

# Financial Statement Review

**JANUARY-DECEMBER 2023** 



### Nanoform's January-December 2023 review:

Project Nanoenzalutamide sees strong momentum. The clinical results in the pilot study were very promising. Now we are preparing for the manufacture of nanoformed material for the registration batches and the EU/US pivotal studies that are planned to start during 2024. In parallel, Nanoform and the members of the ONConcept® Consortium have initiated discussions with many potential partners around this exciting project. The interest in the project is broad and we expect to sign one or several license/commercial supply agreements during 2024. While we signed a record number of new non-GMP projects in 2023, revenues were hampered by low signings in 2H22 and the gross margin by costs related to project Nanoenzalutamide, but the free cash flow continued to improve. The balance sheet remains solid with EUR 47.5m in cash and no debt. The previously communicated target of signing one or several license/commercial supply agreements during 2024 is reiterated, while we add the following targets for 2024: "Increased number of non-GMP and GMP projects in 2024 vs 2023 and "Improved operating free cash flow in 2024 vs 2023".

#### 10-12/2023 key financials

- Revenue was impacted by slow signings during 2H22 and decreased to EUR 0.4 million, compared with EUR 1.0 million in 10–12/2022.
- The gross profit decreased to EUR 0.3 million, with a gross margin of 74% (EUR 0.8 million, 82% in 10-12/2022) due to GMP QC costs related to the Project Nanoenzalutamide.
- Total operating costs\* remained unchanged at EUR 5.8 million (EUR 5.8 million).
- The number of employees grew to 165 (150) compared with one year ago.
- EBITDA came in at EUR -5.4 million (EUR -4.8 million).
- The operating free cash flow improved to EUR -5.9 million (-6.8 million).
- Basic EPS was EUR -0.07 (EUR -0.07).
- Cash position\*\* was EUR 47.5 million on December 31, 2023 (EUR 68.7 million).

#### 1-12/2023 key financials

- Revenue came in at EUR 2.6 million, stemming from 33 different customer projects (EUR 3.5m, 35 projects in 1–12/2022).
- 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 Project Nanoenzalutamide.
- The number of employees increased to 165 (150).
- Total operating costs\* decreased by 1% to EUR 22.2 million (EUR 22.5 million).
- EBITDA came in at EUR -19.6 million (EUR -19.0 million).
- The operating loss was EUR -22.5 million (EUR -21.4 million).

- The operating free cash flow improved to EUR -23.1 million (-28.0 million).
- Basic EPS was EUR -0.26 (EUR -0.29).

(Numbers in brackets refer to the corresponding last year reporting period, unless otherwise mentioned.)

\* Defined as materials & services expenses, employee benefit expenses, and other operating expenses

\*\* Including Treasury bills. Part of the cash has been invested in short-term government bond

#### Significant events during 1-12/2023

- As of January 1, 2023, Antonio da Silva was appointed CBO and a member of the management team.
- On January 3, 2023, Nanoform established a new subsidiary in the UK, Nanoform U.K. Ltd.
- On January 10, 2023, the Board of Directors approved share subscriptions based on stock option programs 3/2019, 5/2019 and 1/2020. A total of 29,000 Nanoform Finland Plc new shares were subscribed and the entire subscription price for subscriptions made with the stock options of EUR 34 thousand was entered in the Company's reserve for invested unrestricted equity.
- On February 28, Nanoform announced two new near-term business targets for 2023: "Increased number of non-GMP and GMP projects signed in 2023 vs 2022" and "Improved operating free cash flow in 2023 vs 2022".
- Nanoform's Annual General Meeting (the "AGM") was held on April 12, 2023. The AGM approved the financial statements and discharged the Board of Directors and the CEO of the Company from liability for the financial year 2022. The Meeting decided that no dividend will be paid for the financial year that ended on December 31, 2022. The AGM further resolved the number of members of the Board of Directors to be four and the AGM re-elected Miguel Calado (Chairperson), Mads Laustsen, Albert Hæggström and Jeanne Thoma as ordinary members of the Board of Directors for the next term of office.
- On April 12, 2023, the Board of Directors approved share subscriptions based on stock option programs 2–3/2019 and 1/2020. A total of 37,000 Nanoform Finland Plc new shares were subscribed and the entire subscription price for subscriptions made with the stock options of EUR 41 thousand was entered in the Company's reserve for invested unrestricted equity.
- In April, Nanoform won a new grant from the Bill & Melinda Gates Foundation to work on several of the foundation's drug development projects.
- In May Nanoform's Manufacturer's Authorization and GMP Certificate were updated to include nanoforming of multiple APIs in the GMP facility.
- In June, Nanoform submitted a notification to the Finnish Medicines Agency to update our Manufacturer's Authorization (MIA). The objective of this notification was to include the fol-



lowing in our MIA: Our new production facilities and equipment (GMP2&3), our new Quality Control laboratory (GMP QC) and Nanoforming of APIs to be used in products with a Marketing Authorization. Due to this notification, a GMP inspection is expected to take place during 1H24.

- Nanoform previously disclosed on November 15, 2021, that it has signed an agreement to manufacture nanoformed GMP material for a European headquartered international company. Following 12 months of preclinical development work, two privately held European pharmaceutical development and manufacturing organizations decided to join Nanoform and the European headquartered international company in funding the development and commercialization of this more patient centric version of a current blockbuster drug. For this purpose, the parties entered into a collaboration agreement on November 17, 2022. Under the terms of the agreement, Nanoform and the three other parties will fund in equal shares the completion of this development program. In the event that the commercialization is successful, Nanoform expects to retain a 25% share of the net-income received by the parties. In May 2023, after Fimea renewed Nanoform's GMP Certificate, Nanoform commenced the clinical manufacture related to this project.
- In June, Nanoform and Celanese Corporation, a global specialty materials company, provided an update on their collaboration to evaluate the synergies between their respective technologies in the field of nanoparticle-enabled drug delivery. The result, presented at the Biotech Outsourcing Strategies Conference in Basel on July 3, 2023, demonstrated significant reduction in the initial burst effect seen commonly in high drug load implants by combining Nanoform's CESS<sup>®</sup> particles with Celanese's Celanese VitalDose<sup>®</sup> EVA copolymer delivery technology for drug-eluting implants. Notably they also demonstrated that nanoformed particles can enable longer sustained release properties for long-acting drug products and smaller implants. This opens up many possibilities for drug developers.
- During the third quarter, the clinical manufacture related to Project Nanoenzalutamide was successfully completed and the produced nanomaterial was released and shipped for manufacture of the final drug product. It was announced that clinical trials are expected to commence in 4Q23, that results are expected in 1Q24 and that if the results are positive, the targeted timeline for one or several license/commercial supply agreements is during 2024.
- Chief Quality Officer Johanna Kause became a member of Nanoform's management team as of September 1st, 2023. Johanna Kause, who is responsible for all matters related to quality, has been with the company since January 2021.
- We received notice of allowance from the United States Patent and Trademark Office (USPTO) for our US patent application (US17947490) directed at the process we have developed to nanoform biological molecules. We are encouraged by this positive response that reflects our innovative work also in the field of large molecules. We have filed several patent applications directed at the biologics nanoforming technology in other jurisdictions that are currently pending. Following granted patents in the United States, Japan, and Canada, we also received notification from the European Patent Office (EPO)

of their intention to grant our corresponding European patent application (EP15793857.2) directed at the CESS® technology for manufacture of our small molecule nanoparticles.

- We conducted promising initial *in vitro* trials with two major pharma companies looking at monoclonal antibodies (mAb's). These results further strengthen our proposition that nanoparticles are relevant for improved product development and more patient centric commercial products in the field of mAb's and we look forward to advancing these developments with our pharma clients.
- In October, Nanoform announced that its customer TargTex S.A. had been granted Orphan Drug Designation by the FDA for its nanoformed drug candidate TTX101 to be used in patients with malignant gliomas. The orphan drug designation follows the generation of a preclinical rodent data package in which a survival advantage was shown for this nanoform-enabled medicine candidate. 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. Hence Nanoform's proprietary technology and nanoformulation expertise will enable TargTex's drug candidate TTX101 to move towards clinic. TargTex is currently raising 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.
- In October, Nanoform announced that it had granted AstraZen-. eca Plc a global online STARMAP<sup>®</sup> license. STARMAP<sup>®</sup> is a digital Al version of the CESS® technology that enables in silico experiments to determine which molecules should be nanoformed. The license will enable AstraZeneca to screen molecules from drug discovery through to lifecycle management. As part of this licensing agreement, Nanoform will receive access to compound libraries and large data sets to undertake STARMAP® screening and propose innovative product development concepts and strategies in collaboration with AstraZeneca. This comes after several years of early-stage collaboration between Nanoform and AstraZeneca and a successfully completed technology evaluation partnership including STARMAP® which has resulted in clinical candidate feasibility studies. STARMAP® is well aligned with AstraZeneca's ambitious sustainability goals.

STARMAP<sup>®</sup> Online has been created as a direct request from Nanoform's current and future partners who seek to maintain the level of confidence STARMAP<sup>®</sup> offers, while integrating it into their own in-house molecule-selection processes. STARMAP<sup>®</sup> Online creates the opportunity for clients to perform large numbers of *in silico* CESS<sup>®</sup> experiments from their desktop. This approach further supports Nanoform's green ambition by ensuring that Nanoform progresses the molecules with the greatest probability of success. STARMAP<sup>®</sup> Online offers:

- Security and safety the interface has been developed in alignment with ISO27001:2017 standards.
- Client submissions are confidential and seen only by clients (not by Nanoform), allowing molecules to be screened without sharing structures. Outputs are presented directly to the client via the system.



- Scalability and agility: The ability to manage thousands of molecules in a single submission to support the selection of candidates from molecule libraries is possible.
- Novel insights: STARMAP<sup>®</sup> Online holds a database of some 20,000 pre-analyzed, public-domain disclosed drugs and candidates. Clients can request thematic evaluations and understand the power of CESS<sup>®</sup> in different therapeutic areas, target classes, and disease areas.
- On December 5, 2023, the Board of Directors approved share subscriptions based on stock option programs 2/2019 and 1/2020. A total of 4,000 Nanoform Finland Plc new shares were subscribed and the entire subscription price for subscriptions made with the stock options of EUR 6 thousand was entered in the Company's reserve for invested unrestricted equity.
- During 2023, 22 new non-GMP projects and one GMP project were signed, both with new and repeat customers, both US and Europe based. We also signed our first major pharma customer from Japan.
- During 2023 one new non-GMP line was commissioned, taking the total number of lines to 19 non-GMP lines and one GMP line. GMP lines 2&3 will be commissioned after they are inspected and approved by Fimea, which is expected to happen during 1H 2024.

#### Significant events after 1-12/2023

- On January 5, 2024, Nanoform announced it had completed the First Subject First Visit (FSFV) in a trial to evaluate the relative bioavailability of its nanocrystalline enabled alternative to an amorphous solid dispersion (ASD); formulation of nanoenzalutamide and Xtandi<sup>®[1]</sup>, the number one prescribed androgen receptor inhibitor first approved by the FDA in 2012 to treat prostate cancer. The single-dose, randomized, comparative bioavailability study, which is performed by a contract research organization in North America, compares enzalutamide 160 mg film-coated tablets (Bluepharma Farmaceutica S.A.) and Xtandi 4x40 mg film-coated tablets (Astellas Pharma Europe B.V.).
- On January 10, 2024, The Board of Directors of Nanoform Finland Plc decided on the issue of stock options under an option program open to all employees. The total number of option rights to be issued is at most 1,240,412. The stock options are entitled to subscribe for at most 1,240,412 shares in Nanoform. Each stock option entitles to subscribe for one new share. The subscription price for shares subscribed with stock options is EUR 1.70 per share. The total subscription price of the shares shall be paid to the company's fund for invested own free equity.
- On January 26, 2024 Nanoform announced that one of its leading nanoformulation drug products had received promising clinical results. These were from a relative bioavailability study of nanocrystalline-enabled enzalutamide (nanoenzalutamide) tablet formulation, an alternative to the amorphous solid dispersion (ASD) used in Xtandi<sup>®[1]</sup>, the number one prescribed androgen receptor inhibitor<sup>[2]</sup> first approved by the FDA in 2012, and by the EMA in 2013 to treat prostate cancer. The nanoenzalutamide tablet formulation was developed in a partnership with the ONConcept<sup>®</sup> Consortium (Bluepharma, Helm, and

Welding) whereby Nanoform's proprietary controlled expansion of supercritical solutions (CESS®) technology provides the opportunity for an improved and differentiated finished product. Tablet-burden and dysphagia are well-documented challenges for prostate cancer patients, and the development of a 160mg, single tablet per day regimen may be preferable for patients in need of reducing their total number of daily pills. The single-dose, randomized, comparative bioavailability study, which was performed by a contract research organization in North America, compared enzalutamide 160mg filmcoated tablets (Bluepharma) and Xtandi® 4x40 mg film-coated tablets (Astellas Pharma Europe B.V.). A patent application for the nanoenzalutamide formulation has already been jointly filed by Helm and Nanoform. We aim for product launch after the expiry of the enzalutamide substance patent in the respective territories. For the United States this patent expiry is expected in 2027, and in Europe in 2028. This 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. [1] Xtandi is a registered trademark of Astellas Pharma Inc. [2] Source: xtandi.com

 On February 15, 2024, Nanoform announced that it has won a grant of up to 4.3 million euros from Business Finland, the Finnish government organization for innovation funding and trade. The grant represents 50% of the costs associated with Nanoform's research and development project for nanoparticle-enabled formulation platforms for oral, inhaled, long-acting injectable, and high-concentration subcutaneous injectable drug delivery technologies for next generation medicines. The work is expected to take place during 2024 and 2025.

## Project Nanoenzalutamide and ASDs (amorphous solid dispersions)

Nanoenzalutamide is a great opportunity for us to show that small is a powerful ingredient in formulation. Due to the inherent poor solubility of the API, the current formulation of this blockbuster medicine - for treatment of prostate cancer - has been an amorphous solid dispersion ("ASD"). Amorphous API materials are notoriously unstable, and therefore require high amounts of polymers to stabilize the API - leading to a low drug load in the product and therefore, in the case of oral solid products, often to a high number of large tablets that need to be taken by the patient. This is a known problem, in particular for patient populations with challenges to swallow. The nanocrystalline formulation developed by Nanoform offers an attractive alternative with a substantially higher drug load in the final drug product and consequently a reduced tablet burden for the patient. We are encouraged by the broad interest shown in this patient centric reformulation and we look forward to signing license/supply agreements around this product opportunity in 2024.

In addition to the patient benefit, we can with our proprietary technology offer opportunities to extend IP protection for the reformulated and improved product, expecting that in many cases



our innovative formulations will be patentable. Importantly, current ASD based medicines are often protected by secondary patents that claim aspects of the ASD formulation. These secondary patents, such as in the case of the product in Project Nanoenzalutamide, often extend by several years the expiration of the primary patent claiming the API. In the case of Project Nanoenzalutamide, we believe that our nanocrystalline formulation is not in the scope of the patents claiming the ASD formulation. This should potentially enable entry earlier into the market, in the jurisdictions where the ASD formulation patents remain active, compared to ASD based generic formulations.

ASDs remain a leading formulation strategy for poorly soluble APIs, particularly for oral solid dosage forms. There are currently some 50 marketed medicines that are ASDs and these sell in aggregate for some USD 50bn annually in the world. We are currently looking at several other marketed ASD opportunities to replicate our early successes with Project Nanoenzalutamide in addition to those ASDs still in the global drug development pipeline. According to STARMAP®, almost 80 percent of the 46 ASDs we so far have starmapped may be well suited to be nanoformed by CESS®.

#### **Financial Statement Review 2023**

Helsinki, Finland – Nanoform Finland Plc ("Nanoform"), an innovative nanoparticle medicine enabling company, will publish its Q4 and FY 2023 report on February 29, 2024, at 8.10 a.m. Finnish time / 7.10 a.m. Swedish time.

The company will hold an online presentation and conference call the same day at 3.00 p.m. Finnish time / 2.00 p.m. Swedish time. Nanoform will be represented by CEO Edward Hæggström, CFO Albert Hæggström and CCO Christian Jones. The presentation will be delivered in English.

## The presentation will be broadcast live as a webcast available at:

https://ir.financialhearings.com/nanoform-q4-report-2023

#### Teleconference dial-in numbers:

Dial-in number to the teleconference will be received by registering on the link below. After the registration you will be provided phone numbers and a conference ID to access the conference. https://conference.financialhearings.com/ teleconference/2id=500/6525

teleconference/?id=50046525



#### CEO's review

What a start to the new year! After years of hard work by many dedicated and talented people both within and outside of Nanoform, it was extremely rewarding to get such a powerful set of promising data from our relative bioavailability study of nanoenzalutamide vs Xtandi<sup>®</sup>. Not only does the data in the clinical study provide a strong indication that our technology can be an improvement for medicines based on the current state-of-the-art and widely accepted industry approach of ASDs (amorphous solid dispersions), but it also gives us and our partners the reason to move forward towards pivotal studies with the aim to launch an improved patient-centric version of this blockbuster medicine in the coming years. From a broader point-of-view, it also shows the potential of what nanoforming potentially can do to many other ASDs both on the market and in the global pharmaceutical pipeline. We are further strengthened in our conviction that nanoforming can become a powerful and green new technology for the entire global pharma industry in their quest to help both patients with new and better medicines, but also help the planet by introducing environmentally friendly manufacturing technologies.

We expect nanoenzalutamide not only to be the first first nanoformed medicine to reach the market - with a planned launch in 2027 in the US and 2028 in the EU - but also to be a significant revenue driver for Nanoform already in the upcoming years. We target to execute one or several licensing/commercial supply agreements in 2024 and expect these to include customary payments already at signing and later when meeting developmental- and regulatory milestones. Long-term we expect to receive royalty payments based on sales when the product is on the market.

Nanoenzalutamide is expected to progress via the ANDA\*/ Hybrid generic pathway and as such will need to show bioequivalence versus the originator product, Xtandi<sup>®</sup>. In the eyes of the regulators, bioequivalence typically means 80%–125% of the Cmax and AUC in a large cohort study in fed and fasted states with a 90% confidence interval.

\*ANDA=Abbreviated New Drug Application

The global annual sales of Xtandi® is presently USD 6bn and growing. We expect nanoenzalutamide to take a meaningful share of this market through its highly patient centric product differentiation (1 tablet vs 4 tablets) and unique IP position (different technology, crystalline product, different excipients). We are now actively pursuing commercial licensing and marketing partners for the product together with our partners in the ONConcept® consortium. We see the program to be attractive to value added medicine companies as a uniquely differentiated and high value supergeneric product that can enable a launch of the product before the entry into the market of other generic products based on the ASD formulation, for which the originator currently holds patents in both Europe and the US (with expiry dates in 2033). For the originator company we believe the nanocrystalline single tablet product offers a patient centric life cycle extension strategy with compelling sustainability advantages that would be difficult for generic competitors to match. Avoiding the inherent stability challenges associated with amorphous materials is also a clear benefit for any company considering alternative formulation approaches.

Xtandi-tablets are formulated using a solubility-enhancement spray-drying process to create an amorphous solid dispersion. The major challenge with spray drying is that the process often requires large amounts of undesirable and toxic organic hydrocarbon solvents. Nanoform's CESS® process uses  $CO_2$  of recycled origin, and is organic hydrocarbon solvent-free, offering a greener alternative to medicine developers that seek to be both patient- and planet-centric. Nanoform are working on continuous improvement of the CESS® technology to further recycle  $CO_2$  used by the process to become a carbon sink. This will be an attractive proposition for the pharma industry to achieve its ambitious net zero goals. There are already concerns in the industry that those industrial approaches that have a heavy carbon footprint, such as spray drying, may even lose their relevance in the future because of their environmental burden.

The timelines for the commercial launch of nanoenzalutamide are demanding, but achievable. In 2024 we need to manufacture circa 100 kg of nanoformed GMP material for the registration batches and the pivotal bioequivalence studies in the EU and the US that are expected to commence late in 2024, with the read-outs in 2025. When positive, the submissions of the dossiers should be in 2025-26, with the aimed product launch after the expiry of the enzalutamide substance patent in the respective territories. For the United States this patent expiry is expected in 2027, and in Europe in 2028.

A few words on the performance outside the nanoenzalutamide project: On the business development side we are making solid progress among large pharma, with a growing interest also in our biologics technology. While the biotech sector is still held back by tough funding conditions, there are clear signs of increased activity levels. While our revenue was hampered in 2H23 by low project signings in 2H22, the higher amount of signings in 2023 vs 2022 and the significant interest in Nanoform we have seen after the announcement of the nanoenzalutamide results make me confident in expecting more projects signed and improved cash flow in 2024 compared with 2023. We also have clearly more - by number and depth - strategic discussions with large and mid sized pharma compared to a year ago.

For Nanoform the last three years since the IPO has been about making large investments and building a capable organization. The coming three to five years will be about preparing to launch nanoformed products together with partners onto the global markets. We are ready for the challenge. I look forward with confidence and excitement to the coming years. None of this can be done without our amazing employees and great partners. My sincere THANK YOU to you all for your continued dedication to Nanoform and for the inspiring and innovative work for which we're known.

Best Regards,

Prof. Edward Hæggström, CEO Nanoform



#### Nanoform Group's key figures

#### 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

# Company near-term business targets for 2024

- Increased number of non-GMP and GMP projects signed in 2024 vs 2023
- Improved operating free cash flow in 2024 vs 2023
- To sign one or several license/commercial supply agreements during 2024

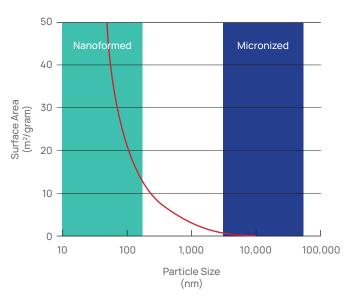
# Company mid-term business targets 2025

- To nanoform at least 70 new Active Pharmaceutical Ingredients (API) annually
- To have in place 35 operating production lines of which 7 to 14 are expected to be GMP production lines
- Over 90 percent gross margin
- To have 200-250 employees
- To be cash flow positive



# Smaller particle size can improve a drug's bioavailability

Specific Surface Area vs. Particle size



The surface area increases 30 fold from a 10 micron' 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

#### Small is powerful - Nanoform in brief

Nanoform Finland Plc is a public company offering expert services in nanotechnology and drug particle engineering for the global pharma industry. The company works with its partners to overcome drug development and delivery challenges through its game-changing technologies and novel formulation and GMP manufacturing capabilities.

Nanoform's services span the full range from small- to large-molecule drugs, and the company has a growing pipeline of customers that represent global large, mid-sized and specialty pharmaceutical as well as biotechnology companies.

Nanoform's mission is to enable a significant increase in the number of drugs that progress to clinical trials and reach the market. The company targets the pharmaceutical developers and manufacturers of drugs for which safety and efficacy could be improved by increased bioavailability or novel drug delivery routes. Nanoform's size reduction technologies, including its patented and scalable CESS® technology and its biologics platform, vastly increase the surface area of drug particles to enhance bioavailability or open up more patient-centric, local drug delivery routes.

Nanoform has not outsourced or out-licensed its patent protected technologies, to keep control of its technology, service offering and know-how.





#### Our technologies – Controlled Expansion of Supercritical Solutions (CESS®)

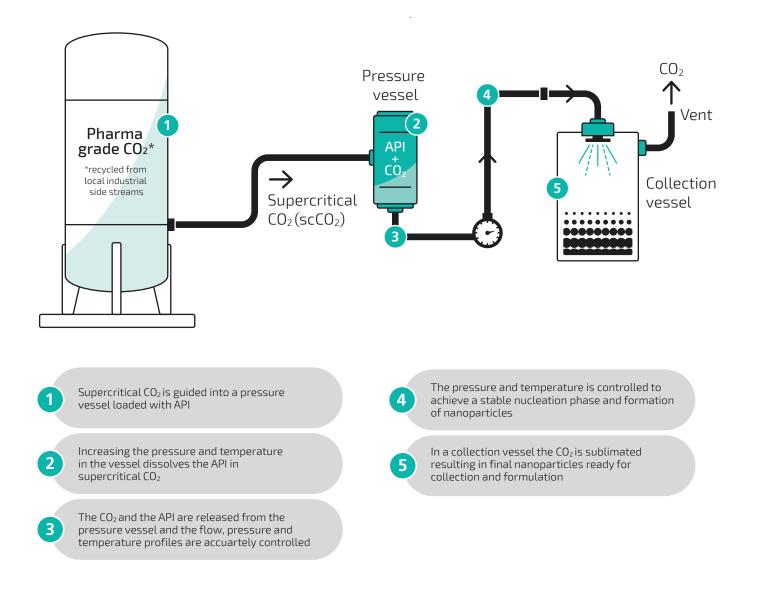
Nanoform's patented CESS® technology has demonstrated its ability to produce crystalline or stable amorphous nanoparticles below 100 nm, and at times as small as 10 nm, from solution without the use of solvents, excipients, or complex production processes. The application of the CESS® technology platform provides an opportunity for Nanoform's customers to improve and tune the particle properties of their small-molecule APIs – for example, size, shape, and polymorphic structure, thus improving API solubility and bioavailability.

The CESS® technology may reduce the failure of drugs during clinical trials by enhancing the performance and safety of APIs. It can also allow drugs that previously failed in clinical trials to be revisited and potentially achieve success. In addition, it may improve the pharmacokinetic properties of drugs (both in the pharmaceutical pipeline and those already on the market), and provide new commercial opportunities for drugs. Ultimately, the benefits unlocked by CESS® will be felt by patients as the technology enables more and enhanced new drugs to reach the market.

#### STARMAP® - The digital twin of CESS®

STARMAP® Online is a predictive sparse-data AI-based platform that can be applied to pick the winners among candidate molecules. It augments historical experimental results with detailed expert knowledge to determine which APIs are most likely to achieve success through the CESS® nanoparticle engineering process.

STARMAP® presents an opportunity for the rational design of patient-centric drug development, and can be applied to novel APIs, as well as existing brands, to ensure that the projects with the highest chances of success are targeted, avoiding wasted resources and improving efficiency. STARMAP® is currently available as a subscription to Nanoform's customers, which can be accessed online.



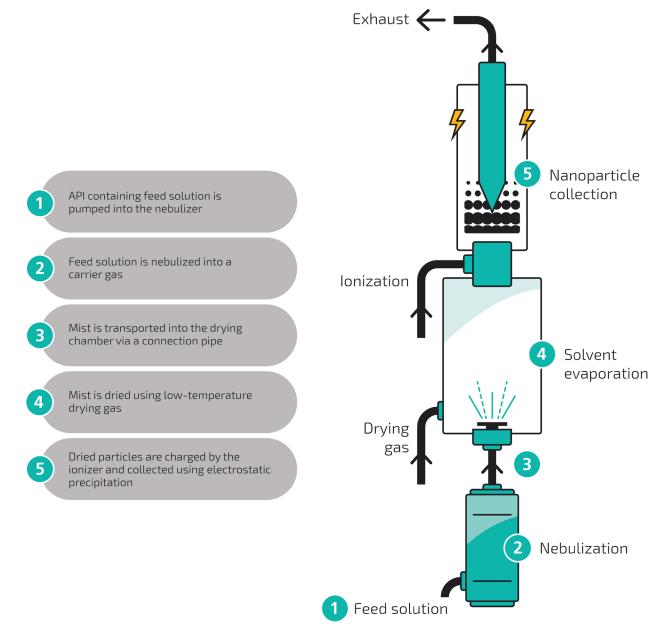


#### **Biologics**

Nanoform's biologics technology is a gentle bottom-up process that nanoforms large-molecule therapeutics, reducing their particle size to as small as 50 nm while retaining their biological activity.

As the technology does not necessitate harsh conditions such as high temperatures, it has wide applicability even for temperature-sensitive therapeutic biomolecules, such as enzymes, and can be applied to large molecules up to 150 kDa. By reducing particle size, the technology opens up new drug delivery opportunities, and may facilitate enhanced drug loading and tailored release profiles.

Most traditional biologics are administered intravenously, however by utilizing Nanoform's technology, it may be possible to formulate for alternative, more patient-centric administration routes, such as intranasal, pulmonary, or oral delivery.





#### Small is an ingredient in formulation

#### Formulating nanoformed particles the right way

Our pharmaceutical development team leverages their deep understanding of nanomaterials science and nanoformation expertise to unlock the full potential of nanoformed APIs and deliver formulations that meet customer requirements. Nanoform supports all dosage form development, with specific expertise in oral, inhaled, injectable, and ophthalmic formulations.

The team follows a well-designed formulation development and selection process, with the goal of rapidly progressing drug candidates and optimizing the formulation for the development phase, from preclinical through to clinic and lifecycle.

The benefits of partnering with Nanoform for nanoparticle-optimized formulations can include enhanced bioavailability and the opportunity to reduce dose, simpler formulations, and increased dosage form flexibility. Additional advantages can include reduced side effects, optimized exposure in toxicology studies, and reduced variability in pharmacokinetic parameters.

## Nanoform's analytical services ensure consistency

Analytical chemistry plays a crucial role in characterizing and understanding materials made from nanoforming and formulation processes. We use a variety of techniques to analyze our nanoparticles and formulations and ensure that they meet strict quality and safety standards. Our analytical team utilizes stateof-the-art equipment and software to accurately measure the properties of our nanoparticles, including purity, size, shape, and crystallinity. This information is essential for understanding how to develop our formulations and predict how our drugs will interact *in vivo* so as to optimize their efficacy.

## Highly-potent APIs can be safely formulated in Nanoform's GMP facilities

Nanoform's globally unique GMP facilities utilize CESS® to manufacture API nanoparticles to GMP standards. The facilities can handle highly-potent APIs (HPAPIs) with occupational exposure limits (OELs) of 30 ng/m<sup>3</sup>. Recipe control via automation as well as Wash-in-Place and Clean-in-Place capabilities enable faster and more efficient cleaning between campaigns, reducing the overall downtime of GMP manufacturing, and increasing productivity.



#### Market outlook

Nanoform operates in one of the world's largest markets, the global pharmaceutical market, whose turnover exceeds USD 1,000 billion and where the annual R&D budget exceeds USD 200 billion. Despite the enormous investments in R&D, less than 50 new drugs have been approved by the FDA annually on average during the last ten years. One of the key reasons why so few medicines are approved each year is low bioavailability of the API. With 70 to 90 percent of new drugs being poorly soluble we expect that the challenges with bioavailability will only increase going forward. Hence, we have seen significant interest in our potentially ground-breaking technology platform from the global pharma market. This broad interest comes from global large, mid-sized, specialty pharmaceutical as well as from biotechnology companies. We expect the high customer interest in our technology offering to continue.

The drug development industry is highly regulated and characterized by a step-by-step development process, from discovery and clinical trials to commercialization. It is considered a defensive industry where the underlying demand is non-cyclical and steadily increasing as the global population grows wealthier and older and as chronic diseases become more prevalent.

The high attrition rate in the global drug development pipeline – with one of the key reasons being low bioavailability – limits the number of new drugs that reach the market. This increases the maturity of pharmaceutical companies' commercial product portfolios, with the average share of revenue stemming from drugs that have been on the market for more than ten years amounting to more than half of their revenue for many of the world's largest pharma companies. With an old product portfolio, the vulnerability to upcoming patent expirations increases as does the importance of lifecycle management of existing drugs. As Nanoform's technology platform provides an opportunity to help not only lower the attrition of new drugs in development but also with lifecycle management of existing drugs on the market, we foresee continued interest in the technology. By providing opportunities for pharma companies to seek to extend patent protection by allowing for patents for, among others, new indications, dosage forms, and delivery mechanisms, our technology may create significant value to our customers. Many jurisdictions allow for alternative simplified regulatory pathways, such as section 505(b) (2) of the Federal Food, Drug and Cosmetic Act in the U.S., for already commercialized drugs for which clinical safety or efficacy data is already available.

Nanoform's commercial operations are at an early stage and during the period its business operations have included R&D activities, non-GMP projects, tech transfer to GMP, and manufacture of GMP material. Our existing customers include global large, midsized, and specialty pharmaceutical as well as biotech companies. Major pharma companies are in general entities integrated across the entire pharmaceutical value chain and therefore often do the marketing and sales of the drugs they have developed. The price of a drug, set by a pharmaceutical company, is often a function of several factors, e.g., the potential competitive landscape it faces, the need for financing future R&D of novel drug candidates, and the benefit or value the drug is deemed to add for its target group. However, actual pricing mechanisms, including, e.g., potential reimbursement and regulatory restrictions on pricing of drugs, vary between different jurisdictions. Contract development and manufacturing organizations (CDMOs) focus specifically on drug development and manufacturing. Pricing of the services of these companies differs from pricing by pharma companies since CDMOs in general do not, by themselves, commercialize the drugs they develop or manufacture. Instead, the compensation for their services is often based on a combination of compensation for supply of material, milestone payments, royalties, and license payments. While price is an important factor in client negotiations, the most important and decisive factor is how much value the technology and service offer. We believe our proprietary technology offers significant value and hence will be priced with a material premium to traditional technologies.



#### Financial review for January 1-December 31, 2023

#### Revenue

Nanoform Group's revenue in January–December decreased by -26% to EUR 2,566 (3,487) thousand.

The revenue in 1–12/23 stemmed from 33 (35) different customer projects. Working hours account for the vast majority of project expenses booked, and revenues are recognized over the course of the projects based on the percentage of completion method.

#### Results

Nanoform Group's gross profit decreased to EUR 1,717 (3,147) thousand and the gross margin was 67% (90%) in January–December 2023.

The gross margin was negatively impacted by the increased amount of external GMP QC services related to the GMP manufacture of Project Nanoenzalutamide. Excluding the cost of the external GMP QC services, our underlying gross margin was above 90% thanks to our new  $40m^3 CO_2$  bulk tank system that was taken into usage in 4Q22 and where the unit cost is a fraction compared with using multiple gas cylinders in the production process. In June Nanoform submitted a notification to Fimea to update our Manufacturer's Authorization. The notification included our new GMP QC laboratory and an inspection is expected to take place during 1H24. This will help our gross margin return to the 90+ levels we target.

#### Financial position and cash flows

The loss before tax was EUR -20,733 (-22,056) thousand. Earnings per share was EUR -0.26 (-0.29).

Nanoform Group's total assets at the end of the review period were EUR 78,135 (100,641) thousand, and equity accounted for EUR 66,947 (87,212) thousand. Cash and cash equivalents were EUR 14,232 (68,740) thousand excluding T-bills. T-bills amounted to EUR 33,261 thousand in the reporting period (balance sheet value). Net debt amounted to EUR –41,235 (-61,807) thousand including T-bills.

Nanoform Group's net cash flow from operating activities in January-December was EUR -18,001 (-20,080) thousand. The change in the working capital was EUR -229 (-2,021) thousand. The Group investments have slowed down significantly as the investments for expanding the manufacturing capacity have been made in previous years (several GMP lines with separate cleanrooms, the 40m<sup>3</sup> CO<sub>2</sub> bulk tank system, a new ERP system and a Biologics pilot line for GMP in addition to additional non-GMP production lines). The total cash-based property, plant, and equipment investments amounted to EUR -3,477 (-8,965) thousand. The net cash flow from investing activities was EUR -35,471 (-9,625) thousand including short-term investments to T-bills. Cash flow from financing activities was EUR -1,195 (22,737) thousand. In the comparable year cash flow was positively affected by a directed share issue in March 2022 increasing the equity by EUR 23,668 thousand net of transaction costs.

#### Investments, research and development

The Group's investments in property, plant, and equipment in January–December 2023 amounted to EUR 3,477 (8,965) thousand, consisting mainly of investments in additional GMP and non–GMP production lines at the current manufacturing site. Additions to GMP and non–GMP facilities are classified as construction in progress until a GMP Certificate is obtained for the new GMP lines and until they are commissioned for customer projects for new non–GMP production lines.

The Group R&D expenditure recognized as expenses, including internal AI expenses, amounted to EUR 4,150 (4,606) thousand. R&D expenses consist of salaries as well as external R&D services. R&D expenditures are recognized as employee benefit expenses and other operating expenses in the consolidated statement of comprehensive income.

#### Personnel and the Board of Directors

During the last twelve months the number of employees has grown by 10 percent and at the end of the review period, the Group had 165 (150) employees representing 38 nationalities. Within Nanoform's international team of highly skilled professionals there are 38 PhD's from different fields including e.g. physics, chemistry, pharma, and biology. Nanoform Group has been able to attract talent with diverse skills. At the end of the review period 23 employees worked in GMP Manufacturing, 45 in R&D (including non-GMP customer projects), and 7 in Customer Project Management. Quality Control had 25 and Quality Assurance 9 professionals. The Commercial team consisted of 9 professionals. The Engineering & Maintenance teams employed 14 employees and Industrialization and Technical Development teams 6 employees. Nanoform has also been able to attract talent in Legal 3 and IT 6 and in corporate functions 18 (e.g., Business Operations, Finance, Procurement, IR, HR).

The company's Annual General Meeting convened on April 12, 2023, re-elected Miguel Calado (Chairperson), Mads Laustsen, Albert Hæggström, and Jeanne Thoma as ordinary members to the company's Board of Directors for the next term of office. The CEO was Edward Hæggström.

#### Shares and shareholders

Nanoform's share is listed on the Premier segment of Nasdaq First North Growth Market in Helsinki (ticker: NANOFH) and Stockholm (ticker: NANOFS).

Nanoform's registered share capital amounted to EUR 80,000 (80,000). At the end of the review period, the company had 78,433,964 (78,363,964) shares after share subscriptions by stock options in 2023. The share's volume weighted average price during the review period was EUR 1.97 (4.02) and SEK 22.99 (41.18). The highest price paid during the January–December review period was EUR 3.30 (6.96) and SEK 38.95 (71.10) and the lowest price paid EUR 1.47 (2.48) and SEK 17.00 (27.05). The closing price of the share at the end of review period was EUR 1.59 (3.20) and SEK 18.80 (37.00). The market value of the share capital on December 31, 2023, was EUR 124 (251) million. Nanoform had more than 9,500 shareholders at the end of the period - some 1,000 more than a year ago - with somewhat more than 75 percent of them holding EUR nominated shares and somewhat less than 25 percent of



them holding SEK nominated shares. The 25 largest shareholders held some 72 percent of all Nanoform's shares and votes at the end of the review period. The ownership structure can be found on Nanoform's internet pages <u>Ownership structure – Nanoform</u> <u>small is powerful</u>. (Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear Sweden, Euroclear Finland and Morningstar)

#### Share-based incentive plans

During the review period Nanoform had 17 active share-based incentive plans for the members of the Board of Directors, key persons, and employees of the Group: option programs 1–5/2019, 1–5/2020, 1–5/2021, 1/2022, and 1/2023. Based on all the option programs, with strike prices ranging from EUR 1.10 to EUR 9.00 a total maximum number of 4,614,510 shares could potentially be subscribed (For more info see Note 7).

#### Near-term risks and uncertainties

Nanoform operates in a strictly regulated industry, the pharmaceutical industry. The Group's business is based on new technology that has not yet been widely applied in humans. As Nanoform is still a young company, the viability of its business model has not yet been proven and the Group has been operating at a loss, with no proof so far of being able to sustainably cover its costs with revenues without additional external funding. The most important business-related risks are associated with the Group's growth targets and their achievement with the company's chosen strategy. Industry-related risks are mainly associated with a target market that is both highly regulated and conservative and where adaptation of new technologies can take longer than expected.

Risks associated with the Group's financial position mainly consist of currency-, credit- and counterparty risks as well as the stock market risk from share investment. Foreign exchange fluctuations arise from SEK, GBP, USD, NOK, and JPY currency exposure. The Company's counterparty risks consist mainly of contracts between external customers, suppliers and partners in co-operation and financial institutions. Direct stock market risk stems from the changes in the market value of the owned Herantis Pharma Plc shares. Investments into short-term government bonds (Treasury Bills, duration less than one year) are considered risk free investments from a counterparty (credit risk) point of view but may include currency risk. Nanoform does not hedge its currency or stock market risk. Risks related to legislation, rules and regulatory compliance are associated with the group's sector of industry. For further risk analysis see Nanoform's annual report: Investors - Nanoform small is powerful.

#### Decisions by the Annual General Meeting and the Constitutive Meeting of the Board of Directors

Nanoform held its Annual General Meeting (the "AGM") for 2023 on April 12, 2023.

The AGM approved the financial statements and discharged the Board of Directors and the CEO of the Company from liability for the financial year 2022. The AGM decided that no dividend will be paid for the financial year that ended on December 31, 2022.

The number of members of the Board of Directors was confirmed to be four and the AGM re-elected Miguel Calado as Chairperson, Mads Laustsen, Albert Hæggström, and Jeanne Thoma as ordinary members of the Board of Directors for the next term of office.

The AGM confirmed a monthly compensation of EUR 8,000 for the Chairman and EUR 5,000 for the Board Members, EUR 2,500 for the Chairman of the Audit and Compensation Committee and EUR 1,500 for the Members of the Audit and Compensation Committee.

The AGM resolved further that the remuneration will be paid in four (4) installments during the term, each installment after the publication of the respective interim report for the periods 1 January 2023–31 March 2023, 1 April 2023–30 June 2023, 1 July 2023–30 September 2023, 1 October 2023–31 December 2023. Each board member has undertaken to use approximately 50% of the aforementioned remuneration to purchase shares in the company within two weeks from the publication of the aforementioned interim reports, or as soon as possible in accordance with applicable legislation. The Annual General Meeting also resolved that the travel expenses of the members of the Board of Directors are compensated in accordance with the Company's travel rules.

The AGM resolved that PricewaterhouseCoopers Oy with Tomi Moisio as the auditor in charge were re-elected as the Group's auditor. The Auditor's fee will be paid in accordance with a reasonable invoice approved by the Company.

The AGM authorized the Board of Directors to repurchase Nanoform's own shares. Altogether no more than 7,700,000 shares may be repurchased. The authorization will be valid until the beginning of the next Annual General Meeting.

On April 12, 2023, at the constitutive meeting following the annual general meeting, the Board of Directors resolved to elect as members of the Audit and Compensation Committee (AC): Miguel Calado (Chairperson), Jeanne Thoma (Ordinary member), and Mads Laustsen (Ordinary member). The Audit and Compensation Committee is a permanent committee of the Board of Directors and acts in accordance with its charter as adopted by the Board of Directors.



## 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
Loss for the period attributable to the equity holders of the parent company		-5,339	-5,568	-20,756	-22,075
Other comprehensive income	-		_		
Items that may be reclassified to loss in subsequent periods					
Translation differences		-5	-8	-4	4
Other comprehensive income, net of tax		-5	-8	-4	4
Total comprehensive income total		-5,344	-5,576	-20,760	-22,071
Total comprehensive income for the period attributable to the equity holders of the parent company		-5,344	-5,576	-20,760	-22,071
Basic earnings per share, EUR	_	-0.07	-0.07	-0.26	-0.29
Diluted earnings per share, EUR		-0.07	-0.07	-0.26	-0.29

The company's potential dilutive instruments consist of stock options. As the company's business has been unprofitable, stock options would have an anti-dilutive effect and therefore they are not taken into account in measuring the dilutive loss per share. Financial income and expenses have not been netted in the quarterly reports during 2023.

### Consolidated statement of financial position

EUR thousand	Note	Dec 31, 2023	Dec 31, 2022
ASSETS			
Non-current assets			
Intangible assets		614	383
Property, plant, and equipment	6	26,704	27,127
Investments in shares		1,479	1,923
Other receivables		288	288
Total non-current receivables		29,085	29,721
Current assets			
Inventories		218	6
Trade receivables		418	829
Other receivables		105	274
Investments in short-term government bonds	9	33,261	
Contract assets and prepayments		816	1,071
Cash and cash equivalents	8	14,232	68,740
Total current assets		49,050	70,920
Total assets		78,135	100,641
EQUITY AND LIABILITIES			
Equity			
Share capital		80	80
Reserve for invested unrestricted equity		152,650	152,569
Accumulated deficit		-65,028	-43,362
Loss for the period		-20,756	-22,075
Total equity		66,947	87,212
Non-current liabilities			
Lease liabilities	8	5,203	5,896
Advances received			
Trade payables			
Total non-current liabilities		5,203	5,896
Current liabilities			
Provisions		19	
Lease liabilities	8	1,054	1,037
Advances received		443	447
Trade payables		883	1,192
Other liabilities		311	233
Accrued expenses	10	3,275	4,624
Total current liabilities		5,985	7,533
Total liabilities		11,188	13,429
Total equity and liabilities		78,135	100,641

## Consolidated statement of changes in equity

EUR thousand	Share capital	Reserve for invested unrestricted equity	Translation differences	Accumulated deficit	Total equity
At January 1, 2023	80	152,569	6	-65,443	87,212
Loss for the period				-20,756	-20,756
Other comprehensive income					
Translation differences			-4		-4
Transactions with equity holders of the Company					
Increase of the share capital					
Share subscription with stock options		81			81
Share issue					
Share-based payments				413	413
At December 31, 2023	80	152,650	2	-85,786	66,947
	Share	Reserve for invested	Translation	Accumulated	Total

EUR thousand	capital	unrestricted equity	differences	Accumulated deficit	equity
At January 1, 2022	80	128,599	2	-44,187	84,494
Loss for the period				-22,075	-22,075
Other comprehensive income					
Translation differences			4		4
Transactions with equity holders of the Company					
Increase of the share capital					
Share subscription with stock options		303			303
Share issue*		23,668			23,668
Share-based payments				819	819
At December 31, 2022	80	152,569	6	-65,443	87,212

\* Netted transaction costs EUR 892 thousand

### Consolidated statement of cash flow

EUR thousand	Note	1-12/2023	1-12/2022
Cash flow from operating activities			
Loss before tax		-20,733	-22,056
Adjustment for:			
Depreciation, amortization, and impairment losses	6	2,878	2,382
Finance income and expenses		-1,518	64
Share-based payments	7	413	785
Other adjustments*		95	37
Change in net working capital:			
Trade and other receivables		65	-1,408
Trade payables and other liabilities		-82	-607
Change in inventory		-212	-6
Change in other receivables (non-current)		-0	-2
Interest paid		-7	-204
Interest received		1,110	373
Paid tax		-11	-19
Net cash used in operating activities		-18,001	-20,080
Cash flow from investing activities	-		
Payments for intangible assets		-329	-160
Payments for property, plant, and equipment	6	-3,477	-8,965
Investments in short-term government bonds		-32,143	
Payments for investments		478	-499
Net cash used in investing activities		-35,471	-9,625
Cash flow from financing activities	-		
Proceeds from share issues			24,560
Transaction costs from the share issues			-892
Acquisitions of treasury shares			
Share subscription with stock options		81	303
Repayment of R&D loans			
Repayment of lease liabilities	8	-1,276	-1,233
Net cash from financing activities		-1,195	22,737
Net increase (+) decrease (-) in cash and cash equivalents		-54,667	-6,968
Cash and cash equivalents at the beginning of period		68,740	75,733
Effects of exchange rate changes on cash and cash equivalents		159	-25
Cash and cash equivalents at the end of the period		14,232	68,740
Cash and cash equivalents and short-term government bonds at the end of pe		46,375	68,740

EUR thousand	1-12/2023	1-12/2022
Lease adjustments		12
Other operating expenses - provision for onerous contract	19	-1
Other adjustments -provision for credit loss	75	26
Total	94	37



### **Selected notes**

#### 1. Company information

Nanoform ("Nanoform", "Group") is an international group offering nanoforming, formulation and analytical services for the global pharma and biotech industry. The parent company, Nanoform Finland Plc (formerly Nanoform Finland Ltd, the "Company") is a company organized under the laws of Finland and its business ID is 2730572-8. The registered address of the head office is Viikinkaari 4, 00790 Helsinki, Finland.

#### 2. Accounting policies

This financial information for the January–December 2023 periods has been prepared in accordance with IAS 34 Interim Financial Reporting. In preparation of this report, Nanoform has applied the same accounting policies, methods of computation and presentation as in the financial statements for the year ended December 31, 2022.

After an entity was established in the USA, a Nanoform Group was founded in 2020. In 2023, a second subsidiary was established in the UK. The consolidated financial statements include the parent company, Nanoform Finland Plc, and the subsidiaries in the USA and in the UK. The parent company holds 100% ownership of its subsidiaries. The subsidiaries are consolidated using the acquisition method. All intragroup transactions, receivables, liabilities, and unrealized gains are eliminated in the consolidated financial statements.

The consolidated financial statements are presented in euros. which is the functional currency of the parent company. The statements of comprehensive income and the statements of cash flows of foreign subsidiaries, whose functional currency is not euro, are translated into euro at the average exchange rates for the reporting period. The statements of financial position of such subsidiaries are translated at the exchange rate prevailing at the reporting date. Translation differences resulting from the translation of profit for the period and other items of comprehensive income in the statement of comprehensive income and statement of financial position are recognized as a separate component of equity and in other comprehensive income. Also, the translation differences arising from the application of the acquisition method and from the translation of equity items cumulated subsequent to acquisition are recognized in other comprehensive income. The figures in this report have been rounded and consequently the sum of individual figures may deviate from the presented sum figure.

The preparation of interim and annual reports requires management to make decisions, estimates and assumptions that affect the application of accounting policies and the recognized amounts of assets, liabilities, revenue, and expenses. Estimates and judgements are reviewed regularly. The Group's management has used judgment to review, analyze and evaluate revenue recognition for non-GMP and GMP projects. Nanoform recognizes revenue over time as the project performance does not create an asset with an alternative use to the Nanoform Group and the Nanoform Group has an enforceable right to payment for performance to date. The Group's management has used judgment when evaluating the leasing agreements e.g., the options to renew and terminate the leasing agreements at specific dates, the probability of Nanoform using these options and by determining the appropriate discount rate for the leasing agreements. The management has also used judgment to evaluate the economic lifetime of property, plant, and equipment. Management will review technological development regularly in the future to ensure that property, plant, and equipment are carried at no more than at their recoverable amount.

Nanoform's Board of Directors has approved this report in its meeting on February 28, 2024. This report is not audited or reviewed by the auditors of the Group.

# 3. Significant changes during the reporting period

The Group's results of operations have fluctuated significantly from period to period in the past and are likely to do so in the future. The financial position and performance of the Group was particularly affected by the following events and transactions during the reporting period:

- Revenue decreased due to the lower order intake in 2H/2022. Revenue consists of multiple projects in which the Group has offered nanoforming, formulation and analytical services for the global pharma and biotech industry. (See note 4 Segment information and revenue).
- Employee benefit expenses continued to represent the majority of the Group's total operating expenses during the review period. Employee benefit expenses consisted of short-term employee benefit expenses (mainly salaries), post-employment benefit expenses (defined contribution pension plans) and share-based payments (stock options). The employee headcount increased by 10% to 165 (150), while the total employee benefit expenses increased by 5% to EUR 14,726 (14,010) thousand in the review period.
- Other operating expenses included premises expenses, IT expenses, marketing and communication expenses, external consultant and professional fees, travel expenses, voluntary personnel related expenses, external R&D expenses, and other expenses. The main reason for the decrease in the other operating expenses compared with the same period last year is the decrease in the IT expenses, SAP S4/HANA was implemented in January 2023 (see note 5 Other operating expenses).
- Finance income and expenses stemmed from changes in foreign exchange rates in SEK, GBP, USD, NOK and JPY currencies and fair market value changes in the owned Herantis Pharma shares as well as interest income and expenses.
- Nanoform has invested part of its cash into short-term government bonds issued by Nordic (Finland, Sweden, Norway) and



European (Germany, France) governments in order to diversify and decrease bank risk. The short-term government bonds are planned to be held until maturity and measured at amortized cost applying the interest rate method. In the future Nanoform may include UK and US T-bills as part of cash management.

- Share subscriptions based on stock option programs approved by the Board of Directors on January 10, 2023, on April 12, 2023, and on December 5, 2023. The total subscription price for subscriptions made with stock options of EUR 81 thousand was booked in the reserve for invested unrestricted equity.
- The change in property, plant, and equipment book value is mainly related to completed constructions in non-GMP lines and quality control equipment. GMP 2&3 construction are classified in progress until new GMP certificates are obtained. Additions to non-GMP facilities are classified as construction in progress until non-GMP production lines are commissioned (see note 6 Property, plant, and equipment).

#### 4. Segment information and revenue

Nanoform offers nanoforming, formulation, and analytical services for the global pharma and biotech industry. Nanoform's chief operating decision maker is the Chief Executive Officer (CEO). The CEO manages the Group as one integrated business and hence, the Group has one operating and reportable segment.

Nanoform's revenue during the reported period is recognized from customer contracts in Europe and the United States (defined by the domicile of customer). The Group's strategy is to offer expert services widely in order to minimize dependence from a single customer or project. Nanoform's revenue consists of non-GMP and GMP projects related to nanoforming, formulation and analytical services provided to customers globally. Nanoform's customer contracts include one or multiple performance obligations. In the customer contracts, every separate nanoformed API is considered as a separate performance obligation, as the customer can receive benefit from every single separately nanoformed API. Nanoform recognizes revenue over time as the project performance does not create an asset with an alternative use to the Nanoform Group and the Nanoform Group has an enforceable right to payment for performance to date. Two different customers' revenue during the reporting period accounts for more than 10% of the total cumulative revenue. The following table summarizes the revenue breakdown

EUR thousand	10-12/2023	10-12/2022	1-12/2023	1-12/2022
Europe	264	568	1,464	1,961
United States	137	418	1,103	1,526
Total	401	986	2,566	3,487
EUR thousand	10-12/2023	10-12/2022	1-12/2023	1-12/2022
EUR thousand Services transferred over time	<b>10-12/2023</b> 401	<b>10-12/2022</b> 986	<b>1-12/2023</b> 2,566	<b>1-12/2022</b> 3,487



#### 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

#### 6. Property, plant, and equipment

Nanoform's property, plant, and equipment consists of leased premises and apartments (right-of-use assets), improvements to leased premises, machinery and equipment and construction in progress.

The right-of-use assets consist of Nanoform's leased premises. Construction in progress consists of expenses related to new GMP lines, and non-GMP lines as well as the new equipment related to quality control which do not yet fulfill the activation criteria. Minor part of the PPE construction in progress has been reclassified to computer software during 2Q2023

EUR thousand	Machinery and equipment	Right-of-use assets	Improvements to leasehold premises	Construction in progress	Total
Net book value at January 1, 2023	5,295	6,437	1,125	14,271	27,128
Additions	624	398	9	1,652	2,684
Disposals*	-165				-165
Reclassification	2,025		424	-2,613	-163
Depreciations	-1,523	-1,076	-180		-2,779
Net book value at December 31, 2023	6,256	5,760	1,378	13,310	26,705
Net book value at January 1, 2022	3,465	7,213	1,233	7,807	19,718
Additions	384	332	31	9,277	10,024
Disposals*		-56		-241	-297
Reclassification	2,565		6	-2,571	
Depreciations and impairments**	-1,120	-1,053	-145		-2,317
Net book value at December 31, 2022	5,295	6,437	1,124	14,272	27,127

\* Disposals consist of the changes in right-of-use assets due to shortening of leasing period. Disposals in machinery and equipment and construction in progress are mainly due to changes in materiality considerations. \*\* Impairments consist of changes in machinery and equipment carrying amount due to fast technological development.



#### 7. Share-based payments

Nanoform has 17 share-based incentive plans: Option programs 1–5/2019, 1–5/2020, 1–5/2021, 1/2022, and 1/2023. The option programs are targeted to members of the Board of Directors, key persons, and employees of the Group. Many of the employees are included in the share-based incentive plans. The 1–5/2019 share-based incentive plans are valid until further notice. The 1–5/2020, 1–5/2021, 1/2022, and 1/2023 share-based incentive plans have vesting periods from 6 to 12 months from the grant date. The effect of all stock options booked to the earnings of the review period was EUR 413 (819) thousand.

The factors used to determine the fair value and the end of the subscription periods of the 2019–2023 stock option programs are presented in the following table

Option program	Fair value of the Company share at grant date, EUR	Subscription price of the Company share with options, EUR	Volatility, %	Risk free interest rate, %	Fair value of the option, EUR	End of the share subscription period
01-05/2019	1.30-1.62	1.10	64.85	0.01	0.74-1.00	Until further notice
01-05/2020	1.77-4.30	1.65-5.00	43.25-64.85	-0.55-0.01	0.97-2.11	Mar 10, 2025-Oct 23, 2025
01-05/2021	5.97-7.50	9.00	44.97-47.62	0.01	1.72-2.49	Apr 6, 2026–Aug 27, 2026
01/2022	3.52	9.00	42.5	1.33	0.65	June 6, 2027
01/2023	2.02	2.5	48.25	3.01	0.79	Sept 11, 2028

#### 8. Net debt

The book value of Nanoform's net debt is summarized in the table below:

EUR thousand	Dec 31, 2023	Dec 31, 2022
Cash and cash equivalents	-14,232	-68,740
Short-term government bonds	-33,261	
Net debt excluding lease liabilities	-47,493	-68,740
Current lease liabilities	1,054	1,037
Non-current lease liabilities	5,203	5,896
Net debt	-41,235	-61,807

#### 9. Financial assets and liabilities

Dec 31, 2023 EUR thousand	Fair Value Hierarchy	Financial assets at fair value	Financial assets at amortized cost	Carrying amount	Fair value
Quoted shares	1	1,479		1,479	1,479
Short-term government bonds	1		33,261	33,261	33,030
Trade receivables			418	418	418
Other receivables			105	105	105
Cash and cash equivalents			14,232	14,232	14,232
Total		1,479	48,016	49,495	49,264
Dec 31, 2023 EUR thousand	Fair Value Hierarchy	Financial liabilities at fair value	Financial liabilities at amortized cost	Carrying amount	Fair value
Trade payables			883	883	883
Lease liabilities			6,257	6,257	6,257
Total			7,140	7,140	7,140



There have not been any transfers between fair value levels during the year 2022-2023.

Dec 31, 2022 EUR thousand	Fair Value Hierarchy	Financial assets at fair value	Financial assets at amortized cost	Carrying amount	Fair value
Quoted shares	1	1,923		1,923	1,923
Short-term government bonds	1				
Trade receivables			829	829	829
Other receivables			274	274	274
Cash and cash equivalents			68,740	68,740	68,740
Total		1,923	69,843	71,766	71,766
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Dec 31, 2022 EUR thousand	Fair Value Hierarchy	Financial liabilities at fair value	Financial liabilities at amortized cost	Carrying amount	Fair value
Trade payables			1,192	1,192	1,192
Lease liabilities			6,933	6,933	6,933
Total			8,124	8,124	8,124

Level 1: The fair value of financial instruments traded in active markets (such as publicly traded equity securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the group is the current bid price.

Level 2: Financial instruments that are not traded in an active market are valued using valuation procedures that minimize the reliance on entity-specific estimations and maximize the use of observable market data to calculate their fair value. An instrument is included in level 2 if all relevant inputs needed to determine its fair value are observable.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.



#### 10. Related party transactions

Related parties are the persons or entities related to any of the companies belonging to the Nanoform Group. The definition of

related parties of the Group is based on the definitions included in the international IAS 24 standards.

# Compensation recognized as an expense for the members of the Board of Directors:

		1-12/2023	
EUR thousand	Fees	Fees settled in shares	Share-based payments
Miguel Maria Calado	47	47	
Albert Hæggström, CFO	23	23	35
Mads Laustsen	30	30	
Jeanne Thoma	30	30	
Total	130	130	35

	1-12/2022				
EUR thousand	Fees settled in cash	Fees settled in shares*	Share-based payments		
Miguel Maria Calado	91	79	19		
Albert Hæggström, CFO	43	37	83		
Mads Laustsen	55	49	12		
Jeanne Thoma	55	49	37		
Total	244	214	151		

\* Fees settled in shares include transfer tax.

#### Compensation for CEO and Management team:

	1-12/2023					
EUR thousand	Salaries and other short-term employee benefits	Post-employment benefits	Share-based compensation			
CEO	280	50				
Management team*	1,131	203	134			
Total	1,411	253	134			
		1-12/2022				
EUR thousand	Salaries and other short-term employee benefits	Post-employment benefits	Share-based compensation			
CEO	295	40				
Management team*	1,354	229	224			
Total	1,649	269	224			

\* The management team without CEO, whose employee benefit expenses are presented separately.



#### Liabilities to key management

The following related party balance is included in the consolidated statement of financial position:

EUR thousand	Dec 31, 2023	Dec 31, 2022
Liabilities to key management	125	156
Total	125	156

#### 11. Commitments and contingencies

The Group commitments to purchase of services and property, plant, and equipment (mainly related to new GMP and non-GMP lines) amounted to EUR 4,167 (2,005) thousand at the end of the review period.

The Group's management is not aware of any open disputes or litigations, which could have a significant impact on the Group's financial position. At the reporting date the Group doesn't have any contingent liabilities.

#### 12. Events after the review period

- On January 5, 2024, Nanoform announced it had completed the First Subject First Visit (FSFV) in a trial to evaluate the relative bioavailability of its nanocrystalline enabled alternative; to an amorphous solid dispersion (ASD); formulation of nanoenzalutamide and Xtandi<sup>@[1]</sup>, the number one prescribed androgen receptor inhibitor first approved by the FDA in 2012 to treat prostate cancer. The single-dose, randomized, comparative bioavailability study, which is performed by a contract research organization in North America, compares enzalutamide 160 mg film-coated tablets (Bluepharma Farmaceutica S.A.) and Xtandi 4x40 mg film-coated tablets (Astellas Pharma Europe B.V.).
- On January 10, 2024, The Board of Directors of Nanoform Finland Plc decided on the issue of stock options under an option program open to all employees. The total number of option rights to be issued is at most 1,240,412. The stock options are entitled to subscribe for at most 1,240,412 shares in Nanoform. Each stock option entitles to subscribe for one new share. The subscription price for shares subscribed with stock options is EUR 1.70 per share. The total subscription price of the shares shall be paid to the company's fund for invested own free equity.
- On January 26, 2024 Nanoform announced that one of its leading nanoformulation drug products had received promising clinical results. These were from a relative bioavailability study of nanocrystalline-enabled enzalutamide (nanoenzalutamide) tablet formulation, an alternative to the amorphous solid dispersion (ASD) used in Xtandi<sup>®[1]</sup>, the number one prescribed androgen receptor inhibitor<sup>[2]</sup> first approved by the FDA in 2012, and by the EMA in 2013 to treat prostate cancer. The nanoenzalutamide tablet formulation was developed in a partnership with the ONConcept<sup>®</sup> Consortium (Bluepharma, Helm, and

Welding) whereby Nanoform's proprietary controlled expansion of supercritical solutions (CESS®) technology provides the opportunity for an improved and differentiated finished product. Tablet-burden and dysphagia are well-documented challenges for prostate cancer patients, and the development of a 160mg, single tablet per day regimen may be preferable for patients in need of reducing their total number of daily pills. The single-dose, randomized, comparative bioavailability study, which was performed by a contract research organization in North America, compared enzalutamide 160mg filmcoated tablets (Bluepharma) and Xtandi® 4x40 mg film-coated tablets (Astellas Pharma Europe B.V.). A patent application for the nanoenzalutamide formulation has already been jointly filed by Helm and Nanoform. We aim for product launch after the expiry of the enzalutamide substance patent in the respective territories. For the United States this patent expiry is expected in 2027, and in Europe in 2028. This 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. [1] Xtandi is a registered trademark of Astellas Pharma Inc. [2] Source: xtandi.com

 On February 15, 2024, Nanoform announced that it has won a grant of up to 4.3 million euros from Business Finland, the Finnish government organization for innovation funding and trade. The grant represents 50% of the costs associated with Nanoform's research and development project for nanoparticle-enabled formulation platforms for oral, inhaled, long-acting injectable, and high-concentration subcutaneous injectable drug delivery technologies for next generation medicines. The work is expected to take place during 2024 and 2025.

# 13. The Board of Directors proposal for the distributable equity

The Board of Directors proposes to the Annual General Meeting that the year's parent company's loss of EUR -20,829,400 will be transferred to the accumulated deficit and that no dividend will be paid. The parent company's distributable equity on December 31, 2023, totaled to EUR 66,705 (2022: 87,040) thousand.



## Appendix 1

### Key figures

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
Personnel at the end of reporting period	165	150	165	150	125	74

### Calculation of key figures

Key figure	Definition	Reason to the use
Revenue growth %	Percentage increase in revenue between two periods of time	Revenue growth indicates the success of the Nanoform business in its growth trajectory
Gross profit	Revenue + Other operating income - Materials and services	Gross profit is the margin, which the Group generates, when its service production related expenses has been decreased
Gross margin	Gross profit/revenue	A complement to the absolute gross profit, showing the proportion of income that is left after direct material costs and external services have been subtracted from the revenues
EBITDA	Operating loss before depreciation, amortization, and impairments	EBITDA is an indicator of the operating result before investments, i.e. a proxy for cash flow generated by operations, if investments roughly equals depreciations
Loss for the period	Loss for the period as presented in the comprehensive income statement	Loss for the period shows the net profit for the Group's owners
Basic EPS	The loss for the period/the weighted average number of ordinary shares during the year	Measure describes the division of profit to each share
Net debt	Short-term loans + Long-term loans + Short-term lease liabilities + Long-term lease liabilities - Cash and cash equivalents and liquid investments	Net debt is an indicator to measure the total external debt financing of Nanoform
Net debt excluding lease liabilities	Short-term loans + Long-term loans - Cash and cash equivalents	Net debt excluding lease liabilities is an indicator to measure the total external debt financing of Nanoform without lease liabilities
Investments in property, plant, and equipment	Investments in property, plant, and equipment as presented in cash flow statement	Measure generates further information for the cash flow needs of investments
Operative free cash flow	EBITDA - growth capex	Free cash flow indicates the cash flow that is largely available for e.g. paying dividends

### **Further enquiries:**

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## **Financial calendar**

February 29, 2024, Annual Review 2023, **Financial Statements Review 2023** 

May 30, 2024, Interim Report January-March 2024

August 29, 2024, Half-year Financial Report January-June 2024

November 22, 2024, Interim Report January-September 2024

February 27, 2025, Annual Review 2024, **Financial Statements Review 2024** 



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