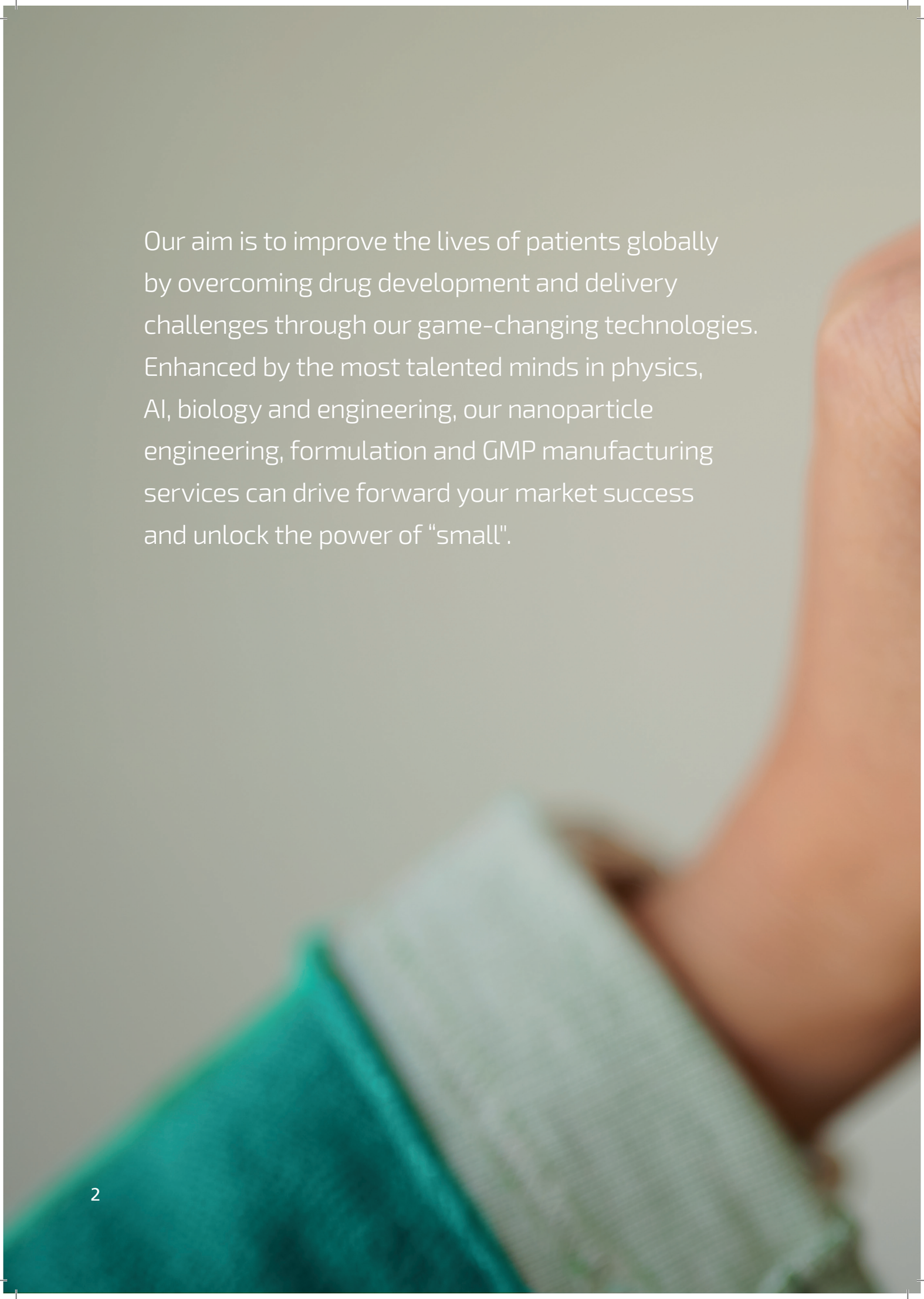
small is powerful®

nanoform

small is powerful®

Global experts in
nanotechnology and drug
particle engineering



Our aim is to improve the lives of patients globally by overcoming drug development and delivery challenges through our game-changing technologies. Enhanced by the most talented minds in physics, AI, biology and engineering, our nanoparticle engineering, formulation and GMP manufacturing services can drive forward your market success and unlock the power of “small".

By working with Nanoform, we were able to increase the drug load by 5x over our previous nanomilling formulations. Nanoforming has been highly enabling for our drug candidate.

João Seixas

CEO, TargTex

Our story

Our story started in 2008 when Prof. Jouko Yliruusi and Prof. Edward Hæggström first combined their respective expertise in pharmaceutical technology and physics. This extraordinary collaboration produced a novel particle engineering technology with the ability to transform the pharmaceutical industry.

They discovered the Controlled Expansion of Supercritical Solutions (CESS®) process in 2012 at the University of Helsinki and Nanoform was founded in 2015. Since then, Nanoform has expanded rapidly, transforming into a company with global ambition. Our cutting-edge nanoforming services are intended to help the global pharmaceutical industry to double its annual new medicines output. We are proud to be a Finnish success story with an international outlook.

Recent milestones

2020

May
Nanoform awarded GMP certification

June
Initial Public Offering of Nanoform on Nasdaq First North Premier Growth Market

November
Nanoform launches technology for biologics

December
Nanoform makes US TV debut in Advancements with Ted Danson (CNBC) and lights up Times Square, New York

2021

February
Nanoform and Herantis sign Biologics Proof of Concept Agreement

March
CESS® benchmarking study with Johnson Matthey Plc

March
Nanoform and Nacuity Pharmaceuticals sign Technology Proof of Concept Agreement for two ophthalmic drug candidates

April
Nanoform and Aprecia collaborate to advance 3D printed nanomedicines

May
Nanoform and Celanese explore ways to enhance drug delivery

August
Nanoform and Boehringer Ingelheim execute master services agreement to assess the added value Nanoform's award-winning CESS® technology can deliver to drug development projects

September
Nanoform technology delivers successful results for Herantis CDNF drug candidate

September
Proof of Concept studies to be funded by the Bill & Melinda Gates Foundation to assess the added value Nanoform's award-winning CESS® nanoparticle engineering technology can deliver to several of its drug development projects

November
Nanoform wins the Star of Innovations award at the European Small and Mid-Cap Awards 2021

2022

February
Nanoform signs GMP manufacturing program with TargTex following formulation success

March
Successful completion of new share issue raising EUR 25 million to prepare for GMP manufacturing in the USA

March
Nanoform tripled its GMP capacity and added high potency handling (OEL <30 ng/m3) capabilities to our Helsinki facility to meet increasing demand

June
STARMAP® Online is launched, placing AI-power the fingertips of medicine developers

small is transfo

Our nanoforming technologies and services span the full range of drug development, from small-molecule nanoparticles to large-molecule biologics. We support all phases of drug development, accelerating your time to clinic for GMP manufacture while also increasing the possibilities and probabilities of success in taking your product to market. Nanoform's technology offerings have the capability to transform the pharmaceutical industry.

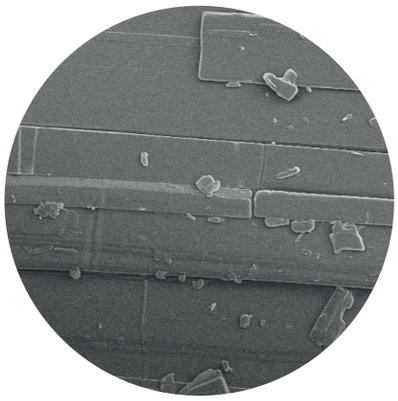
rmative

nanoform
small molecules

Small Molecule Nanoparticles

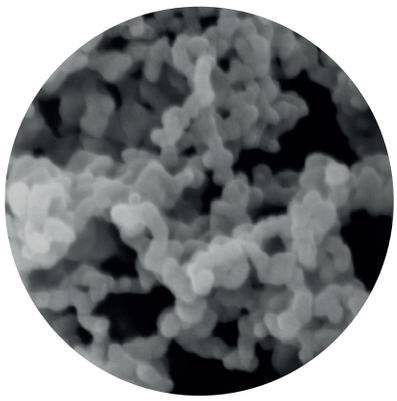
What is CESS® and how does it work?

Our multi-patented Controlled Expansion of Supercritical Solutions (CESS®) technology is a bottom-up recrystallization technique that enables the creation of API nanoparticles directly from solution. The technique works by controlling the solubility of an API in supercritical carbon dioxide ($scCO_2$) in a process that is free from excipients and organic solvents. CESS® represents a significant improvement over previous supercritical technologies due to the employment of controlled mass transfer, flow and pressure reduction.



Before nanoforming

20µm



After nanoforming

200 nm

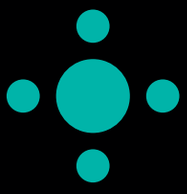
Benefits of CESS®

Controlled particle shape

Our nanoforming process can control the shape of particles, leading to greater uniformity.

Controlled particle size

Our technology can produce nanoparticles as small as 10 nm. Smaller particles have greater active surface areas, which permits an increased rate of dissolution.



Controlled polymorphism

Polymorphic purity tests have shown that stable single polymorphs can be produced with defined process parameters, enabling polymorphic control.

Opening up novel drug delivery routes

By increasing the solubility and thus bioavailability of API particles, CESS® creates opportunities for drugs that would otherwise fail in clinical development to reach the patients who need them. Reducing the size to as small as 10nm using CESS® can enable novel drug delivery routes by facilitating penetration through previously impassable biological membranes, such as the blood-brain barrier. This could open up new drug targets for currently incurable CNS disorders, and empower new oral, dermal, ocular and inhaled therapies.

nanoform biologics

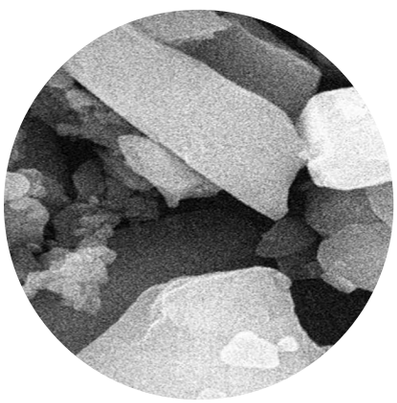
Large Molecule Nanoparticles

Small is now possible in biologics

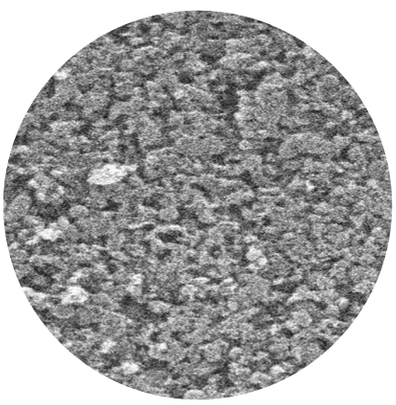
To keep up with the rapidly expanding biologics industry, we developed our game-changing biological nanoforming technology. Our unique platform can produce large-molecule drug particles as small as 50 nm while retaining biological activity. Its effectiveness has been demonstrated on proteins in the 6 kDa – 140 kDa range, and it is capable of engineering particle sizes to specific requirements. Our advanced technology can be applied across the biologics field to potentially:

- Change delivery routes
- Increase uptake
- Enable new drug combinations
- Tailor release profiles
- Enhance drug loading capacity in formulations
- Implement lighter infrastructures for drug logistics

Bulk insulin
5k magnification



Nanoformed insulin
10k magnification



This novel nanoparticle engineering technology can improve the possibilities and probabilities of developing better medicines for patients.

nanoform
formulation

Formulations

Accelerating small-molecule formulation development

Our experienced clinical formulation development team can support formulation development for small-molecule therapies across a vast range of dosage forms, including:

Tablets | Eye drops | Creams | Injections | Inhalers

Whether NCE or 505(b)(2), we can work with our partners to help rapidly progress drugs from the preclinical stage through to commercial formulation development as part of an integrated process.

Game-changing biological formulation services

Our expert team supports formulation development for biologics. We utilize rapid formulation screening to accelerate process parameters, excipient selection & compatibility studies to prevent protein degradation.

Key features:

- Formulation for nanoformed biologics can be adapted for different administration routes
- Our unique biologics production platform operates at low temperatures – ideal for sensitive biologics

Small is green

Our company roots are in the luscious Finnish countryside, and this is reflected in our commitment to sustainability. Our CESS® nanoparticle engineering technology is a bottom-up recrystallization process utilizing supercritical carbon dioxide repurposed from industry waste as a solvent. The process can eliminate the need for excipients and has a small manufacturing footprint, while the use of a green solvent facilitates environmentally friendly scale up.

nanoform
formulation

Our nanoforming services provide solutions to complex formulation challenges

Pharmacokinetic improvements

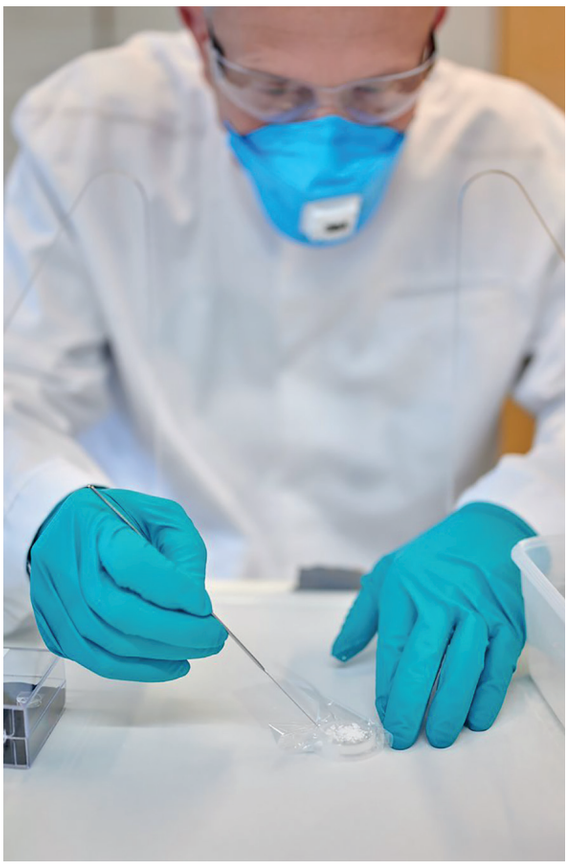
Low drug compound solubility is a major cause of attrition in the pharmaceutical industry. Nanoforming increases the specific surface area of API particles, enabling significant improvements in dissolution rate and thus bioavailability. Increased bioavailability also means a lower dosage is required for a therapeutic effect.

Additional drug delivery applications

Our nanoparticles are being used in drug developments to improve brain penetration via intranasal administration. Nanoparticles can also be used for novel applications in ocular, pulmonary and transdermal drug delivery.

Commercial opportunities

Our particle engineering services can improve the performance of both NCEs and drugs currently on the market by enhancing formulations. The commercial opportunities of our work also include life cycle extension, additional patent protection and the creation of barriers to generic competition.



What is STARMAP® Online?

STARMAP® Online is a next-generation sparse-data AI-based platform that can predict drug candidates' success. It is able to rapidly identify the drug candidates best suited to our bioavailability-enhancing CESS® nanoparticle engineering process. STARMAP® Online represents the first ever deployment of a customer-facing AI-based portal aimed at growing confidence in nanoparticle technology to empower medicine development.

What can STARMAP® Online do for you?

Our AI platform augments sparse-data AI with detailed expert knowledge to provide reliable and accurate predictions of CESS®-powered nanoforming success. STARMAP® Online can help reduce the time and cost of drug development and de-risk the process by enhancing and accelerating developers' decision making. It also offers the potential to reassess libraries of previously undruggable compounds and rapidly identify promising new candidates.

To date, our technology has run predictions on every drug molecule ever disclosed. Our large database enables STARMAP® to conduct thematic evaluations to help companies understand the power of CESS® in different therapeutic areas, target classes and disease areas. By limiting the number of experiments needed, STARMAP® Online can additionally help reduce waste to help the pharmaceutical industry meets its green objectives.

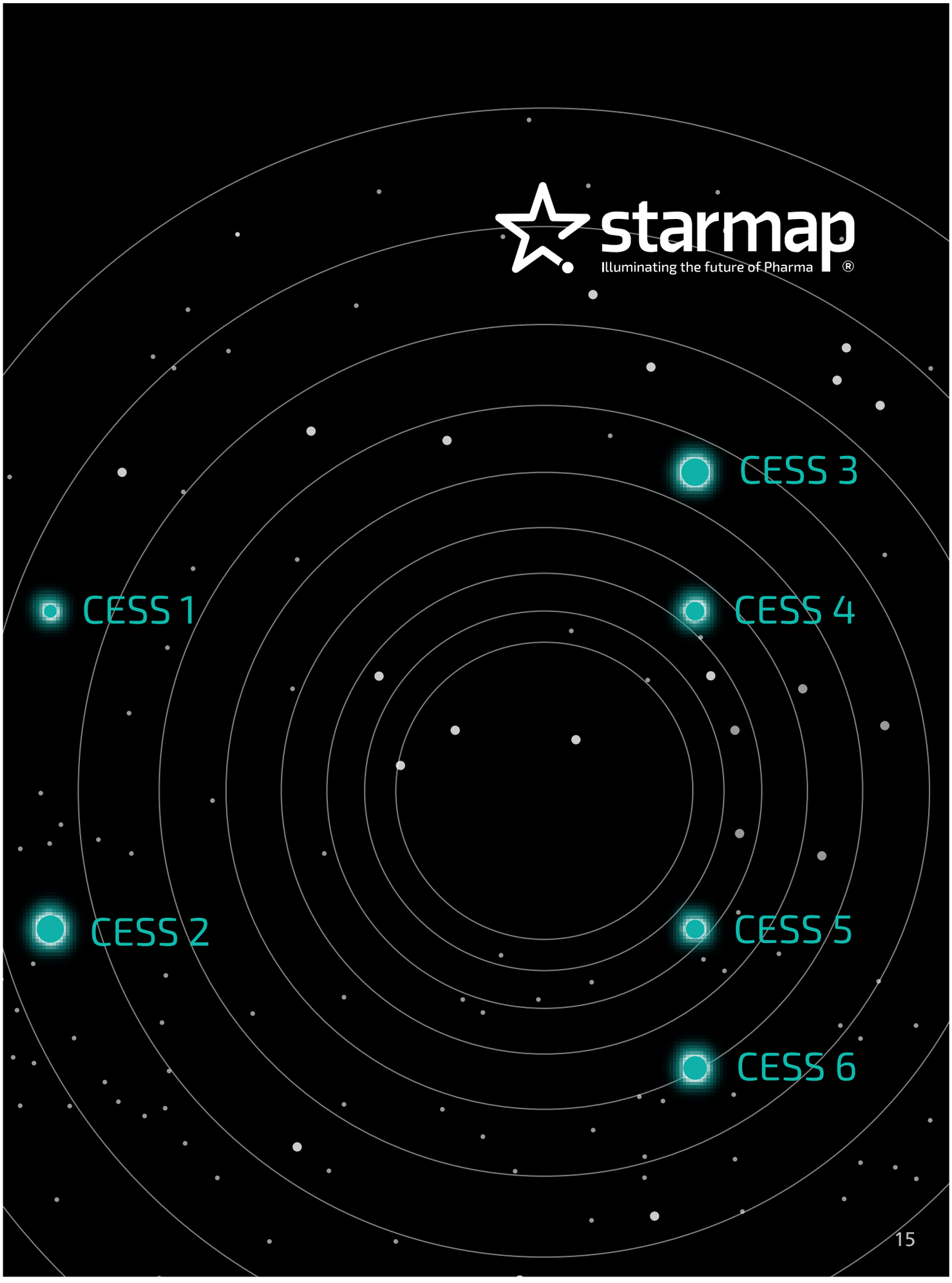
Data privacy

Our accessible STARMAP® Online portal places the power of AI at the fingertips of drug developers. STARMAP® Online provides full control to our partners through a secure and private online platform, ensuring data remains completely confidential. Drug developers are able to conduct drug screenings in private, without needing to disclose asset performance.

Meeting the needs of patients

Our goal is to benefit a billion patients globally. STARMAP® Online facilitates streamlined drug development, which will be felt by patients as new therapies are accelerated to market. By embracing the power of AI to improve decision-making, STARMAP® Online can ultimately help provide life-changing treatments to patients that need them.

Visit nanoform.com/starmap to request access to this ground-breaking platform.


starmap
Illuminating the future of Pharma ®
CESS 3
CESS 1
CESS 4
CESS 2
CESS 5
CESS 6

Our latest clinical results confirm value proposition to the pharma industry

What did we study?

In partnership with Quotient Sciences, we completed a human trial of an immediate-release (IR) tablet formulation of piroxicam – the world's first human trial of a nanoformed drug candidate.

The 20mg nanoformed piroxicam tablets were tested against reference products Felden® 20 mg tablets (Pfizer) and Brexidol® 20 mg tablets (Chiesi) in healthy subjects in the fasted state. Brexidol® is a ß-cyclodextrin coupled formulation designed for fast absorption, so rapid absorption for this reference product was expected in vivo.

What were the results?

The results showed similar bioavailability of nanoformed piroxicam compared to both reference products, with no statistically significant difference in maximum plasma concentrations (C_{max}). Meanwhile, nanoformed piroxicam demonstrated a time of maximum plasma concentration (T_{max} = 1.75 h, ranging from 0.75 h to 4.00 h) earlier relative to both reference products: Felden (T_{max} = 2.75 h, ranging from 0.75 h to 12.00 h) and Brexidol® (T_{max} = 2.25 h, ranging from 0.5 h to 8.00 h).

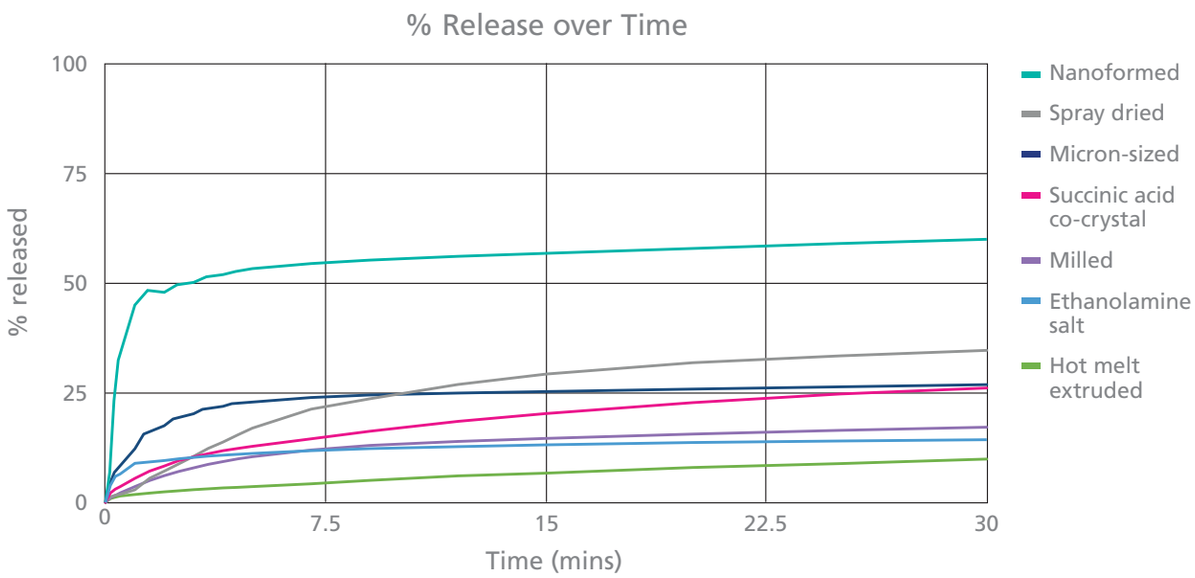
The slightly faster absorption observed for the nanoformed piroxicam tablets compared to Brexidol® shows that nanoforming can be used as an alternative or improvement to complex formulation approaches, such as those using ß-cyclodextrin, with the potential for having improved performance without the need for additional excipients.

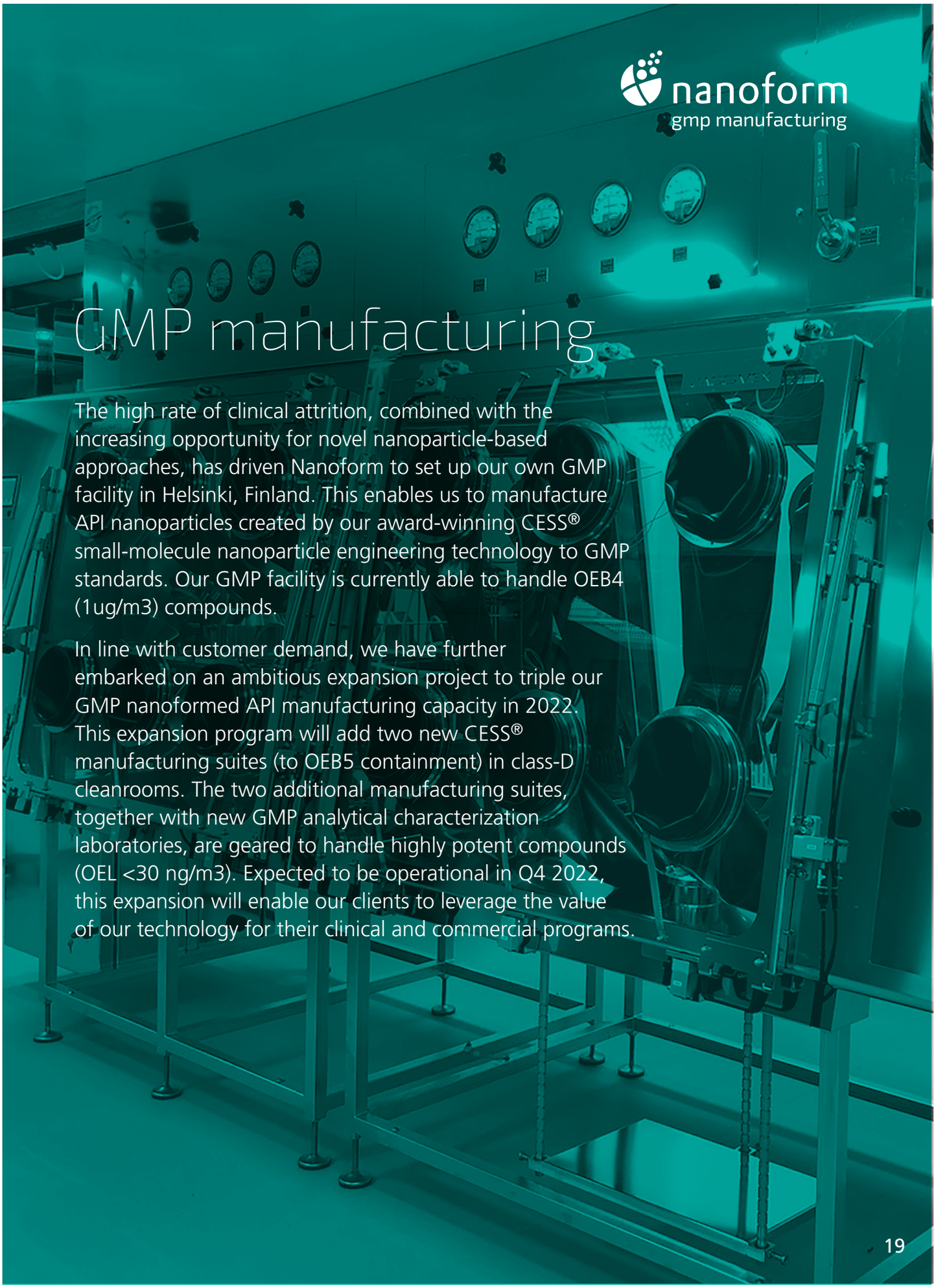
What are the conclusions?

The results support our value proposition that nanoparticles can enable a faster dissolution rate, more rapid absorption, and improved drug delivery performance. By improving absorption and increasing drug load while also enabling simpler formulations, novel therapies can potentially be developed using our CESS® technology that ultimately maximize patient benefit.

CESS® benchmarking study shows that nanoformed particles exhibit dramatically improved dissolution performance results

We collaborated with Johnson Matthey Pharmorphix® solid state services to evaluate the performance of our CESS® technology relative to industry-standard particle engineering techniques, including spray-dried and holt-melt extruded amorphous solid dispersions, salt, co-crystal, milled and micron-sized active pharmaceutical ingredients.



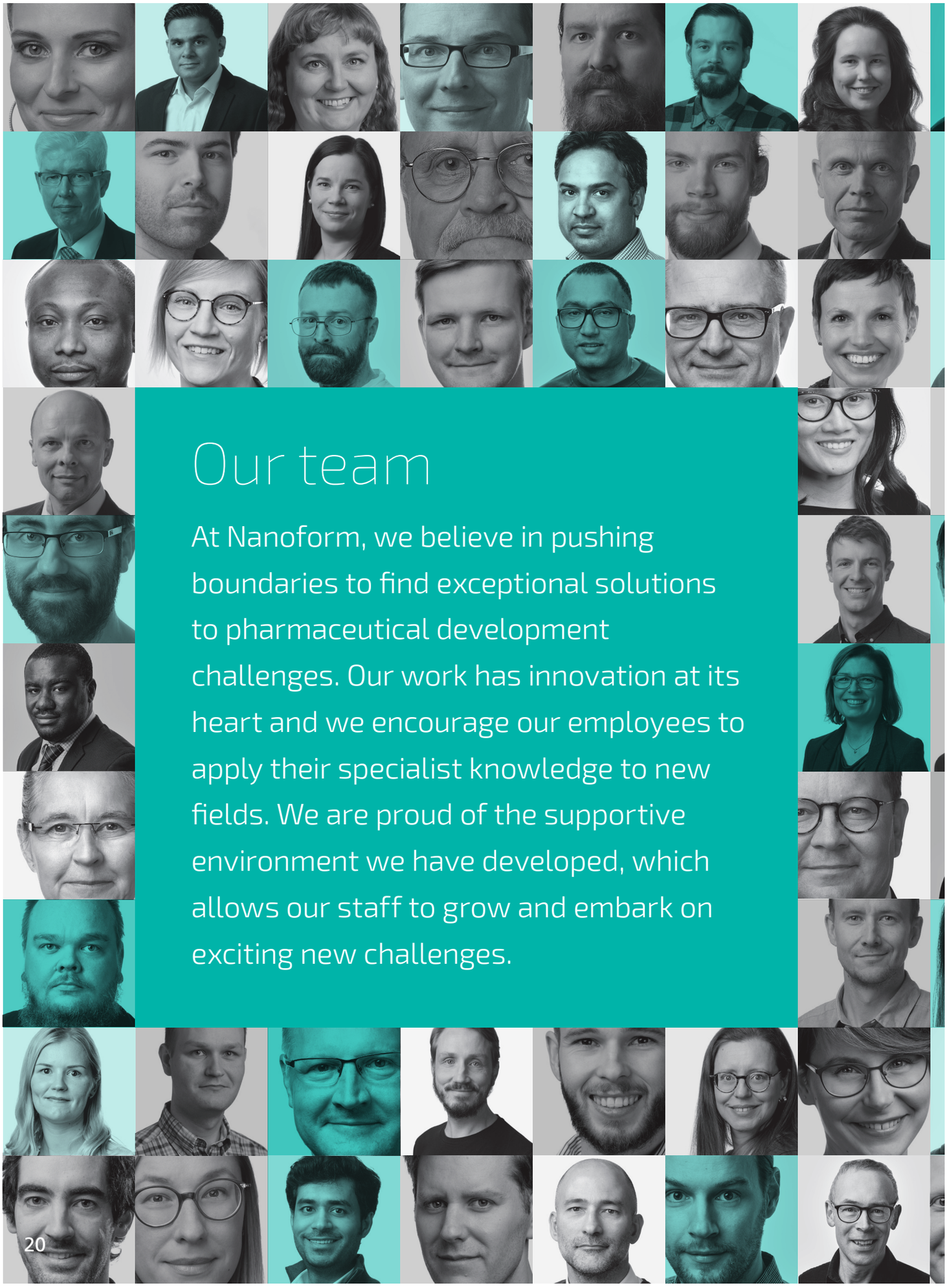


nanoform
gmp manufacturing

GMP manufacturing

The high rate of clinical attrition, combined with the increasing opportunity for novel nanoparticle-based approaches, has driven Nanoform to set up our own GMP facility in Helsinki, Finland. This enables us to manufacture API nanoparticles created by our award-winning CESS® small-molecule nanoparticle engineering technology to GMP standards. Our GMP facility is currently able to handle OEB4 (1ug/m3) compounds.

In line with customer demand, we have further embarked on an ambitious expansion project to triple our GMP nanoformed API manufacturing capacity in 2022. This expansion program will add two new CESS® manufacturing suites (to OEB5 containment) in class-D cleanrooms. The two additional manufacturing suites, together with new GMP analytical characterization laboratories, are geared to handle highly potent compounds (OEL <30 ng/m3). Expected to be operational in Q4 2022, this expansion will enable our clients to leverage the value of our technology for their clinical and commercial programs.



Our team

At Nanoform, we believe in pushing boundaries to find exceptional solutions to pharmaceutical development challenges. Our work has innovation at its heart and we encourage our employees to apply their specialist knowledge to new fields. We are proud of the supportive environment we have developed, which allows our staff to grow and embark on exciting new challenges.

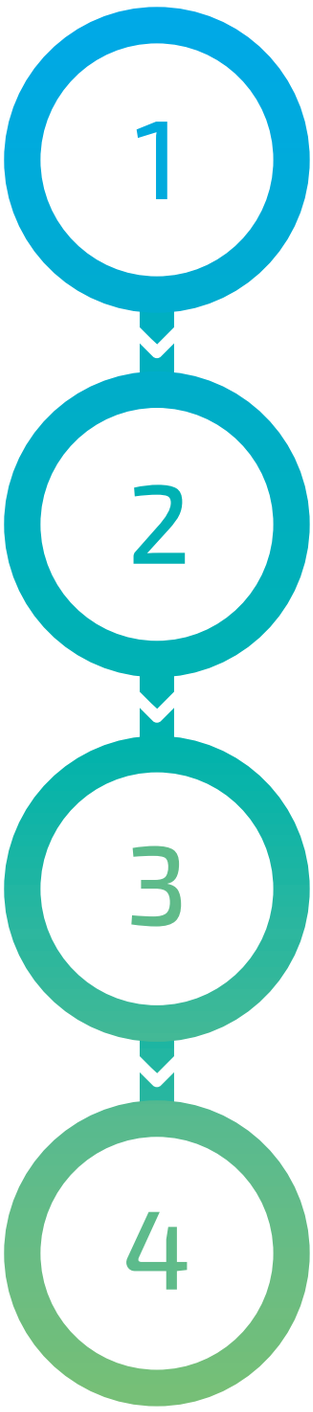
Our facility

Nanoform's headquarters, R&D and manufacturing are located at the Cultivator II building housed within the Viikki Life Science Park – one of Finland's largest bioscience hubs. The Viikki site fits in with Nanoform's ambitions to expand the current facilities. The certification of GMP status means that the facility represents the first GMP nanoforming capability in the world. The growth in capacity has enabled us to meet the growing demand for formulations with improved solubility and bioavailability. Additional non-GMP and GMP lines are to be constructed continuously until the end of 2025. We are committed to continual improvement in the areas of Environmental, Health and Safety (EHS), to ensure compliance with Good Manufacturing Practice (GMP).

We help partners around the world by nanoforming APIs for a range of therapeutic areas.

Edward Hæggström
CEO

See what small can do for you



Initial evaluation

We first perform an initial evaluation to understand compound characteristics. Our extensive conversations with partners enable us to fully define what we aim to achieve and the challenges involved.

Proof of concept and process

A proof of concept study is initiated to determine the feasibility of nanoforming the material. A proof of process study is then performed to find the optimal process parameters for consistent, reproducible results.

Technology transfer

A demonstration batch is produced at a larger scale in preparation for GMP manufacture.

GMP manufacture

Your product is moved to a GMP facility for clinical production.

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Contact us
to unlock the
potential of
your molecules

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