATES WITH TAKEDA ON THEIR PLASMA-DERIVED THERAPY DEVELOPMENT**

**Nanoform enter into a pre-clinical development agreement with the Plasma-derived Therapies Business Unit of Takeda Pharmaceuticals Inc. to develop innovative plasma-derived therapy formulations for the treatment of rare conditions. Following the completion of in vitro proof of concept studies of a novel plasma-derived therapy formulation, Nanoform will provide non-GMP nanomaterial to Takeda for in vivo studies. The first results of these studies are expected by early 2025. It is the intention of both Nanoform and Takeda to develop medicine candidates to clinic and then take them as products to the market.**

**Nanoform Biologics' nanoforming technology can deliver large-molecule drug particles of tuneable size and morphology, while retaining biological activity. The technology can be applied across the biologics field, from 1 to 150KDa, to enable novel routes of delivery, enhance drug loading, tailor release profiles and engineer new drug combinations.**

# Project Glioblastoma (hydrogel for central nervous system cancer)

**Nanoform customer TargTex S.A. was granted Orphan Drug Designation by FDA for its nanoformed drug candidate TTX101 to be used in patients with malignant gliomas (October 2023). The orphan drug designation follows the generation of a preclinical rodent data package in which a survival advantage was shown for this nanoform-enabled medicine candidate.**

**The hydrogel nanoformulation developed by Nanoform enabled a 200-fold increase in drug load compared to bulk and a 5-fold increase in drug load compared to nanomilling.**

**In November 2023, the European Innovation Council and SMEs Executive Agency (EISMEA) awarded TargTex €14m in funding.**

**TargTex is currently raising additional funds to take this innovative treatment to clinic and is planning a phase 1/2a clinical trial in recurrent glioblastoma (GBM) patients across the US and EU, in which nanoformed TTX101 is applied as adjunct to surgery after tumour excision.**

# Nanoform is here to fill the gap

**Enabling new drugs**

**> 20,000 drugs in development***

**Improving existing drugs**

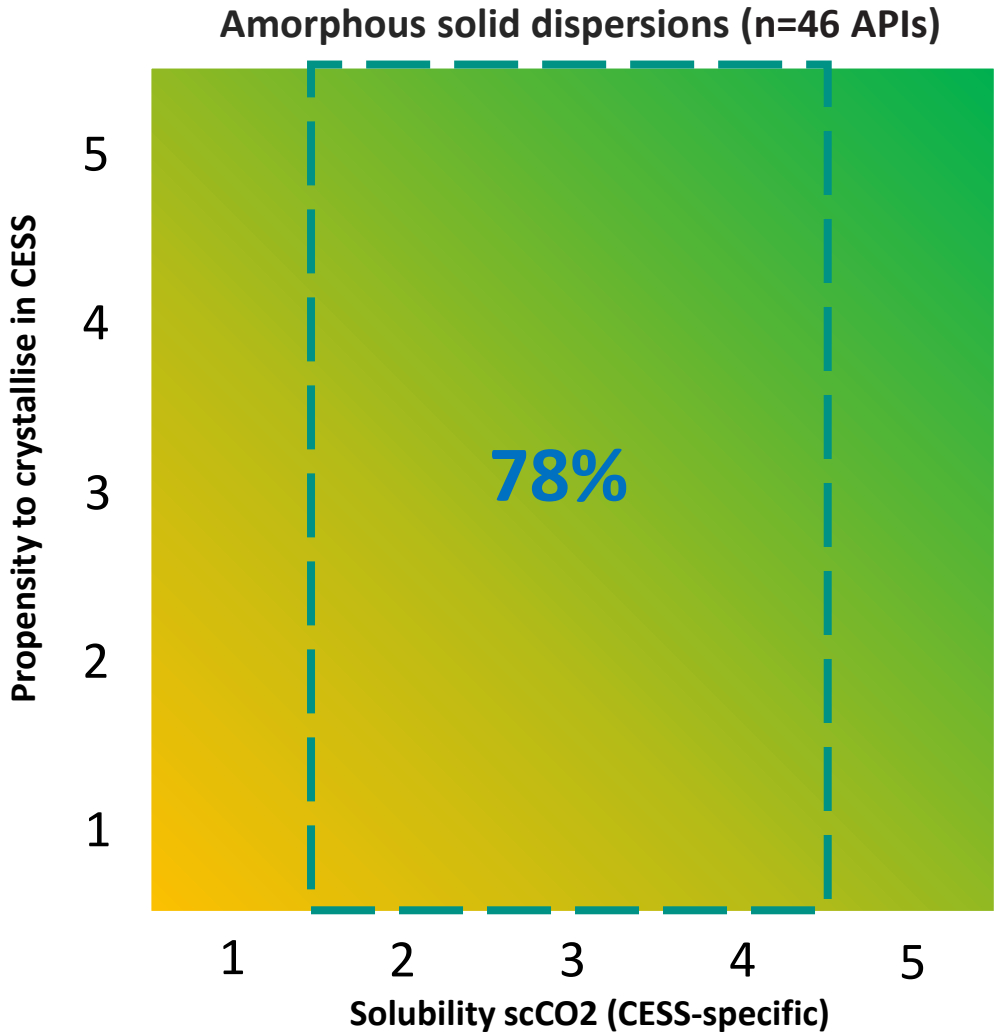
**> 5,800 existing drugs***

**Giving unsuccessful drug candidates a second chance**

**> 58,000 failed drugs in the last 40 years***

*Source: Nanoform and Pharmaprojects® | Informa, 2022

# STARMAP® predicts that nanoforming is an attractive alternative to ASDs (Amorphous Solid Dispersions)




- ✓ STARMAP predicts that 78% of marketed ASD APIs fall within our processing “sweet spot"
- ✓ 46 ASDs have been Starmapped
- ✓ There are ~50 ASDs on the market selling globally for ~USD 50bn, while there are 30+ candidates disclosed in the clinical pipe-line and most likely hundreds in the preclinical state.
- ✓ The Nanoenzalutamide and Nanoapalutamide projects are first examples of what nanoforming potentially can do to/for ASDs

***Nanoform uses its expertise at the interface of nanoparticles and polymer science to enable a more patient- and planet centric alternative to ASDs***

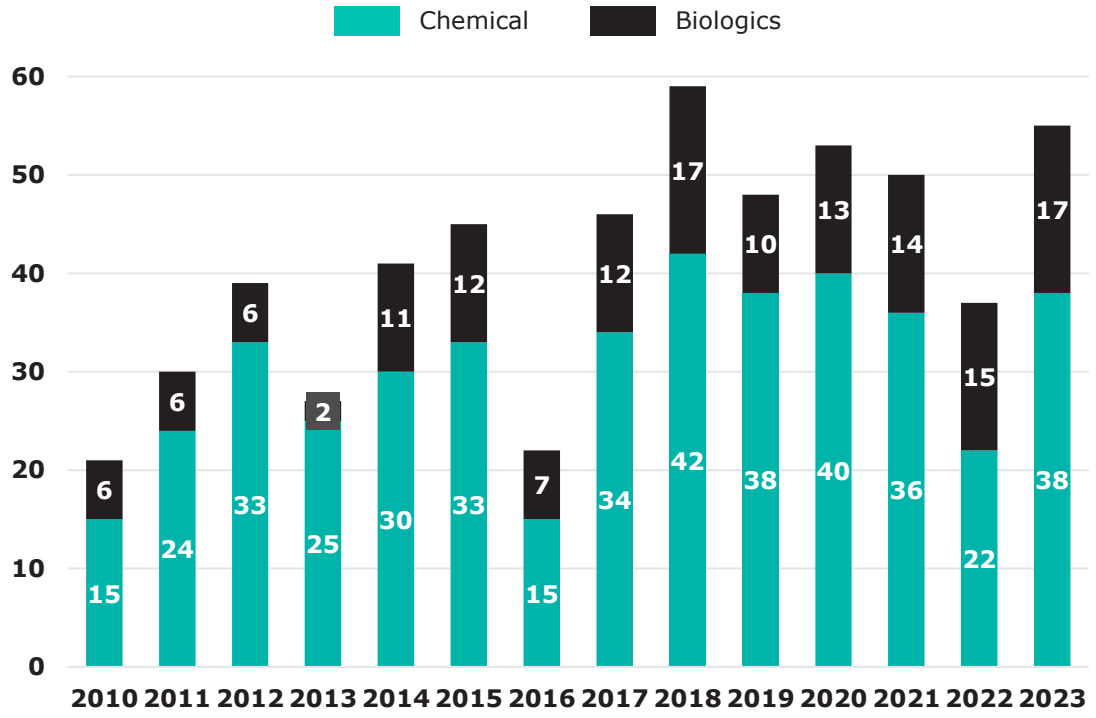
# Within marketed ASDs 31/39 passed our STARMAP® screen and are predicted to be amenable to nanoforming*

| | |
|---|---|
| Belsomra® | suvorexant |
| Braftovi® | encorafenib |
| Cesamet® | nabilone |
| Deltyba® | delamanid |
| Erleada® | apalutamide |
| Febuxostat® | febuxostat |
| Gavreto® | pralsetinib |
| Incivek® | telaprevir |
| Intelence® | etravirine |
| Jinarc/Samsca® | tolvaptan |
| Kaletra® | ritonavir/lopinavir |
| Kalydeco® | ivacaftor |
| Lynparza® | olaparib |
| Norvir® | ritonavir |
| Noxafil® | posaconazole |
| Orkambi® | ivacaftor/lumacaftor |
| Pifeltro® | doravirine |
| Prezista® | darunavir |
| Prograf® | tacrolimus |
| Qinlock® | ripretinib |
| Sotyktu® | deucravatinib |
| Sporanox® | itraconazole |
| Stivarga® | regorafenib |
| Sunlenca® | lenacapavir |
| Symdeco/Symkevi® | ivacaftor/tezacaftor |
| Tavneos® | avacopan |
| Trikata® | ivacaftor/tezacaftor/elexecaftor |
| Tukysa® | tucatinib |
| Xtandi® | enzalutamide |
| Zokinvy® | lonafarnib |
| Zortress® | everolimus |

# The structural pharma R&D problem in the pharma industry

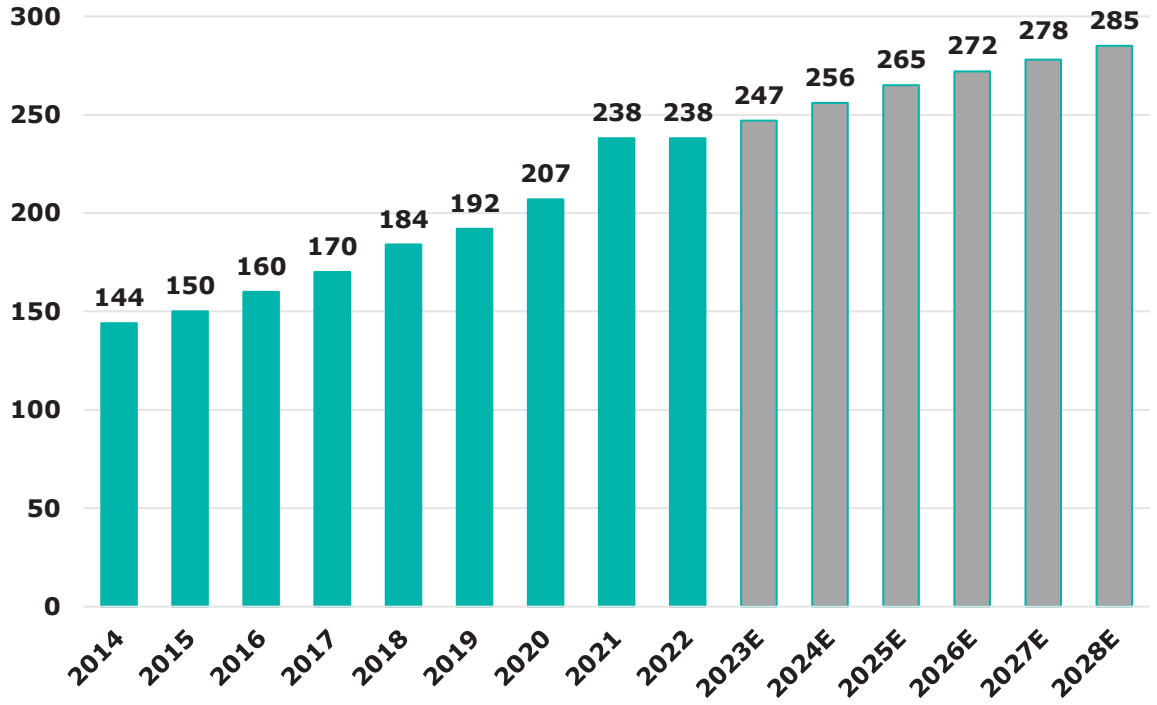
## Fewer than 50 drugs approved in the US annually on average…

**Annual number of novel drug approvals by FDA 2010-2023**




## …while the global pharma industry R&D expenditure exceeds $200B

**Global pharmaceutical R&D spending 2014-2028E (USDbn)**



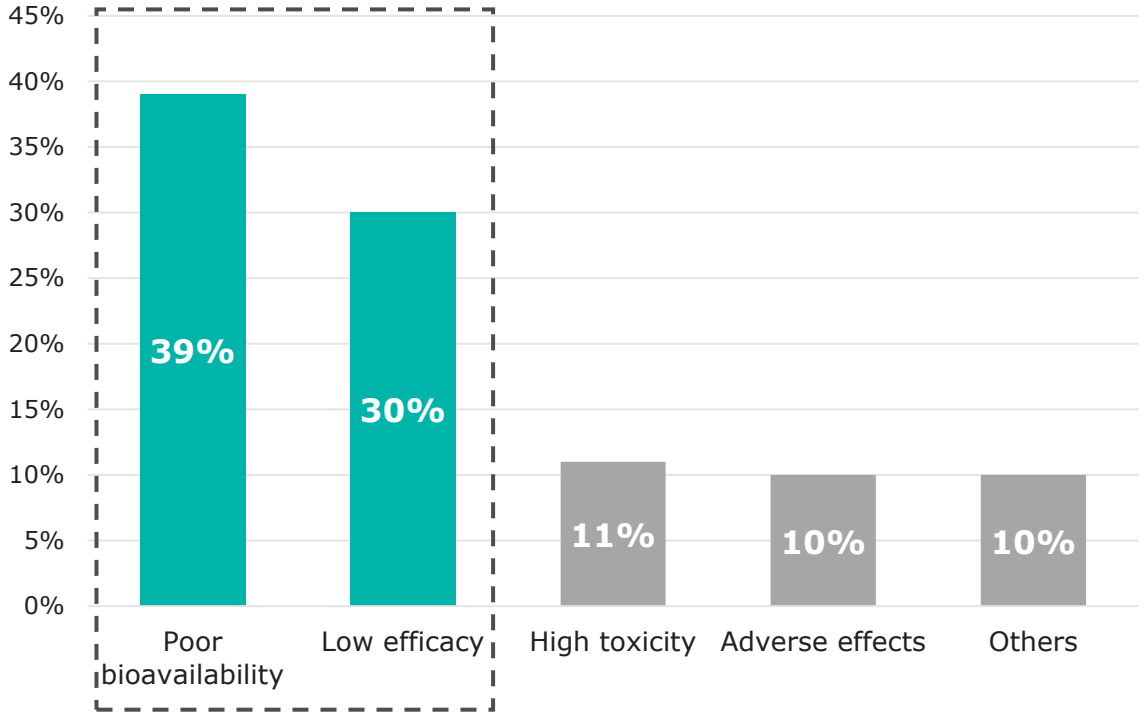

➢ **A game changer is needed to improve R&D yield**

Source: U.S. Food and Drug Administration (FDA); IQVIA Institute for Human Data Science; Statista; Nature

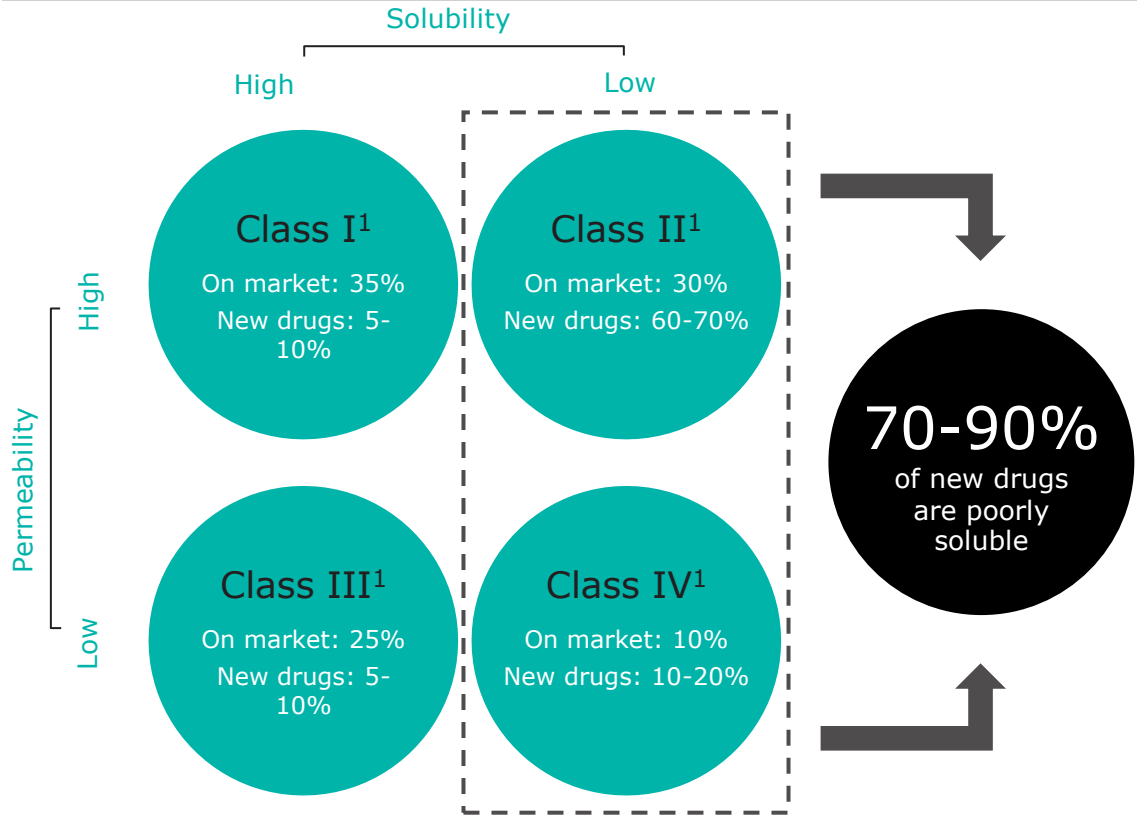
# Low bioavailability is the key issue

## Poor bioavailability and low efficacy most common reasons for drug failure

**Reasons for drug failure in pre-clinical trials (share of molecules)**




## Majority of new drugs suffer from poor solubility

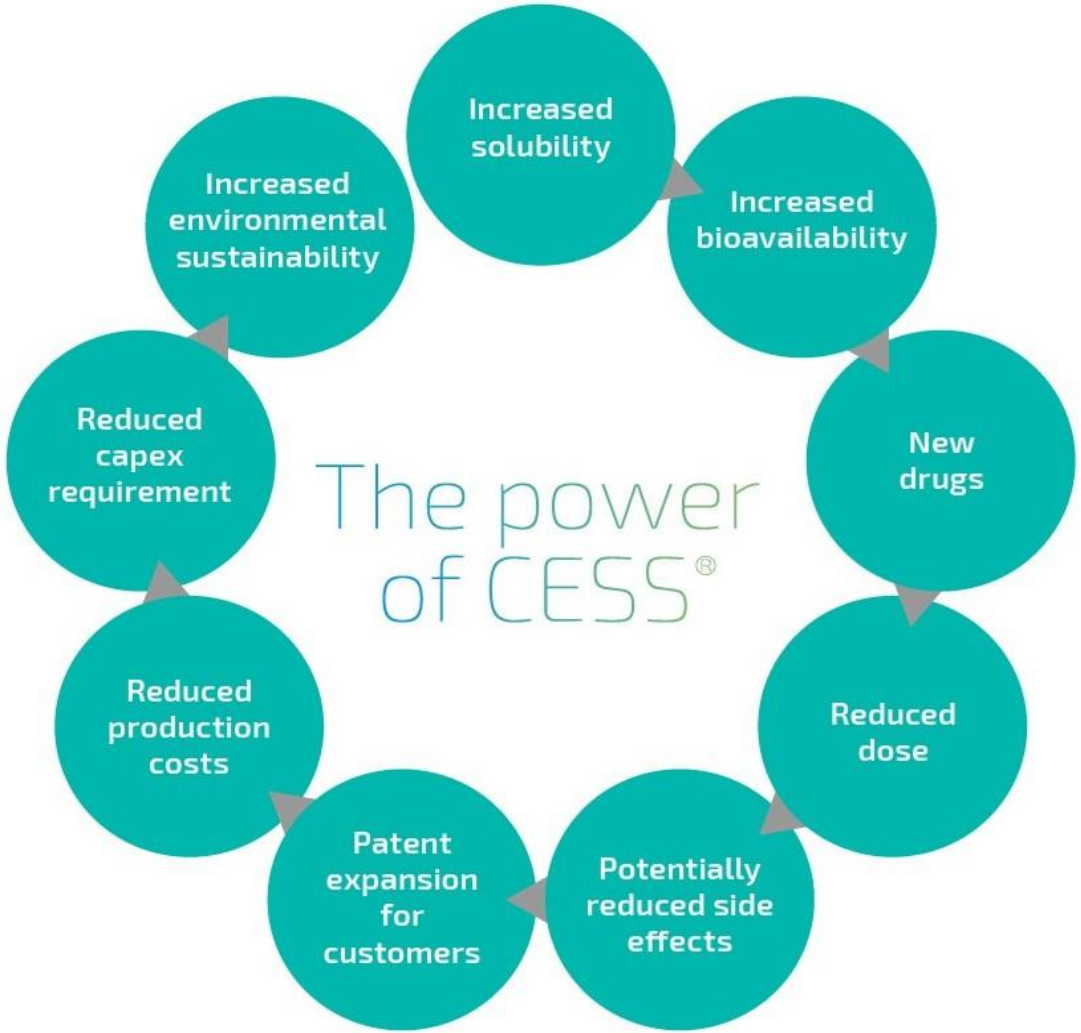



➢ **Nanoform can enhance the pharma industry output by targeting poorly soluble drugs**



Source: GlobalData 2009, Cutting Edge Water-based Nanotechnology in Drug Development (Reasons for drug failure); Nikolakakis & Partheniadis (2017), Self-Emulsifying Granules and Pellets: Composition and Formation Mechanisms for Instant or Controlled Release (Share of poorly soluble drugs) 1) Classification of drug substance according to Biopharmaceutics Classification System (BCS)

# Small molecules - Small is powerful®

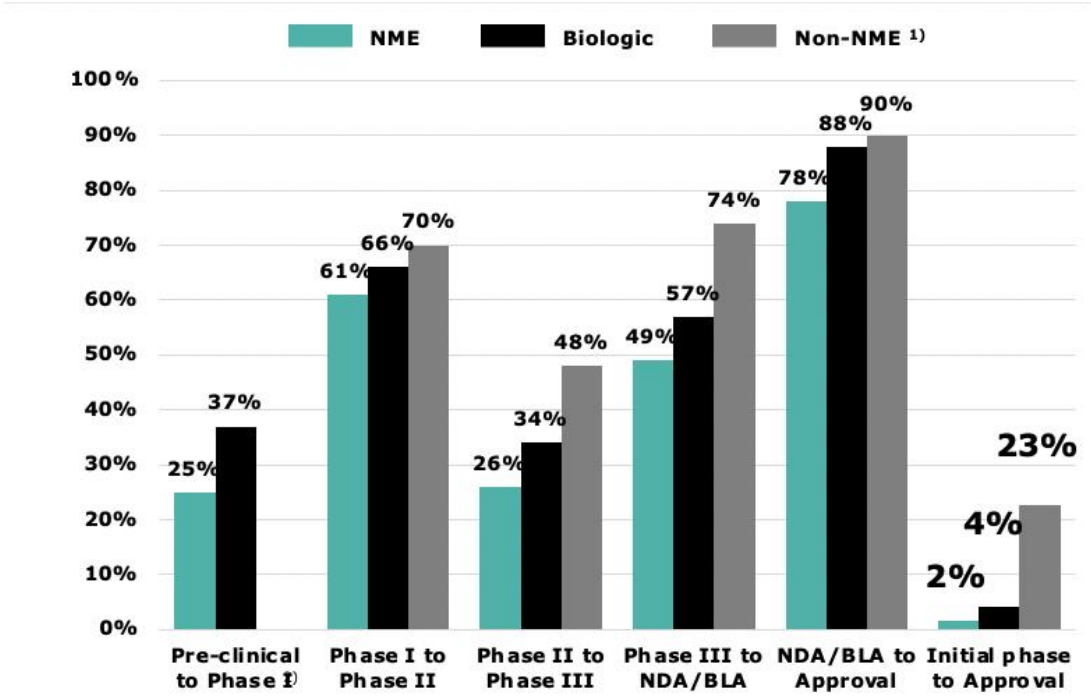


# Revenue drivers & industry attrition rates

## Nanoform pre-clinical and clinical revenue drivers

| | Non-GMP | GMP |
|---|---|---|
| Proof of Concept (PoC) | ➢ # of active customers<br>➢ # of APIs per customer<br>➢ Price per PoC per API | |
| Phase I, II & III and/or 505(b)(2) | | ➢ Attrition between previous and current phase<br>➢ Price per phase per API<br>➢ Time lag between previous and current phase<br>➢ # of customers with 505(b)(2) strategy<br>➢ Proportion of new drug candidates and 505(b)(2) APIs |
| Proof of Process (PoP) | ➢ Attrition between PoC and PoP<br>➢ Price per PoP per API<br>➢ Time lag between PoC and PoP | |
| Drugs on the market | | ➢ # of drugs on the market using CESS®<br>➢ License fee & royalty level per drug<br>➢ Net revenues per drug<br>➢ Time lag Phase II and market (505b2)<br>➢ Time lag Phase III and market<br>➢ Speed of uptake on market |

## Global Pharmaceutical industry's pre-clinical and clinical success rates




| Timeline (years) | Pre-clinical | Phase I | Phase II | Phase III | Approval | Total |
|---|---|---|---|---|---|---|
| New drugs | ~1-4 | ~2 | ~2 | ~3-4 | ~1 | ~9-13 |
| Existing drugs | - | Clinical development for 505(b)(2) ~2-5 | | | ~1 | ~3-6 |

Source: Company information; Takebe, Imai & Ono (2018), Clinical and Translational Science (11) (Pre-clinical to Phase I); Biotechnology Innovation Organization, Biomedtracker and Amplion, Clinical Development Success Rates 2006-2015 (Clinical success rates); Kaur, Sharma & Sharma (2014), Journal of Drug Delivery and & Therapeutics (4) (Timeline); The Pharmaceutical Journal, Drug Development: The Journey of a Medicine from Lab to Shelf (Timeline); Camargo Pharmaceutical Services, Understanding the 505(b)(2) Approval Pathway (Timeline); 1) Non-NMEs often use 505(b)(2) pathway to gain FDA approval, source: Biotechnology Innovation Organization, Biomedtracker and Amplion 2) Academic drug discovery, NME consisting only of small molecules

# Nanoform – Attractive revenue model

## Predictable revenue streams through capitalizing the entire pharmaceuticals value chain

| Phase | Proof of Concept / Proof of Process | Phase I – III trials | Drugs on the market |
|---|---|---|---|
| Certification | Non-GMP | GMP | GMP |
| Description | • *Proof of concept study* - assessment of the possibility to nanoform a specific API<br>• *Proof of process study* - definition of parameters to establish the optimal process and controls for a specific API | • API for clinical trials are manufactured in Nanoforms GMP facility<br>• Supply of material for customers' Phase I, II and III trials<br>• Nanoform gets paid regardless of the outcome of the trials | • Drugs that have passed the trials and reached commercialization<br>• In practice, if a company has taken its drug through Phase II trials, it is difficult to switch manufacturer<br>• Significant potential from patent extension (505b2 projects) of drugs already on the market |
| Revenue model | Fixed fee per project<br>*Estimated project fee of EUR 50-500k per API per project* | Fixed fee per project<br>*Estimated project fee of EUR 0.5-10m per API per phase* | Royalty as a % on drug sales or supply price per kg<br>*Estimated royalty fee of 1-20%* |

# Management team: Multi-disciplinary with international merits

**CEO & Co-founder; Ph.D. (Applied physics), MBA**

## Edward Hæggström

- Professor at the University of Helsinki, Head of Electronics Research Lab. within the Dept. of Physics
- Previously visiting professor at Harvard Medical School, visiting scholar at Stanford University and project leader at CERN
- Has led large number of scientific projects
- *Current ownership: 5,409,405 shares and 204,000 options*

**CCO; M.Sc. (Chemistry)**

## Christian Jones

- Previously Commercial Director and member of the Senior Leadership Team for the Global Health Sector at Johnson Matthey
- Senior roles at Dr. Reddy's Global Custom Pharma Solutions and Prosonix
- **Key area of responsibility:** Commercial strategy and business development
- *Current ownership: 384,000 options*

**General Counsel & Chief Development Officer; LL.M**

## Peter Hänninen

- Previously Attorney, Borenius Attorneys
- Successful track-record of advising technology companies from founding to exit in key transactions and collaborations
- **Key area of Responsibility:** Legal, Compliance, IPR, HR, IT
- *Current ownership: 103,125 shares and 530,000 options*

**Chief Quality Officer, M.Sc. (Pharmacology)**

## Johanna Kause

- Previously Head of Quality, Regulatory and Safety for Finland and the Baltics at Takeda Pharmaceuticals
- 25 years of experience in Quality Management in the Pharma sector
- **Key area of responsibility:** Quality Management, GMP, GDP
- *Current ownership: 130,000 options*

**CFO and member of the Board; B.Sc. (Economics)**

## Albert Hæggström

- 20 years of finance and investing experience
- Prior roles include positions at Alfred Berg, BNP Paribas, Nordea and SEB
- *Current ownership: 726,419 shares and 670,000 options*

**Head of Manufacturing; Ph.D. (Chemistry)**

## David Rowe

- Previously Particle Size Reduction Lead for GlaxoSmithKline
- Chaired the PSR Centre of Excellence
- **Key area of responsibility:** Technical leadership within new chemical entities and commercial assets
- *Current ownership: 413,720 options*

**Chief of Business Operations (Chemistry and Quality)**

## Antonio da Silva

- Degree in Chemistry from Lisbon University and Master degree in Quality from the University Aberta of Lisbon
- Extensive background in the CDMO and particle engineering space (19 years at Hovione)
- **Key area of responsinility:** Pharmaceutical product launches
- *Current ownership: 24,500 shares and 224,516 options*

# Board of directors: Top executives from leading industry positions

## Miguel Calado

**Chairman of the Board**

- Previously CFO at international particle engineering CDMO company Hovione Group
- Other previous roles include CFO at PepsiCo International and President International Operations at Dean Foods
- Experienced Board member in both the EU and the US
- *Current ownership: 70,043 shares and 380,000 options*
- **Key experience:**

PEPSICO Hovione Dean FOODS

## Albert Hæggström

**CFO and Board Member**

- 20 years of finance and investing experience
- Prior roles include positions at Alfred Berg, BNP Paribas, Nordea and SEB
- *Current ownership: 711,494 shares and 670,000 options*
- **Key experience:**

Alfred Berg BNP PARIBAS Nordea SEB

## Mads Laustsen

**Board Member**

- Over 30 years of experience in pharmaceutical development and manufacturing
- Co-Founder and former CEO of international biologics CDMO company CMC Biologics and former CEO of Bactolife A/S
- Extensive experience in process development and patenting
- Senior positions within several Danish biotech companies
- *Current ownership: 25,649 shares and 300,000 options*
- **Key experience:**

CMC biologics BACTOLIFE symphogen

## Jeanne Thoma

**Board Member**

- 30+ years of experience in global pharmaceutical and life science leadership
- Prior roles include executive positions at BASF Inc, Lonza AG and SPI Pharmaceuticals
- *Current ownership: 25,649 shares and 38,630 options*
- **Key experience:**

BASF We create chemistry Lonza SPI Pharma An ABF Ingredients Company

nanoform
small is powerful®

## FURTHER ENQUIRIES

**CEO Edward Hæggström - edward.haeggstrom@nanoform.com, +358 29 370 0150**
**CFO Albert Hæggström - albert.haeggstrom@nanoform.com, +358 29 370 0150**
**DIR Henri von Haartman - hvh@nanoform.com, +46 76866 50 11**