

WELCOME Q&A WITH PODD 2021 LEAD SPONSOR NANOFORM

Professor Edward Hæggström, PhD, is the CEO of Nanoform. In 2015, Professor Hæggström commercialized the CESS® nanoparticle engineering platform he developed with Professor Jouko Yliruusi by spinning out Nanoform as a new company from the University of Helsinki. The company's multi-patented CESS® technology significantly reduces the size of drug APIs, addressing a leading cause of drug development failure.



Going into the 2021 PODD conference, what were you hoping to hear more about, in terms of new data or new progress?

Staying informed of industry developments is vital in order to identify potential opportunities for collaborating and combining approaches for maximum impact. At Nanoform, we are constantly on the lookout for new advances that can complement our own approaches, whether in the nanoparticle engineering space or in terms of new formulation approaches and drug manufacturing innovations. Going into the PODD conference, we were keen to hear from our peers on the latest developments in these spaces.

What emerged as the bigger themes, in your view?

There can be no doubt that it's an exciting time to be in the industry. The PODD conference provided an excellent forum to discuss the latest innovations in areas such as injectable formulation technologies, non-invasive oral/non-injectable technologies and digital health technologies. A clear focus was placed on the amazing advancements in accelerating therapeutics for COVID through collaboration and partnership in drug delivery. It just goes to show what is possible when everyone works together towards a common objective. At Nanoform our goal is to touch the lives of one billion patients and it will only be possible through close collaboration and industry partnership. PODD has this theme at the heart of the conference and it is why we were proud to be the lead sponsor. We look forward to the next event!

Can you tell us about the work that Nanoform is leading?

We provide game-changing nanoparticle engineering and formulation services to the industry. Through our innovative technologies, we cover the full range of therapeutics from biologics to small molecules. Whether the drug suffers from poor solubility or drug delivery challenges, once the issue

is identified we can work together to decide the best way forward. Using our technologies and formulation expertise, we work with partners to deliver solutions that can enable more and enhanced therapeutics to reach patients.

What was the gap or lack in the marketplace that led to the formation of Nanoform?

Nanoform was founded to commercialize our multi-patented CESS® technology in order to help more life-saving drugs reach patients. More specifically, CESS® was developed to help address the high rate of attrition in clinical development, with the failure rate of drugs entering clinical development approximately 90%. A significant obstacle to the release of new medicines is the increasing complexity of drug molecules, which contributes to increased hydrophobicity and poorer water solubility. In fact, 70–90% of pipeline drugs fall into the low solubility categories of the Biopharmaceutical Classification System (BCS). Poor solubility can lead to poor absorption in the GI tract and thus poor bioavailability, resulting in drug failure.

Our CESS® technology can address this common issue by increasing the specific surface area of API particles as part of a gentle, bottom-up process. Building on the momentum created by the launch of CESS® and the increasing popularity of biologics, we have now expanded our offerings to include our unique biological nanoparticle technology, which can help facilitate a shift to more patient-centric drug delivery routes.

What is the North Star for Nanoform, in terms of what you'd like to achieve?

Our guiding star is our goal to touch the lives of a billion patients worldwide through our game-changing technological innovations. By enabling more and enhanced therapeutics to reach the patients who need them, we hope to transform patient care and quality of life.

PODD is all about forming partnerships for drug delivery. What is your partnering philosophy, and what do you see as the keys to success for a partnership?

Together we can achieve things that would simply not be possible from working in isolation. However, collaboration is a two-way street, and communication and a clear understanding of the needs and objectives on both sides is essential for an effective partnership. In addition, being connected to the latest industry trends and new technology releases is important as a first step toward identifying opportunities to combine approaches for maximum impact.

We employed this philosophy in our collaboration with Aprecia, where we investigated how our nanoparticle engineering technology could be combined with their 3D printing platform to create optimized therapeutics for patients. Ultimately, it is the patient who stands to benefit from successful collaborations in Pharma that focus on enabling and enhancing life-saving therapies. By placing this common goal first and foremost, any bumps in the road can be overcome.

When you're going into a new partnership, what are the questions you're asking?

At Nanoform, we put the patient first and ask ourselves the question: does this add value to patients' lives? When embarking on initial discussions with potential partners we want to know first and foremost what the problem is that needs to be solved, and then we can put a plan in place to address that. Our multidisciplinary team combines the expertise of leading minds in physics and chemistry to develop innovative solutions to industry challenges. When combining technologies in pharmaceutical development, we look to establish a 1 + 1 = 3 value add. It takes time to assess and evaluate technology partnerships and so it is essential that the value the combined approach delivers to the patient is greater than the sum of the two parts.

At PODD 2021, Nanoform's VP of US Business Development Eric Peter presented on a piroxicam clinical trial where the product was nanoformed. What are the implications/impact of that, and how is that guiding your future work?

In collaboration with Quotient Sciences, we completed the first human trial of a nanoformed drug candidate – in this case, piroxicam, an anti-inflammatory drug. The positive results from the trial provided strong evidence for the efficacy of our CESS® technology – in particular, that it can enable a faster dissolution rate, more rapid absorption, and improved drug delivery performance.

This provides hope for quickly introducing improved versions of existing products and for adding value to those already in clinical development. Altogether, the exciting results pave the way for improving absorption and increasing drug load while enabling simpler formulations to maximize patient benefit. The strong data from the clinical trial has provided invaluable insights and will continue to inform our future work.

What do you see as the next phase of drug delivery: either the challenges that you'd like to see addressed, or previously unreachable targets, etc?

The size of drug particles can present a significant drug delivery challenge, rendering beneficial drug delivery routes off limits due to the drug particles' inability to cross biological membranes. For example, solutions that can enable drugs to improve brain penetration can open up a wide array of possibilities for treating central nervous system (CNS) disorders.

In addition to the advantages of opening up new drug targets and delivery routes, there is also a significant opportunity to help patients and improve uptake of medicines by creating more opportunities for less invasive administration routes to be accessed. Finally, by helping to facilitate local delivery of drugs, therapeutics with fewer side effects that bypass systemic circulation can be brought to market.

By addressing these key challenges, which we can help to do at Nanoform, the scope can be widened for drugs in development and significant patient benefit can be achieved down the line.

Can you tell us about some of your new collaborations and partnerships, such as the Gates Foundation?

We are working with a number of organizations to assess the added value our nanoparticle engineering technologies can bring. I'll give you a few examples: we are working with Aprecia, a three-dimensional printing (3DP) pharmaceutical company, to explore how their respective technologies can be combined to create nanoparticle enabled 3DP dosage forms. Our CESS® platform can improve the dissolution of poorly soluble APIs, when combined with Aprecia's fast disintegrating 3DP dosage form this should enable even the most poorly soluble drugs to be absorbed rapidly by the patient.

We are also working with Herantis Pharma Plc to assess the potential of Nanoform's platform technology to improve the administration of rhCDNF, a Parkinson's disease drug candidate, via a minimally invasive intranasal spray route. This collaboration has yielded promising initial results.

Recent positive results from our award-winning CESS® nanoparticle engineering technology with our client TargTex, who are developing targeted therapeutics for glioblastoma multiforme, has proven that nanoformed API particles deliver a five-fold increase in drug load in their proprietary formulation compared to various nanomilled materials they had previously tried. This should enable an improved product for the patient aligned with their vision of giving the patient a chance to live instead of survive.

In addition, we received funding from the Bill & Melinda Gates Foundation for Proof of Concept studies to assess the added value our CESS® technology can deliver to several of its drug development projects.

