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Nanoform Capital Markets Day

Breakthrough Strategy

Breaching ‘The Wall’ in 2 Places:

Small & Large Molecules

Viikinkaari 4, Helsinki

December 16th, 2025

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, 2024 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.

AGENDA

09.00	**CEO Edward Hæggström, Chairman Miguel Calado and Board Member Jeanne Thoma - Nanoform Strategy 2026-2030**
09.10	**CFO Albert Hæggström - New midterm business targets 2030**
09.20	**Director Intellectual Property Winfried Ness - Nanoenzalutamide European IP landscape**
09.30	**Dr. Katja Dreyer, Director Onconcept & Specialty Generics, Helm Pharmaceuticals GmbH - Nanoenzalutamide European roadmap and commercial launch**
09.40	**Kurt Nielsen, Managing Director Expert Insights - Nanoenzalutamide US launch roadmap**
09.50	**Chief Quality Officer Johanna Kause - Nanoenzalutamide regulatory strategy**
10.00	***15 min break***
10.15	**Chief of Business Operations Antonio da Silva - 3 Nanoformed medicines launched by 2030**
10.30	**Steen Vangsgaard, CEO A.forall Group NV and Tiago Geraldes Investment Director IMGA - Why we invested in Nanoencorafenib/Brafmed Ltd**
10.40	**Sreevatsa Natarajan, Co-Founder and CEO Revio Therapeutics - GLIORA partnership with Nanoform**
10.50	**Nanoform's CESS® rocket science - Senior Scientist Ari Kauppinen, Senior Engineer Tuomas Malve and Senior Scientist Petteri Helander**
11.10	***15min break***
11.25	**Chief Development Officer Peter Hänninen - A large biologics market is forming in subcutaneous delivery of monoclonal antibodies**
11.40	**Director Biologics Maria Lume - Working with large pharma: What we have done and learnt**
11.50	**Q&A**
12.15	***Closing remarks - Lunch - Factory Tour***

CEO Edward Hæggström, Chairman Miguel Calado, Board Member Jeanne Thoma

Nanoform Strategy 2026-2030

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Nanoform Strategy 2026-2030

Nanoform technologies break the wall

CESS® for small molecules

Patients treated with Nanoformed medicines with 5 years

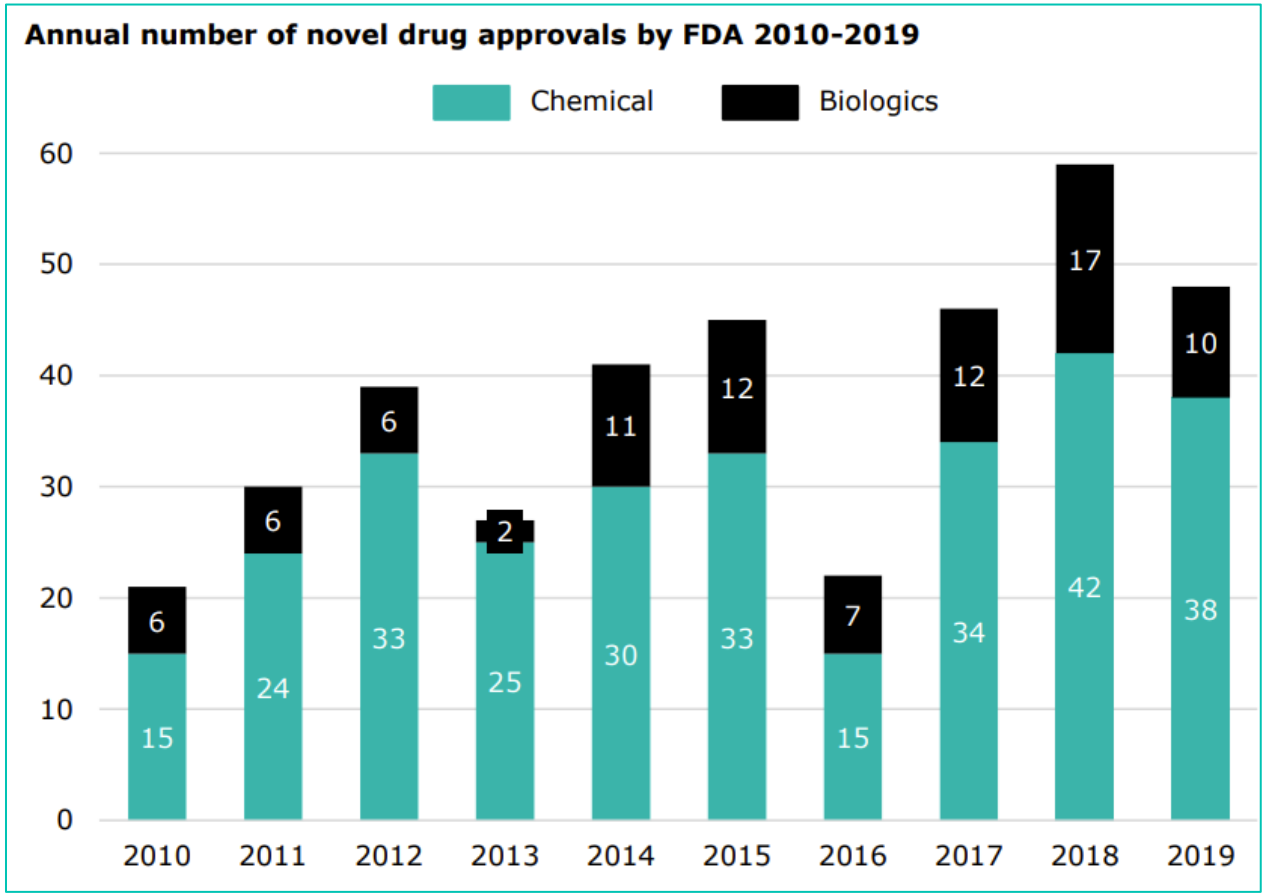
BioLine for biologics

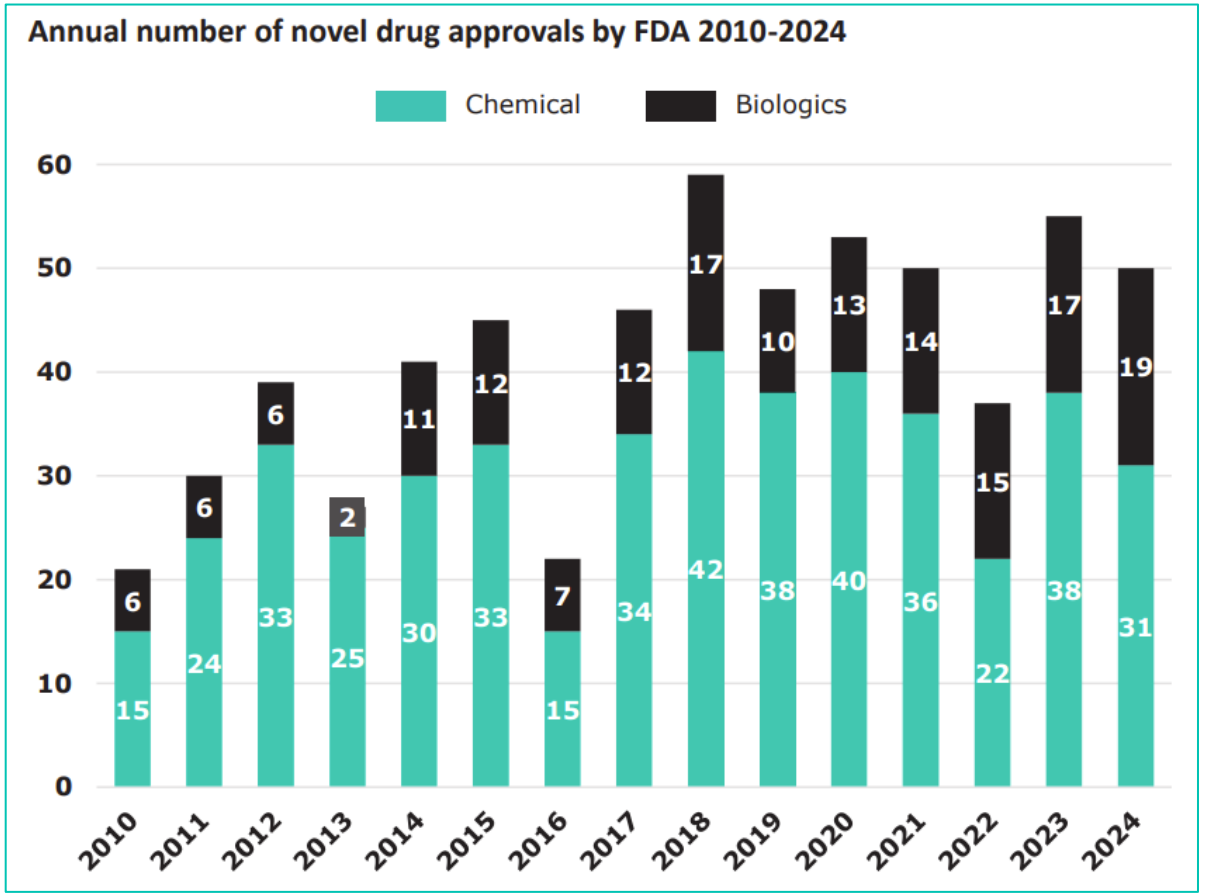
Clinical data with several major clients support nanoforming as a significant technology in the major industrial shift from IV to SC

CFO Albert Hæggström

Midterm business targets 2030

What has happened in the industry since the IPO? Nr of new approvals flat…

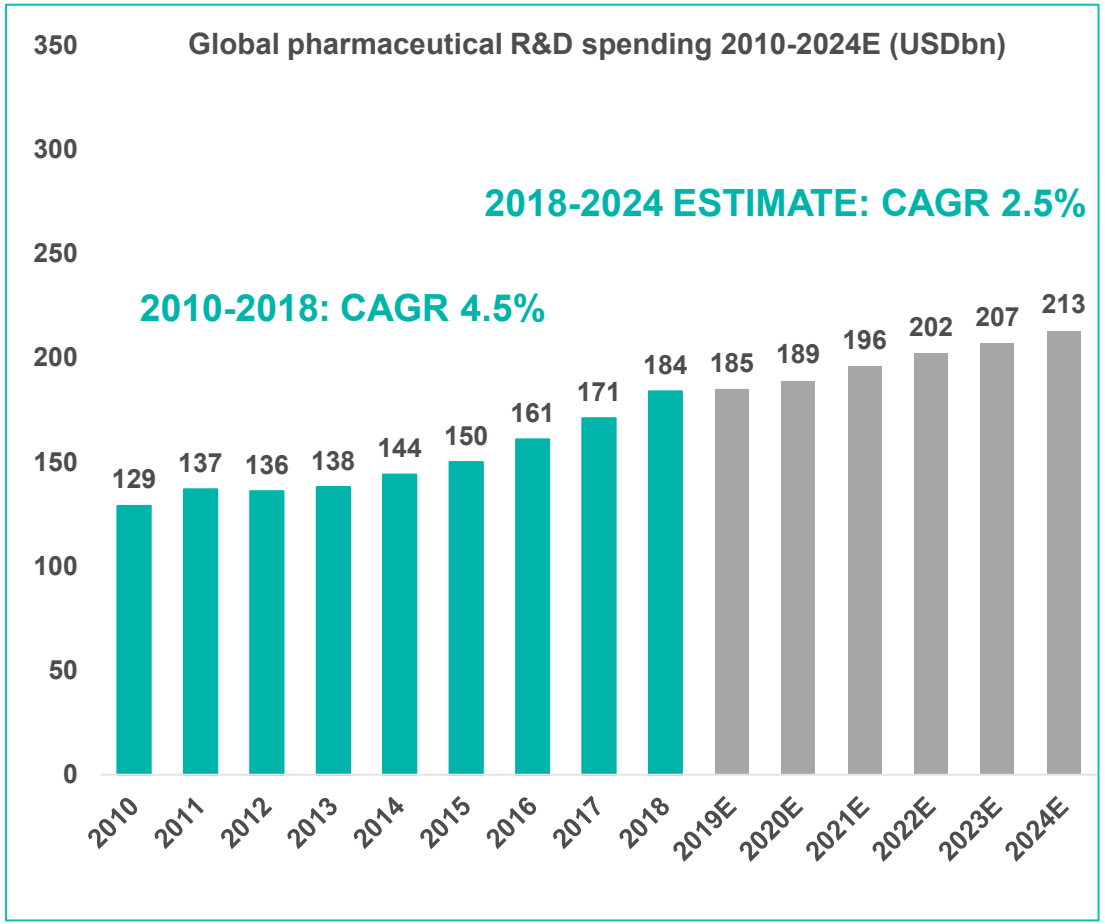




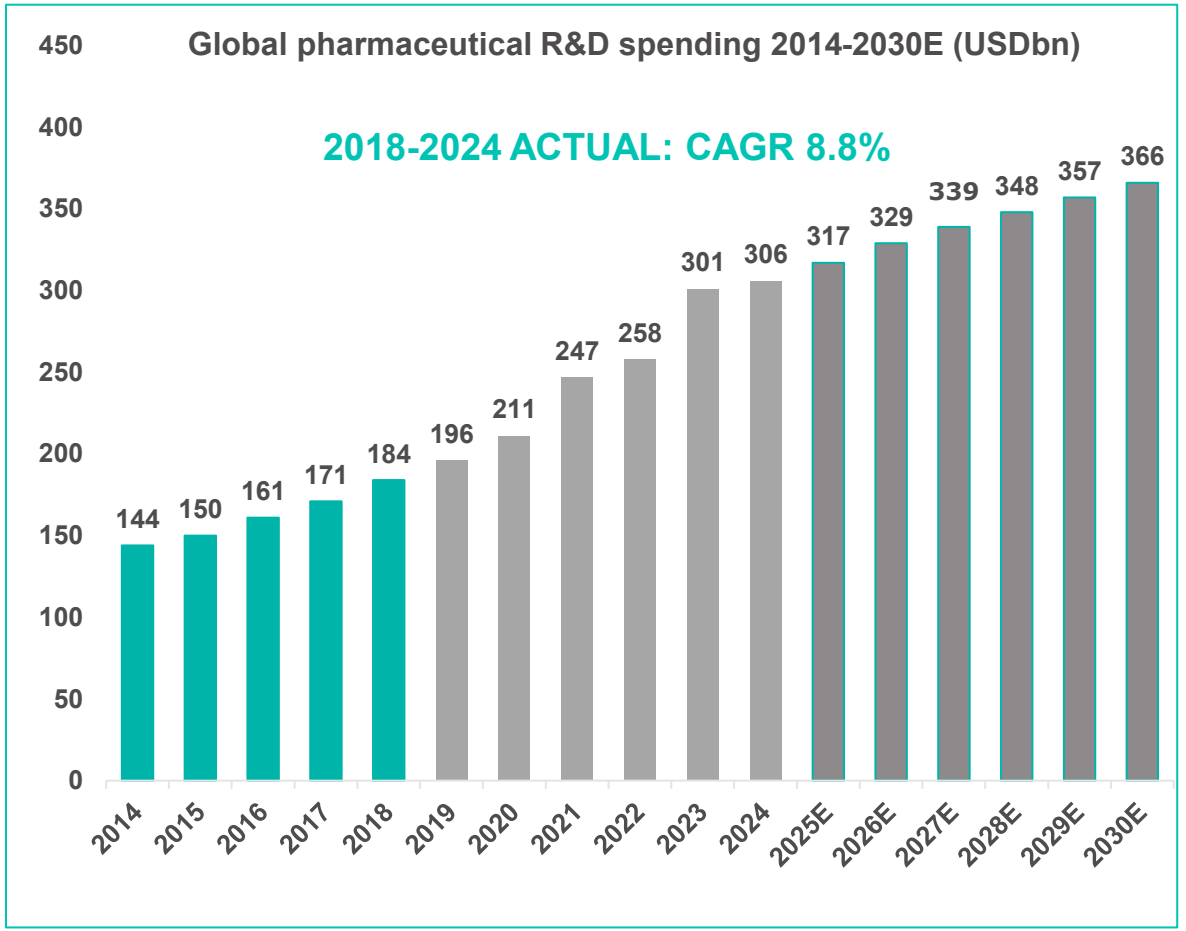
Source: U.S. Food and Drug Administration (FDA); IQVIA Institute for Human Data Science; Statista; Nature

Despite an enormous growth in R&D spending in last five years

2018

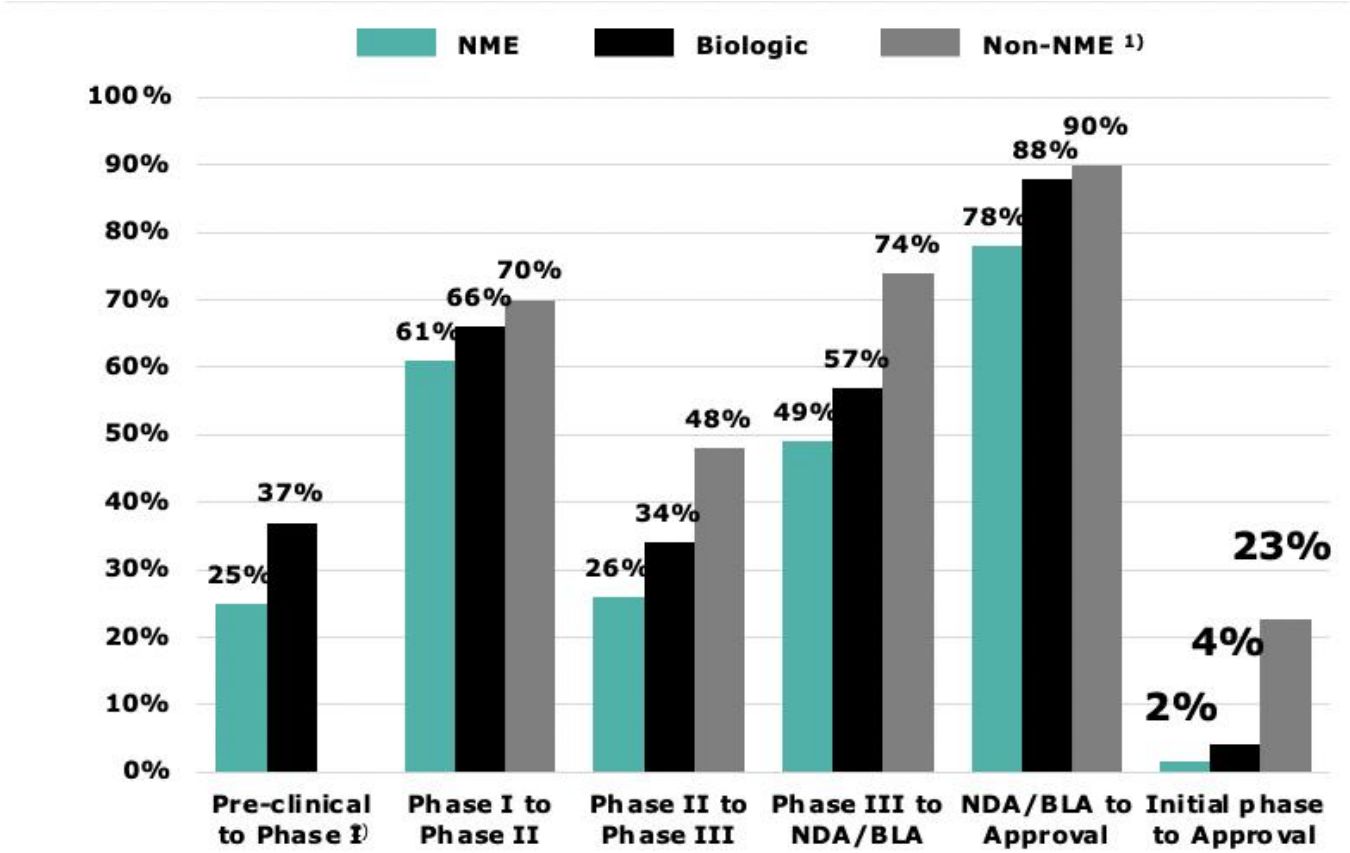


2025



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

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

From non-GMP to GMP (small molecules)

Transition probability from non-GMP to GMP

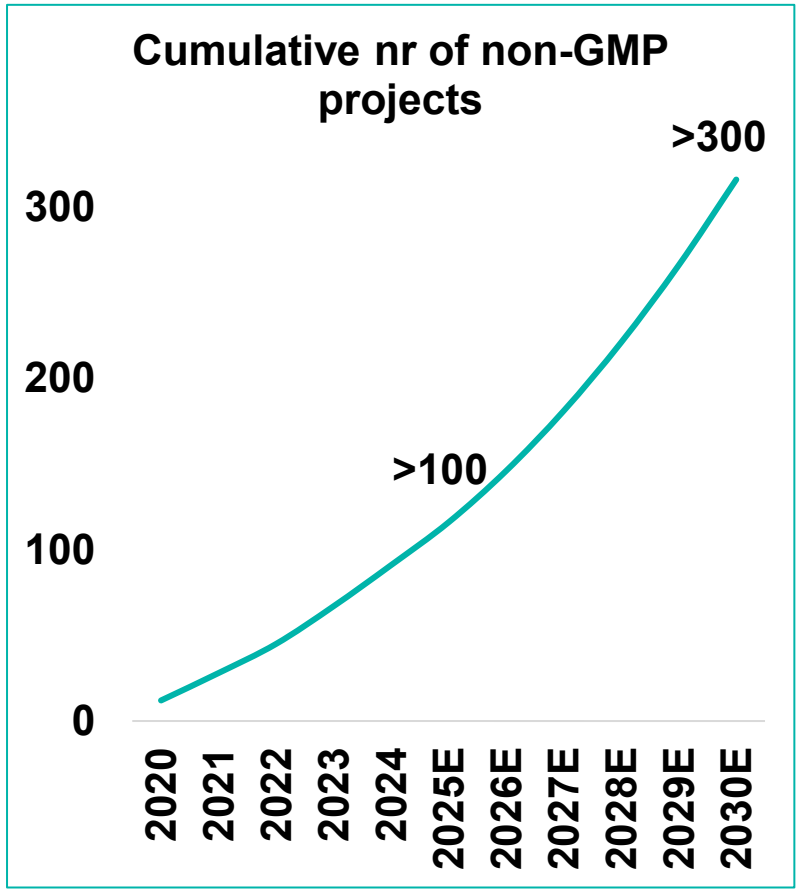
- Total industry number: 20-25%
- New technologies: anecdotal guesstimate by industry veterans: ~5%
- CDMOs using mature technologies and choosing projects selectively: ~50%
- Nanoform assumption at IPO 2020: ~20-25%
- Nanoform realized number 2020-25: ~5%
- **Nanoform target for 2030: 20-25%**

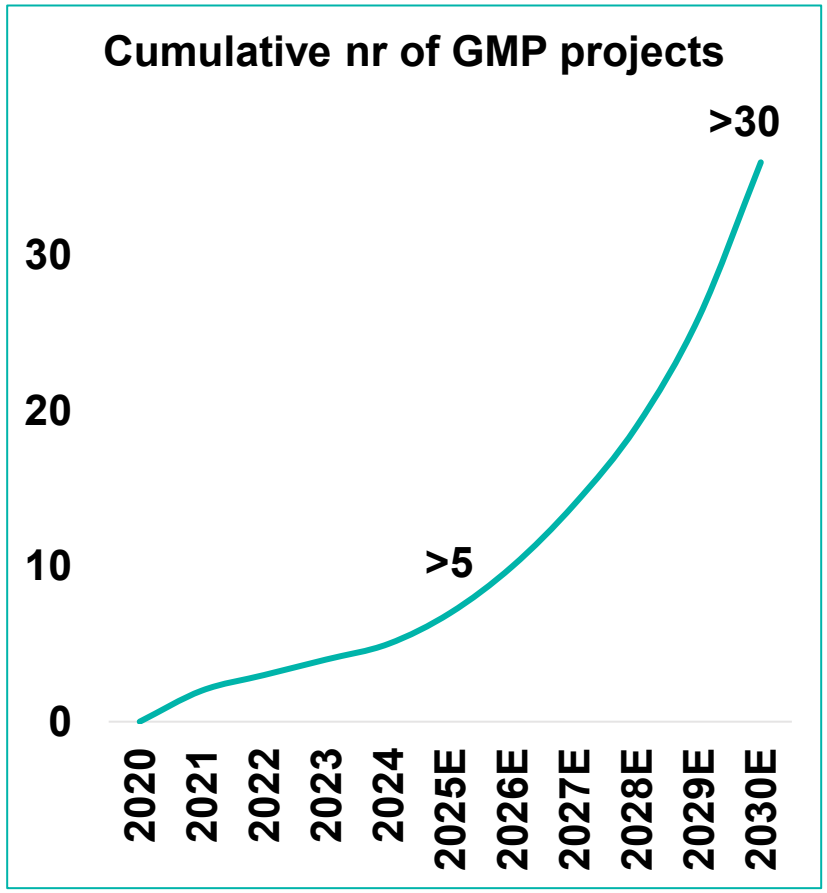
Cumulative nr of non-GMP projects during 2020-25: >100
Cumulative nr of non-GMP projects targeted during 2026-30: >200

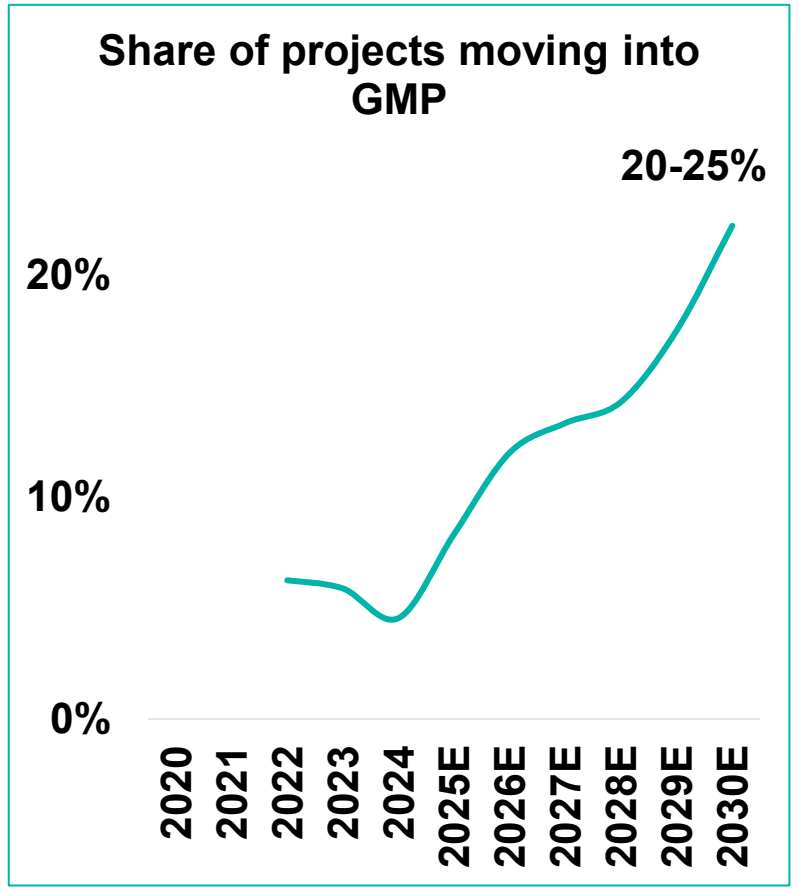
Cumulative nr of GMP projects during 2020-25: >5
Cumulative nr of GMP projects targeted during 2026-30: >25

Non-GMP = pre-clinical and GMP = clinical

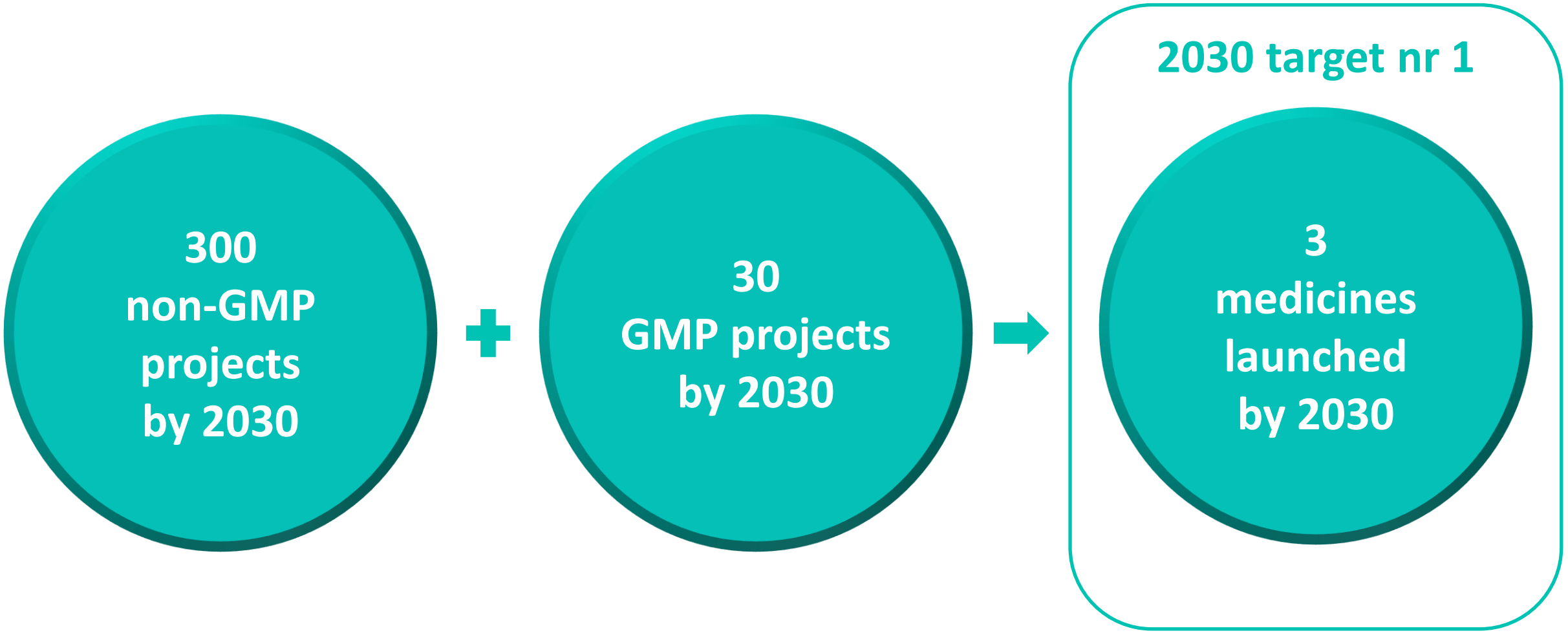
Transition into GMP targeted to reach industry levels by 2030







From preclinical to first 3 market launches in 10 years (2020 to 2030)



Nanoform mid-term annual income potential by 2030

Exclusivity fees & royalties & profit share:	> EUR 50m
Commercial milestones, small molecules:	> EUR 25m
Commercial GMP supply, small molecules:	> EUR 10m
Development milestones, Biologics:	> EUR 10m
Development milestones, small molecules:	> EUR 10m
Clinical GMP supply, Biologics:	> EUR 10m
Clinical GMP supply, small molecules:	> EUR 10m
Non-GMP projects, Biologics:	> EUR 5m
Non-GMP projects, small molecules:	> EUR 5m

Income growth target

Revenue >EUR 30m by 2030

+

Cumulative milestones >EUR 30m by 2030

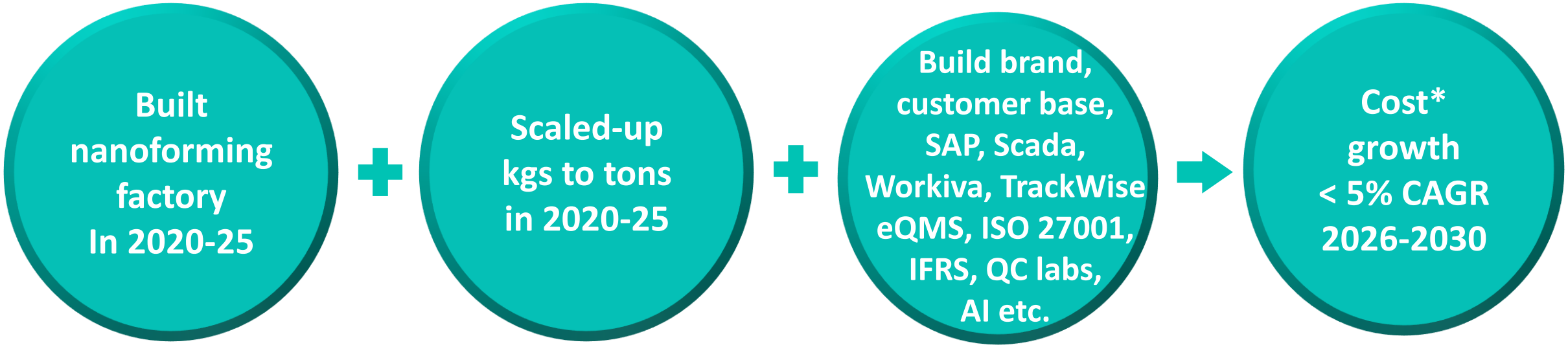
→

2030 target nr 2

Income* growth > 50% CAGR 2026-2030

* Revenue + other operating income (milestones, fees, royalties, profit shares etc.)

Large investments in 2020-25 lead to moderate cost growth in 2026-30



*Operating costs ex options (COGS + employee costs + other operating costs)

Profitability target by 2030

Income* growth
> 50% CAGR
2026-2030

+

Cost** growth
< 5% CAGR
2026-2030

→

2030 target nr 3

>30% EBIT margin by 2030

*Revenue + other operating income (milestones, fees, royalties, profit shares etc.)
**Operating costs ex options (COGS + employee costs + other operating costs)

Nanoform midterm business targets 2030

3 nanoformed medicines launched by 2030

Income* growth > 50% CAGR 2026-2030

EBIT margin > 30% by 2030

* Revenue + other operating income (milestones, fees, royalties, profit shares etc.)

Winfried Ness

Director Intellectual Property

Nanoenzalutamide

European IP landscape

Enzalutamide

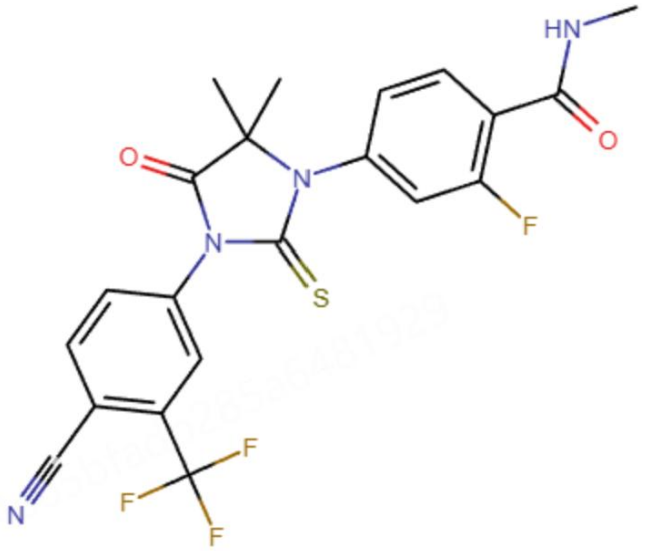
Until **2002** there was **a need for a more effective therapy** for metastatic prostate cancer beyond traditional androgen deprivation therapy (ADT) with medicaments

- leading to medical castration (Leuprorelide) or
- blocking androgen receptors (Bicalutamide)

The concept for enzalutamide began around **2002**, driven by the Prostate Cancer Foundation PCF

see article: **Out of the Box: How PCF Funded the Creation of Enzalutamide**

Initial scientific work was carried out at the **University of California, Los Angeles (UCLA)** in the early 2000s, focusing on creating next-generation drugs that could overcome resistance seen with first-generation drugs (Bicalutamide).



2005

First patents for a new substance
Enzalutamide
were filed, and UCLA licensed them to Medivation

BUT

https://www.pcf.org/our-work/early-research-breakthroughs/how-pcf-funded-enzalutamide-creation/

Enzalutamide created problems

On one hand

The development of a pharmaceutical formulation for enzalutamide faced several significant technological challenges

- Very poor aqueous solubility
- Crystallization tendency of the pure substance
- Stability issues

On the other hand

- **Time to market was key**

40 mg soft gelatin capsule filled with a <u>liquid lipid-based formulation</u>

August 31, 2012:

FDA approved Xtandi with a posology of 160 mg/daily

And the first urgent clinical needs were met

Why came the tablets later

The substance still has disadvantages

- Very poor aqueous solubility
- Crystallization tendency of the pure substance
- Stability issues

The capsules had disadvantages

- Difficult to swallow
- High pill burden with 4 capsules, 40 mg dose each
- Size
- No higher dose available

Xtandi
40 mg, 20 x 9 mm

- Gelatin (dietary restrictions, religion,...)
- Low/No patient convenience and adherence (patient centricity)
- Capsule filling technology is costly and labour intensive

Only 1 technology might solve the problems:
The amorphous solid dispersion (ASD) technology

BUT

in 2012 the ASD was still not advanced enough

The tablets were approved in/ after 2017 but are still not good enough

5 to 6 years later

TABLETS based on ASD technology were approved and launched

2012

Xtandi capsules
40 mg 20 x 9 mm

2017 / 2018 / 2019

Xtandi tablets
40 mg 10 mm

Xtandi tablets
80 mg 17 mm

BUT

- The tablets are still too big, better than capsules but still too big and too many
- No daily dose in 1 tablet available with appropriate size
- The tablets are still not patient centric

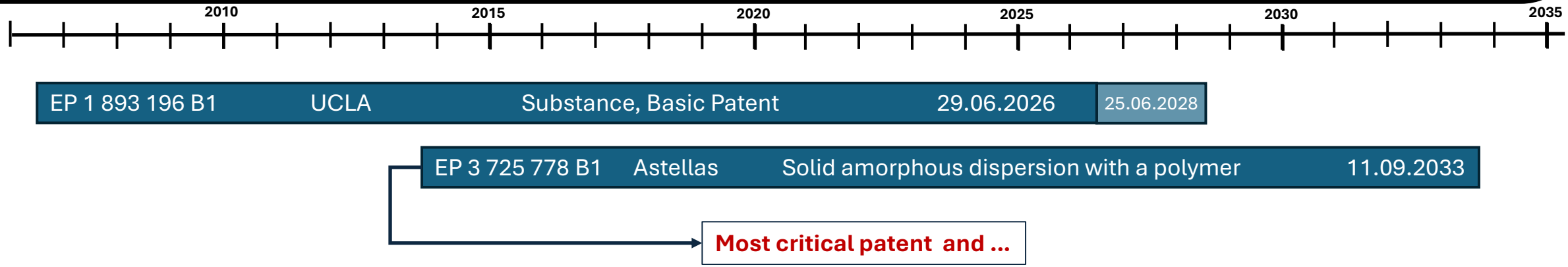
AND

The tablets are patent protected

To develop a better alternative you have to take 2 challenges/hurdles

- Patent hurdle
- Technology hurdle

High level summary



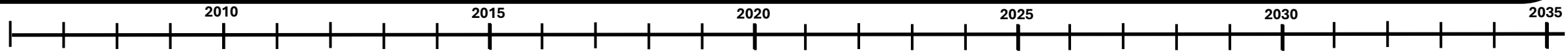
… it is technically **nearly** impossible to develop an alternative without making use of the teaching of this patent

In other words it is **nearly** impossible **NOT** to infringe it

What to do

Get rid of it !!

High level summary



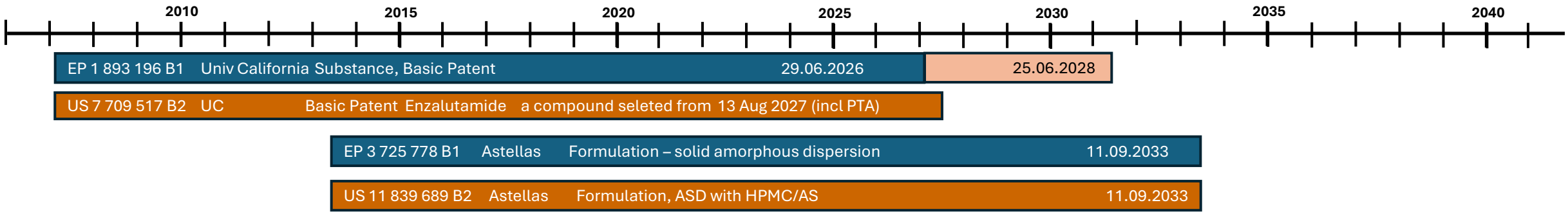
EP 1 893 196 B1	UCLA	Substance, Basic Patent	29.06.2026	25.06.2028
EP 3 725 778 B1	Astellas	Solid amorphous dispersion with a polymer	11.09.2033	

Most critical patent

1. Sandoz
2. Zentiva
3. Dr. Schön
4. Hamm Witkopp
5. Stada
6. Synthon
7. AET
8. Maiwald
9. Accord
10. Kutzenberger
11. Elkington + Fife

All 11 failed 2 times !!

High level summary



- United States
- EPO
- Japan
- China Hong Kong
- EAPO
- Israel
- Mexico
- Australia
- China
- Brazil
- Canada
- Indonesia
- India
- Korea
- Chinese Taiwan
- South Africa
- Austria
- Cyprus
- Germany
- Denmark
- Spain
- Croatia
- Hungary
- Lithuania
- Malta
- Norway
- Philippines
- Poland
- Portugal
- Republic of Serbia
- Slovenia
- Slovakia
- Thailand
- Ukraine

All major markets are covered

Is there a way out?

Xtandi capsules
40 mg 20 x 9 mm

Xtandi tablets
40 mg 10 mm

Xtandi tablets
80 mg 17 mm

Enzalutamide tablets ?

?

Is there still room for improvement?

YES there is !!

The magic word is

Polymer embedded **Nanoparticles - PeN**

- There is a now newly invented, patented and **alternative technology platform** to ASD available
- It can be applied to **all substances** having the same disadvantages like Enzalutamide substances like Apalutamide, Encorafenib, …… (very slow solubility)
- It is patent protected and embedding in polymer is also protected
- For all developments further patent protection is possible
- Technically outside of ASDs so no problems with ASD patents
- It overcomes the disadvantages of too many pills – reduction to 1 pill from 4 even at highest dose
- It overcomes the disadvantages of too big pill size
- It is patient centric and lowers pill burden

and

- It shows the same bioavailability and bioequivalence

SIMPLY.BETTER

YES it is !!

Technology hurdle solved

Xtandi capsules
40 mg 20 x 9 mm

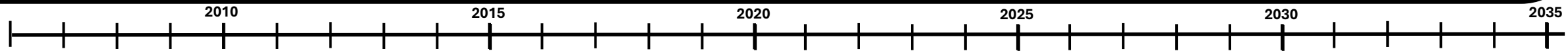
Xtandi tablets
40 mg 10 mm

Xtandi tablets
80 mg 17 mm

Nanoform
Enzalutamide tablets
160 mg

What about the patent hurdle

It is possible



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EP 3 725 778 B1	Astellas	Solid amorphous dispersion with a polymer	11.09.2033	

Most critical patent and

It is **nearly** impossible to develop an alternative tablet without infringing this patent

It **is possible** to develop an alternative without infringing this patent by using

nanoform
small is powerful

Dr. Katja Dreyer

Director Onconcept & Specialty Generics,
Helm Pharmaceuticals GmbH

Nanoenzalutamide

European roadmap & commercial launch

nanoform
small is powerful®

ONConcept®

WELDING GROUP

HELM

bluepharma

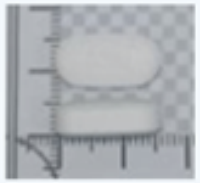
NANOENZALUTAMIDE EUROPEAN ROADMAP AND COMMERCIAL LAUNCH

Dr. Katja Dreyer,
Helm Pharmaceuticals GmbH,
Director Onconcept & Specialty Generics

OUR VALUE PROPOSITION:
ENHANCING PATIENT NEEDS AND COMMERCIAL VIABILITY

Nanoenzalutamide tablets






40 mg	80 mg	120 mg	160 mg
Ø 8.0 mm	13.5 x 6.5 mm	16 x 8 mm	18 x 8 mm

Originator availabale dosage forms / Xtandi®



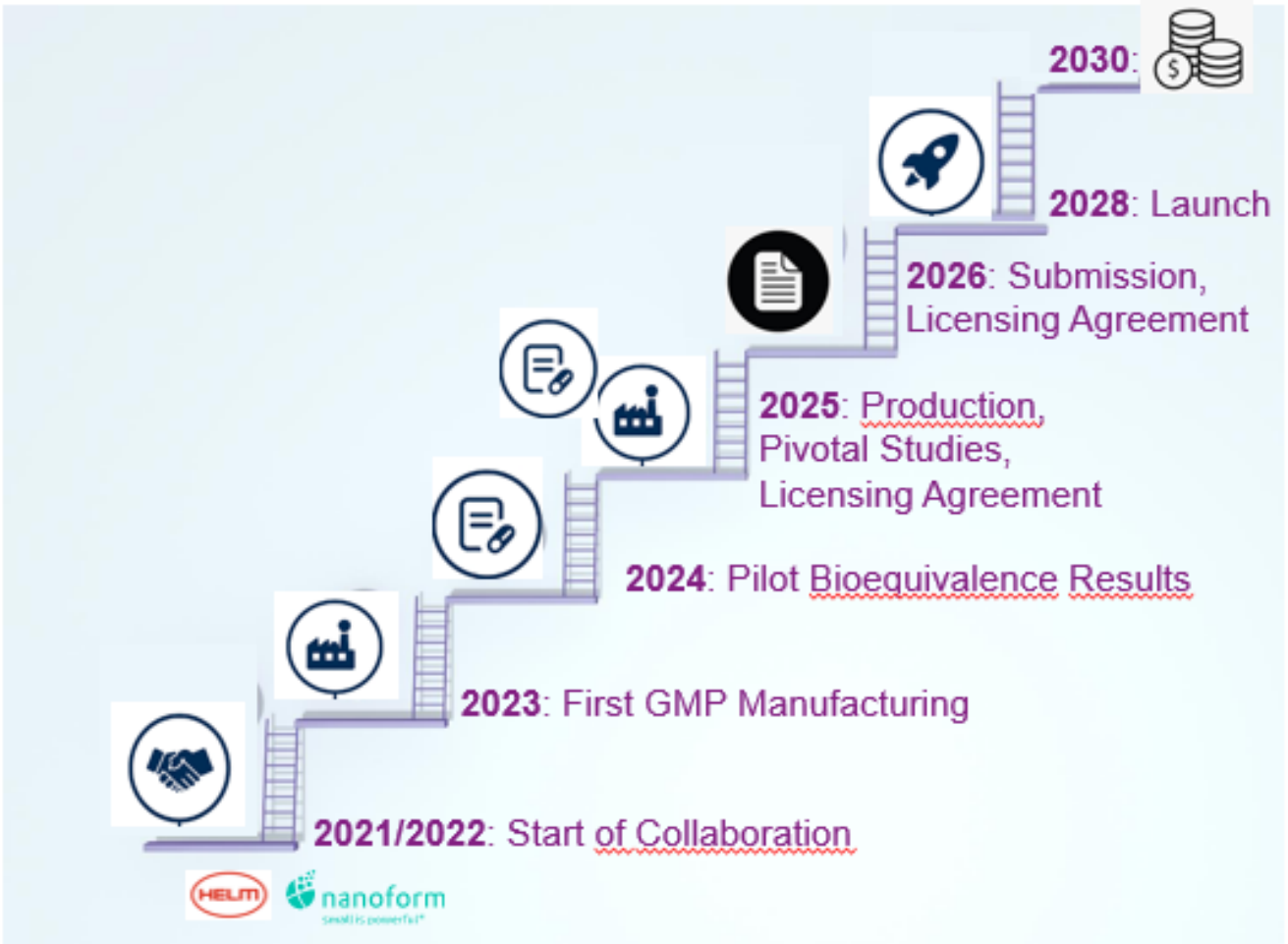
80 mg	40 mg	40 mg
17.1 x 9 mm	10 x 4.5 mm	20.0 x 9 mm

Flexible Dosage Options
Offering flexible daily dose and dose adjustments simplifies treatment and improves patient adherence.

Smaller Tablet Sizes
Developing smaller tablets addresses swallowing difficulties, enhancing patient comfort and convenience.

Robust Intellectual Property
Strong IP positioning secures market exclusivity and sustains commercialization beyond patent expiry.

OUR JOURNEY
MILESTONES FROM 2021 TO 2030



Partnership Formation and Expansion

The partnership started in 2021 and expanded in 2022 through entry into a strategic consortium enhancing collaboration.

Technical Achievements and Manufacturing

In 2023, production of GMP materials and tablet development marked key advances toward scalable manufacturing.

Clinical and Regulatory Progress

Pilot bioequivalence study in 2024 and dossier submission in 2026 ensured regulatory compliance and clinical evidence.

Commercialization and Product EU Launch

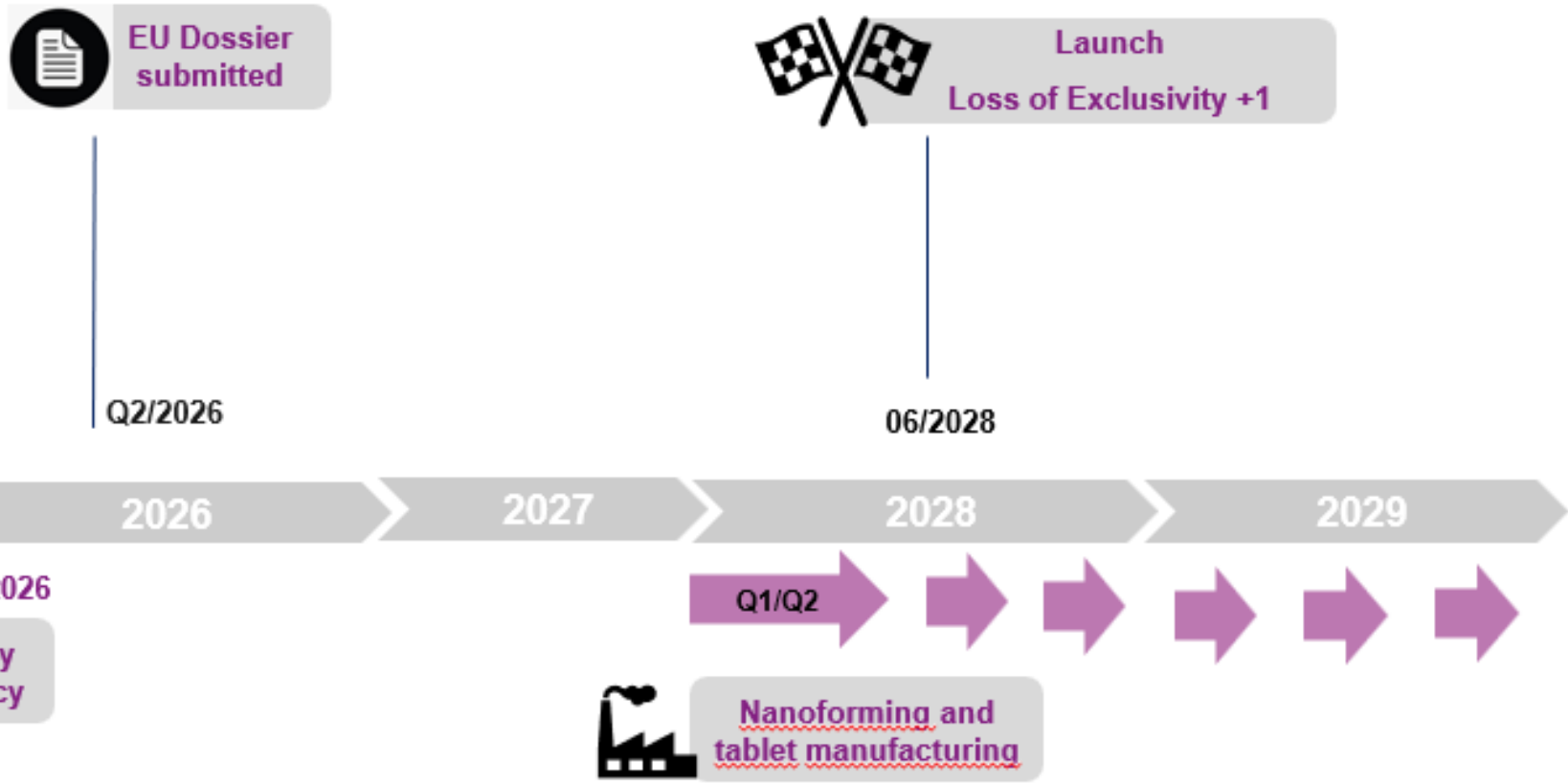
By 2028, the partnership culminates in the product launch and enters in the commercial product supply.

XTANDI® –
FLAGSHIP PRODUCT IN ASTELLAS/PFIZER ONCOLOGY PIPELINE, DRIVING GROWTH AND COMBINATION STRATEGIES

- **Global Sales Powerhouse:** $6.2Bn in 2024 **US:** $2.5Bn | **Europe:** ~$2Bn
- **Cornerstone in Prostate Cancer Therapy:** Sustained growth trajectory with predicted increasing sales
- **Broad Label Coverage:** Approved for **mCRPC**, **mHSPC**, **nmCRPC**, **high-risk nmHSPC**
- **Strong Market Position:** Extensive clinical adoption across multiple indications
- **Future Outlook:** Generic entry in Europe **possible in 2028**, reinforcing current premium positioning

REACHING THE TARGET OF COMMERCIAL LAUNCH IN 2028

- Secure Marketing authorization
- MAXIMISE Market value
- STRATEGIC PLANNING



nanoform ONConcept®

Kurt Nielsen

Managing Director Expert Insights

Nanoenzalutamide US launch roadmap

Background and Context for US NanoEnzalutamide Market

A Large, Durable US Market with a Real Patient Problem

- Xtandi® is a **multi-billion-dollar US prostate cancer therapy**, taken daily by patients over long treatment durations
- The standard regimen requires **multiple large capsules**, creating real-world swallowing and adherence challenges for older patients
- Nano-Enzalutamide enables **clinically equivalent dosing in smaller, swallowable single 120 mg / 160 mg tablets**
- This creates **patient-centric differentiation**, not simply a lower-priced copy of the Xtandi® or other generic Enzalutamide tablets or capsules
- In the US, **launch timing, auto substitution at the pharmacy, and differentiation** ultimately determine commercial value capture

This is a large market where patient usability and launch strategy materially influence commercial success.

What We Have Done So Far

De-Risked the Asset

- Advanced Nano-Enzalutamide to **GMP-ready formulations suitable for late-stage development**
- Generated **initial human pharmacokinetic (PK) data**, reducing early clinical uncertainty
- Built **strong, non-infringing IP** around single table 120 mg / 160 mg dose strengths
- Defined a **scalable manufacturing and supply strategy**, beyond lab-scale feasibility
- Demonstrated interest **from several partners well established in the US** , validating external commercial interest

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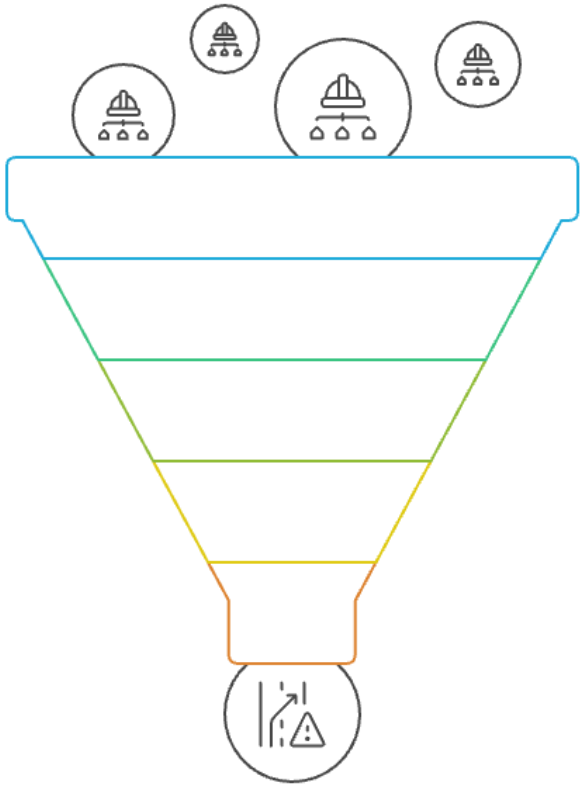

GMP-Ready Formulations
Preparing for late-stage development

Human PK Data
Reducing clinical uncertainty

Strong IP
Securing market exclusivity

Scalable Manufacturing
Ensuring supply chain feasibility

Partner Interest
Validating commercial viability

This program is past the feasibility stage — remaining risks are predominantly execution-driven.

What We Are Going to Do (Strategy)

- Pursue **multiple US regulatory pathways in parallel**, rather than a single bet
- Preserve flexibility across **ANDA and 505(b)(2)** filing options
- Maintain the ability to pursue **AB-rated or differentiated launch strategies**
- Structure all development paths to support a **fastest possible filing, FDA approval and launch**

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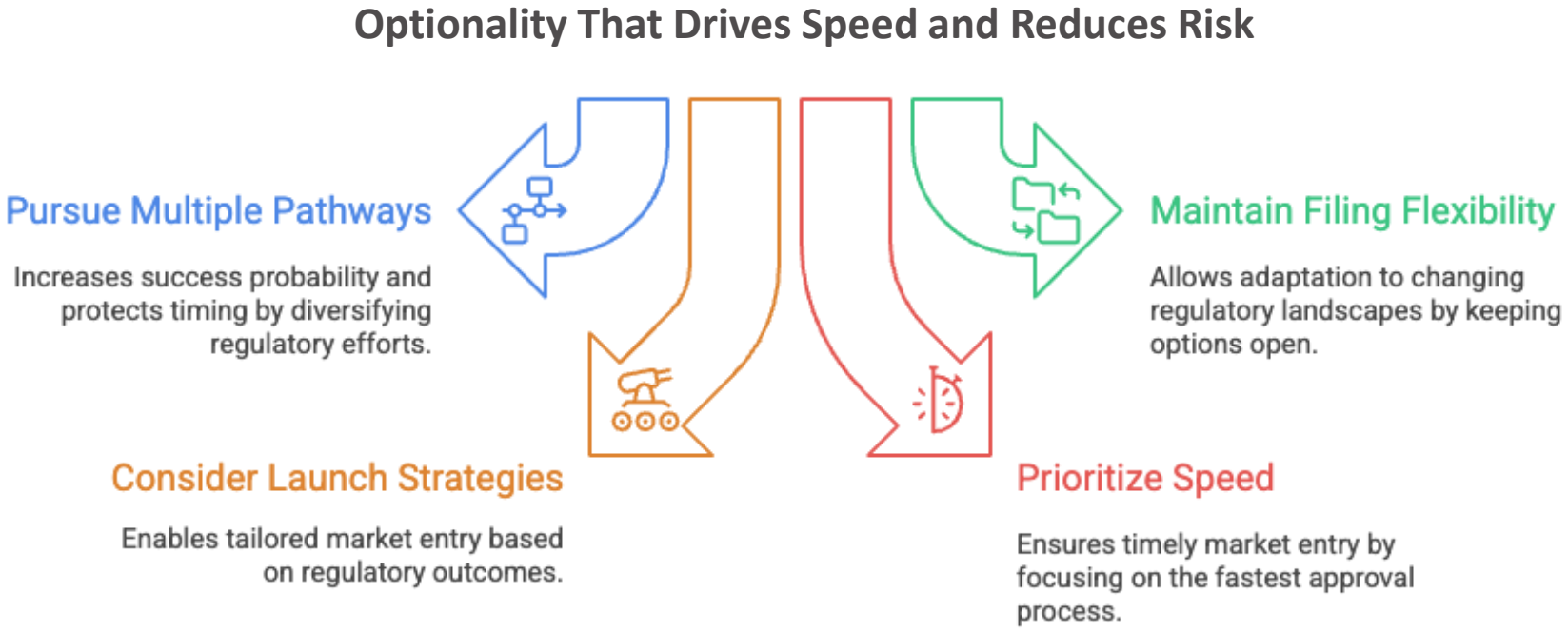
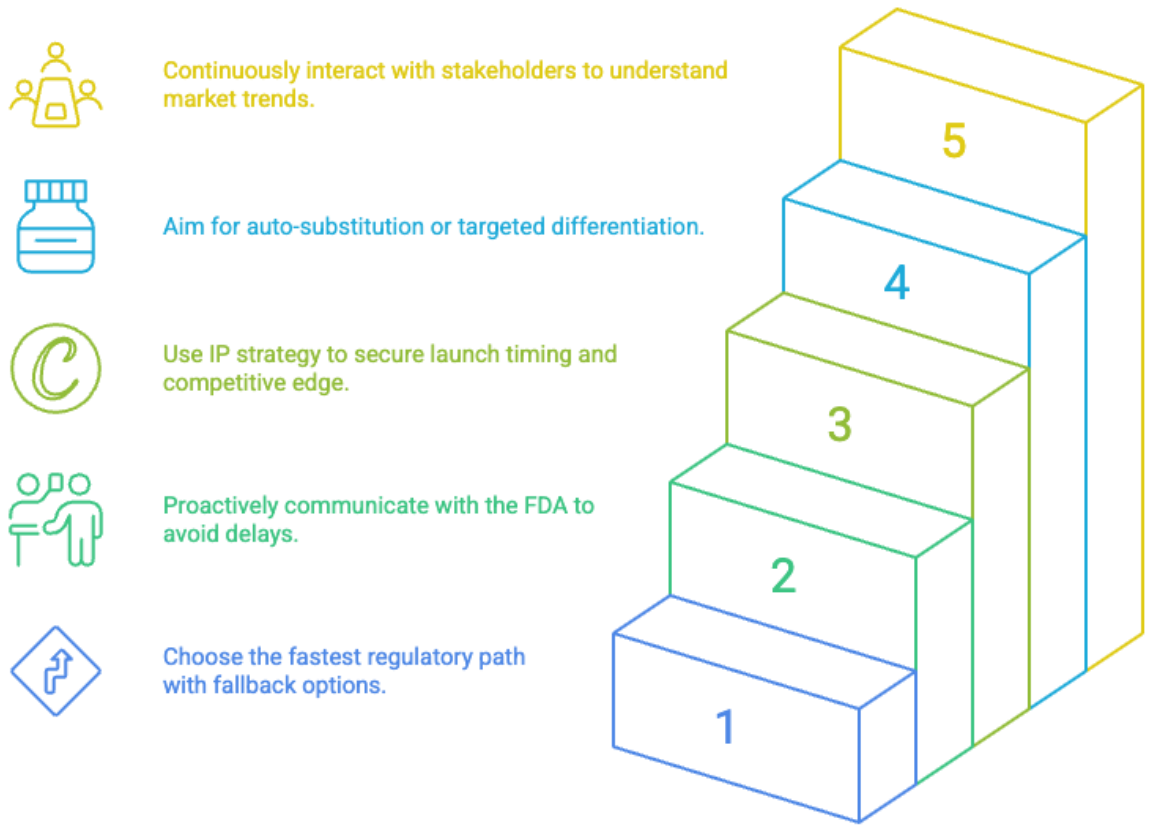


Optionality here is a risk-management tool — it increases probability of success and protects launch timing.

What Are We Going to Do (Execution and Value Capture)

Turning Regulatory Progress into US Commercial Value

- Select the **fastest approvable US path** while retaining fallback options
- Engage FDA early to minimize approval delays and regulatory surprises
- Use IP strategy to **protect launch timing and competitive position**
- Enable **auto-substitution (AB rated) or targeted differentiation**, depending on final pathway
- Continually engage US stakeholders (e.g. physicians, payors and closed systems) to **fully understand market access and prescribing trends**



Approval creates opportunity; disciplined execution determines how much value is captured.

A Patient-Centric Product with a Disciplined US Launch Strategy

Large, durable market: Xtandi® represents a multi-billion-dollar US franchise with long treatment durations, creating sustained generic opportunity

Real patient differentiation: Smaller, swallowable 120 mg / 160 mg doses address adherence and usability issues in an older patient population

De-risked foundation: GMP-ready formulations, human BE data, scalable supply, and non-infringing IP reduce technical and development uncertainty

Smart regulatory strategy: Parallel ANDA and 505(b)(2) pathways preserve speed, flexibility, and optionality for AB-rated or differentiated launches

Execution-driven value capture: Early FDA engagement, IP-aware timing, and proactive payer positioning maximize uptake and economic outcomes

Nano-Enzalutamide combines a clear patient benefit with a launch strategy designed to win on timing, substitution, and differentiation.

Johanna Kause

Chief Quality Officer

Nanoenzalutamide regulatory strategy

Drug Substance (DS) or Active Pharmaceutical Ingredient (API)

The specific chemical compound or molecule within a drug product that provides the intended therapeutic effect (e.g. Nanoenzalutamide)

Drug Product Intermediate

A material produced during the drug manufacturing process that is not yet the final product but a crucial step in the process

Drug Product

Final dosage form, containing the drug substance and excipients (e.g. tablet, capsule, cream)

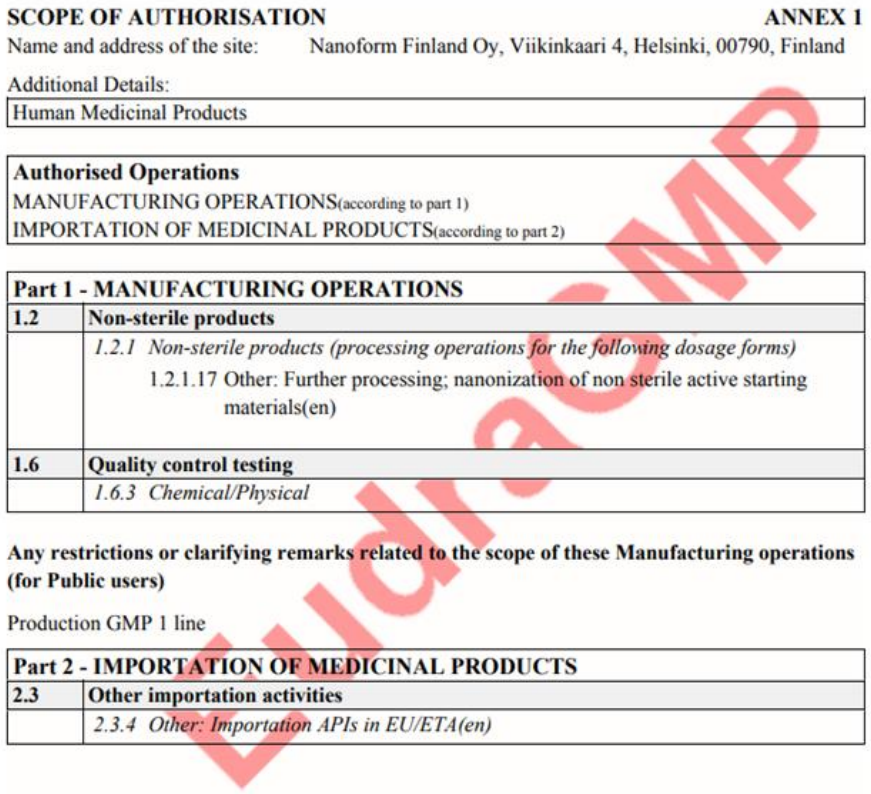
Evolution of GMP* at Nanoform

2020-2025: Building

- From a single-API clinical manufacturing site to a multi-API commercial manufacturing site with an in-house QC laboratory
- 4 GMP inspections by the Finnish Medicines Agency

2026-3030: Expanding

- Expansion of commercial manufacturing authorization to GMP2 and GMP3
- Inspections from relevant authorities, e.g. US FDA, PDMA (Japan)



SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Nanoform Finland Oy, Viikinkaari 4, Helsinki, 00790, Finland

Additional Details:

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS(according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS(according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.17 Other: Further processing; nanonization of non sterile active starting materials(en)
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

Production GMP 1 line

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.4 Other: Importation APIs in EU/ETA(en)

* GMP: Good Manufacturing Practice

Regulatory steps for an Active Substance

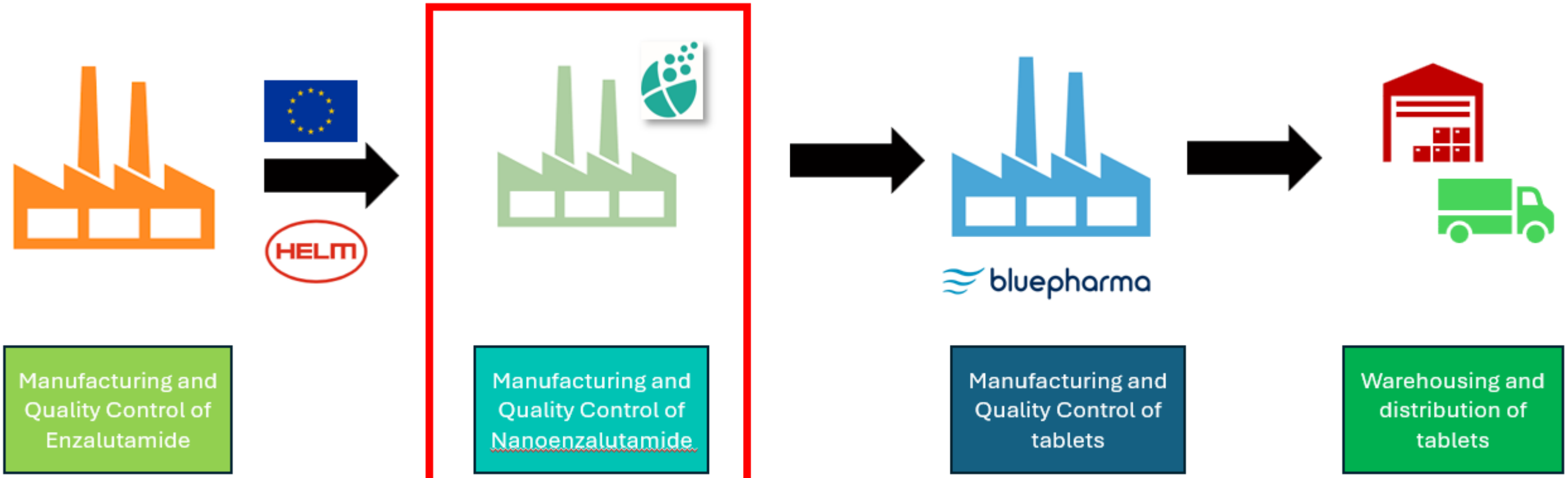
- A Marketing Authorization Application (MAA) contains parts for the **Drug Substance** (API) and **Drug Product**

- The **Drug Substance** part can be submitted
  - as part of the Marketing Authorization Application or
  - as a separate dossier, referred to as **Active Substance Master File** (ASMF) in the EU and **Drug Master File** (DMF) in the US

- Nanoform will use the ASMF/DMF approach
  - The ASMF and DMF consist of an **Open Part** which is shared with the MAA applicant and a **Closed Part** which is shared only with the regulatory authority
  - In US the DMF can be submitted six months prior to the submission of the MAA
    - This will enable any potential technical issues with the DMF to be clarified already before the assessment of the MAA begins

- In addition to Nanoform's ASMF/DMF, the manufacturer of the bulk API will also submit their ASMF/DMF

Nanoenzalutamide Supply Chain



ASMF/DMF

Nanoform ASMF/DMF

Marketing Authorization Application

HELM

Regulatory Strategy (Nanoenzalutamide)

- The regulatory strategy and regulatory procedure for the Drug Product is selected by the MA applicant
  - For Nanoenzalutamide
    - EU (*hybrid generic via decentralized procedure*) and US (TBD)

- For regulatory success of the Drug Product, Nanoform will:
  - Maintain GxP **compliance**, ensure **security of supply**
  - Build internal expertise on regulatory **guidance for nanomaterials**
  - Ensure solid **scientific foundation** of the ASMF/DMF
  - Collaborate with MA applicants on **educating regulators** on the CESS® technology

- This is applicable for all future products containing nanoformed API, meaning that **the template we have created for Nanoenzalutamide will be leveraged for other products**.

Nanoenzalutamide regulatory timeline

Q1/2026

Active Substance Master File ready for submission

An ASMF is submitted together with the MAA

Q2/2026

Drug Master File ready for submission

A DMF can be submitted 6 months prior to the MAA

2026-2030

eCTD* dossier available for submissions

Applicable in EU, US, Japan and other territories

*eCTD: Electronic Common Technical Document, a global standard format for regulatory submissions

Antonio da Silva

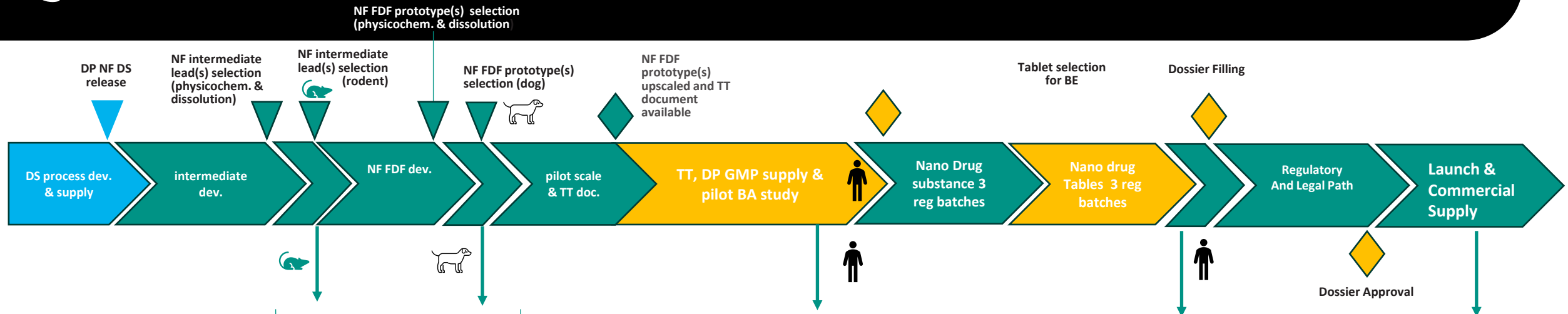
Chief of Business Operations

3 Nanoformed medicines launched by 2030

Kernel Pipeline

Originator	Indication	Expected originator peak sales	Nanoformed API	Delivery route / dosage form	Nanoform ownership today	Development partnering status	Targeted commercial partnering	Phase 1 / Pilot clinical trial	Pivotal - final - clinical trial	Earliest possible market launch
			Nanoform Product Kernels					**Nanoform Clinical (GMP)**		**Nanoform at Market (GMP)**
Astellas/ Pfizer	XTANDI®/ Prostate cancer	~$5bln	Nanoenzalutamide	Oral / Tablet	25 %	OnConcept Consortium	Ongoing			2027 US & 2028 EU
Johnson & Johnson	ERLEADA®/ Prostate cancer	~$5bln	Nanoapalutamide	Oral / Tablet	100 %	Ongoing	Ongoing	2026	2026-2027	2032 US & EU
Pfizer	BRAFTOVI®/ Melanoma and colorectal cancer	~$800mln	Nanoencorafenib	Oral / Tablet	57 %	BRAFMed Lda	Ongoing	2026	2027	2030 US & 2033 EU
Merck/ AstraZeneca	Glioma		NanoO+T (GLIORA)	Long Acting	50 %	Revio Therapeutics	2026-2027	2026	2028	2030 US & EU
Genentech/ Roche	Oncology		Nanotrastuzumab	High Conc. Sub.Cut. Bio	100 %	2026	2026-2027			
Novo Nordisk	Obesity		Nanosemaglutide	Inhaled	100 %	2026	2027-2028			
Undisclosed	Inflammation		Undisclosed	Oral / Tablet	100 %	Partnered	2026-2027			
Undisclosed	Oncology		Undisclosed	Oral / Tablet	100 %	2026	2027-2028			
Undisclosed	Prostate cancer		Undisclosed	Long Acting	100 %	2026	2026-2027			

Kernel development pathway



- Preclinical *in vivo* studies as tool for intermediate & FDF development
- *In vivo* data serves intermediate and FDF optimization and selection in an iterative process
- PBPBM Modeling also possible with no animal testing

- Demonstration of rel. BA of a smaller FDF with a higher drug load/ improving pill burden *vs*. RLD

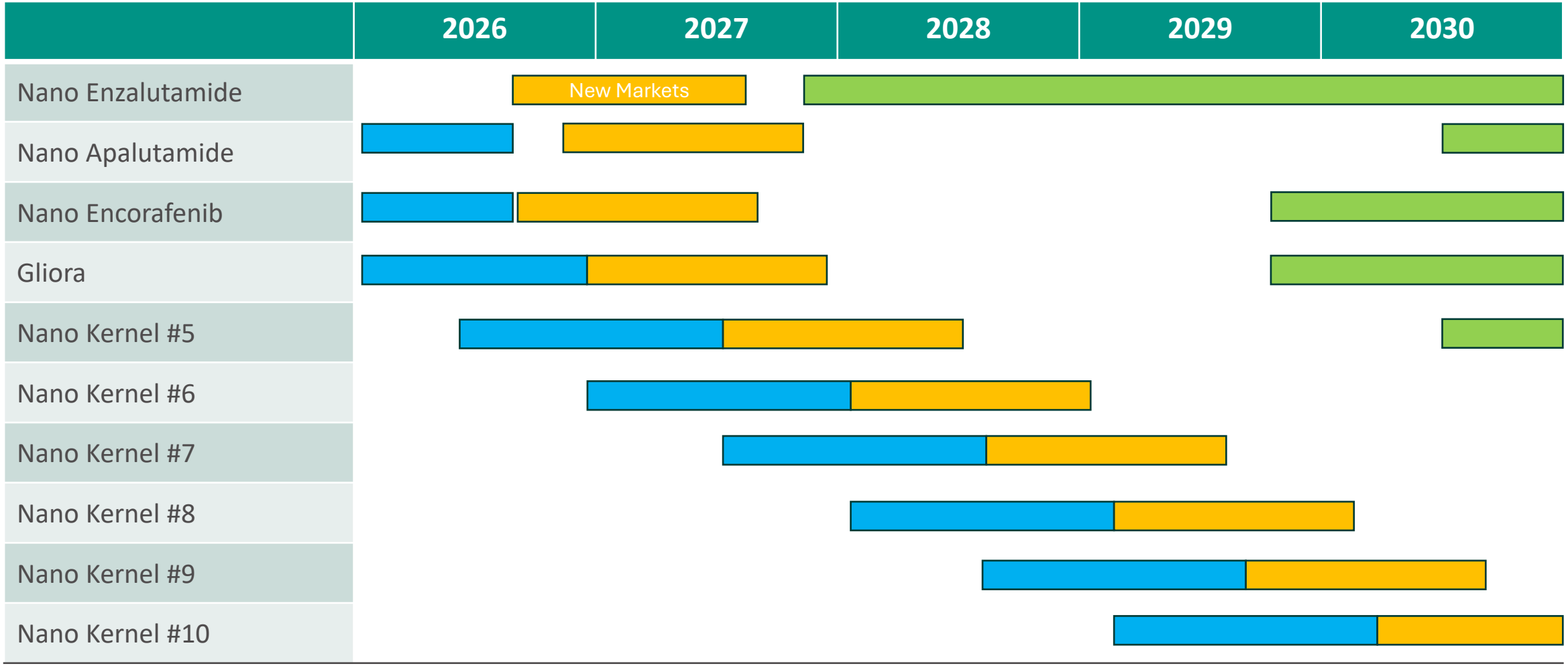
- PV studies
- Demonstrate bioequivalence
- 6 to 12 month stability
- Filling

Ready for any Market according to business needs:

- EU
- US
- Japan
- Others

Commercial Value

Activity plan



Process Development (R&D activities including nanoDS and nanoFormulation development)

Nano DS Clinical Supply (100 to 150 kg / Kernel)

Nano DS Commercial Supply (Depending on Kernel: NanoEnza Peak demand > 1ton)

Plant Plan

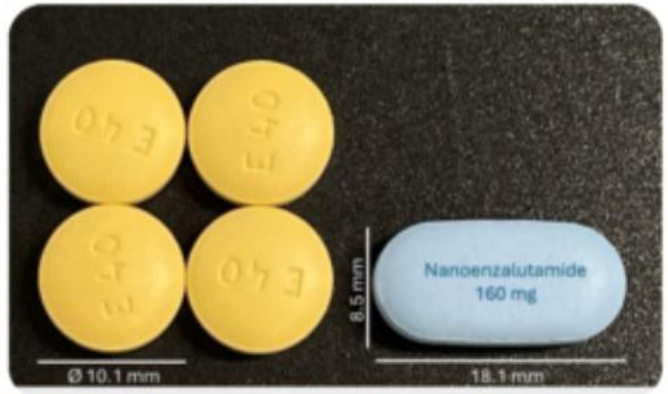
Lines	2026	2027	2028	2029	2030
GMP1					
GMP2					
GMP3					

EMEA, FDA, PMDA Ready
10 ton/year Facility

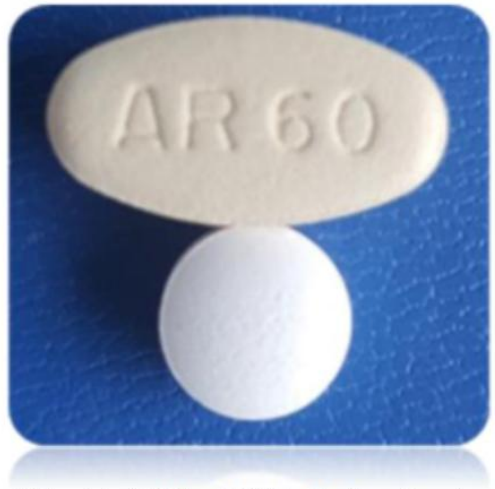
Under Installation

Clinical Manufacturing License

Commercial Manufacturing License



Daily treatment regimens for Xtandi® (enzalutamide) and nanoformed enzalutamide (nanoenzalutamide)



Erleada® (apalutamide) 60 mg tablet (top) and nanoformed apalutamide (nanoapalutamide)

Steen Vangsgaard, CEO A.forall Group NV

&

Tiago Geraldeso, Investment Director IMGA

Why we invested in Nanoencorafenib

Who is Aforall Pharma?

Aforall – Value-added generic medicines, asset light specialty pharma.

- Develop and register products (partner to get access to relevant technologies)
- Establish and manage supply chains
- Launch, commercialize/out-license products

Value-added generic medicines:

- 3 Ps: Patients, physicians, payors
- Complex formulation and manufacturing. Device interdependence

Steen's background

- Aforall launches 3-4 products annually
- Mylan days (now Viatris) 15-20 launches annually

Why encorafenib and Brafmed

Benefits of nanoformed encorafenib:

- Reduced pill burden (6 to 1) - enhanced patient compliance - better patient outcomes
- Competitive advantage over generic encorafenib/life-cycle management option

Nanoforms technology:

- High yield & promising results
- Platform technology: Promise of broad application

Brafmed:

- Leverages each others respective strengths
- Favourable risk/return
- Model for future pipeline expansion

gestão de ativos
sgoic

Why Futurum Tech invested in the Brafmed project?

Nanoform Investor's call, **16 December 2025**

IMGA and Futurum Tech Venture Capital Fund

Main facts and figures

Largest independent asset manager in Portugal, with over 6 billion euro in AuMs at the end of 2025.

- Over 35 years of experience, mostly in the mutual fund industry (UCITS open ended funds: 33 funds)
- Over 200.000 retail and institutional clients

In 2021, launched its private equity and venture capital practice

- In 2024, launched its first venture capital fund – Futurum Tech
- Currently manages 5 different PE and VC funds

FUTURUM TECH

A late-stage venture capital fund focused on two investment themes' aggregators:

Future Tech & Life sciences

Blockchain	Artificial Intelligence
Cleantech	Advanced Materials
Cyber Security	Apps&Platforms
Fintech	Robotics
Quantum Computing	Nano-technology
Circular Economy	Advanced Mobility

Health Tech	Biotechnology
Mental Health	Food engineering

- Target: SMEs, late seed and series A, B and C rounds
- Market validation - post revenues and/or IP
- Relevant participation in investees' capital
- Active participation in their management

Futurum Tech Venture Capital Fund and Brafmed

Why did the Futurum Tech Fund invested in the Brafmed project

FUTURUM TECH

BRAFMED

What we were looking for:

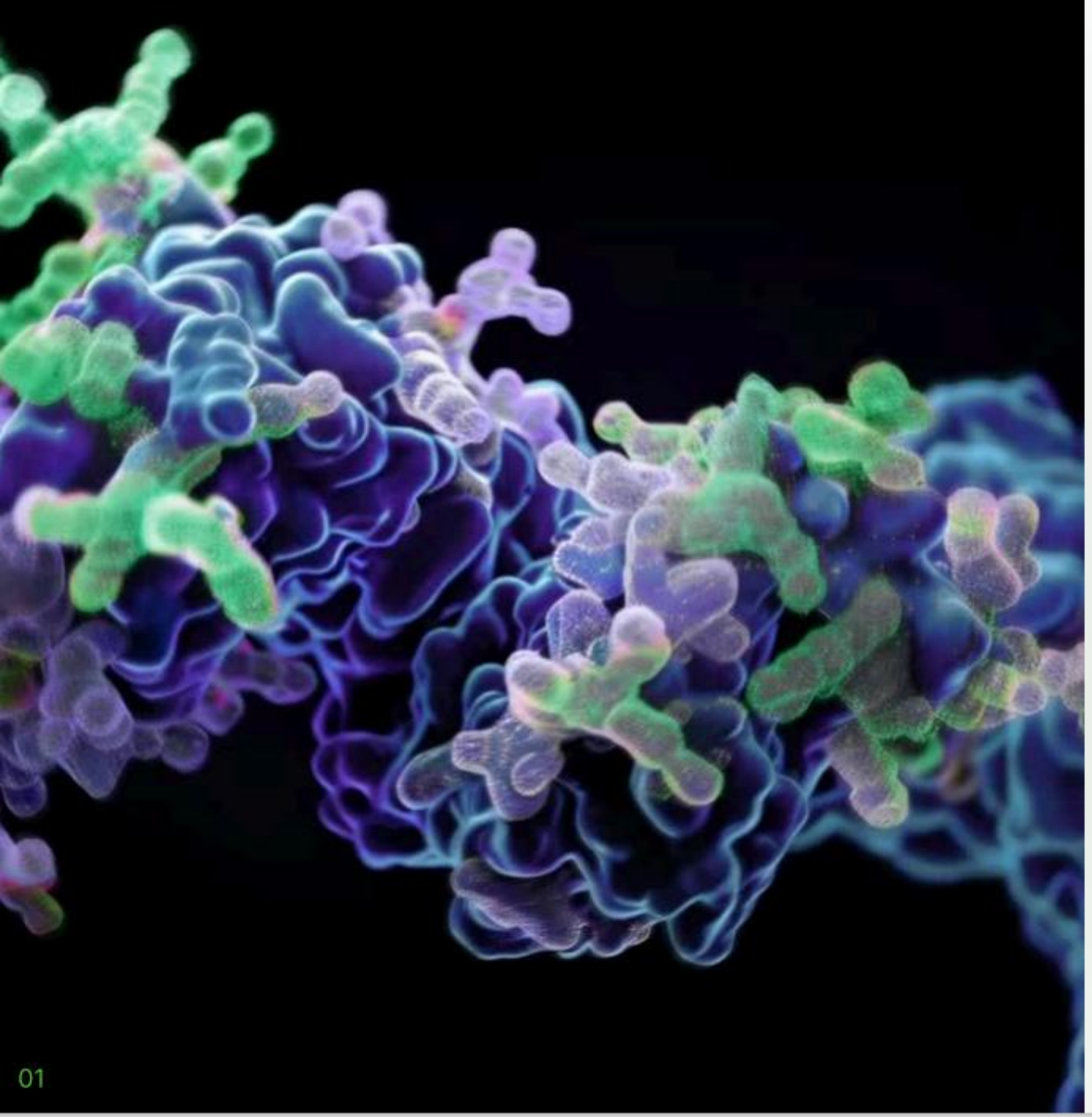
1. Good strategic fit with the Fund's Investment thesis
2. Strong and complete team
3. Cutting edge products / technology
4. Sound and profitable business model
5. Sound financial plan and funding strategy
6. Investable cap table
7. Big serviceable market
8. Ticket size between 1 million and 5 million euro for a relevant capital participation
9. Clear exit strategy or alternative exit strategies

What we found in Brafmed (Nanoform & Aforall):

1. **Good strategic fit: sector; stage; etc…**
2. **Strong scientific and corporate teams** (Nanoform & Aforall)
3. **Cutting edge product / technology** (Nanoform´s technology)
4. **Risky, but sound and likely profitable business model**
5. **Measured funding needs, well defined financial plan**
6. **Ability to acquire a >20% stake**
7. **Established global market with a crucial IP change ahead**
8. **Two stage investment enabled measured risk approach by the Fund**
9. **Multiple exit strategies possible in max 5-year timeframe**

Sreevatsa Natarajan
Co-Founder and CEO Revio Therapeutics

GLIORA partnership with Nanoform



nanoform
small is powerful®

revio therapeutics
adding life to medicines

GLIORA™

An Intra-Tumoral Thermo-Responsive Long-Acting Nano-Hydrogel for High Grade Glioma & Glioblastoma

Collaboration between
Revio Therapeutics LLP & Nanoform PLC

DECEMBER 2025

Speaker Introduction

Sreevatsa Natarajan

Co-Founder
Chief Executive Officer

revio therapeutics
adding life to medicines

Scientist-entrepreneur with more than ~25 years of global R&D and business experience in the life sciences industry.

Holds dual Masters' Degrees in Chemistry & Pharmacokinetics from Birla Institute of Technology & Sciences, Pilani and Medical College of Virginia, VA, USA.

Contributed to 15 NDAs, >25 INDs, countless pre-INDs, 505(b)(2) / Hybrids & ANDAs and launched several products across various therapeutic areas such as oncology, neurology, pain, inflammation, rare diseases, infection etc.

Held leadership positions across various domains in companies such as PPD, Vertex Pharma, Glenmark Pharma, Sapien (JV with Apollo Hospitals), Rhizen and Dr Reddy's - Aurigene.

About Revio Therapeutics

Adding life to medicines

revio tx

What we do

AI-enabled new product development engine – focused on 505(b)(2) / Hybrid products

Why

Existing medicines often sub-optimal – residual unmet need

Untapped opportunities for improvement & repositioning into new indications

How

AI enables creative & efficient new product ideation, analyses & development planning

Deep product expertise spanning decades, product archetypes & therapeutic areas

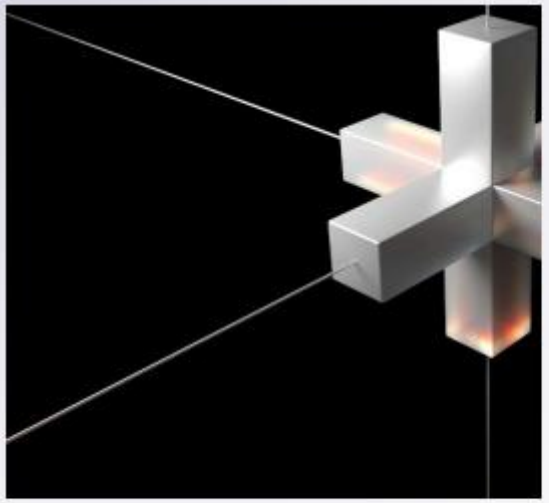
Accomplishments

Proprietary AI Engine (*re*think Tx™) & pipeline built

Partnerships being forged

GLIORA – opportunity validated by *re*think Tx™

*re*think Tx™ able to match tech platforms to optimal product ideas



Why Glioma

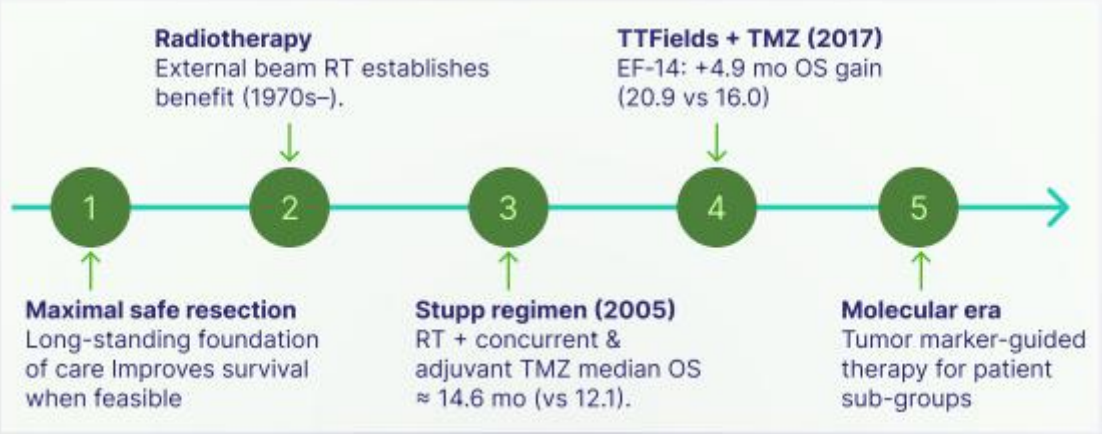
High-Grade Glioma (HGG) & Glioblastoma (GBM) — Global Burden, Care Evolution & Unmet Need

Annual Incidence

HGG (incl. GBM): ≈ 0.20M / year
GBM alone: ≈ 0.16–0.18M / year

Prevalence

HGG (incl. GBM): ≈ 0.33–0.39M people
GBM alone: ≈ 0.23–0.27M people



There are substantive number of patients for whom the outcomes have not improved dramatically.TMZ remains the benchmark for SoC treatment & outcomes for most patients

Setting	Typical median OS	Unmet need
Newly diagnosed GBM (maximal resection + RT + TMZ)	Newly diagnosed GBM (maximal resection + RT + TMZ)	Most relapse within 1–2 years Long-term survival remains low (<15%)
Recurrent GBM after TMZ	TMZ not tolerable Best OS ~8.6–9.1 mo with lomustine± bevacizumab	No established OS-prolonging SoC treatment TMZ rechallenge limited due to limiting toxicities & poor patient performance status

TMZ - Temozolomide, RT - Radiotherapy, SoC - Standard of Care, OS - Overall Survival, TT Fields - Tumor Treating Fields

Why GLIORA

Power of local treatment that synergizes with current standard of care

Long-acting, locally delivered, intra-tumoral, thermo-responsive hydrogel containing TMZ + OLA for patients with resectable high-grade gliomas

Long-Acting Treatment

12 wks - to address the lack of treatment during the post-surgical window (4-6 wks) and as an adjunct to RT (6wks)

Thermo-Responsive Hydrogel

Easy-to-prep/handle liquid at room temp; gellifies at physiological temp

Gel releases drug at a steady rate for the duration of 12 weeks and stays in place

Locally-Delivered, Intra-Tumoral

Into the tumor void space

Locally high concentrations; limited systemic spill-over

Containing TMZ + OLA

TMZ already approved for Glioma Tx; early TMZ Tx via GLIORA during post-surgery window will improve outcomes

OLA synergy with TMZ & RT in GBM already tested; systemic toxicity limits utility of the combination – local application via GLIORA better

OLA - Olaparib

Why Nanoform

Enabling technology that perfectly fits the requirements for GLIORA

Technology Aspects Required

- **Reproducibly & efficiently generate nano-sized particles of Onco APIs via a validated GMP process**
- **Strong IP cover on the process & nano-sized API – CESS® process differentiated from other nano-sizing approaches**
- **Non-infringement of any limiting IP on the chosen APIs**
- **Experience in developing high-drug load, long-acting formulations with robust IP cover**
- **GBM disease area experience**

nanoform
small is powerful®

Nanoform technology checks all these boxes

GLIORA success requires development of a product with high-drug loading, exquisite particle size control & constant release of both drugs for the entire duration of the treatment

Revio-Nanoform Partnership

- Synergistic Capabilities
- Proven product development experience
- Complementary roles on the program
- Co-development partnership

API - Active Pharmaceutical Ingredient, GMP - Good Manufacturing Practice, IP - Intellectual Property, CESS - Controlled Expansion of Super-critical Solutions

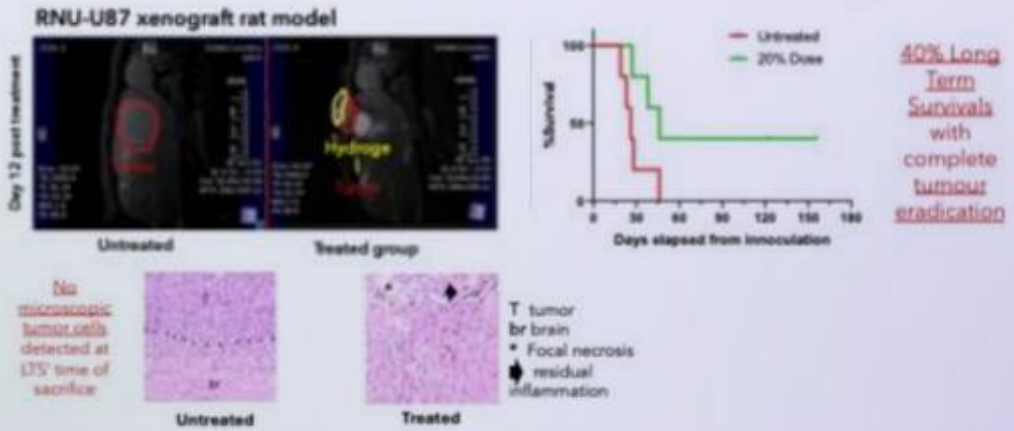
Promising Data

GLIORA: Progress So Far & Next Steps

Product concept crystallized; Clear FTO; IP filing underway

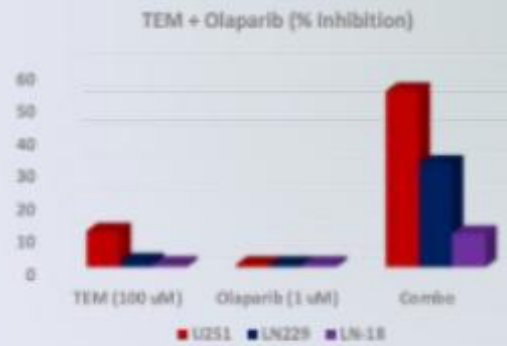
Strong product IP moat that is imbued with Nanoform platform technology IP

Covers other indications (prostate ca, sarcoma) where such a product may be relevant



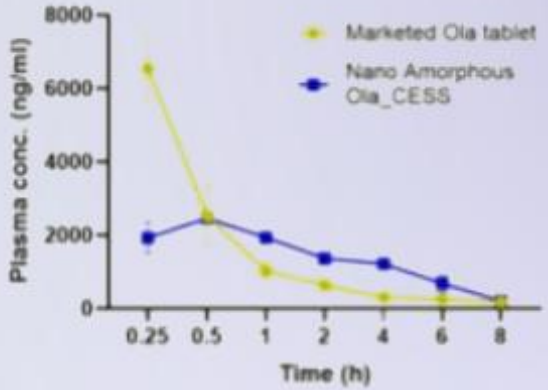
Hydrogel concept formulation (with a different API) proven by Nanoform

Demonstrated efficacy in xenograft model



PoC on synergy between TMZ & OLA established

Substantive potentiation of TMZ activity



API nanosizing & release-tuning demonstrated & PK established

Crystalline polymer embedded nano-OLA shows gradual release - Preferred

May potentially also enable a ER oral OLA program (once-a-day)

TPP validated with KOLs

Development plan detailed

Regulatory strategy formulated

Product design-space clear & being finalized

Partner CROs for efficacy studies in place

FTO - Freedom to Operate, KOL - Key Opinion Leader, PoC - Proof of Concept, PK - Pharmacokinetics, ER - Extended Release

Why GLIORA will succeed

GLIORA is a highly de-risked program with several success factors in place and a high IP & capability moat against competition

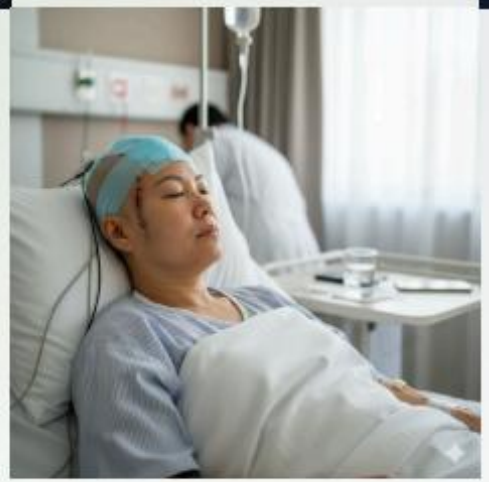
Both drugs already proven & synergistic in Glioma

Our data validates this synergy

Nanoform has successfully developed similar product prototypes earlier

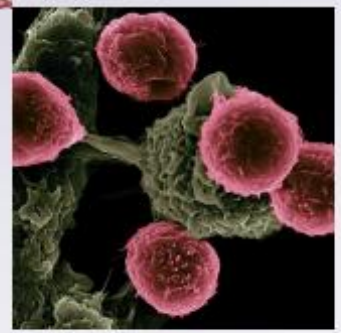
Favorable competitive landscape

Clear unmet need; KOL validation in place



Robust IP moat – technology, product concept etc

Orphan designations and exclusivities eligible



Path Ahead & Next Steps

De-risked development plan in place

Through 2026

Product prototype and animal studies

Regulatory filings (to initiate clinical trials)

Commercial partner, additional investors signed up

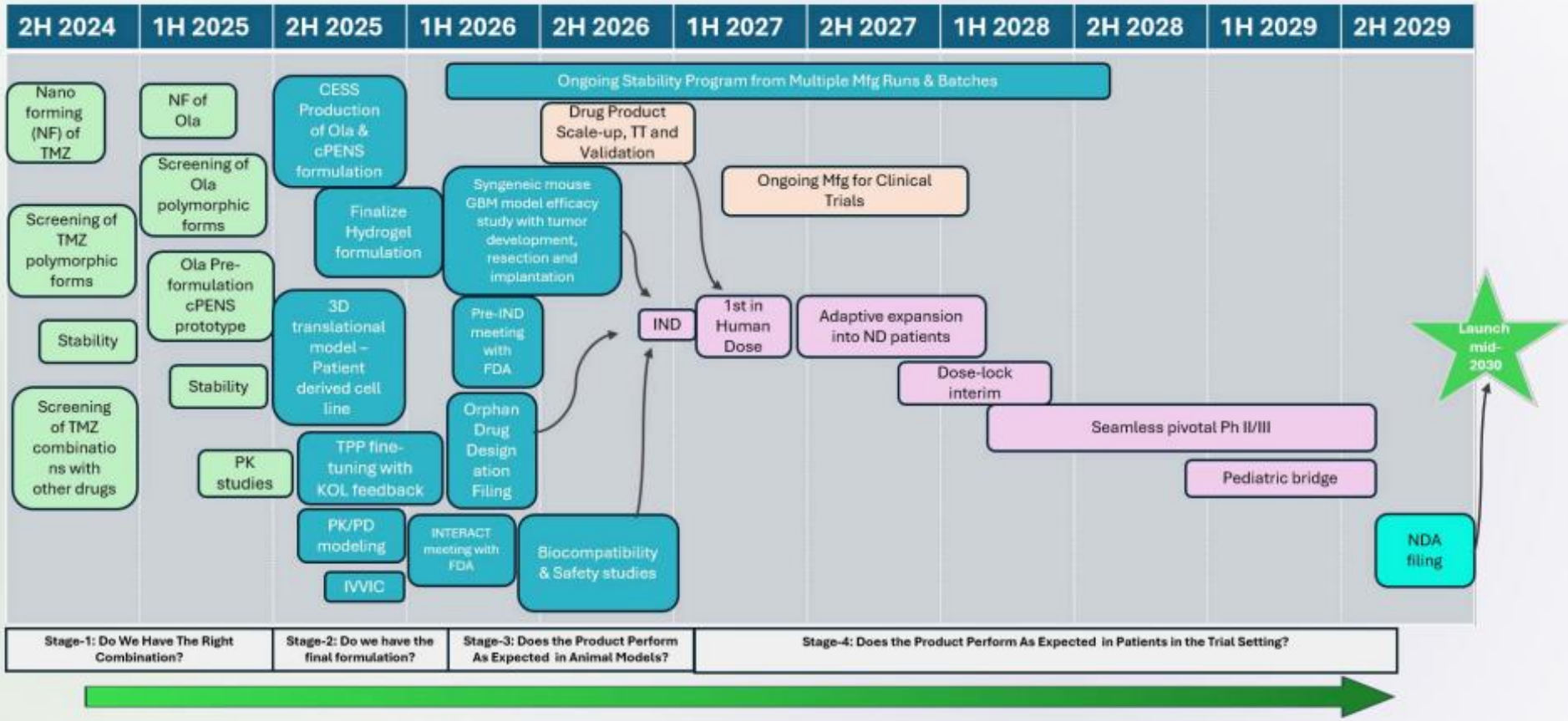
Through 2027-29

GMP manufacturing & Clinical Trials

Through 2029-30

Product filing

Approvals & launch



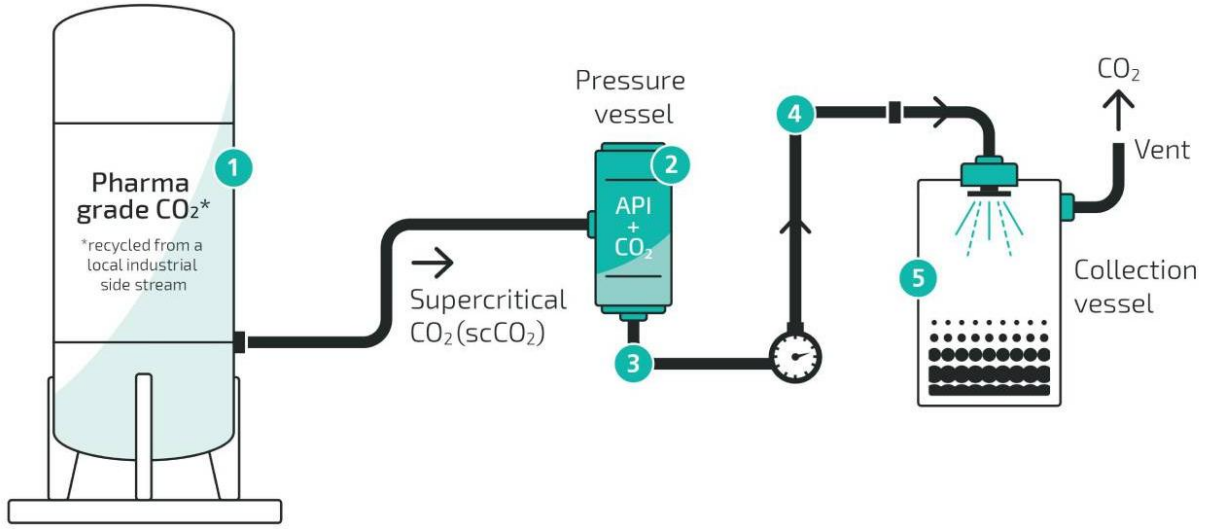
Ari Kauppinen, Sr Scientist
Tuomas Malve, Sr Engineer
Petteri Helander, Sr Scientist

Nanoform's CESS® rocket science

CESS® process throughput – Success recipe

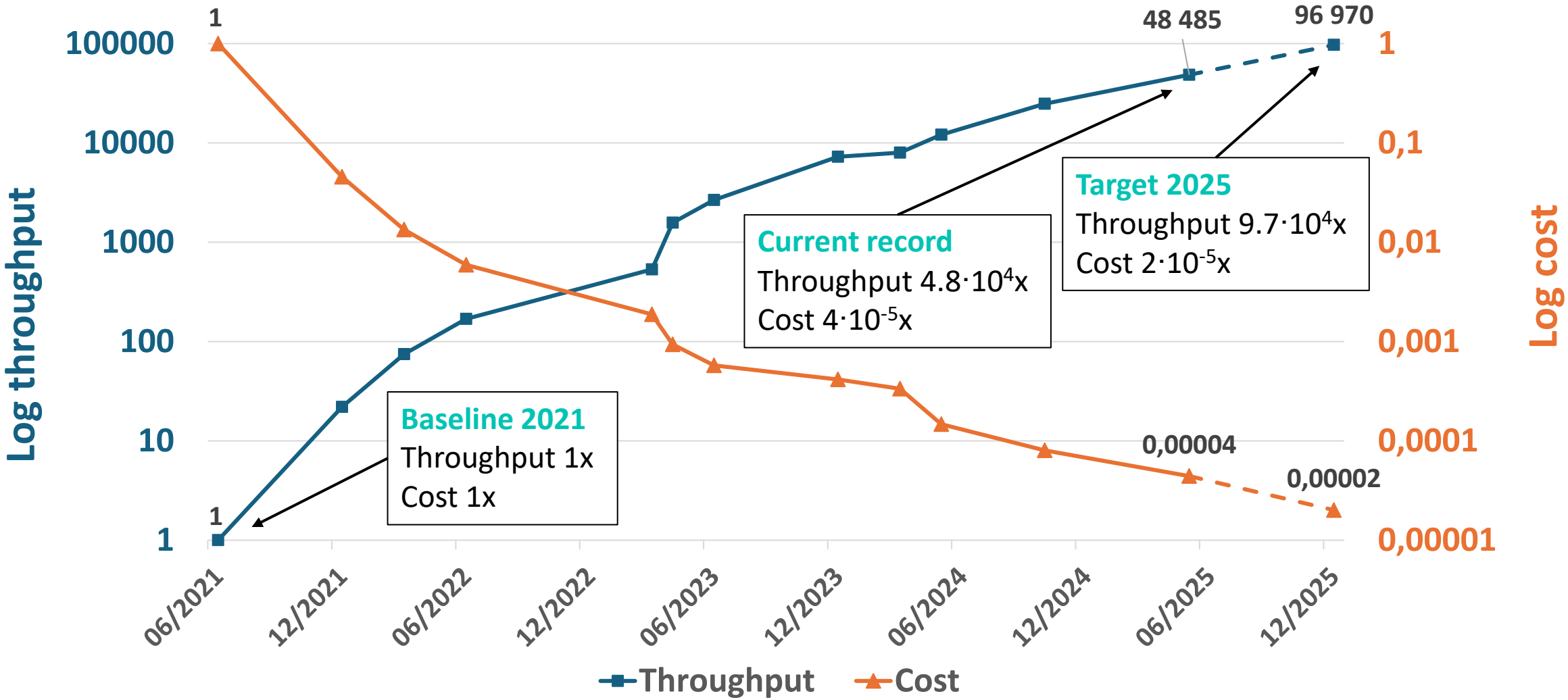
$$\text{API throughput } (kg/h) = y \cdot f_{CO_2} \cdot S \cdot E$$

- y: API solubility in CO_2
- f_{CO_2}: CO_2 flowrate
- S: API saturation
- E: Collection efficiency



Factor	Main contributor	Range
y	API nature, p, T_s	0.01 – 20 g/kg
f_{CO_2}	Pump capacity	6 – 300 kg/h
S	Vessel residence time, dissolution aids	50 – 100 %
E	Collector performance (CO_2 flow and T_n)	50 – 98 %

2021 ⇨ 2025 Demonstrators – Throughput & cost evolution

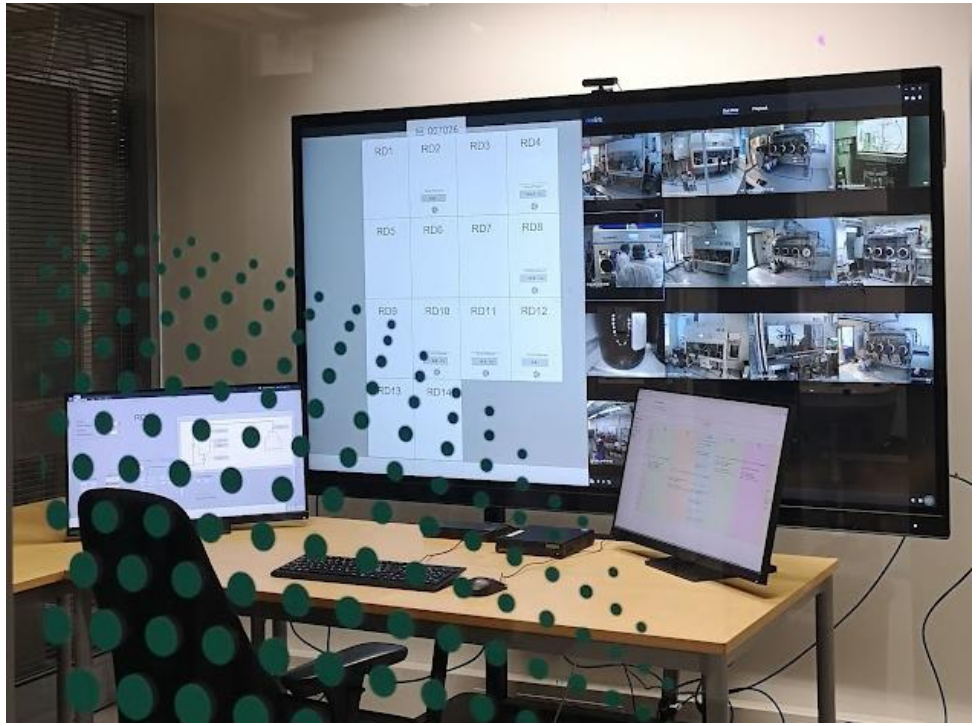


R&D Fleet Control Hardware Standardization

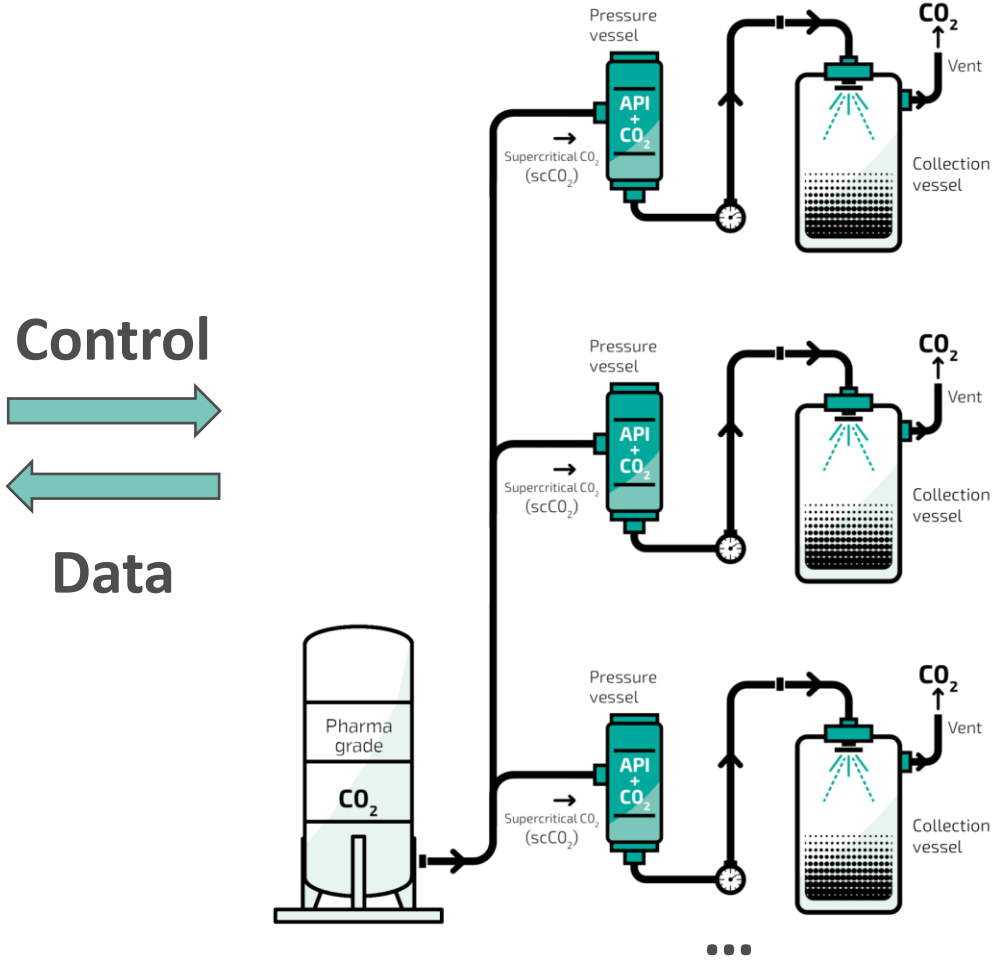
- All R&D lines upgraded to a common hardware platform
- Based on modern IEC 61499 standard enabling industry 4.0
- Faster development cycles
  - Critical for meeting scale-up timelines

Control Room Brings Efficiency

Control Room



R&D Fleet



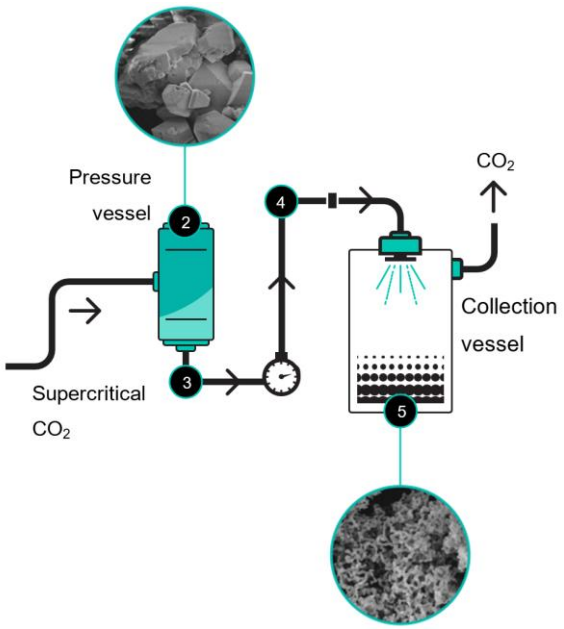
Streamlined Data Flow

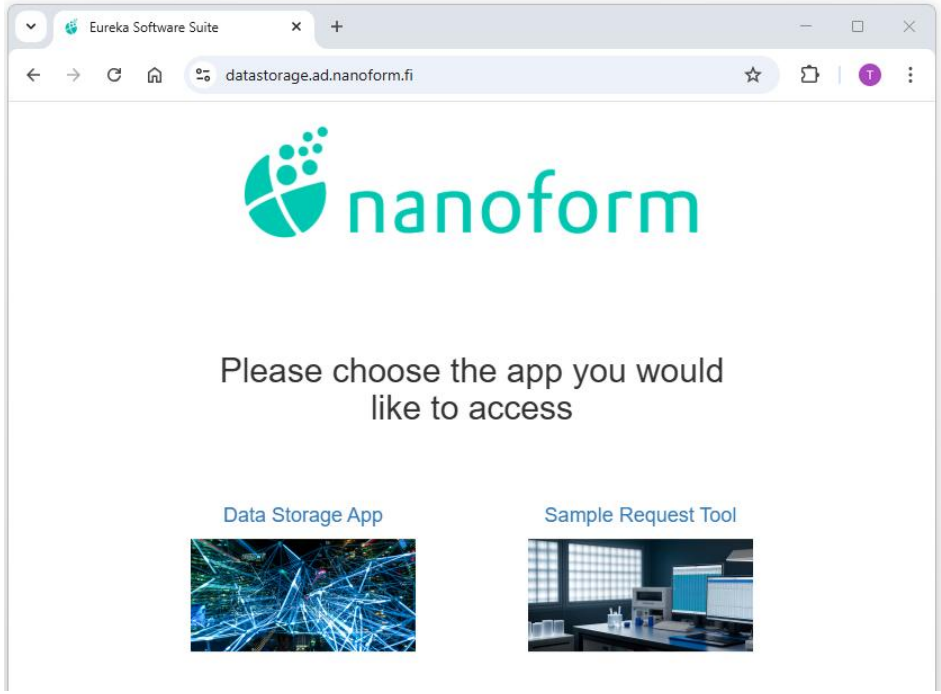
Process

Control System

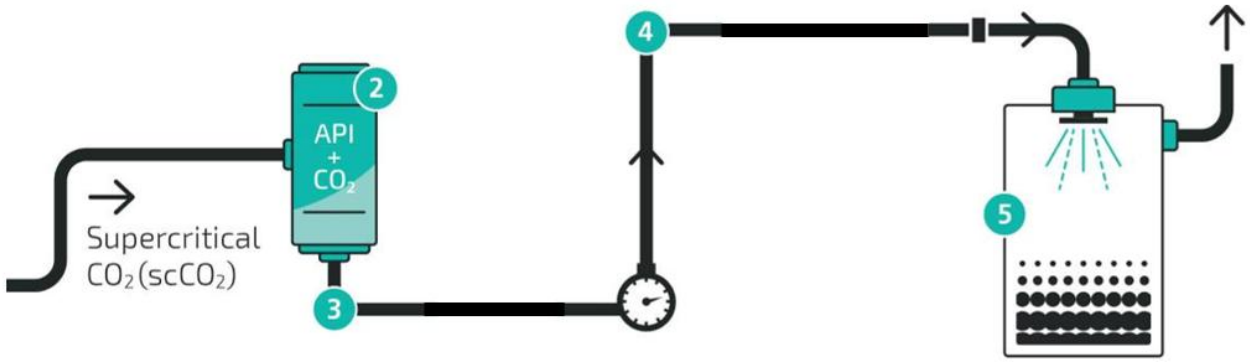
Data Historian

Data Analysis and Reporting Tools





Science of Particle Formation in CESS®



Dissolution → **Nanoforming** → **Collection**

1000 bar — **1 bar**

Solution

$$\Delta H^* = -R\left(\frac{\partial \ln(x_{sat})}{\partial T^{-1}}\right)_P$$

$$\ln x_{sat} = A + \frac{B}{T} + C\rho.$$

$$\langle \Theta \rangle = \dot{m} c_{sat}\left(1 + \frac{\rho_{API} r_0}{b m_{API,0}}\dot{m}\right)^{-1}$$

Suspension

$$\frac{\partial c}{\partial t} = D\nabla^2 c. \qquad J \propto \exp\left(-\frac{\Delta G^*}{kT}\right)$$

$$\frac{\pi}{6} d_q^3 \approx \chi_q \frac{kT\rho_{CO_2}}{\mu_{CO_2}\rho_{API}} c_0 t,$$

$$\frac{dn_i}{dt} = \underbrace{\sum_{j=1}^{i/2} \beta_{j,i-j}\, n_j n_{(i-j)}}_{\text{collisions}} - \sum_j \beta_{i,j} n_i n_j + \underbrace{\sum_{j>i} \Gamma_{j\to i,(j-i)}}_{\text{br}}$$

Solid mixture

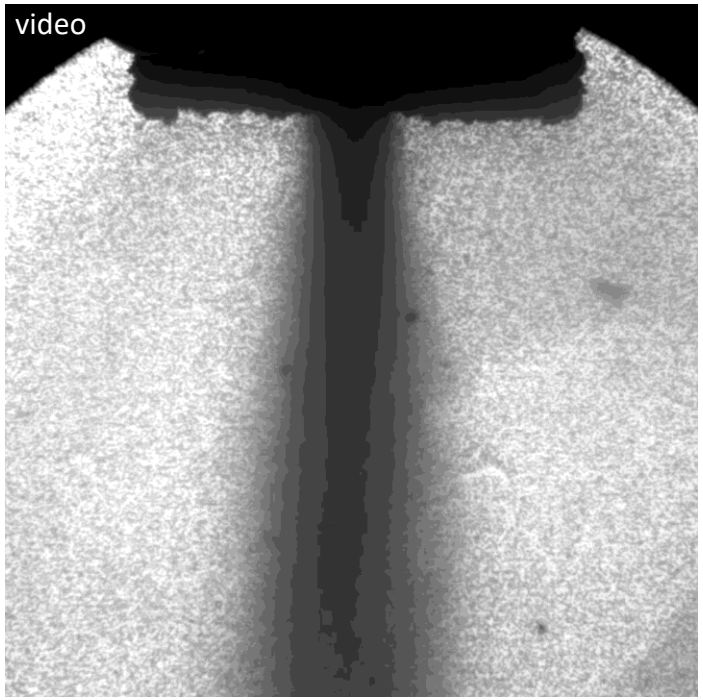
$$\Delta G^* = \frac{4\pi}{3}\gamma\, r_{crit}^2 = \frac{16\pi\gamma^3}{3\Delta G_v^2}.$$

$$T_{g,\,mix} = \frac{w_1 T_{g1} + k w_2 T_{g2}}{w_1 + k w_2},$$

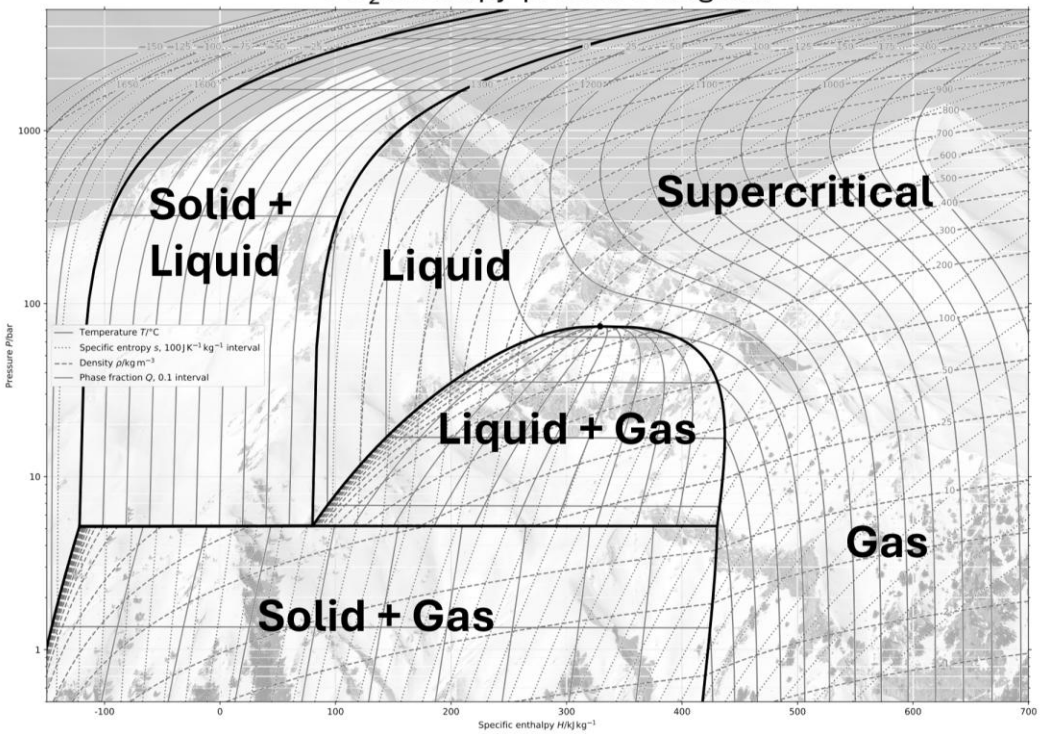
$$\lambda \approx \left(C D_s \frac{\delta\Omega\gamma}{kT} t + \lambda_0^4\right)^{\frac{1}{4}},$$

Controlling supercritical-CO_2 and API

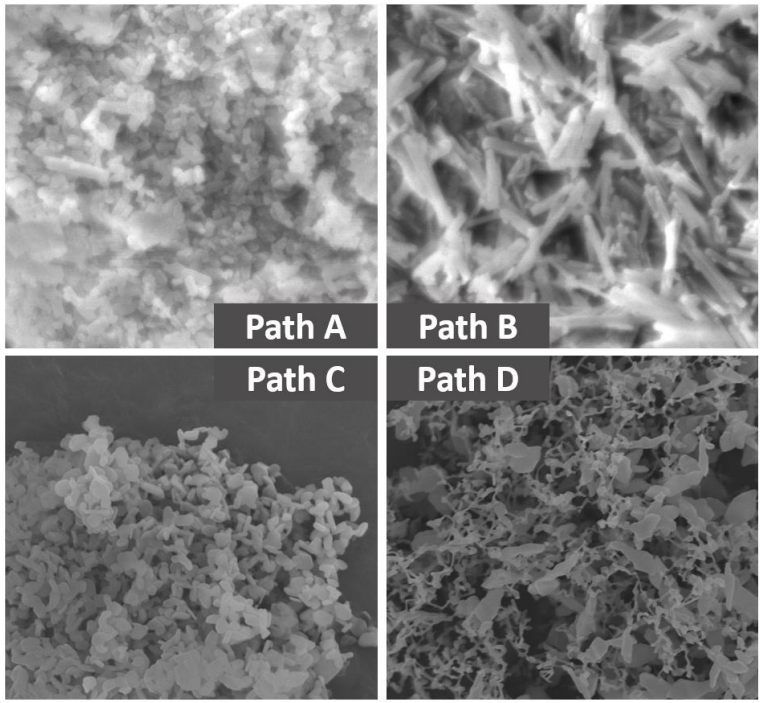
CO_2 jet



CO_2 enthalpy-pressure diagram



Particle Engineering



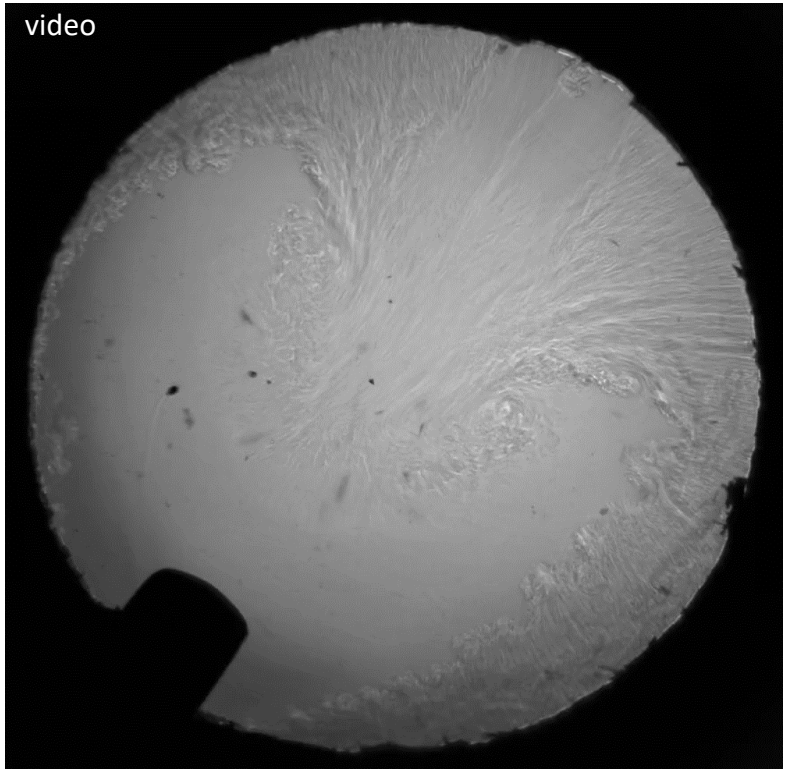
- Thermodynamic path sets CO2 and API behavior

Seeing CESS®

- In standard CESS-lines nanoforming is indirectly measured.
- Here we show a rare look into API+scCO_2 nanosuspension

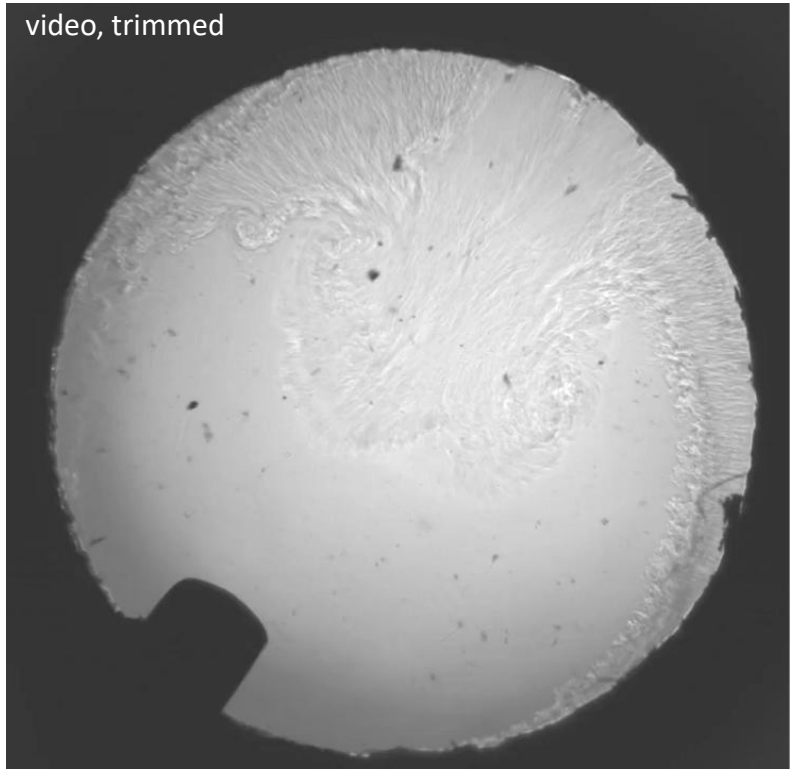
1) Thermodynamic path A

→ **Large crystals**

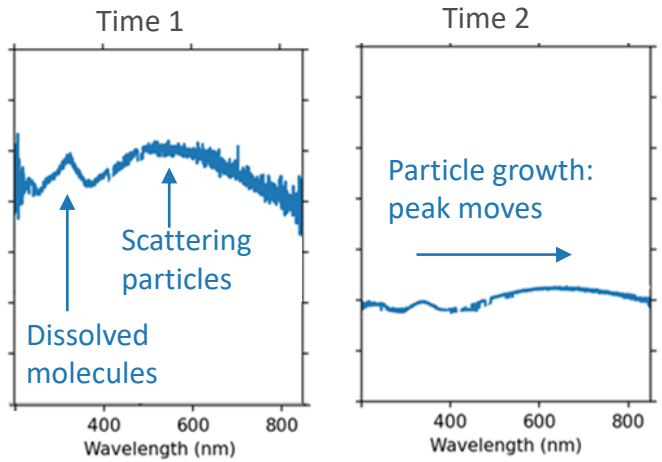


2) Thermodynamic path B

→ **Nanoparticles in CO_2**



UV-vis absorbance spectrum



Peter Hänninen

Chief Development Officer

A large biologics market is forming in subcutaneous delivery of monoclonal antibodies

Future of Biologics Delivery & Formulation

Subcutaneous delivery will become the **dominant standard** (>50%) for new and marketed biologics.

Suspension formulations enable **high drug concentrations → lower injection volumes**, making them a **preferred choice**.

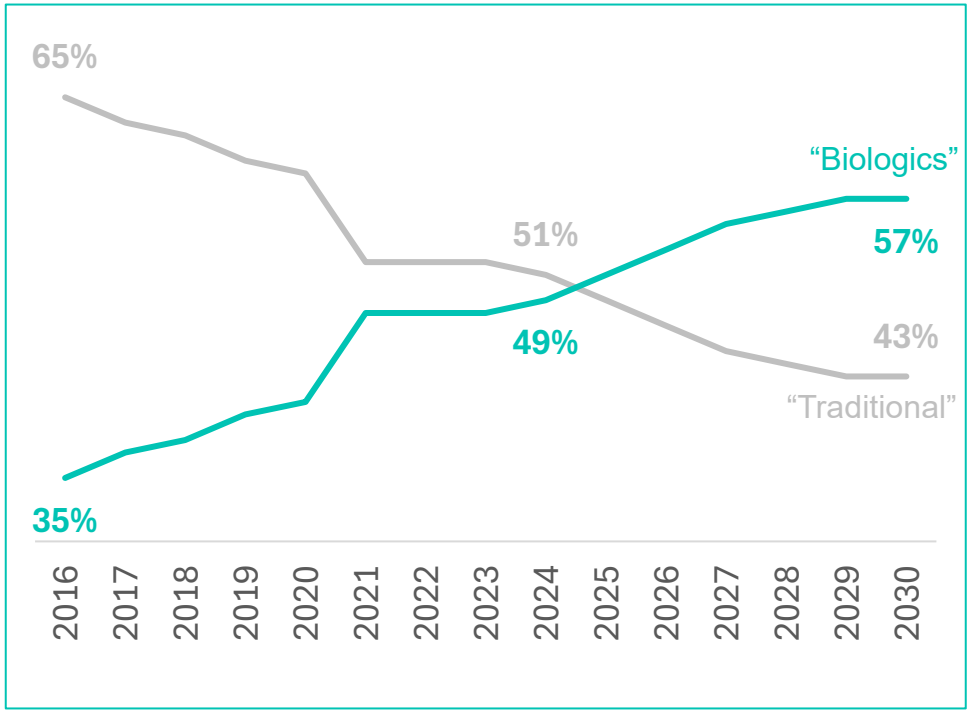
Particle properties are critical for suspension performance → Nanoform's technology can become the **"technology of choice".**

Biologics (and more specifically antibodies and GLP-1s) will dominate future value creation for the industry

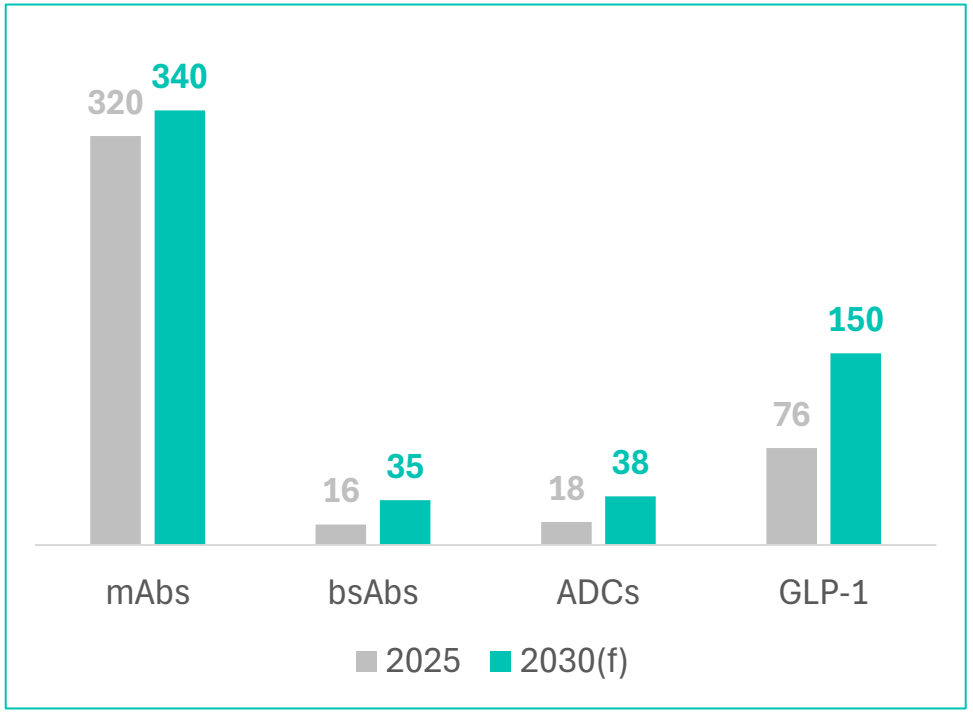
By 2030 biologics will represent 57% of industry sales and two thirds of the Top100 sellers

Antibodies and GLP-1s are the primary future revenue pools and market growth drivers for the pharmaceutical industry

Share of total market value



Sales, Bn USD



[1]Evaluate Pharma World Preview 2025. [2]Analyst consensus. [3] mAbs = monoclonal antibodies, bsAbs = bispecific antibodies, ADCs = antibody/drug conjugates

Fundamentals of the IV-to-SC Switch

Faster to Inject

Tecentriq Hyqreza
~7 min vs 30–60 minutes

Opdivo Qvantig
3–5 minute injection vs 30 minutes

Improved Safety and Tolerabiity

IRR[1]s vs IV

Darzalex Faspro ↓~3x

Rybrevant SC ↓~5x

+

Patient & Physician Preference

85% of patients prefer SC

60% of neurologists prefer SC

System Savings

RWE[2] examples:
Nurse time $179 (IV) to $59 (SC)
Infusion bed overhead from $910 to $101 per patient

→

Market Growth

Ocrevus Zunovo
expanding into practices with limited IV capacity (site-of-care flexibility)

Share Growth

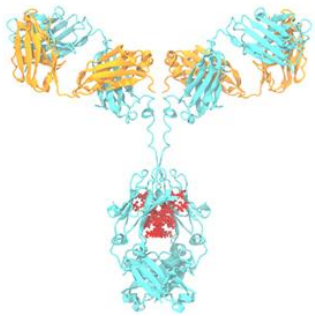
DARZALEX Faspro ~96% US conversion
Keytruda SC forecast ~40% IV-to-SC conversion in 18–24 months

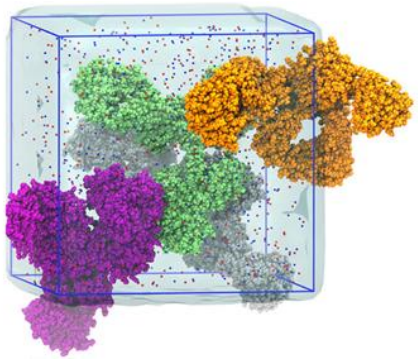
Huge potential for branded IV franchises across oncology, immunology, neurology, and metabolic disease to be partially or predominantly shifted to high-dose SC

[1]Injection-related reactions. [2]Real World Evidence

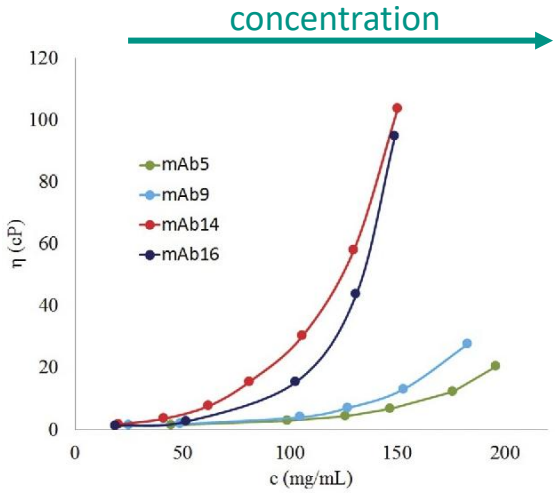
Innovative Approaches to Address the High-Dose Challenge

- About 140 biologics are currently on the market. [1]
- No marketed products contain more than 200 mg/ml protein concentration, and typically closer to 100 mg/ml, due to **increasing viscosity** that renders a product non-injectable and the **risk of protein aggregation** causing immune response and reduced overall efficacy. [2-6]





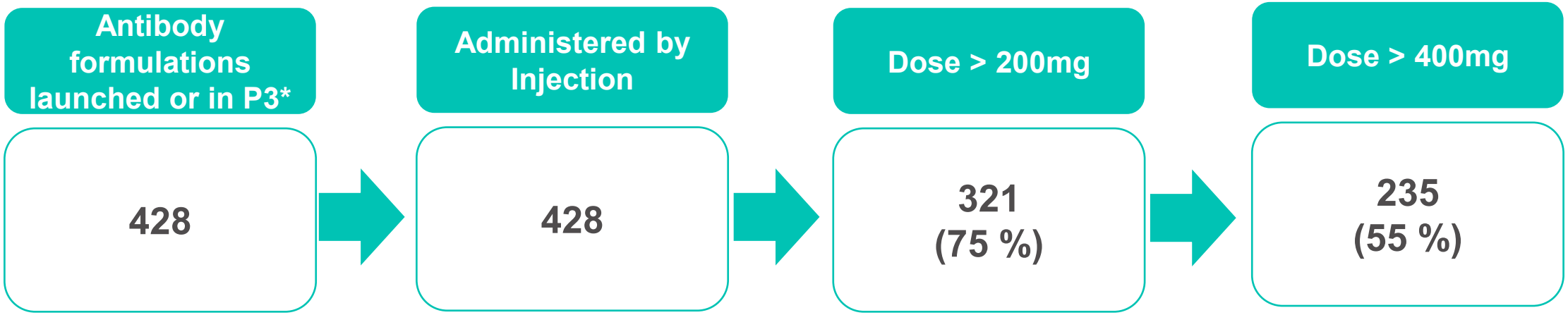
High conc



Innovative approaches required to allow the SC delivery of high dose biologics

[1] Ghosh et al, ***MAbs***, 2023, DOI: 10.1080/19420862.2023.2205540
[2] Zarzar et al, ***MAbs***, 2023, DOI: 10.1080/19420862.2023.2211185
[3] Prass et al, ***J Chem Inf Model***, 2023, DOI: 10.1021/acs.jcim.3c00947
[4] Schmitt et al, ***MAbs***, 2023, DOI: 10.1080/19420862.2023.2169440
[5] Kollar et al, ***Drug Disc Today Technol***, 2020, DOI: 10.1016/j.ddtec.2020.08.005
[6] Tomar et al, ***Mabs***, 2017, DOI: 10.1080/19420862.2017.1285479

All antibody formulations are injected, and their high dose is a challenge for SC delivery



55 - 75% of antibody formulations likely require enabling technologies to be administered subcutaneously

*Where data on dosing is publicly available

Technology Landscape – As Seen by the Head, Pharmaceutical Development, Biologics, Merck

Looking to the Future...

ENHANZE

Trusted Technology

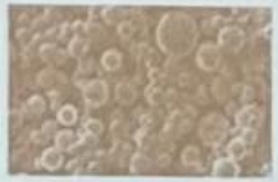
Products using our rHuPH20 technology are approved and sold in over 100 countries

DARZALEX®	HERCEPTIN® SC	RITUXAN HYCELA®
DARZALEX FASPRO®	HERCEPTIN® HYLECTA™	MABTHERA® SC
PHESGO™	HYQVIA®	RITUXAN® SC

Halozyme website

elektrofi

nanoform
small is powerful®



nanoform

Lindy Biosciences

MEDIA RELEASE

LINDY BIOSCIENCES ENTERS LICENSING AND COLLABORATION AGREEMENT WITH NOVARTIS FOR MULTI-TARGET DRUG DELIVERY INNOVATION

xeris BIOPHARMA

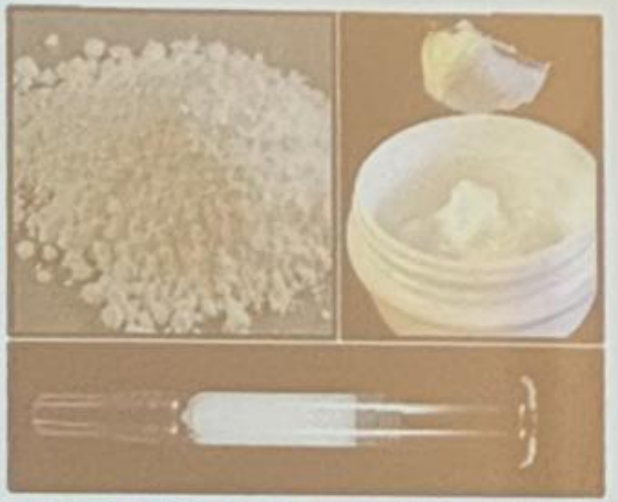


Figure 3: Example XeriJect™ spray-dried powder, visco-elastic suspension and prefilled syringe.

Prestrelski, 2022

Limited Technology Availability is Driver for Strategic Positioning in the Market through Acquisitions and Exclusive Deals

Aug 28, 2024 6:58 AM Eastern Daylight Time

Lindy Biosciences Enters Licensing and Collaboration Agreement With Novartis for Multi-target Drug Delivery Innovation

Share

- *Novartis secures exclusive global rights across multiple biologic targets to Lindy Biosciences' microglassification technology*
- *Collaboration aims to enable high-concentration self-administered drug treatments, improving patient outcomes and compliance*
- *Lindy Biosciences to receive an upfront payment of US$20 million and eligible to recei up to US$934 million in milestone payments plus tiered royalties*

Halozyme to buy Elektrofi in up to $900 million deal to expand drug delivery lineup

Jan 10, 2024 8:00 AM Eastern Standard Time

Xeris Biopharma Enters Into an Exclusive Worldwide License Agreement for Xeriject® Formulation of Teprotumumab

Halozyme Dominated Exclusivity Matrix Makes Biologics Developers Thirsty for Alternatives

Target Receptor	Acumen	Alexion/AZ	Amgen	Argenx	BMS	Lilly	JnJ	Merck	Novartis	Regeneron	Roche	Takeda	ViiV	OTHERS
Amyloid A4 protein	Halozyme													4
C2				Halozyme										1
C5		Halozyme												10
CD20											Halozyme			8
CD38							Halozyme							12
EGFRxMET							Halozyme							7
FcRn				Halozyme& Elektrofi										6
gp120													Halozyme	1
HER2											Halozyme			3
HIV integrase													Halozyme	0
IGF-1R			Xeris											7
IgG												Halozyme		7
LAG-3					Halozyme									9
PD-1					Halozyme			Alteogen						20
PDL-1											Halozyme			13
Plasma Proteins												Elektrofi		0
Unknown		Alteogen				Elektrofi	Elektrofi	Xeris	Lindy	Xeris				n/a

[1]Source: PatSnap Synapse database accessed 12Jul25; various corporate releases

Subcutaneous delivery will become the **dominant standard** (>50%) for new and marketed biologics.

Suspension formulations enable **high drug concentrations → lower injection volumes**, making them a **preferred choice**.

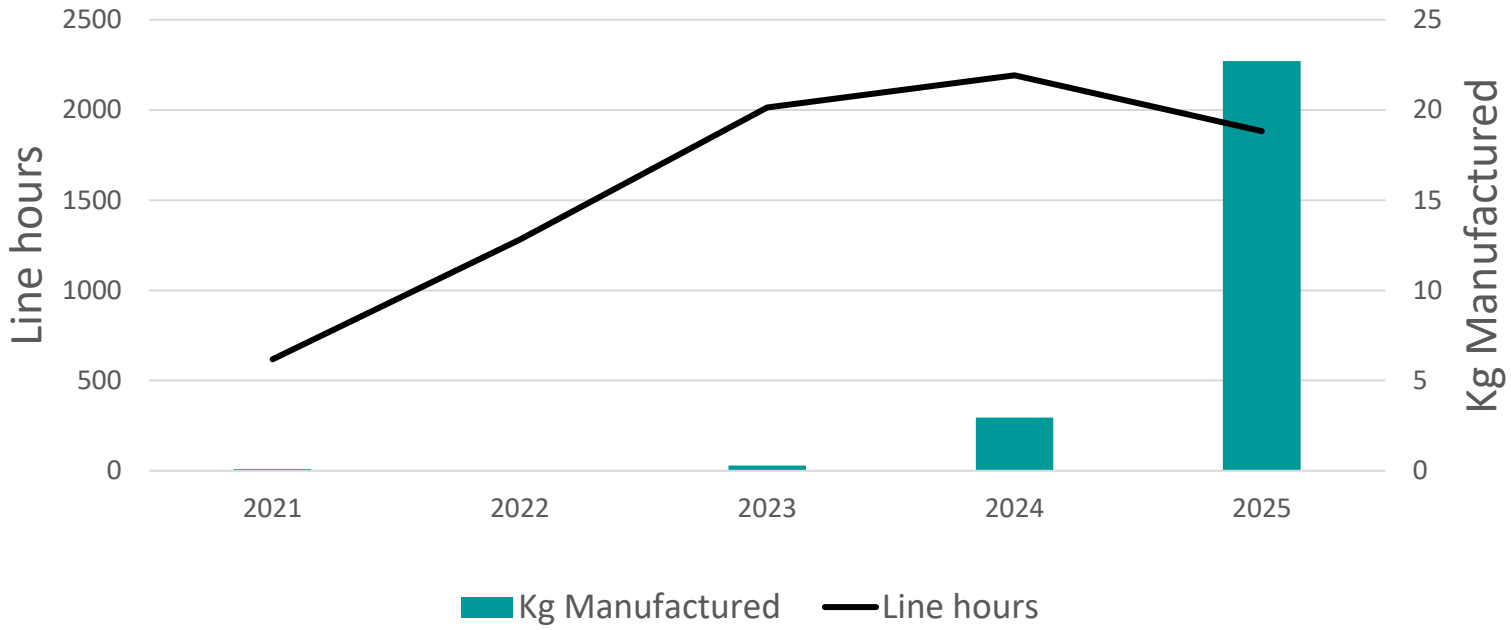
Particle properties are critical for suspension performance → Nanoform's technology can become the **"technology of choice".**

Maria Lume

Director Biologics

Working with large pharma:
What we have done and learnt

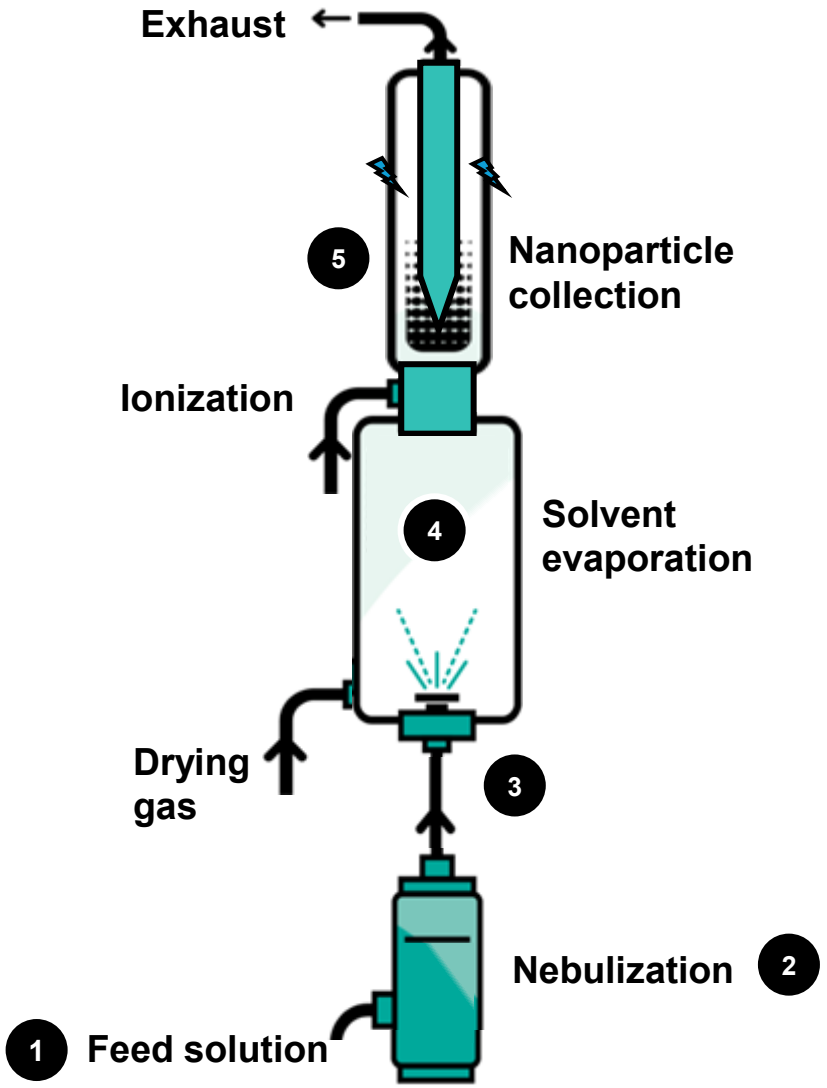
Bio process evolution 2021-2025



- Manual control of the BIO process
- First customer projects
- Setting up the quality control methods
- Process patent filed

- Automated process
- 1000x scale-up completed
- Several projects with Big Pharma
- Broad range of analytical methods in place

Nanoform's Bio Line Forms Dry Particles as Small as 50 nm

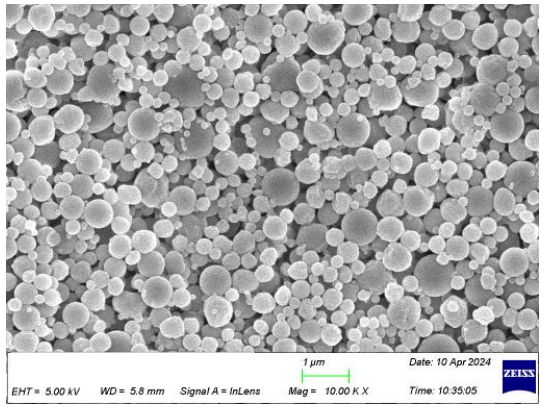


1. API containing feed solution is pumped into nebulizer
2. Feed solution is nebulized into mist droplets and mixed with the carrier gas
3. Mist is transported into the drying chamber via a connective pipe
4. Mist is dried using low-temperature drying gas
5. Particles are charged by the ionizer and collected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

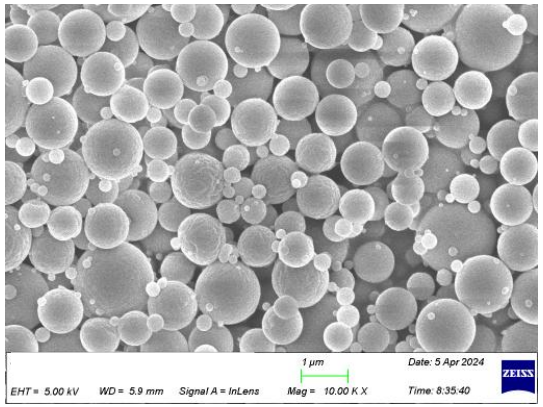
Consistent Spherical Particles, Tunable in Size, Distinct from those Produced by Conventional Techniques

Tunable particle size distribution in the Nanoform Biologics – highly spherical particles retained

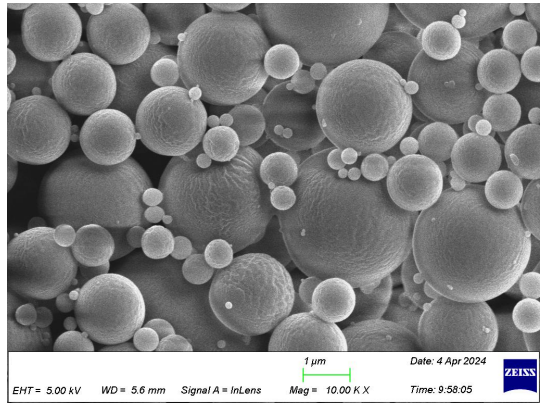
PSD (nm)	**dn50**	dv50
	250	450



PSD (nm)	**dn50**	dv50
	375	1065

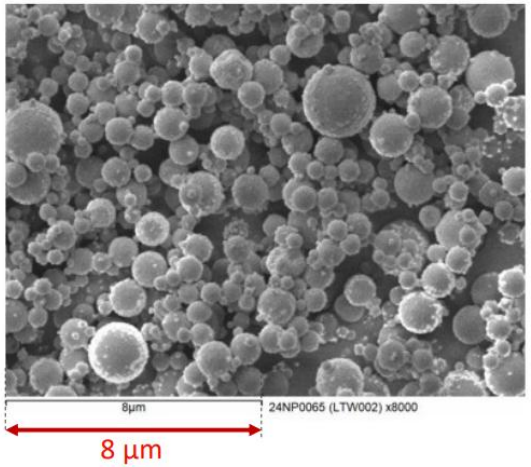


PSD (nm)	**dn50**	dv50
	425	2080

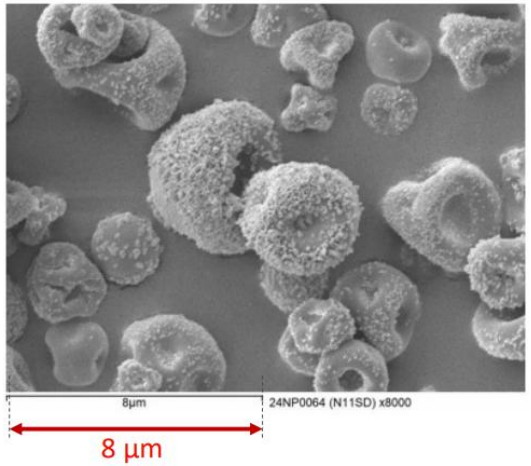


Takeda data: Nanoformed particles distinct from those produced by conventional technologies using an identical feedstock formulation

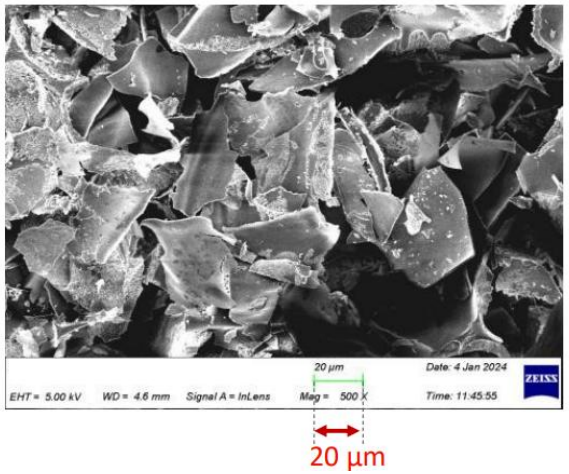
Nanoform



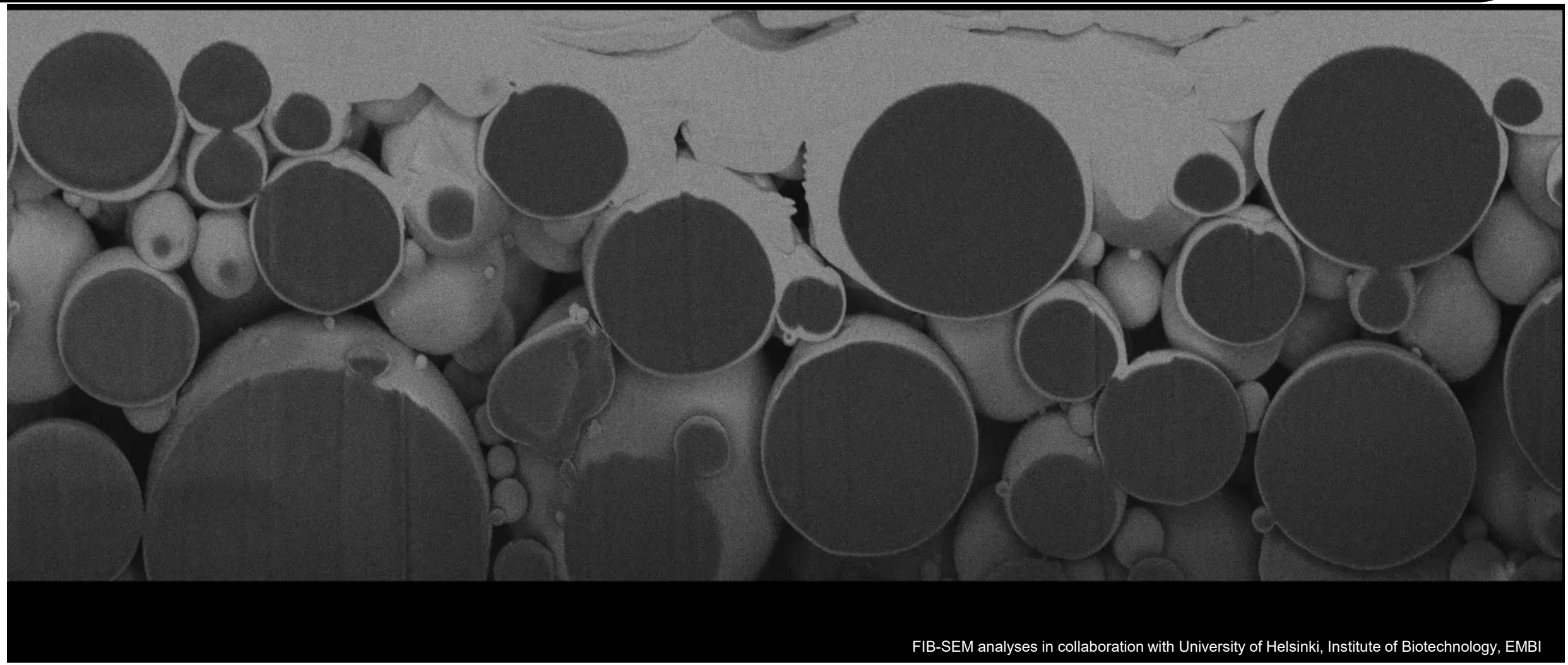
Spray dried



Lyophilized



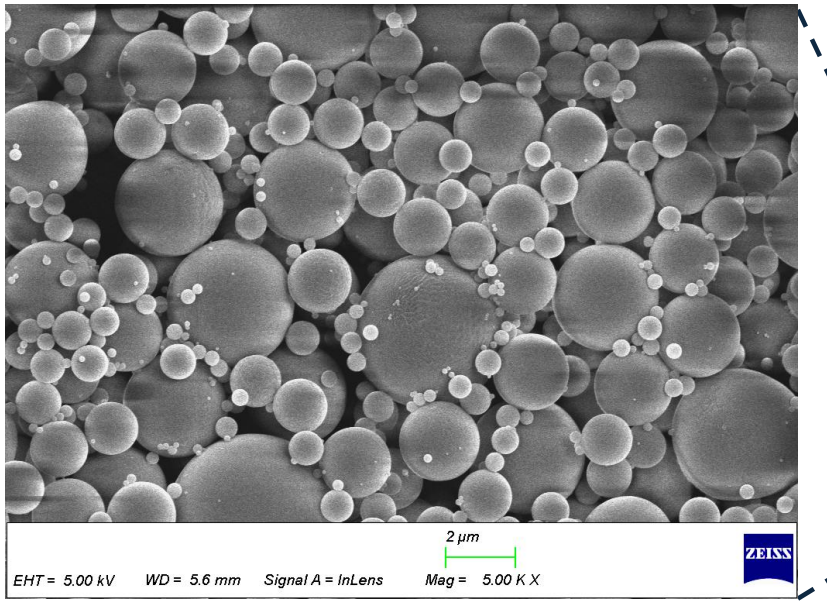
Nanoformed Particles are compact structures with high packing density.
(Method: Focused Ion Beam-Scanning Electron Microscopy (FIB-SEM)



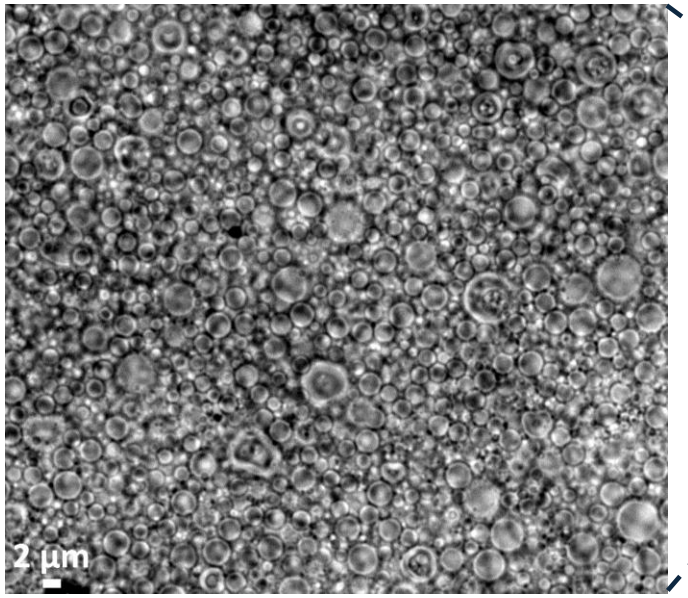
FIB-SEM analyses in collaboration with University of Helsinki, Institute of Biotechnology, EMBI

Applications of the Nanoformed Biologics

Dry Protein particles



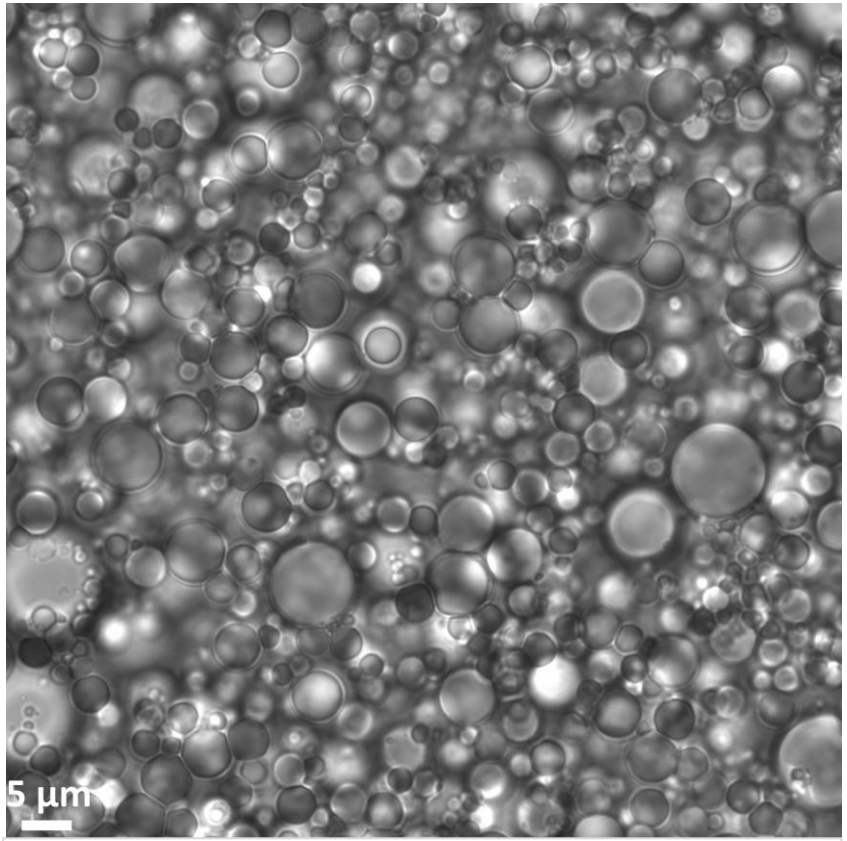
Particles in suspension
Optical microscopy (bright field mode)



Protein concentration
exceeding 400 mg/mL can be achieved

Video embedded

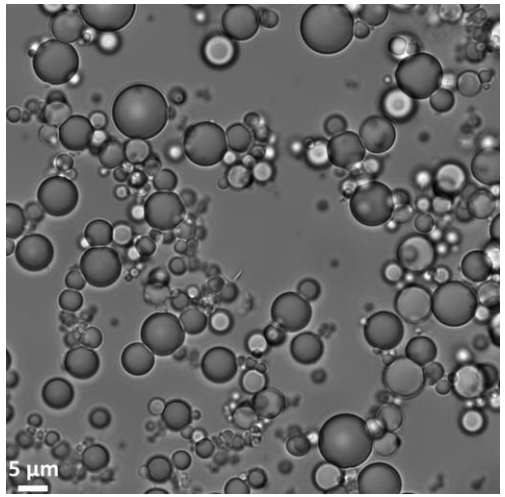
No change on particles in the suspension – after 6 months



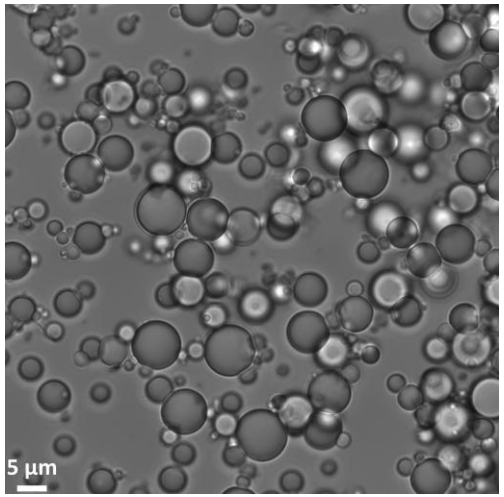
Sample stored for 6 months at +4°C and +25°C, 600 mg/mL dry mass, 300 mg/mL API.

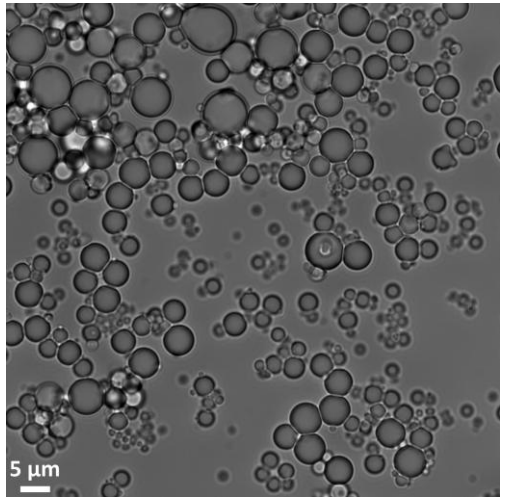
Diluted to 200 mg/mL dry mass to enable acquiring of sharp images

Time zero at +25°C

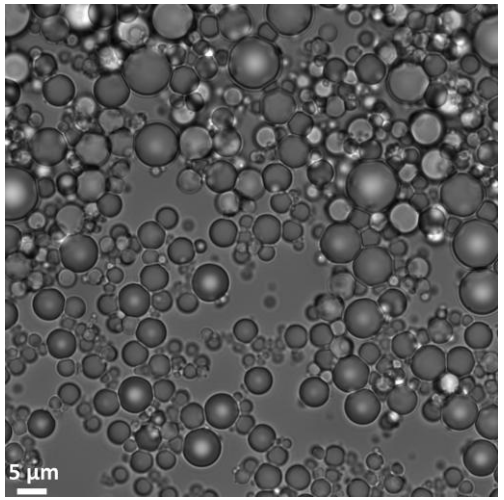


Time zero at +4°C





6 months at +25°C



6 months at +4°C

Our ability to develop very high concentrations of stable, injectable biological material has been validated by large pharma partners

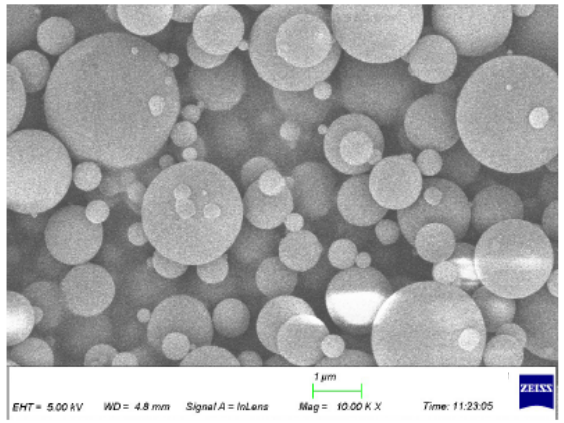
Feasibility study with nanoform

small is powerful®

Takeda

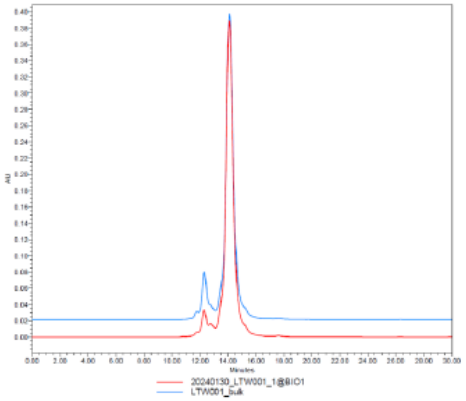
Nanoforming of IgG

IgG was successfully solidified to nanoparticles (D50: 900 nm)



Testing of drying impact

Protein was confirmed to be stable during solidification.



Batch	Aggregates %	Monomer+dimer %
Bulk (blue)	0,63	99,37
Nano (red)	0,23	99,77

40% IgG suspension

Benzyl Benzoate | MCT oil

Confirmed to be injectable

Viscosity: ~70 cp.
Injection force: 8-9N
Syringe: 25G, 1.3 ml/min

Protein concentrations >400 mg/ml

Takeda Pharmaceutical Company Limited

Applications of the Nanoformed Biologics – pulmonary delivery

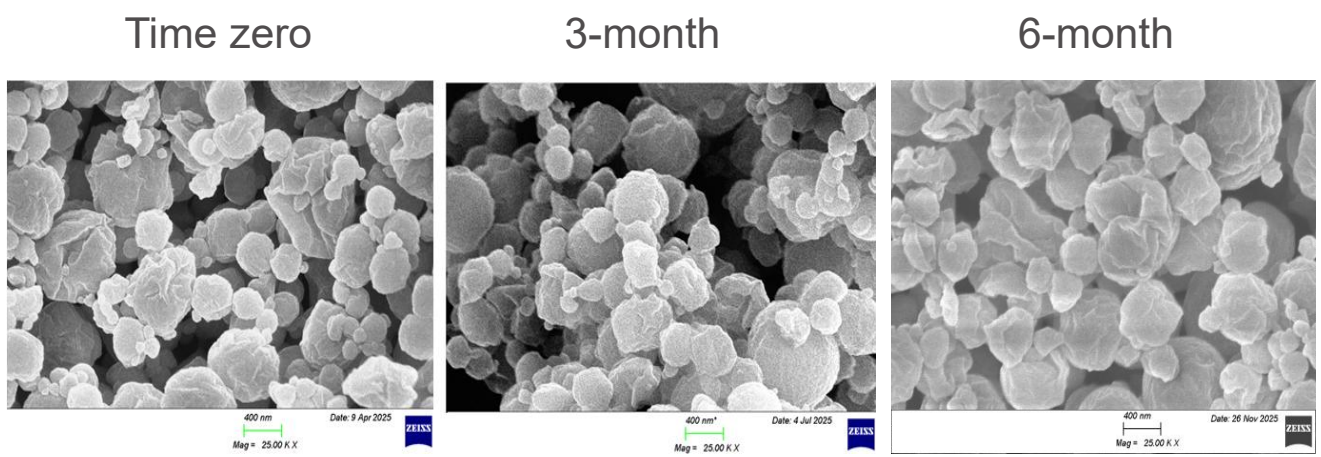


Fig. 1 Formulated semaglutide powder by SEM at 25K magnification

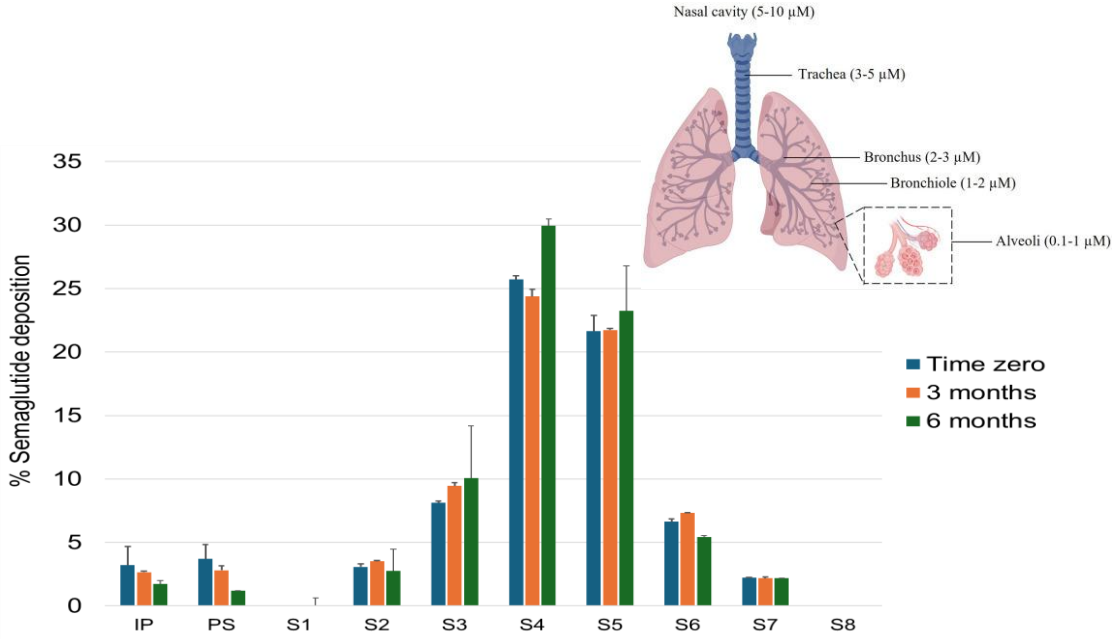


Fig. 2 Semaglutide deep lung deposition profiles measured using Next Generation Impactor (NGI)

Analytical Methods for Stability trial at 25 °C:

- RP-HPLC: No change in related impurities from manufacture
- SEC-HPLC: No change in aggregation state from manufacture

Particle Size:

- SEM: Size, shape and morphology – no change

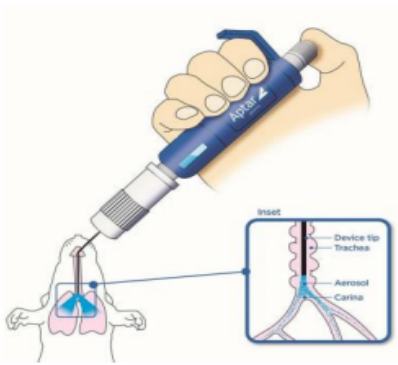
Nanoformed Semaglutide is stable for at least 6 months

Consistent particle size enables deep alveolar deposition, enhancing systemic uptake

Takeda in-vivo data confirm promising in-vitro data

PK Profile of Nanoformed AAT in a Murine Model

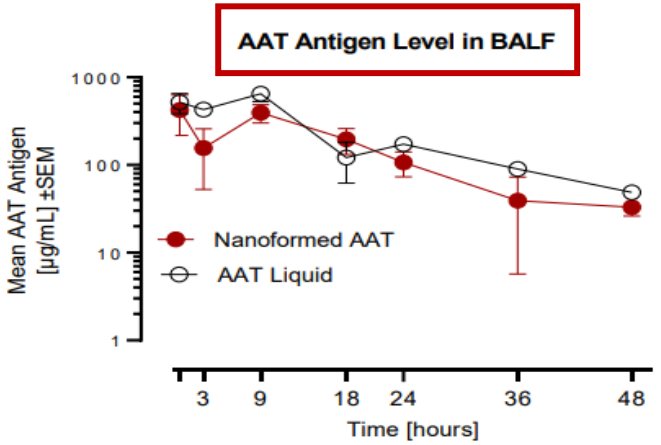
- Mice received 500 µg AAT intratracheally, either as nanoformed particles via PADA device* or as a reconstituted formulation (AAT Liquid).
- Terminal lung lavage and serum collection were performed at seven time points, with clinical signs monitored throughout the 48-hour observation period.

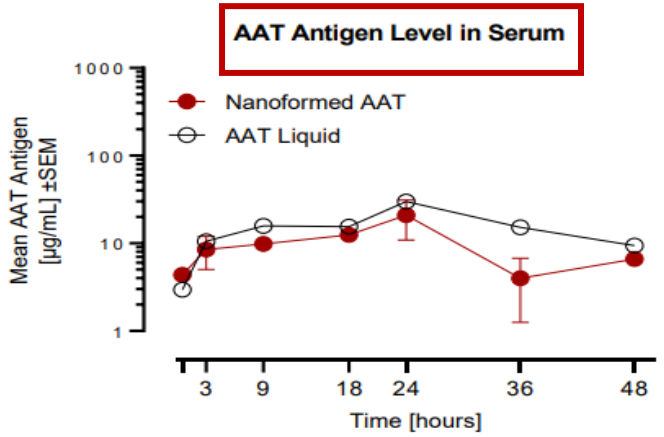


Aptar pharma

*courtesy of Aptar Pharma

Preliminary pharmacokinetic profile of intratracheally administered Nanoformed AAT powder in murine lung tissue.





Preliminary PK Parameters

	Nanoformed AAT	AAT Liquid
Lung		
Half-life [h]	13.1	13.5
$AUC_{0\text{-}48h}$ [h*µg/mL]	9600	10,700
C_{max} [µg/mL]	550	650
Serum		
Half-life [h]	~14.5	~17.2
$AUC_{0\text{-}48h}$ [h*µg/mL]	460	780
C_{max} [µg/mL]	21.0	29.9
T_{max} [h]	24	24

- Intratracheal (IT) administration of Nanoformed AAT particles or AAT liquid was well tolerated in mice.
- Lung exposure to AAT was achieved in all animals, resulting in comparable pharmacokinetic (PK) parameters between the two formulations.
- Systemic exposure following IT administration of both nanoformed and liquid AAT was approximately 5% of the lung exposure.

Pulmonary delivery of Nanoformed AAT constitutes a promising targeted therapeutic approach.

Markus Weiller, Director PDT Translational Science

AAT: human Alpha-1 Antitrypsin; BALF: Bronchoalveolar Lavage Fluid


Q&A


CLOSING
REMARKS

nanoform
small is powerful

CEO Edward Hæggström
edward.haeggstrom@nanoform.com
+358 50 317 54 93

CFO Albert Hæggström
albert.haeggstrom@nanoform.com
+358 40 161 4191

DIR Henri von Haartman
hvh@nanoform.com
+46 76866 50 11