

Nanoform Management Presentation

Q4 & FY 2023

February 29th, 2024



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Forward-Looking Statements

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SHORT INTRODUCTION TO NANOFORM

CEO Edward Hæggström



The structural pharma R&D problem

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

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



Annual number of novel drug approvals by FDA 2010-2023

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



A game changer is needed to improve R&D yield



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

Nanoform in a snapshot

TECHNOLOGY	PEOPLE	MEDICINES	FINANCE	PATIENTS
Global experts in nanotechnology & drug particle engineering	165 employees, 38 nationalities, 38 PhD's in US, UK, Europe	Staff with combined experience of launching 100+ medicines	Strong balance sheet & institutional ownership	Improving lives of patients through game-changing technologies & novel formulations



Proprietary technology platforms





*CESS® = Controlled Expansion of Supercritical Solutions

***API = Active Pharmaceutical Ingredient**

Low bioavailability is the key issue



Majority of new drugs suffer from poor solubility

Poor bioavailability and low efficacy most common reasons for drug failure

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



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

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Particle size is key

Smaller particle size can improve a drug's bioavailability



- The surface area increases 30 fold from a 10 micron¹ sized particle once the particle size is reduced to 100nm
- Reduction of particle size down to 50nm increases the surface area by 1,000 fold



- Improved bioavailability implies increased absorption of a drug by the body's circular system
- CESS[®] can produce API with large surface areas which can significantly improve the bioavailability of drugs

> CESS[®] produced nanoparticles have a larger surface area and as such improved bioavailability.



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

Small molecules - Small is powerful®





Nanoform is here to fill the gap

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



Nanoform's CESS[®] is the only technology that can manufacture nanoparticles without solvents, excipients, and complex production processes



API = Active Pharmaceutical Ingredient CESS[®] ⁼ Controlled Expansion of Supercritical Solutions *Source: Nanoform and Pharmaprojects® | Informa, 2022

Simplified value chain

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



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



API = Active Pharmaceutical Ingredient CESS[®] ⁼ Controlled Expansion of Supercritical Solutions GMP = Good Manufacturing Practice

2023 HIGHLIGHTS

CEO Edward Hæggström



✓ Project Nanoenzalutamide progressing well with a powerful set of very promising clinical data

✓ New promising data on project Nanoapalutamide (PR Feb 29th, 2024)

Strong business opportunity within Amorphous Solid Dispersions (ASDs)

Record number (22+1) of new projects signed during 2023

✓ Grant of EUR 4.3M from Business Finland to create nanoparticle formulation platforms

STARMAP[®] licensed to AstraZeneca Plc

Customer TargTex's Project Glioblastoma receives FDA orphan drug designation and wins EU-EIC funding

✓ Multi-API license received by FIMEA (Finnish Medicines Agency), additional notification submitted

Promising initial in-vitro trials with two major pharma looking at monoclonal antibodies

manoform

FINANCIALS

CFO Albert Hæggström



Nr of employees & nr of lines





GMP lines 2&3 will be commissioned after inspection by Fimea, expected during 1H24



Nr of projects signed and nr of projects generating revenue







Nr of projects generating revenue





Nr of projects signed





Revenue recognized impacted by slow signings in 2H22^{*}





*Impact on revenue can in a quarter(s) for some of the projects be negative if budgeted costs increase significantly.



Project Nanoenzalutamide has led to increased external GMP QC cost





Excluding the cost of external GMP QC services, related to Project Nanoenzalutamide, our underlying gross margin has remained above 90%. In June 2023, Nanoform submitted a notification to the Finnish Medicines Agency to update our Manufacturer's Authorization. The notification included our new Quality Control laboratory (GMP QC) and an inspection is expected to take place during 1H24. This will help our gross margin return to the 90+ levels we target.



Improvement in cash flow continued throughout the year





Nanoform had EUR 47.5m in cash & short-term government bonds and no debt at the end of 2023.



NANOFORMING VS ASDs

Peter Hänninen



ASDs = Amorphous Solid Dispersions

Business case Amorphous Solid Dispersions (ASDs)

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

Nanoformed and nanocrystalline medicines (e.g. Nanoenzalutamide and Nanoapalutamide) offer an attractive alternative to ASD medicines (and other) with the following benefits:

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

Several opportunities for Nanoform to replicate early successes with project Nanoenzalutamide and project Nanoapalutamide



STARMAP® predicts that nanoforming is an attractive alternative to ASDs



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

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

PROJECT NANOENZALUTAMIDE

VP Strategic Insights Jamie Unwin



Project Nanoenzalutamide – a potential breakthrough

Existing blockbuster drug

- Xtandi[®] #1 prescribed androgen receptor inhibitor, approved by FDA (2012) to treat prostate cancer
- Sales >\$5bln per year
- Amorphous solid dispersion (ASD) drug



Nanoformed drug Nanoenzalutamide

- Development & commercialization of a more patient-centric drug
- Nanoform ownership 25%, in a consortium with four equal owners
- Strong interest in the project from value-

added medicine companies

*Xtandi is a registered trademark of Astellas Pharma Inc.



Clinical trial: Very promising relative bioavailability study of nanocrystalline-enabled enzalutamide (nanoenzalutamide) tablet formulation

Nanoforming benefits:

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

Next steps: Manufacture Nanoformed material for registration batches and EU/US pivotal bioequivalence clinical trials that are expected to start in 2024 - with read-outs in 2025, <u>licensing deals targeted to be signed in 2024</u>

Target launch: Submissions of dossiers 2025-26, launch after expiry of the enzalutamide substance patent in USA 2027 & in Europe 2028



Multiple routes to create value





PROJECT NANOAPALUTAMIDE

VP Strategic Insights Jamie Unwin



Promising results for Project Nanoapalutamide

Apalutamide Study Again Demonstrates the Advantages of Nanoforming Over Traditional Cancer Treatment Formulations

Helsinki, Finland – February 29, 2024 – Nanoform Finland Plc ("Nanoform"), the medicine performance-enhancing company, today announced it had received positive results from its own pre-clinical, *in-vivo* study of a nanocrystalline-enabled apalutamide oral formulation, which shows potential to enable a much smaller tablet than Erleada^{® [1]}, a nonsteroidal antiandrogen (NSAA) blockbuster amorphous solid dispersion (ASD) medicine used to treat prostate cancer.

The nanocrystalline-enabled formulation provided high serum concentration (Cmax), fast time to peak drug concentration (Tmax), and 100% absolute bioavailability. This study was conducted in order to provide further validation of nanocrystalline formulations as effective alternatives to amorphous solid dispersions.

"These encouraging results follow our successful clinical study on nanoenzalutamide, our improved version of yet another blockbuster ASD product in the prostate cancer field, and further validates the opportunity to leverage our formulation platforms to help patients by transitioning to nanoformed products," said Dr. Edward Haeggström, CEO of Nanoform. "Through our proprietary AI technology platform, we've identified that most ASD products are amenable for improvements with Nanoform technologies, covering multiple therapy areas including cancer, HIV and CNS."



Latest press releases: Press releases – Nanoform small is powerful

Business Finland Grant

Peter Hänninen



Business Finland Grant

EUR 4.3M Grant

- Business Finland the Finnish government organization for innovation funding and trade
- For the development of nanoparticle-enabled formulation platforms for next generation medicines within the following drug delivery technology areas:
 - Oral* (the green alternative to amorphous solid dispersions)
 - Inhaled
 - Long-acting injectable
 - High-concentration subcutaneous injectables of biologics
- > The work is expected to take place during 2024 and 2025



Commercial

CCO Christian Jones



Cumulative nr of customer projects signed





Cumulative nr of customers signed



Commercial Relationships 2019-2023





Selection of Nanoform Pharmaceutical Partnerships

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





Nanoform customer projects – therapy area overview*

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



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

Examples of areas in which STARMAP[®] sees strong potential for nanoforming



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



Please read more here about STARMAP® here: <u>STARMAP – Nanoform small is powerful</u>

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Q & A

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



APPENDIX



Financial KPI's

Financial KPI's

EUR thousand	10-12/2023	10-12/2022	1-12/2023	1-12/2022	1-12/2021	1-12/2020
Revenue	401	986	2,566	3,487	1,955	687
Revenue growth %	-59%	51%	-26%	78%	185%	n.m.
Gross profit	296	812	1,717	3,147	1,792	497
Gross margin	74%	82%	67%	90%	92%	72%
EBITDA	-5,353	-4,784	-19,597	-19,027	-17,745	-18,196
Operating loss	-6,122	-5,430	-22,476	-21,409	-19,705	-19,423
Loss for the period	-5,339	-5,568	-20,756	-22,075	-19,690	-19,441
Basic EPS (EUR)	-0.07	-0.07	-0.26	-0.29	-0.29	-0.35
Net debt	-41,235	-61,807	-41,235	-61,807	-68,070	-54,156
Net debt excluding lease liabilities	-47,493	-68,740	-47,493	-68,740	-75,733	-59,977
Investments in property, plant, and equipment	-546	-2,044	-3,477	-8,965	-7,737	-2,336
Operative free cash flow	-5,899	-6,829	-23,075	-27,992	-25,482	-20,532
Cash and cash equivalents excluding short-term government bonds (end of period)	14,232	68,740	14,232	68,740	75,733	61,025
Cash and cash equivalents including short-term government bonds (end of period)	47,493	68,740	47,493	68,740	75,733	61,025

Operational KPI's

	10-12/2023	10-12/2022	1-12/2023	1-12/2022	1-12/2021	1-12/2020
Number of new customer projects signed during the period						
Non-GMP	5	2	22	17	16	10
GMP		1	1	1	2	
Total number of new customer projects	5	3	23	18	18	10
Number of lines (end of the period)						
Non-GMP	19	18	19	18	14	8
GMP	1	1	1	1	1	1
Total number of lines (end of period)	20	19	20	19	15	9
Personnel at the end of reporting period	165	150	165	150	125	74



Income statement

Condensed financial information January-December 2023

Consolidated statement of comprehensive income

EUR thousand	Note	10-12/2023	10-12/2022	1-12/2023	1-12/2022
Revenue	4	401	986	2,566	3,487
Other operating income					
Materials and services		-105	-174	-849	-340
Employee benefits	7	-4,003	-3,345	-14,726	-14,010
Depreciation, amortization, and impairment losses	6	-769	-645	-2,878	-2,382
Other operating expenses	5	-1,645	-2,252	-6,589	-8,164
Total expenses		-6,523	-6,416	-25,042	-24,896
Operating loss		-6,122	-5,430	-22,476	-21,409
Finance income		1,696	356	6,214	957
Finance expenses		-905	-496	-4,471	-1,604
Total finance income and expenses		791	-140	1,743	-647
Loss before tax		-5,331	-5,570	-20,733	-22,056
Income tax		-8	1	-23	-19
Loss for the period		-5,339	-5,568	-20,756	-22,075

1-12/2023 comments

Revenue came in at EUR 2.6 million, stemming from 33 different customer projects (EUR 3.5m, 35 projects in 2022).

The gross profit decreased to EUR 1.7 million, with a gross margin of 67% (EUR 3.1 million, 90%) due to GMP QC costs related to the nanoenzalutamide project. Excluding these, the gm was above 90%. Revenues are recognized over the lifetime of the projects, based on expenses (mostly hours worked) booked for the projects.

The operating free cash flow continued to improve, and the cash burn was less than EUR 20m annualized in 4Q, helped by lower investments in property, plant and equipment.

Cash position (incl. T-bills) was EUR 47.5 million (EUR 68.7m) at the end of 2023, down EUR 4.3m during the last quarter (EUR 51.8m at the end of 3Q23).

5. Other operating expenses

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

EUR thousand	10-12/2023	10-12/2022	1-12/2023	1-12/2022
Premises expenses	66	57	242	159
IT expenses	217	339	1,019	2,064
Marketing and communication expenses	225	277	648	825
Consultant and professional fees	286	428	1,245	1,355
Travel expenses	116	103	392	353
Voluntary personnel related expenses	114	201	580	781
R&D expenses - external	251	391	999	1,008
Other expenses	370	455	1,464	1,620
Total	1,645	2,252	6,589	8,164



Project Glioblastoma





Nanoform customer TargTex S.A. was granted Orphan Drug Designation by FDA for its nanoformed drug candidate TTX101 to be used in patients with malignant gliomas

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

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

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

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



Selection of Nanoform Institutional Shareholders





1) Latest ownerhsip data can be found at https://nanoform.com/en/ownership-structure/

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Revenue drivers & industry attrition rates

Nanoform pre-clinical and clinical revenue drivers



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



Timeline (years)	Pre-clinical	Phase I	Phase II	Phase III	Approval	Total
New drugs	~1-4	~2	~2	~3-4	~1	~9-13
Existing drugs	-	Clinical deve	lopment for 50	5(b)(2) ~2-5	~1	~3-6

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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

Small Molecules - Proprietary technology

Controlled Expansion of Supercritical Solutions - CESS[®]



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



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

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Green

technology

Large molecules - Proprietary technology





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

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CESS[®] Superior to Existing Technologies

	Controlled Expansion of Supercritical Solutions (CESS [®])	Solid dispersion (e.g. spray drying)	Jet milling	Nanomilling
Description	Extracts API from supercritical CO ₂ by applying controlled reduction in pressure	API is dispersed into a solid material, which dissolves when exposed to an aqueous media	Application of energy to physically break down API particles to finer ones	API particle size is reduced in a liquid vehicle via grinding
Particle size	Down to 10nm	300nm-25μm	800nm-10μm	>150nm
Particle formation	Controlled crystalline or amorphous and stable	Amorphous (unstable without excipients)	Unstable (crystalline and amorphous structures)	Unstable (crystalline and amorphous – needs excipient to stabilise)
Ease of formulation	✓	×	×	×
Reproducibility	✓	✓	×	×
Free from excipients and solvents	✓	×	✓	×
Yield	High	Low	High	Low
Investment	Low	High	Low	Low
4				

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

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Nanoform – Attractive revenue model, stands the test of time

Predictable revenue streams through capitalizing the entire pharmaceuticals value chain

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

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



Nanoform near-term business targets 2024





GMP = Good Manufacturing Practice

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

Nanoform mid-term business targets 2025





Management team: Multi-disciplinary with international merits



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

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



CCO; M.Sc. (Chemistry) Christian Jones



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



General Counsel; LL.M Peter Hänninen

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



Chief Quality Officer, M.Sc. (Pharmacology) Johanna Kause

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





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

20 years of finance and investing experience

Previously Particle Size Reduction Lead for GlaxoSmithKline

Current ownership: 709,010 shares and 670,000 options

Chaired the PSR Centre of Excellence

SFB

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

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

Current ownership: 413,720 options



Chief of Business Operations (Chemistry and Quality) Antonio da Silva

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



Board of directors: Top executives from leading industry positions



Miguel Calado



Chairman of the Board

- Previously CFO at international particle engineering CDMO company Hovione Group
- Other previous roles include CFO at PepsiCo International and President International Operations at Dean Foods
- Experienced Board member in both the EU and the US
- Current ownership: 64,826 shares and 380,000 options
- **Key experience: PEPSICO** Hovione





Albert Hæggström

CFO and Board Member

- 20 years of finance and investing experience
- Prior roles include positions at Alfred Berg, BNP Paribas, Nordea and SEB
- Current ownership: 709,010 shares and 670,000 options
- Kev experience:





Mads Laustsen

Board Member

 Over 30 years of experience in pharmaceutical development and manufacturing

BACTOLIFE

- Co-Founder and former CEO of international biologics CDMO company CMC Biologics and former CEO of Bactolife A/S
- Extensive experience in process development and patenting
- Senior positions within several Danish biotech companies
- Current ownership: 22,419 shares and 300,000 options CMC

Key experience:



symphoge

Jeanne Thoma

Board Member

- 30+ years of experience in global pharmaceutical and life science leadership
- Prior roles include executive positions at BASF Inc, Lonza AG and SPI Pharmaceuticals
- Current ownership: 22,419 shares and 38,630 options
- Key experience:







SPI Pharma^{*}

An ABE Ingredients Compar





FURTHER ENQUIRIES

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