

# Nanoform Management Presentation

SEB Nordic Seminar Copenhagen

January 9, 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, 2022 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.



## KEY TOPICS AT SEB NORDIC SEMINAR COPENHAGEN

- > Nanoform technologies
- Highlights
- Project Glioblastoma
- Project Nanoenzalutamide ("Blockbuster")
- Nanoforming Amorphous Solid Dispersions (ASDs)

#### Financials



## SHORT INTRODUCTION TO NANOFORM

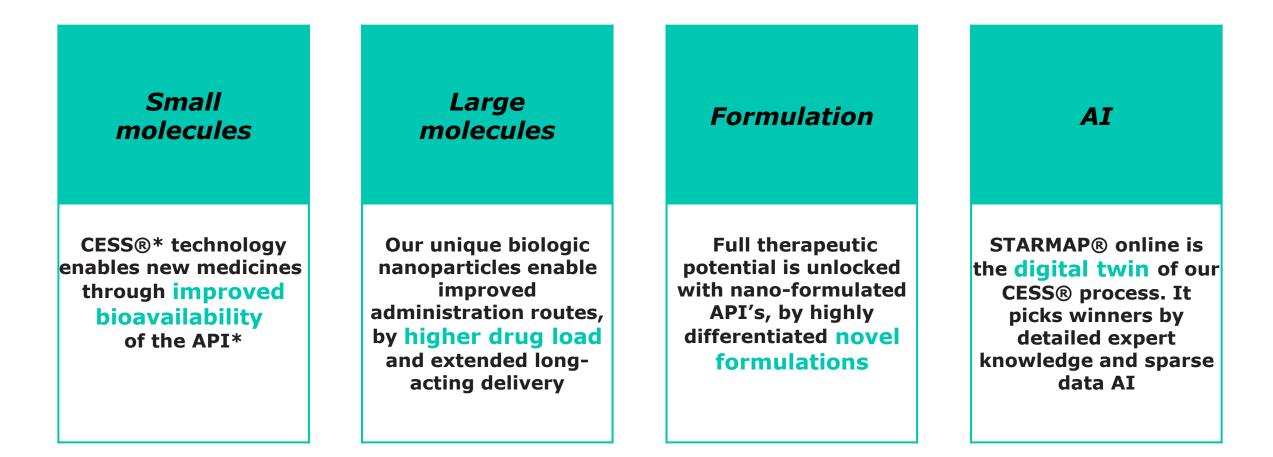


#### Nanoform in a snapshot

TECHNOLOGY	PEOPLE	MEDICINES	FINANCE	PATIENTS
Global experts in nanotechnology & drug particle engineering	165 employees, 35 nationalities, 39 PhD's in US, UK, Europe	Staff with combined experience of launching 100+ medicines	Strong balance sheet & institutional ownership	Improving lives of patients through game-changing technologies & novel formulations



## Proprietary platform technology





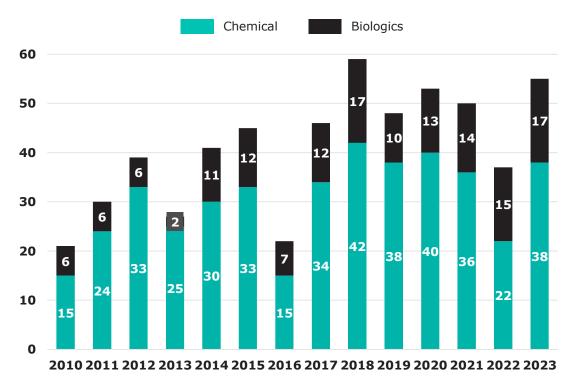
\*CESS<sup>®</sup> = Controlled Expansion of Supercritical Solutions

**\*API = Active Pharmaceutical Ingredient** 

#### The structural pharma R&D problem

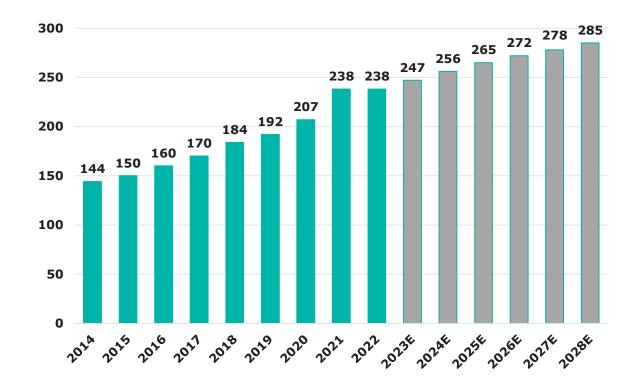
#### Fever than 50 drugs approved in the US annually on average...

...while the global pharma industry R&D expenditure exceeds \$200B



Annual number of novel drug approvals by FDA 2010-2023

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

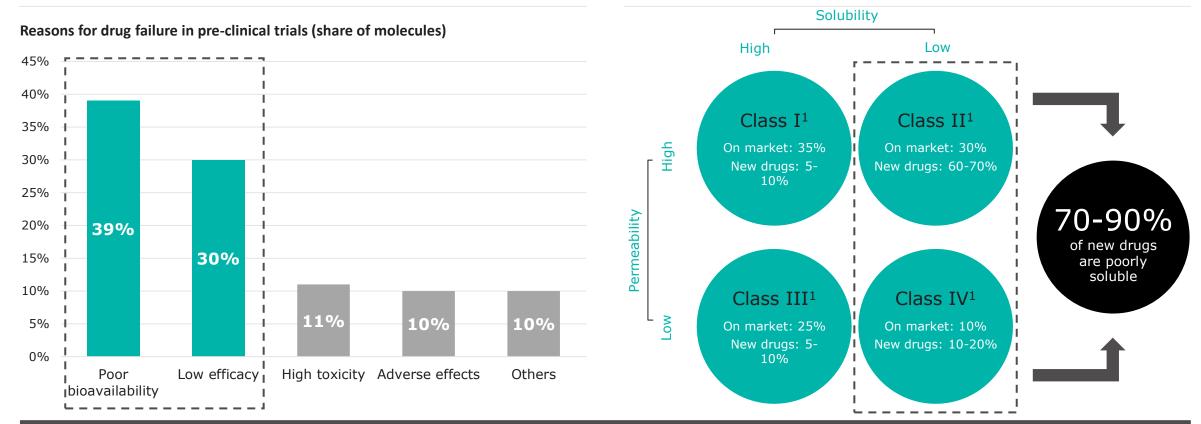


A game changer is needed to improve R&D yield



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

#### Low bioavailability is the key issue



Majority of new drugs suffer from poor solubility

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

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

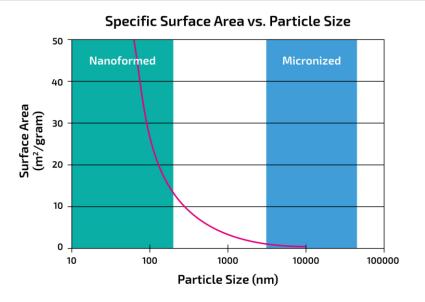


Source: GlobalData 2009, Cutting Edge Water-based Nanotechnology in Drug Development (Reasons for drug failure); Nikolakakis & Partheniadis (2017), Self-Emulsifying Granules and Pellets: Composition and Formation Mechanisms for Instant or Controlled Release (Share of poorly soluble drugs) 1) Classification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

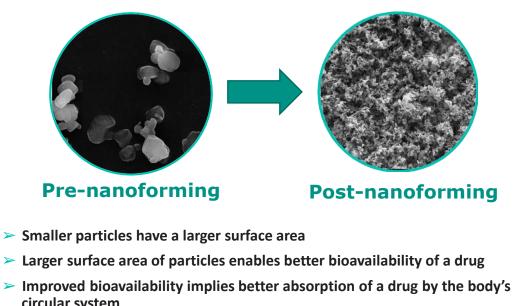
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#### Particle size is key

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



- The surface area increases 30 fold from a 10 micron<sup>1</sup> 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



circular system
 CESS<sup>®</sup> can produce API with large surface areas which can significantly improve

> CESS<sup>®</sup> produced nanoparticles have a larger surface area and as such improved bioavailability.

the bioavailability of drugs



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

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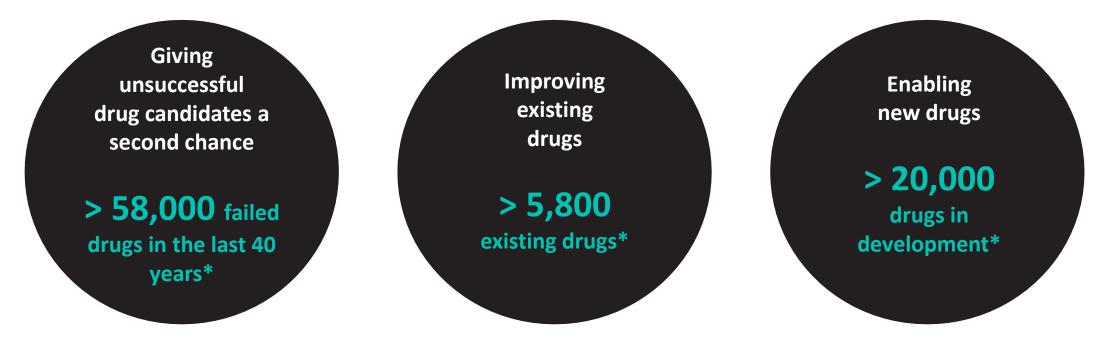
#### Small molecules - Small is powerful®





## Nanoform is here to fill the gap

## The solution to low bioavailability is to decrease the particle size of the Active Pharmaceutical Ingredient (API)



Nanoform's CESS<sup>®</sup> is the only technology that can manufacture nanoparticles without solvents, excipients, and complex production processes

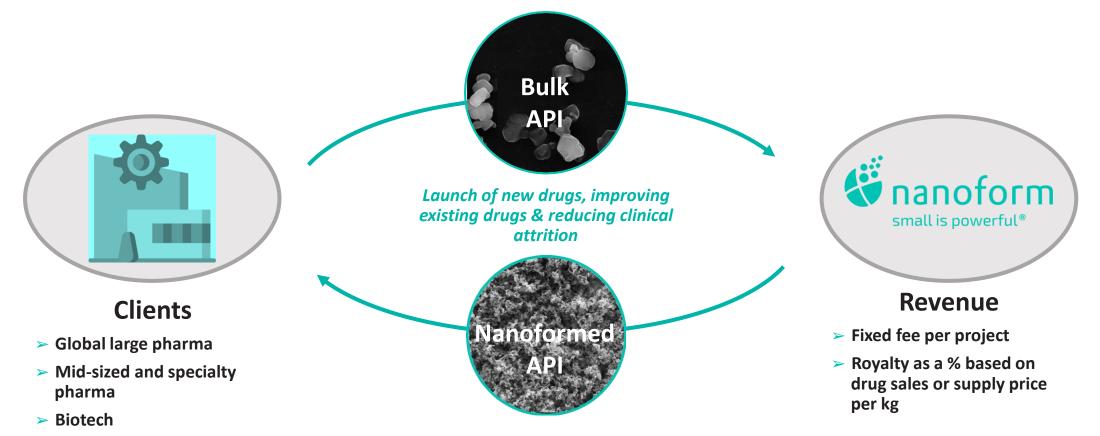


API = Active Pharmaceutical Ingredient CESS<sup>®</sup> <sup>=</sup> Controlled Expansion of Supercritical Solutions \*Source: Nanoform and Pharmaprojects® | Informa, 2022

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#### Simplified value chain

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



> Nanoform nanoforms APIs for the pharma and biotech industry using its patented CESS® technology



API = Active Pharmaceutical Ingredient CESS<sup>®</sup> <sup>=</sup> Controlled Expansion of Supercritical Solutions GMP = Good Manufacturing Practice

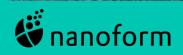
#### Selection of Nanoform Institutional Shareholders





1) Latest ownerhsip data can be found at <a href="https://nanoform.com/en/ownership-structure/">https://nanoform.com/en/ownership-structure/</a>

# HIGHLIGHTS



#### Nanoform from June 2020 IPO to September 2023

Q4 and FY2023 results due February 29<sup>th</sup>, 2024

	IPO June 2020	Sept 2023	Growth
Employees	50	~160	~3x
Manufacturing lines	5	~20	~4x
Customers enrolled	5	~40	~8x
Customer projects started	5	~60	~12x



#### ✓ Project Nanoenzalutamide\* ("Blockbuster") is progressing well

- Strong business opportunity identified within Amorphous Solid Dispersions (ASD)
- ✓ STARMAP<sup>®</sup> licensed to AstraZeneca Plc
- ✓ **Project Glioblastoma** customer Targtex's nanoformed drug candidate received FDA orphan drug designation
- Multi-API license received by FIMEA; Marketing Authorization and additional facilities review expected in Q1 2024
- Promising initial in-vitro trials with two major pharma looking at monoclonal antibodies
- Improved cash flow

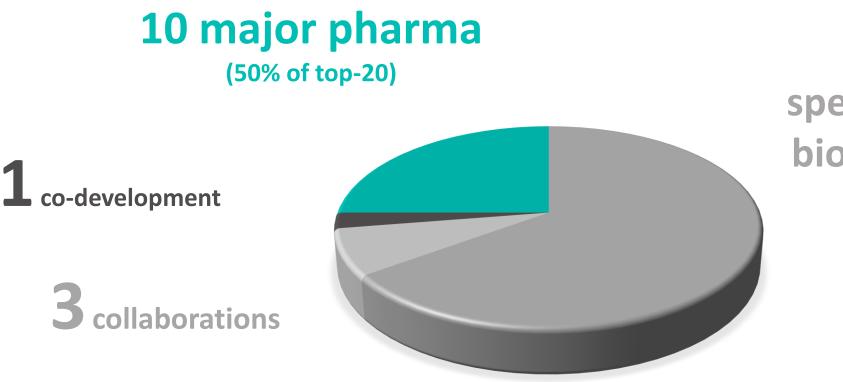
#### Balance sheet remains strong



\*Project Nanoenzalutamide ("Blockbuster"): The development and commercialization of a more patient centric and nanoformed version of an existing blockbuster drug

## Commercial Relationships 2019 to 3Q 2023

Q4 and FY2023 results due February 29<sup>th</sup>, 2024



## 26 mid-sized, specialty pharma & biotech companies



6 new clients in Jan-Sep 2023

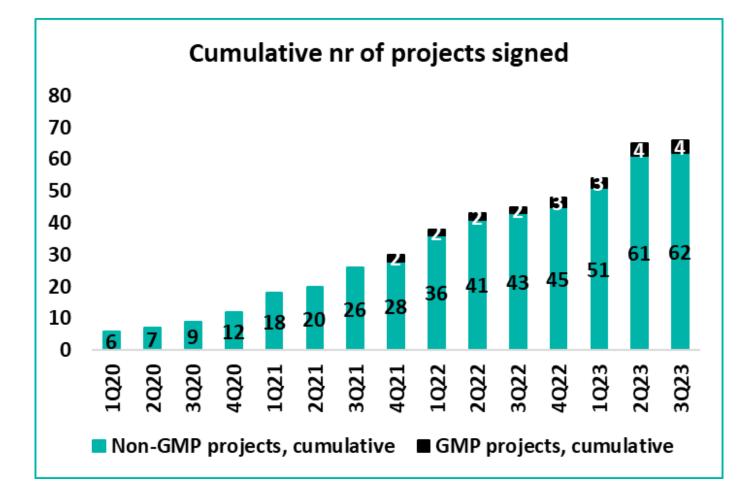
#### Selection of Nanoform Pharmaceutical Partnerships

- 10 of the top 20 Major Pharma and many Biotechs including





#### Cumulative nr of projects signed





# PROJECT GLIOBLASTOMA



#### Project Glioblastoma





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

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

Find press release here: Nanoformed TargTex oncology drug candidate TTX101 receives FDA Orphan Drug Designation – Nanoform small is powerful



# PROJECT NANOENZALUTAMIDE



## Project Nanoenzalutamide – a potential breakthrough

#### Existing blockbuster drug Xtandi<sup>®\*</sup>

- Xtandi<sup>®</sup> #1 prescribed androgen receptor inhibitor, approved by FDA in 2012 to treat prostate cancer
- Sells for >\$5bln per year
- Amorphous solid dispersion (ASD)

\*Xtandi is a registered trademark of Astellas Pharma Inc.



#### Nanoformed drug Nanoenzalutamide

- The development and commercialization of a more patient centric drug
- Nanoform ownership 25%, in a consortium of four equal owners
- Strong interest in the project from valueadded medicine companies

Press release here: Nanoform Commenced Relative Bioavailability Study of Nanotechnology-Enhanced Enzalutamide – Nanoform small is powerful

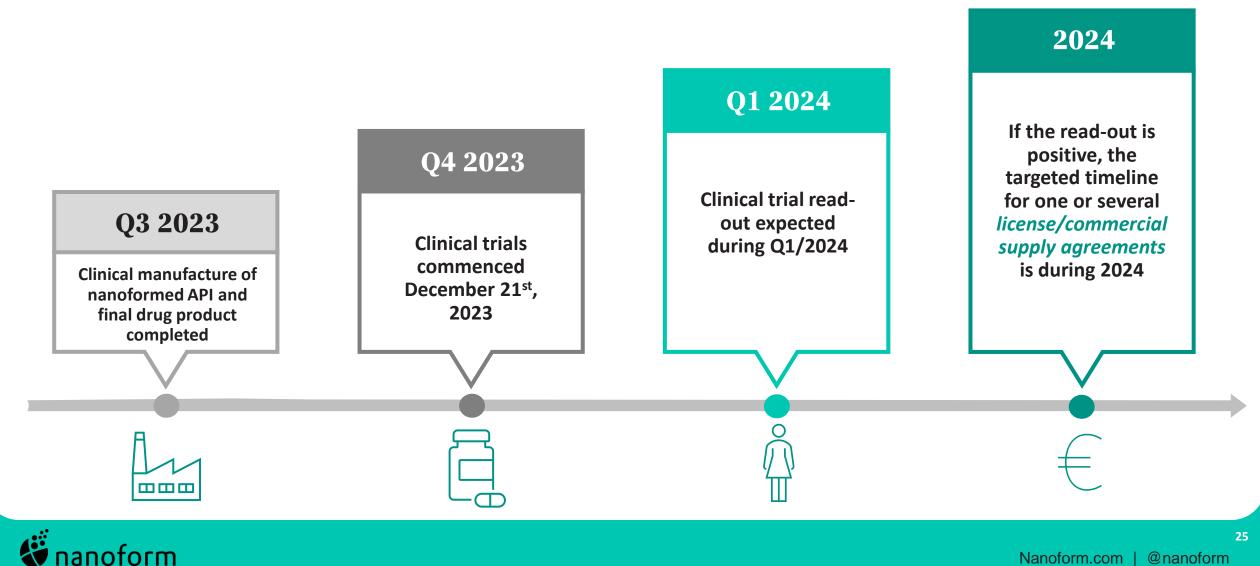


#### Relative Bioavailability Study of Nanotechnology-Enhanced Reformulation of Enzalutamide

- First Subject First Visit (FSFV) done study results expected in 1Q 2024
- Trial to evaluate the relative bioavailability of a nanotechnology enabled amorphous solid dispersion (ASD) reformulation of Nanoenzalutamide and Xtandi<sup>®</sup>, #1 prescribed androgen receptor inhibitor first approved by FDA in 2012 to treat prostate cancer
- The single-dose, randomized, comparative bioavailability study, performed by a contract research organization (CRO) in North America, compares enzalutamide 160 mg film-coated tablets (Bluepharma Farmaceutica S.A.) and Xtandi 4x40 mg film-coated tablets (Astellas Pharma Europe B.V.).
- Tablet-burden and dysphagia are well-documented challenges for prostate cancer patients, and the development of a 160mg, single tablet per day regimen enabled by Nanoform technology and formulation expertise may be preferable for patients in need of reducing their total number of daily pills



#### Project Nanoenzalutamide – near-term timeline



# NANOFORMING AMORPHOUS SOLID DISPERSIONS



#### Project Nanoenzalutamide and Amorphous Solid Dispersions

Project Nanoenzalutamide: development and commercialization of a more patient centric and a nanoformed version of an existing amorphous solid dispersion (ASD) blockbuster drug called Xtandi

<u>Nanoformed and nanocrystalline drugs (e.g. Nanoenzalutamide) offer an attractive alternative to ASDs</u> with:

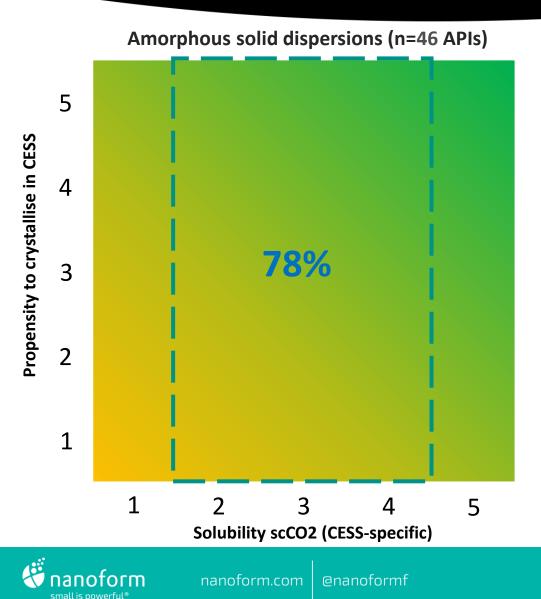
- ⇒ substantially <u>higher drug load</u> in the final drug product
- ⇒ reduced <u>pill burden</u> for the patient
- ⇒ opportunity to <u>extend IP protection</u> for the reformulated and improved product
- ⇒ opportunity for <u>earlier market entry</u>

ASDs are currently the leading formulation strategy for poorly soluble APIs and there are ~50 marketed medicines in US that are ASDs

Several opportunities for Nanoform to replicate early successes with Project Nanoenzalutamide



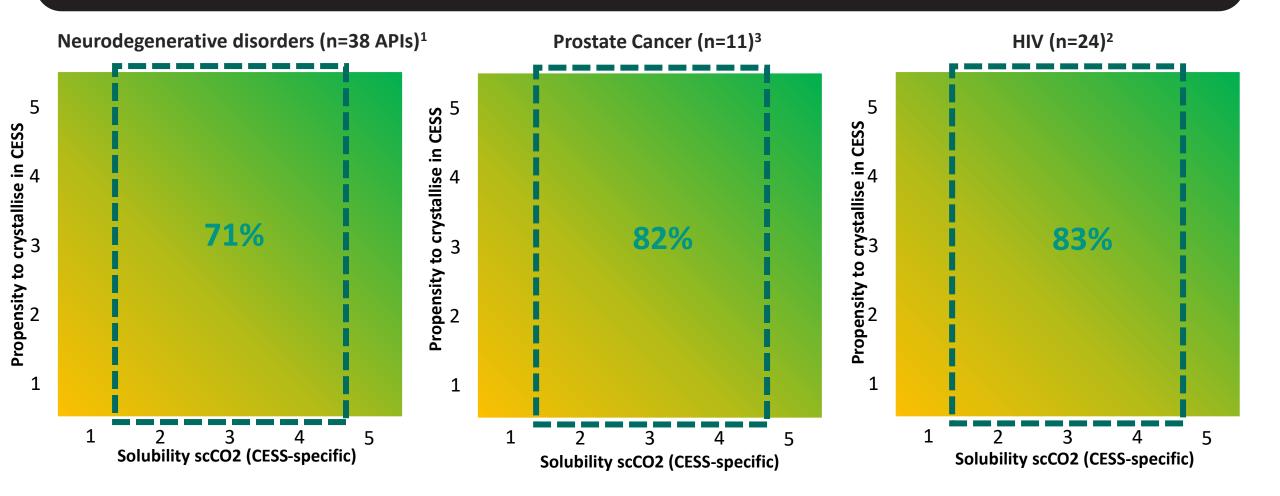
# STARMAP® predicts that nanoforming is an attractive alternative to ASDs



- ✓ STARMAP predicts that 78% of marketed ASD APIs fall within our processing "sweet spot"
- ✓ 46 ASDs have been Starmapped
- ✓ There are ~<u>50 ASDs on the market</u> selling annually for USD 15+ bn in the US alone, while there are 30+ candidates disclosed in the clinical pipe-line and most likely hundreds in the preclinical state.
- ✓ The Blockbuster project is our <u>first example of what</u> <u>nanoforming potentially can do to/for ASDs</u>

Nanoform uses its expertise at the interface of nanoparticles and polymer science to rationally design an alternative approach to ASDs

#### Examples of areas in which STARMAP<sup>®</sup> sees strong potential for nanoforming





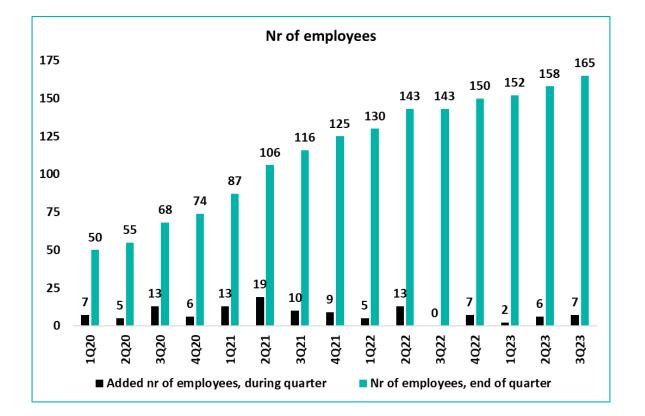
Individual APIs from FDA-approved medicines for: <sup>1</sup>amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, Alzheimer's disease, Huntington's disease, <sup>2</sup>Human Immunodeficiency Virus and <sup>3</sup>Prostate Cancer

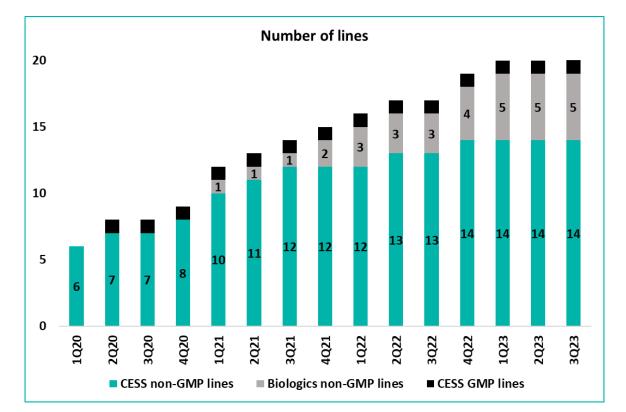
## FINANCIALS

Q4 and FY2023 results due February 29<sup>th</sup>, 2024



#### Nr of employees & nr of lines

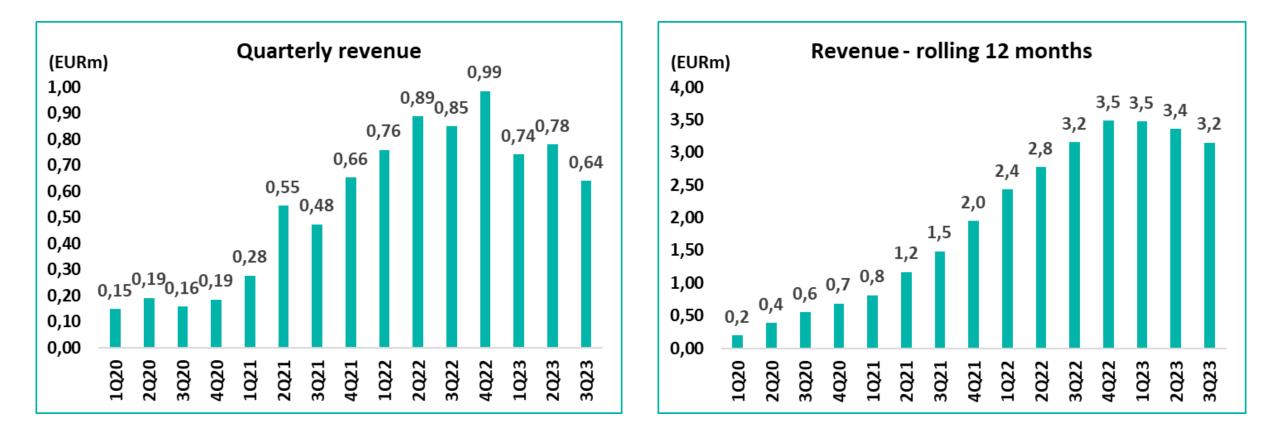




GMP2&3 will be commissioned after inspection by Fimea, expected during 1Q 2024

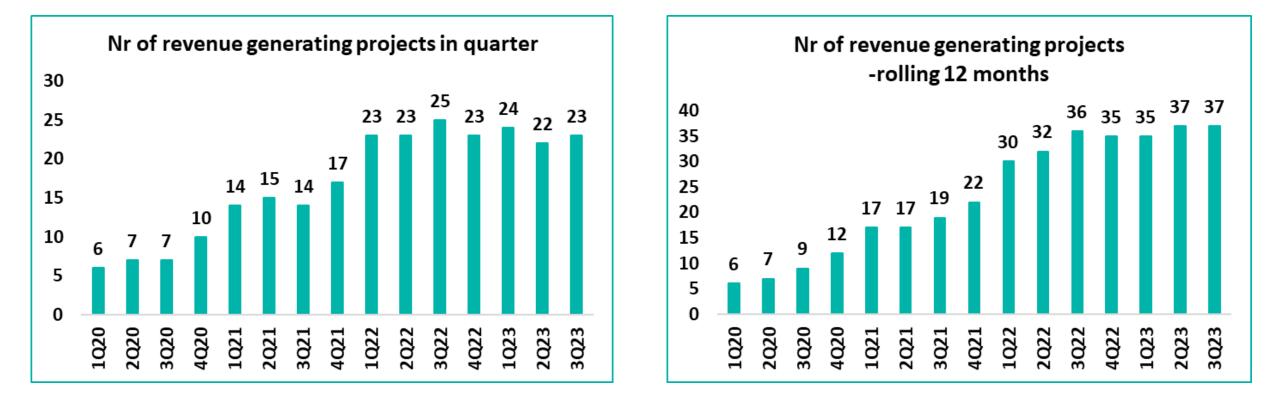


#### Revenue recognized impacted by slow signings in 2H22, marginal impact on rolling 12m





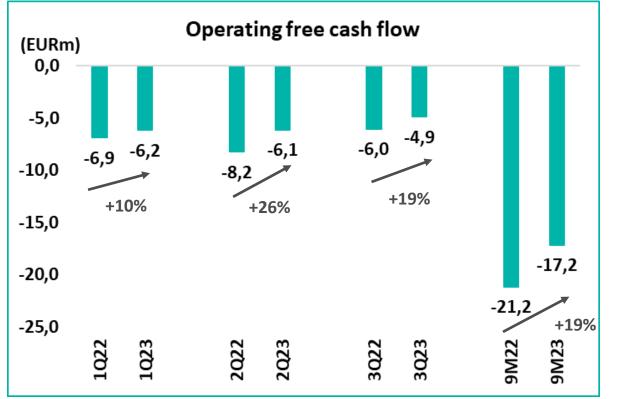
## Nr of projects generating revenue\*

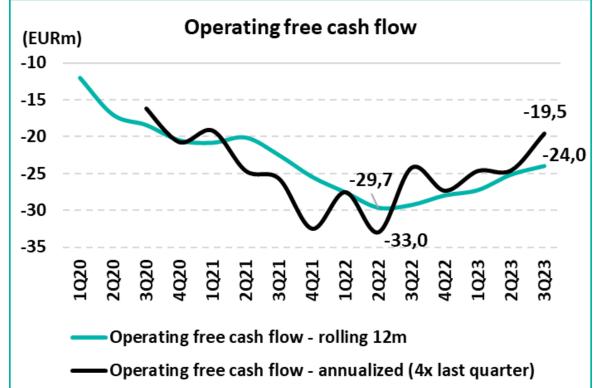


\*Impact on revenue can in a quarter for some of the projects be negative if budgeted costs increase significantly (often related to hours worked).



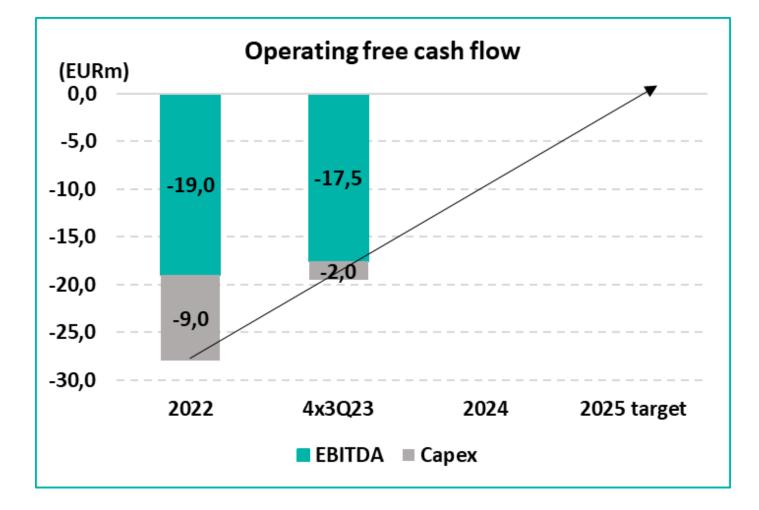
#### Improvement in operating free cash flow continued in 3Q







#### Operating free cash flow trend towards 2025 target on track





# **Q & A**

www.nanoform.com

San Diego - New York - Lisbon - Oxford – London - Cambridge - Bordeaux - Stockholm - Helsinki



# APPENDIX



## Nanoform grants AstraZeneca Plc STARMAP® license





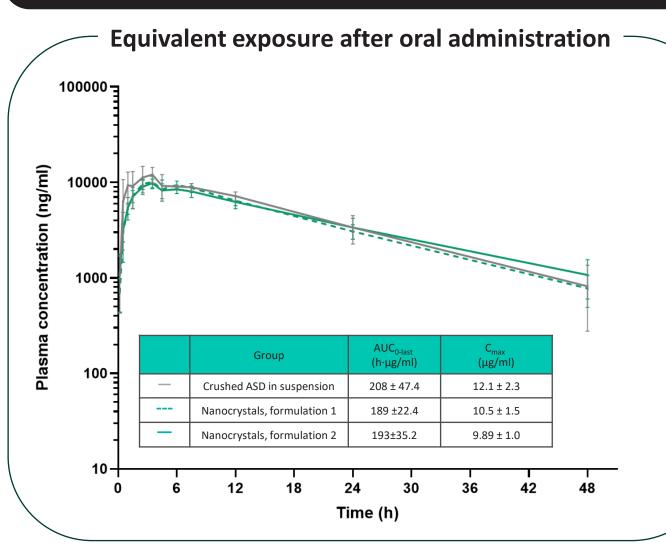


- AstraZeneca to screen with STARMAP® its molecules from drug discovery through to lifecycle management
- Nanoform has access to AstraZeneca compound libraries and large data sets => Nanoform to screen and propose innovative product development concepts and strategies to AstraZeneca

Find press release here: <u>Nanoform grant Global STARMAP[®]</u> AI License to AstraZeneca – <u>Nanoform small is powerful</u>



# Project Nanoenzalutamide: Nanoform's intermediate product matches ASD exposure *in-vivo* and is stable



### **Performance and stability**

- Equivalent exposure compared to ASD product, after oral suspension administration in rodents
- Polymorph and particle size are **stable**

### Patient adherence and convenience

- Nanoform have taken a multi tablet ASD product, reduced it to a <u>single tablet, the same size as one</u> <u>of the original tablets, for the same combined</u> <u>dose</u> with a nanocrystalline formulation
- Nanoform's approach improved the loading degree thus reducing pill burden and could enable fixed dose combination possibilities



## A selection of major pharma companies with ASD drugs in the market





# Nanoform – Attractive revenue model, stands the test of time

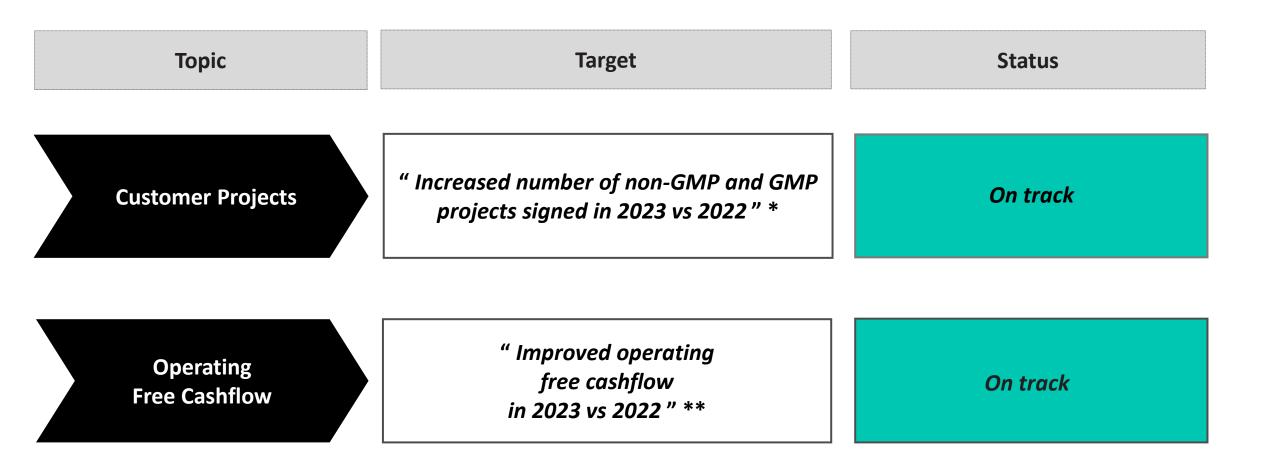
### Predictable revenue streams through capitalizing the entire pharmaceuticals value chain

Phase	Proof of Concept / Proof of Process	Phase I – III trials	Drugs on the market
Certification	Non-GMP	GMP	GMP
Description	<ul> <li>Proof of concept study - assessment of the possibility to nanoform a specific API</li> <li>Proof of process study - definition of parameters to establish the optimal process and controls for a specific API</li> </ul>	<ul> <li>API for clinical trials are manufactured in Nanoforms GMP facility</li> <li>Supply of material for customers' Phase I, II and III trials</li> <li>Nanoform gets paid regardless of the outcome of the trials</li> </ul>	<ul> <li>Drugs that have passed the trials and reached commercialization</li> <li>In practice, if a company has taken its drug through Phase II trials, it is difficult to switch manufacturer</li> <li>Significant potential from patent extension (505b2 projects) of drugs already on the market</li> </ul>
Revenue model	<u>Fixed fee per project</u> Estimated project fee of EUR 50-500k per API per project	<u>Fixed fee per project</u> Estimated project fee of EUR 0.5-10m per API per phase	Royalty as a % on drug sales or supply price per kg Estimated royalty fee of 1-20%
	> Attractive business model	with diversified risk profile due to not	having to carry the

Attractive business model with diversified risk profile due to not having to carry the cost & risk of drug development or being dependent on a single drug



# Nanoform near-term business targets 2023

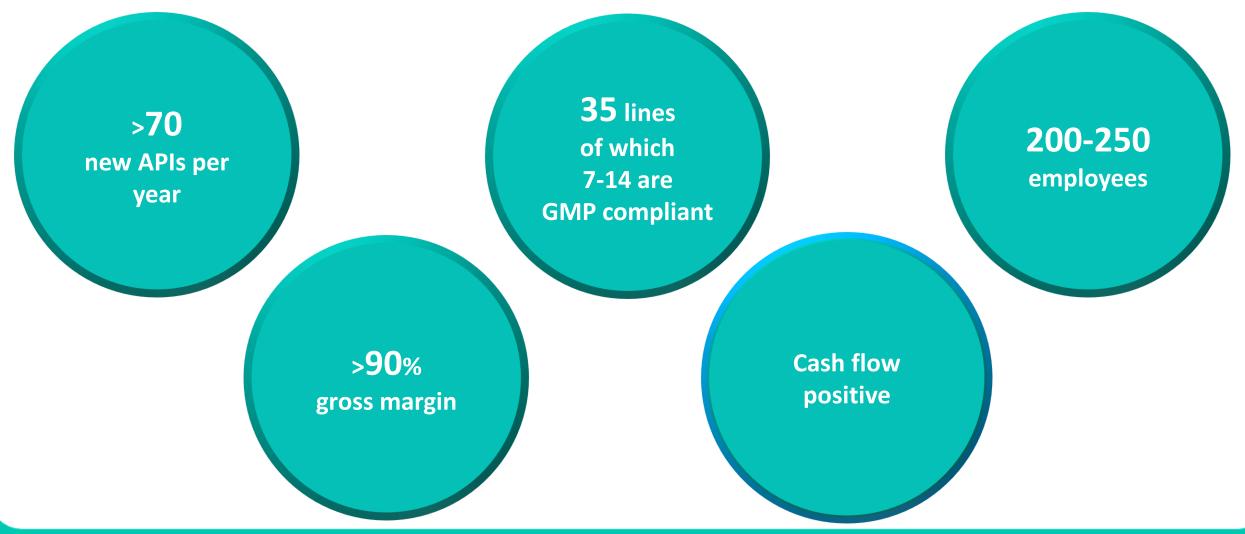




GMP = Good Manufacturing Practice \* 17 non-GMP and 1 GMP projects signed in 2022

\*\* Operating free cash flow EUR -28m in 2022

# Nanoform mid-term business targets 2025





# 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)		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)			
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)

# CESS<sup>®</sup> Superior to Existing Technologies

	Controlled Expansion of Supercritical Solutions (CESS <sup>®</sup> )	Solid dispersion (e.g. spray drying)	Jet milling	Nanomilling
Description	Extracts API from supercritical CO <sub>2</sub> 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	✓	×	$\checkmark$	×
Yield	High	Low	High	Low
Investment	Low	High	Low	Low
🖗 nanoform	Source: Company inform Drying Market, 2014-202	nation; Chimica Oggi: Chemistry Today; Roots 24	a Analysis, Pharmaceutical Spray	Nanoform.com   @nanoforr

# Nanoform educational material

#### **VIDEOS**

PODD 2022 Video – "How drug delivery is enabling a clinical trial for Glioblastoma" – TargTex CEO João Seixas and Nanoform CCO Christian Jones present promising data enabled by a nanoformed drug product for the treatment of glioblastoma multiforme (GBM): <u>https://player.vimeo.com/video/791949368</u>

American Association of Pharmaceutical Scientists (AAPS) webinar – We hosted a webinar "Tailored API Nanoparticles: How Powerful Can Small Be?" in partnership with the American Association of Pharmaceutical Scientists (AAPS): <a href="https://player.vimeo.com/video/684197206?h=6dac8c956d">https://player.vimeo.com/video/684197206?h=6dac8c956d</a>

Nanoform's Collaboration with TargTex Video – TargTex CEO João Seixas discusses the value Nanoform's CESS<sup>®</sup> technology delivered for TargTex's novel drug candidate targeting glioblastoma: https://nanoform.com/en/nanoforms-collaboration-with-targtex-2/

ADHD Awareness Month – How can STARMAP<sup>®</sup> Online guide the way? – In recognition of ADHD Awareness Month, we discuss the value our nanoparticle technology can bring to novel medicines for ADHD: <a href="https://player.vimeo.com/video/768531631">https://player.vimeo.com/video/768531631</a>

BOS 2023 Video – Nanoforming – the Patient- and Planet-Centric Approach From Increasing Bioavailability to Enabling Sustained Drug Delivery – Nanoform CCO Christian Jones delves into the benefits that can be unlocked for both patients and the planet through the Nanoform toolbox, supported by data from relevant case studies: <a href="https://nanoform.com/en/nanoforming-the-patient-and-planet-centric-approach-from-increasing-bioavailability-to-enabling-sustained-drug-delivery/">https://nanoform.com/en/nanoforming-the-patient-and-planet-centric-approach-from-increasing-bioavailability-to-enabling-sustained-drug-delivery/</a>

Drug Hunter Webinar – Not Your Grandparents' Drugs: How Approved Drugs Have Evolved Since the 70's – Nanoform & Drug Hunter explore how the lipophilicity (LogP) of drugs has changed over time: <a href="https://nanoform.com/en/not-your-grandparents-drugs-how-approved-drugs-have-evolved-since-the-70s/">https://nanoform.com/en/not-your-grandparents-drugs-how-approved-drugs-have-evolved-since-the-70s/</a>

#### **ARTICLES & OTHER MATERIALS**

Streamlining Drug Development with AI – Nanoform delved into this topic in CHEManager. Discover the company's insights here, including how Nanoform's pioneering AI-based STARMAP<sup>®</sup> platform can help: <u>https://www.chemanager-online.com/en/news/nanoparticle-engineering</u>

Small is Powerful: A Globally Unique Capability for Nanoforming HPAPIs – Nanoform discusses high-potency API handling capabilities with DCAT Value Chain Insights: <u>https://www.dcatvci.org/sponsored/small-is-powerful-a-globally-unique-capability-for-nanoforming-hpapis/</u>

Celanese Case Study – Nanoform and Celanese use drug nanoparticles to modify the release kinetics of ethylene vinyl acetate long-acting implants: <u>https://nanoform.com/en/nanoform-and-celanese-use-drug-nanoparticles-to-modify-the-release-kinetics-of-ethylene-vinyl-acetate-long-acting-implants/</u>

Nanoform White Paper – "Strategies for patient-centric differentiation through the USFDA 505(b)(2) pathway" – With faster routes to approval, the volume of 505(b)(2) applications now exceeds that of 505(b)(1). Discover the reasons for this in our white paper: <a href="https://nanoform.com/en/wp-content/uploads/sites/2/2022/05/whitepaper-march-2022.pdf">https://nanoform.com/en/wp-content/uploads/sites/2/2022/05/whitepaper-march-2022.pdf</a>

PION Partnership – Characterization of the Flux Performance of Nanoformed and Untreated Crystalline Piroxicam Solid Suspensions, and the Relative Contributions of the Particle Drifting Effect to In Vitro Flux – Nanoform and PION performed MicroFLUX analysis on nanoformed piroxicam to investigate nanoparticle flux performance compared to crystalline solid suspensions: <a href="https://nanoform.com/en/wp-content/uploads/sites/2/2023/07/Nanoform-Poster-91-x-91-cm-V7.pdf">https://nanoform.com/en/wp-content/uploads/sites/2/2023/07/Nanoform-Poster-91-x-91-cm-V7.pdf</a>

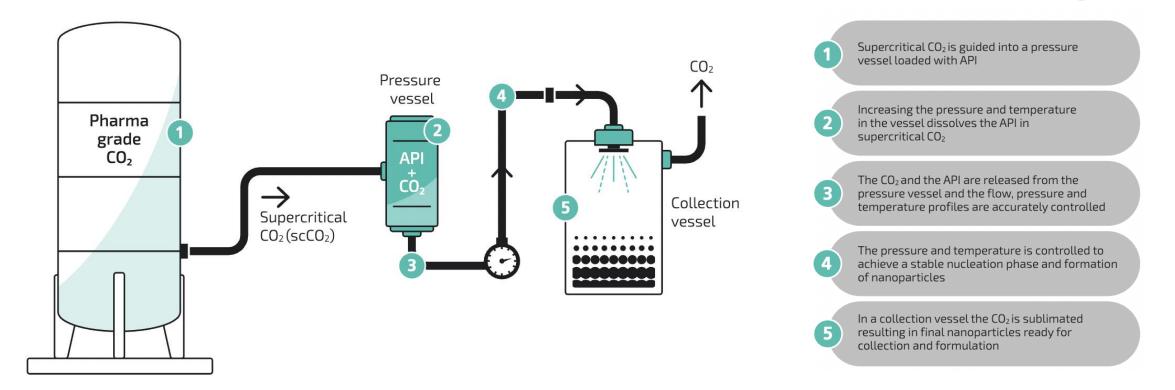
Nanoform Sustainability Ebook – Discover how we are driving sustainability across the pharmaceutical industry in our ebook: <a href="https://nanoform.com/en/sustainability-ebook/">https://nanoform.com/en/sustainability-ebook/</a>

Nanoform Brochure to the Pharma Industry – <a href="https://nanoform.com/en/brochure/">https://nanoform.com/en/brochure/</a>



# Small Molecules - Proprietary technology

### **Controlled Expansion of Supercritical Solutions - CESS**<sup>®</sup>



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



The CESS® technology platform was described in detail in the IPO prospectus (offering circular) on pages 76-80. The prospectus can be found via the following link: <u>https://nanoform.com/en/ipo-materials/</u>

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Green

technology

# Large molecules – Small is powerful in biologics too

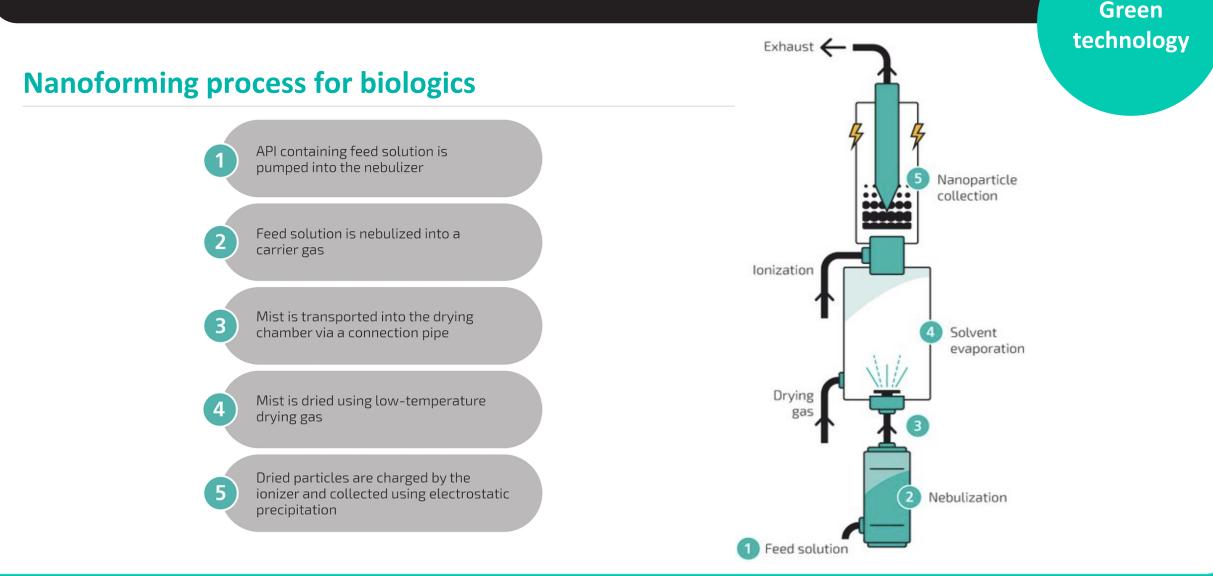
Our unique biological nanoforming technology can produce drug particles as small as 50 nm in diameter while retaining biological activity. It is a gentle bottom-up process, and its effectiveness has been demonstrated on peptides and proteins in the 1 kDa\* – 150 kDa range. We can engineer particle sizes to specific requirements. Our advanced technology can be applied across the biologics field to potentially:





\*1 kDa = One thousand daltons. A dalton is the weight of a hydrogen atom. Kilodalton is the standard unit used to represent the weight of large molecules such as proteins.

# Large molecules - Proprietary technology

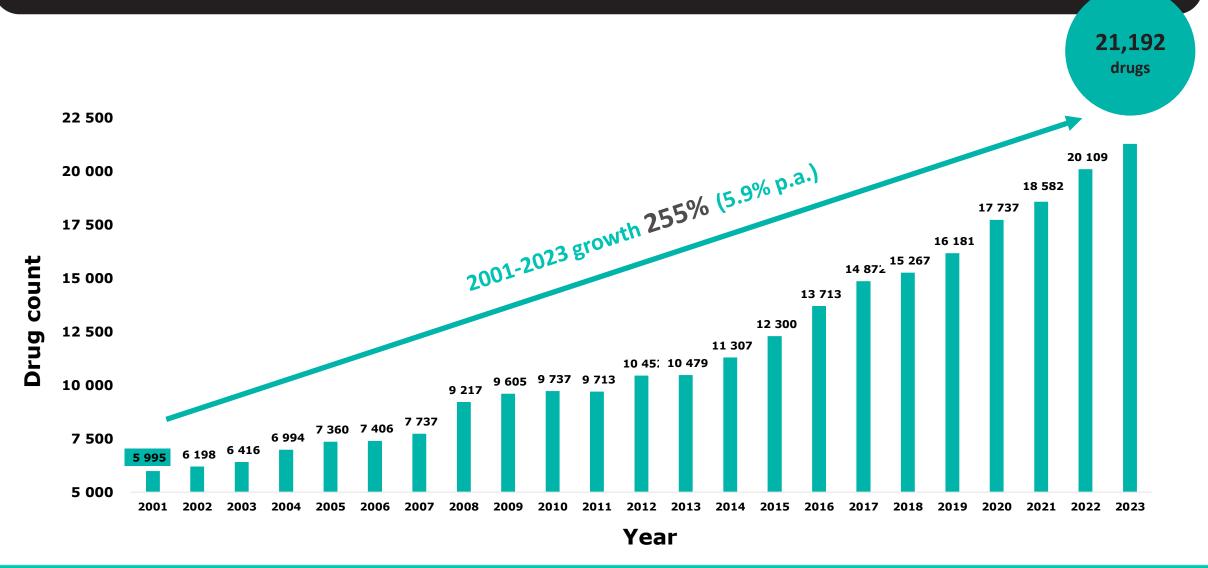




API = active pharmaceutical ingredient Nebulization = turns liquid into mist Ionization = particles electrically charged

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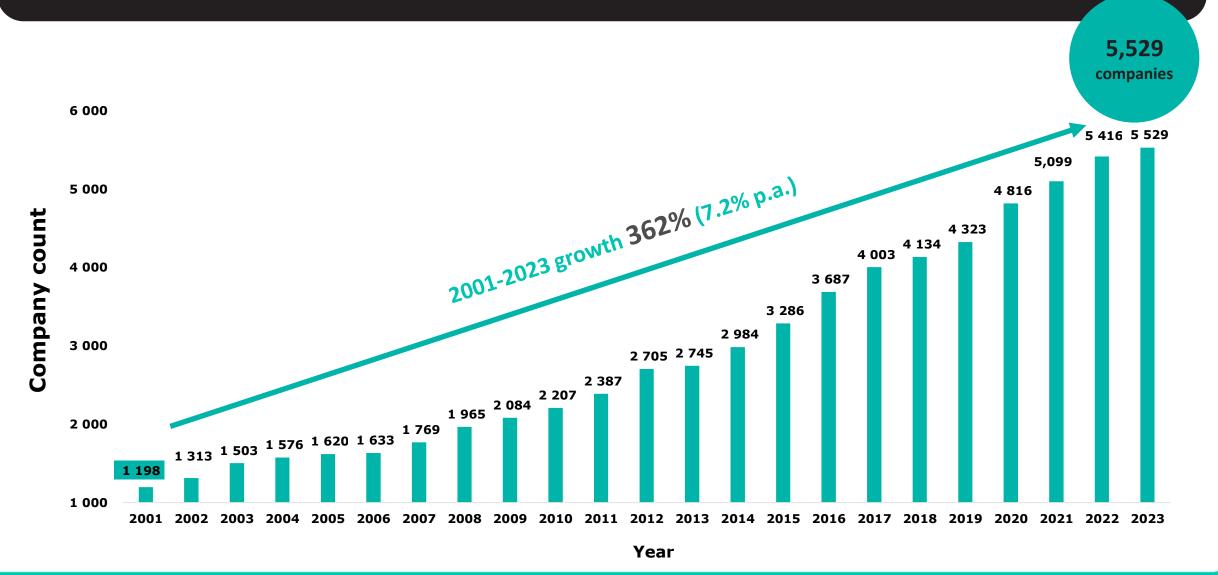
# Global drug R&D pipeline size and growth





Source: Pharmaprojects®, January 2023

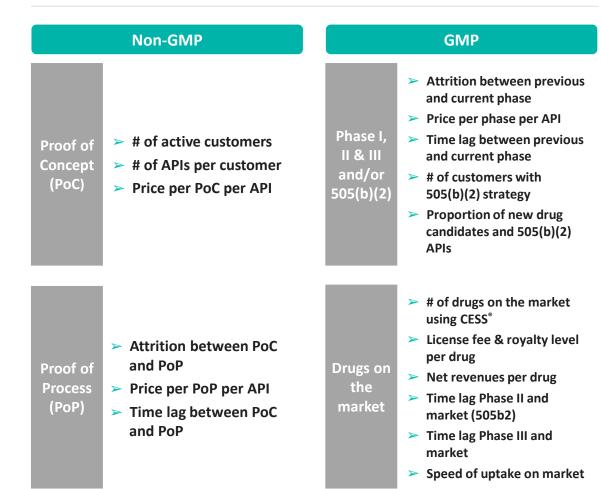
# Global number of companies with active pipelines



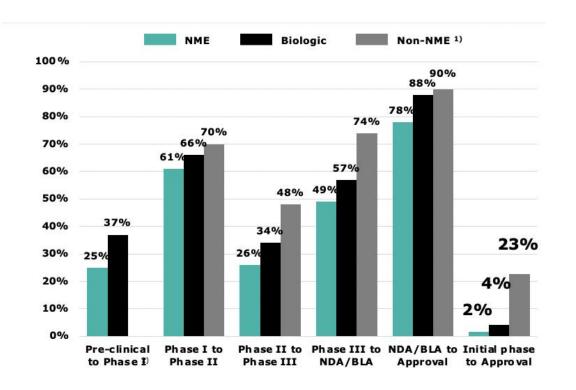


# Revenue drivers & industry attrition rates

### Nanoform pre-clinical and clinical revenue drivers



#### 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 deve	lopment for 50	)5(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

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# Nanoform GMP Manufacturer's Authorization

### **GMP** Manufacturer's Authorization April 2020, by FIMEA:

Human Investigational Medicinal products: GMP manufacturing/nanoforming API for clinical trial

### **GMP Manufacturer's Authorization May 2023, by FIMEA:**

Human Investigational Medicinal products: GMP manufacturing/nanoforming multi-API's for clinical trials

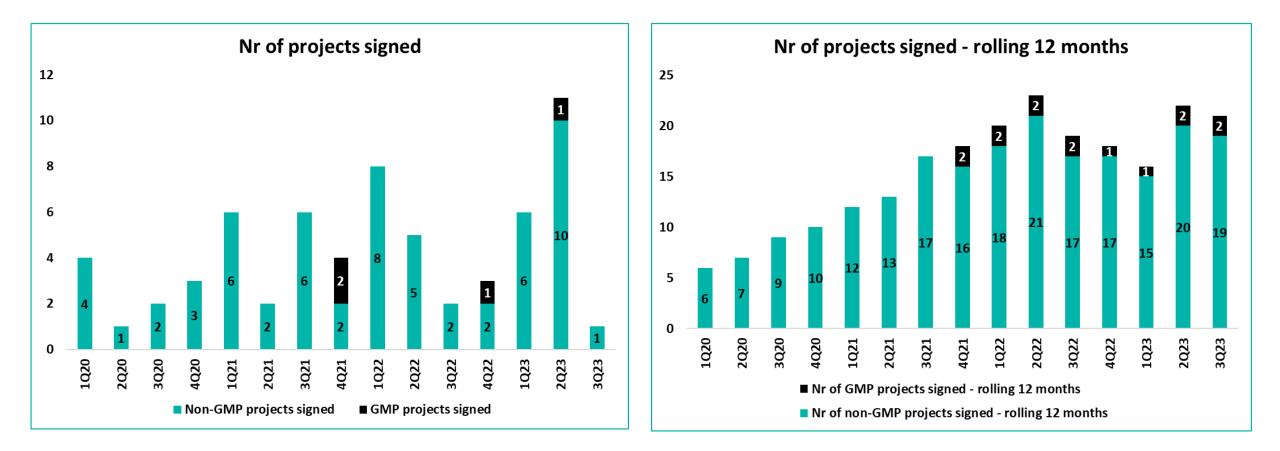
### Notification submitted to FIMEA in June 2023:

- New GMP manufacturing/nanoforming facilities and equipment (GMP2 & GMP3)
- New GMP Quality Control laboratory
- Manufacturing/nanoforming APIs to be used in products with a Marketing Authorization
- FIMEA inspection expected during Q1 2024



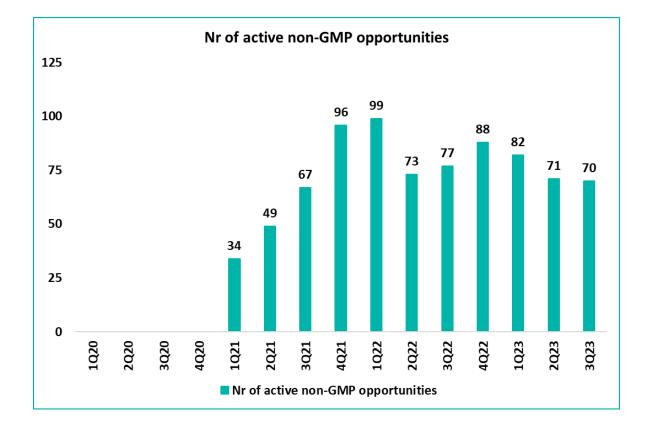
FIMEA = Finnish Medicines Agency GMP = Good Manufacturing Practice API = Active Pharmaceutical Ingredient QC = Quality Control

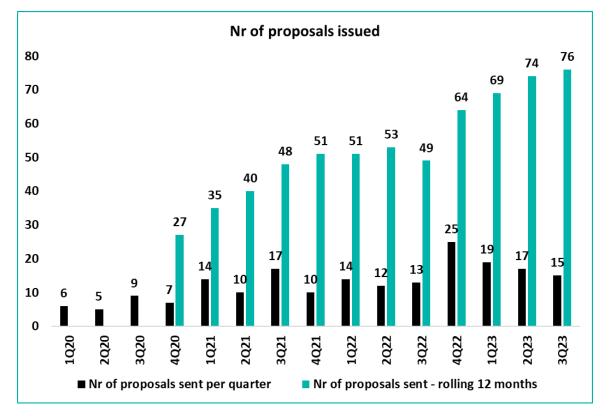
# Nr of projects signed





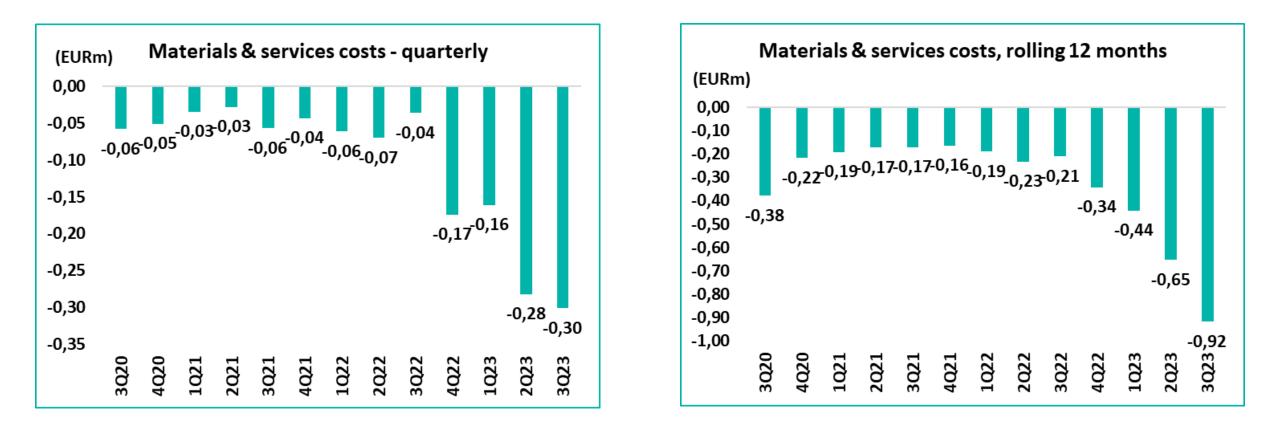
# Nr of opportunities and proposals issued







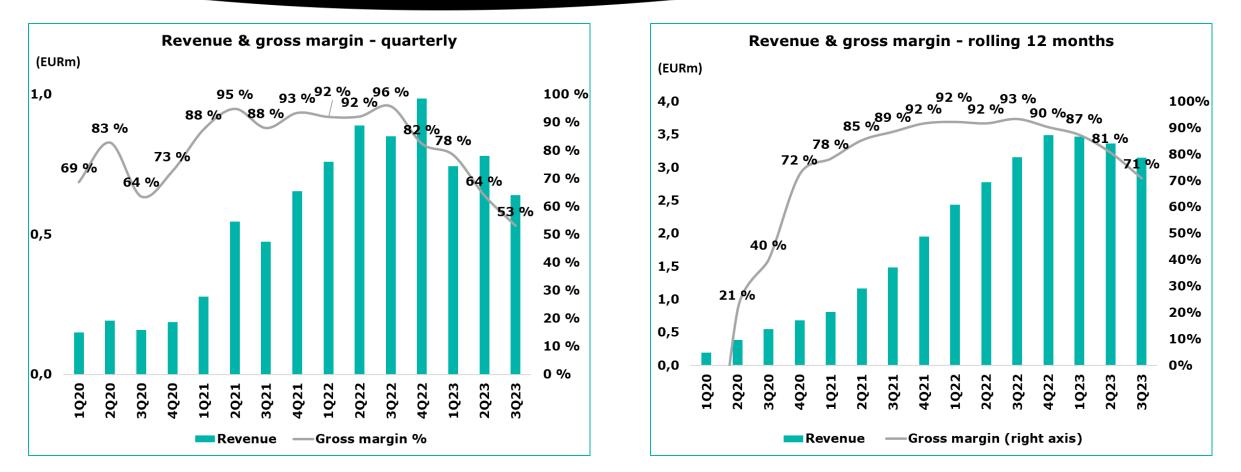
Project Blockbuster has led to increased external GMP QC cost, (will be mitigated once GMP-QC gets FIMEA approval)



Excluding the cost of external GMP QC services, related to the Blockbuster project, our underlying materials & services costs have remained between low. In June, Nanoform submitted a notification to the Finnish Medicines Agency (Fimea) to update our Manufacturer's Authorization (MIA). The notification included our new Quality Control laboratory (GMP QC) and an inspection is expected to take place in 1Q24. This will help our gross margin return to the 90+ levels we target.



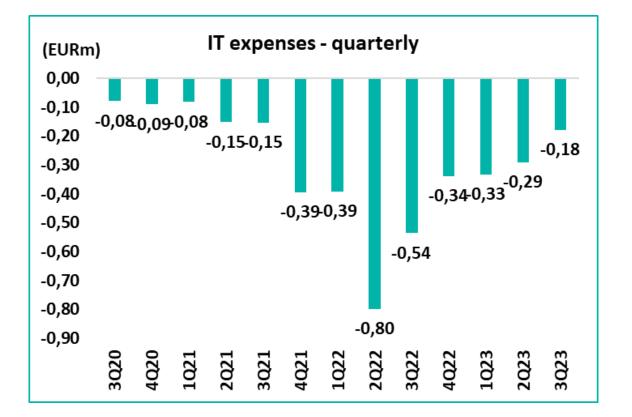
# ...which had an effect on the gross margin. Excluding the Blockbuster project, gm was > 90%

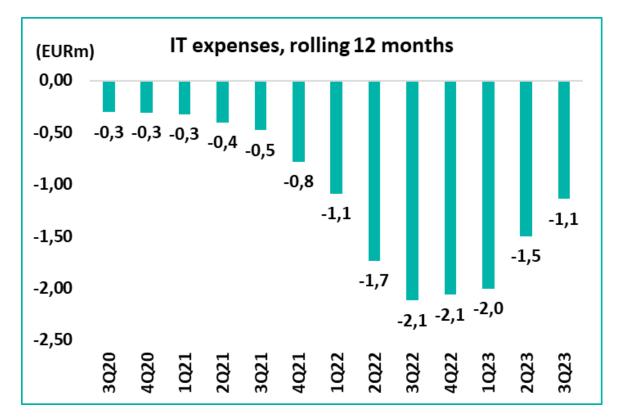


Excluding the cost of external GMP QC services, related to the Blockbuster project, our underlying in 9M23 gross margin was >90%. In June, Nanoform submitted a notification to the Finnish Medicines Agency (Fimea) to update our Manufacturer's Authorization (MIA). The notification included our new Quality Control laboratory (GMP QC) and an inspection is expected to take place in 1Q24. This will help our gross margin return to the 90+ levels we target.



### IT expenses reduced after successful SAP implementation







### Financial KPI's

EUR thousand	7-9/2023	7-9/2022	1-9/2023	1-9/2022	1-12/2022	1-12/2021	1-12/2020
Revenue	641	851	2,166	2,501	3,487	1,955	687
Revenue growth %	-25%	79%	-13%	92%	78%	185%	n.m.
Gross profit	340	816	1,422	2,334	3,147	1,792	497
Gross margin	53%	96%	66%	93%	90%	92%	72%
EBITDA	-4,380	-4,186	-14,245	-14,243	-19,027	-17,745	-18,196
Operating loss	-5,102	-4,796	-16,354	-15,979	-21,409	-19,705	-19,423
Loss for the period	-4,122	-5,155	-15,417	-16,506	-22,075	-19,690	-19,441
Basic EPS (EUR)	-0.05	-0.07	-0.20	-0.22	-0.29	-0.29	-0.35
Net debt	-45,486	-69,220	-45,486	-69,220	-61,807	-68,070	-54,156
Net debt excluding lease liabilities	-51,818	-76,329	-51,818	-76,329	-68,740	-75,733	-59,977
Investments in property, plant, and equipment	-503	-1,857	-2,931	-6,920	-8,965	-7,737	-2,336
Operative free cash flow	-4,883	-6,044	-17,176	-21,164	-27,992	-25,482	-20,532
Cash and cash equivalents excluding short- term government bonds (end of period)	18,432	76,329	18,432	76,329	68,740	75,733	61,025
Cash and cash equivalents including short- term government bonds (end of period)	51,818	76,329	51,818	76,329	68,740	75,733	61,025

### Operational KPI's

#### 7-9/2023 7-9/2022 1-9/2023 1-9/2022 1-12/2022 1-12/2021 1-12/2020

Number of new customer projects signed during the period							
Non-GMP	1	2	17	15	17	16	10
GMP			1		1	2	
Total number of new customer projects	1	2	18	15	18	18	10
Number of lines (end of the period)							
Non-GMP	19	16	19	16	18	14	8
GMP	1	1	1	1	1	1	1
Total number of lines (end of period)	20	17	20	17	19	15	9
Personnel at the end of reporting period	165	143	165	143	150	125	74



## Income statement

### Condensed financial information January-September 2023

#### Consolidated statement of comprehensive income

EUR thousand	Note	7-9/2023	7-9/2022	1-9/2023	1-9/2022	1-12/2022
Revenue	4	641	851	2,166	2,501	3,487
Other operating income						
Materials and services		-301	-36	-744	-167	-340
Employee benefits	7	-3,434	-3,029	-10,723	-10,665	-14,010
Depreciation, amortization, and impairment losses	6	-722	-610	-2,109	-1,736	-2,382
Other operating expenses	5	-1,287	-1,973	-4,944	-5,912	-8,164
Total expenses		-5,744	-5,647	-18,519	-18,481	-24,896
Operating loss		-5,102	-4,796	-16,354	-15,979	-21,409
Finance income		1,388	106	4,518	601	957
Finance expenses		-401	-461	-3,567	-1,108	-1,604
Total finance income and expenses		986	-355	952	-507	-647
Loss before tax		-4,116	-5,151	-15,402	-16,486	-22,056
Income tax		-6	-4	-15	-20	-19
Loss for the period		-4,122	-5,155	-15,417	-16,506	-22,075

#### **1-9/2023** comments

- Revenue came in at EUR 2.2 million, stemming from 32 different customer projects (EUR 2.5m, 33 projects in 1–9/2022).
- The gross profit decreased to EUR 1.4 million, with a gross margin of 66% (EUR 2.3 million, 93%) due to GMP QC costs related to the Blockbuster project. Excluding these, the gm was above 90%. Revenues are recognized over the lifetime of the projects, based on expenses (mostly hours worked) booked for the projects.
- > The operating free cash flow continued to improve and was less than EUR 20m annualized in 3Q, helped by lower investments in property, plant and equipment. Operating costs, excluding depreciation, fell compared with last year.
- Cash position (incl. T-bills) was EUR 51.8 million (EUR 76.3m) at the end of 3Q23, down EUR 5.0m during the last quarter (EUR 56.8m at the ned of 2Q23).

#### 5. Other operating expenses

The decrease in other operating expenses stems mainly from the decrease in IT expenses (SAP S4/ HANA was implemented in early January 2023).

EUR thousand	7-9/2023	7-9/2022	1-9/2023	1-9/2022	1-12/2022
Premises expenses	53	38	176	101	159
Πexpenses	178	536	803	1,725	2,064
Marketing and communication expenses	158	206	423	548	825
Consultant and professional fees	301	288	958	927	1,355
Travel expenses	63	83	276	250	353
Voluntary personnel related expenses	113	167	466	580	781
R&D expenses - external	204	251	748	616	1,008
Other expenses	217	405	1,093	1,164	1,620
Total	1,287	1,973	4,944	5,912	8,164



### 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



#### 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: 300,000 options



#### General Counsel; 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 380,000 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: 50,000 options



### Head of Manufacturing; Ph.D. (Chemistry) David Rowe

#### 

Previously Particle Size Reduction Lead for GlaxoSmithKline

Current ownership: 704,516 shares and 450,000 options

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

20 years of finance and investing experience

Chaired the PSR Centre of Excellence

Albert Hægaström

SFB

• Key area of responsibility: Technical leadership within new chemical entities and commercial assets

Prior roles include positions at Alfred Berg, BNP Paribas, Nordea and

Current ownership: 340,000 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 136,000 options



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## Board of directors: Top executives from leading industry positions



### **Miguel Calado**



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#### 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: 46,895 shares and 380,000 options
- Key experience: **PEPSICO** Hovione



### Albert Hæggström

#### **CFO and Board Member**

- 20 years of finance and investing experience
- Prior roles include senior positions at Alfred Berg, BNP Paribas, Nordea and SEB

Alfred Berg 🖸 BNP PARIBAS NORCEO SEB

- Current ownership: 704,516 shares and 450,000 options
- Kev experience:





### Mads Laustsen

#### **Board Member**

 Over 30 years of experience in pharmaceutical development and manufacturing

BACTOLIFE

- 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: 16,577 shares and 300,000 options CMC

Key experience:



### **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: 16,577 shares and 38,630 options
- Key experience:







SPI Pharma<sup>\*</sup>

An ABE Ingredients Compar



### **FURTHER ENQUIRIES**

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