

# Nanoform Q3 and 9M 2022 report: Continued solid progress

Company Announcement

## **Nanoform Finland Plc**

November 29, 2022

08:10 a.m. Finnish time / 07:10 a.m. Swedish time

# Nanoform Q3 and 9M 2022 report: Continued solid progress

Highly promising *in-vivo* data for the treatment of glioblastoma multiforme presented with TargTex, new collaboration agreement signed with European consortium, first runs completed on both GMP line 2 and Biologics pilot line for GMP, work to find a manufacturing site in the US progressed well, while macroeconomic turbulence now present in talks with some smaller biotech companies. Q3 revenue growth of 79% combined with operating costs down 1% compared with a year ago led to smallest EBITDA loss since 1Q21. Productivity gains and economies of scale will enable continued slow growth in costs while expanding our manufacturing capacity and customer base.

## 7-9/2022 key financials:

- Revenue grew by 79% to EUR 0.85 million, compared with EUR 0.48m in 7-9/2021.
- The gross profit nearly doubled to EUR 0.82 million as the gross margin rose to a new quarterly high of 96% (EUR 0.42 million, 88% in 7-9/2021).
- EBITDA improved to EUR -4.19 million (EUR -4.62 million) as the operating costs\* were down 1% at EUR 5.04 million (5.09 million).
- The operating loss improved to EUR -4.80 million (EUR -5.11 million).
- The loss for the period was EUR -5.16 million (EUR -4.51 million).
- Basic EPS was EUR -0.07 (EUR -0.06).
- Cash position was EUR 76.3 million on September 30, 2022 (EUR 82.4 million).

#### 1-9/2022 key financials:

- -Revenue grew by 92% to EUR 2.50 million, stemming from 33 different customer projects (EUR 1.30m, 18 projects in 1-9/2021).
- -The gross profit almost doubled, from EUR 1.18 million to EUR 2,33 million, while the gross margin increased from 91% to 93%.
- The number of employees grew by 23 % to 143 (116) compared with one year ago.
- The total operating costs\* grew by 18 % to EUR 16.7 million (EUR 14.2 million).
- EBITDA came in at EUR -14.2 million (EUR -12.9 million).
- The operating loss was EUR -16.0 million (EUR -14.3 million).
- The loss for the period was EUR –16.5 million (EUR –14.1 million).
- Basic EPS was EUR -0.22 (EUR -0.21).
- EUR 25 million (gross) was raised in a new share issue in the first quarter.

(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

# Significant events during 1-9/2022

- On January 3, Nanoform announced two new near-term business targets for 2022: "At least 20 new customer non-GMP projects in 2022" and "At least 3 new customer GMP projects in 2022".
- In March, EUR 25 million (gross) was raised in a successful new share issue through an accelerated bookbuilding process. The considerably oversubscribed capital raise attracted strong interest from Nordic and international investors, including a considerable number of large global Tier 1 institutional investors.
- On May 4, 2022, Nanoform announced that it has launched its sparse-data Al solution, STARMAP® as a secure online portal. STARMAP® Online creates the opportunity for clients to perform large numbers of *in-silico* CESS® experiments from their desktop, prior to approaching Nanoform to perform experimental validation. This approach further supports Nanoform's green ambition by ensuring that Nanoform progresses the molecules with the greatest probability of success. STARMAP® Online offers increased user confidence through:

Security and safety – the interface has been developed in alignment with ISO27001:2017 standards.

Client submissions are 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 over 17,000 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.

- During Q2 AstraZeneca Plc concluded its thorough technology evaluation of Nanoform's proprietary CESS® Technology (see Nanoform's press release September 25, 2019: <a href="http://nanoform.com/en/nanoform-and-astrazeneca-initiate-technology-evaluation/">http://nanoform.com/en/nanoform-and-astrazeneca-initiate-technology-evaluation/</a>. The outcome of the technology evaluation was positive, and AstraZeneca is now moving forward to an identification and implementation stage for the technology where it will look to implement the technology on current and future development projects.
- In July, Nanoform announced that it has partnered with Pharmanovia, a fast-growing specialty pharma business with a portfolio of over 20 branded drugs in 140 markets. The new strategic partnership aims to add value to branded prescription medicines. Pharmanovia will look to apply Nanoform's proprietary nanoparticle technologies and formulation know-how to leading established pharmaceutical brands. The partnership starts with an iconic branded medicine where both parties see value in enhancing bioavailability for patient benefit. The value of the stage-gated agreement is according to Nanoform's business model for non-GMP and cGMP work.
- During 1-9/2022 fifteen (15) new non-GMP projects were signed, with more than a dozen customers, both new and repeat customers, both US and Europe based.

## Significant events after 1-9/2022

- On October 25, Nanoform and TargTex, a European biotech company, presented highly promising *in-vivo* data, enabled by a nanoformed drug product for the treatment of glioblastoma multiforme (GBM), at the PODD Conference in Boston, USA.

The data was generated for a planned Phase 1/2a clinical trial, due to commence in early 2024. Nanoform will deliver GMP grade nanoformed material to TargTex for the clinical trial. The drug is a selective Ca2+ channel blocker delivered by implantation at the site of the resected tumor in the brain. Nanoform and TargTex have collaborated in the optimization of a hydrogel formulation enabled by nanoformulation of the drug.

The study was conducted in a rat model for GBM in which tumor cells are injected into the brain. After 2-3 weeks, the nanoformulated hydrogel was delivered locally in the brain of the animal, on top of the tumor. The study results showed long term survival of 40 per cent of the treated animals and no microscopic tumor cells were detected in these animals at sacrifice.

The nanoformed drug product provided a controlled release and deep drug diffusion across the brain parenchyma. The data showed no systemic exposure, and the drug was not toxic at maximum loading concentration. The study was performed at a sub-therapeutic dose that can be increased by at least 2-fold. Future studies are planned to be performed at increased drug concentrations with the goal to further improve long term survival.

- 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 have now 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. As Nanoform will continue to be remunerated for its work, the development stage of the collaboration is not expected to have a negative cash flow effect on Nanoform. In the event that the commercialization is successful, Nanoform expects to retain a 25 % share of the net-income received by the parties. First clinical trials on the improved drug product are expected to commence in 2023.
- In November, Nanoform filed to FIMEA a notification of an update to our manufacturer's authorization. This relates to additional API and manufacturing lines.

# CEO's review

Another quarter of solid progress at Nanoform, despite the ongoing macroeconomic turbulence. We've continued to invest in and execute on our main tasks; client relationships & brand recognition, line capacity, IT & automation, processes, facilities, preparing for the US and the ability to help our clients generate positive data in biology, with the ultimate goal to help patients. Not forgetting our main 2025 target of becoming cashflow positive.

Speaking of biological data and the potential of helping patients in the future, I'm very pleased with the progress we've made with TargTex, where we jointly in Boston presented highly promising *in-vivo* data, enabled by a nanoformed drug product for the treatment of glioblastoma multiforme. Even though it is still early days, the fact is that nanoforming enabled a sufficient drug load where other technologies had failed, and as a result this promising API – the study showed long term survival of 40% of the treated animals – is on its way towards the clinic. Small is indeed a powerful ingredient in formulation work.

I'm also pleased to announce that after a year of extensive preclinical work with a European headquartered international company, two privately held European pharmaceutical development and manufacturing organizations have decided to join the drug development program. Together with Nanoform, the four parties will in equal shares fund the development and commercialization of a more patient centric version of a current blockbuster drug.

Related to our substantial ongoing investments, I am happy to inform you that we have completed the first runs on both our GMP2 line and on our Biologics pilot line for GMP. The clean room for GMP3 line is finished and the line equipment and main isolator have arrived. Our ERP project, evident in the IT costs during 2022, has progressed well and we will go live with SAP after closing the books for this financial year.

Our preparation for GMP manufacturing in the US has progressed well during the last months. After dozens of meetings with state representatives - including one governor, municipalities, real estate companies, developers, advisors, and life science companies that have set up manufacturing in different parts of the US, we have now chosen a leading diversified professional services and investment management company, to help us find and establish the manufacturing site in the US.

About the macroeconomic situation. There are many headwinds impacting the global economy; the war in Ukraine, the continued covid shutdowns in China, the rapidly rising cost of capital and in some cases even the complete lack thereof. While our brand recognition and service offering continue to grow stronger and the client response to that keeps growing, it is clear that higher interest rates and tighter financial conditions are impacting investment decisions, especially among small biotech companies with limited resources. Nevertheless, the problem with bioavailability is enormous in the pharma

industry, the R&D budgets of large pharma companies are huge, the amount of money raised by biotech companies and life science funds during 2020-21 was record-breaking so we expect the interest in our technology to continue to grow. Naturally, the strong dollar and significant price increases in the global CDMO industry help us as our cost base is mostly in euros. It's also clear that our strong balance sheet is a positive aspect when partners evaluate us.

All in all, I look with confidence and excitement forward to the coming quarters and years. We'll continue to work relentlessly towards our 2025 mid-term business targets, while executing as fast as possible on our near-term targets. 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's complete Q3 and 9M 2022 report can also be found at: http://nanoform.com/en/financial-reports-and-presentations/

Nanoform online presentation and conference call November 29, at 3:00 p.m. Helsinki time / 2:00 p.m. Stockholm time:

Nanoform Finland Plc will publish its Interim Report January-September 2022 on November 29, 2022, 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:

### http://financialhearings.com/event/44325

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## Company near-term business targets for 2022

- 2 new GMP lines (announced Feb-21)
- Biologics pilot line for GMP (announced Nov-21)
- At least 20 new customer non-GMP projects (announced Jan-22)
- At least 3 new customer GMP projects (announced Jan-22)

# 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

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#### **About Nanoform**

Nanoform is an innovative nanoparticle medicine enabling company. Nanoform works together with pharma and biotech partners globally to provide hope for patients in developing new and improved medicines utilizing Nanoform's platform technologies. The company focuses on reducing clinical attrition and on enhancing drug molecules' performance through its Nanoforming technologies and formulation services. Nanoform's capabilities include GMP manufacturing, and its services span the small to large molecule development space with a focus on solving key issues in drug solubility and bioavailability and on enabling novel drug delivery applications. Nanoform's shares are listed on the Premier-segment of Nasdaq First North Growth Market in Helsinki (ticker: NANOFH) and Stockholm (ticker: NANOFS). Certified Adviser: Danske Bank A/S, Finland Branch, +358 40 744 1900. For more information, please visit www.nanoform.com.

#### Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements regarding Nanoform's strategy, business plans and focus. The words may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," believe," "estimate," "predict," "project," "potential," "continue,"

"target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Nanoform's business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other companies, and other risks described in the Report of the Board of Directors and Financial Statements for the year ended December 31, 2021 as well as our other past disclosures. Nanoform cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Nanoform disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Nanoform's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.