

Summer letter from Nanexa

The second quarter of 2023 has come to its end and many of us in Sweden go into the holiday season. We at Nanexa can summarize the first half of 2023 as being very productive with both our own projects and our partner projects. Also, we have had the chance to meet new potential partners at different conferences in EU and US where we can see that the interest for our drug delivery system PharmaShell is increasing as we are able to present more and more data describing the unique features of the system. One clear reflection from these conferences is that our ability to work with and improve formulations of biologics such as peptides and monoclonal antibodies generates great interest among many of the big pharma companies.

All our projects are developing as expected and we see great opportunities in all of them; however, in this letter, I would like to take the opportunity to highlight our latest project, NEX-22, that we launched last fall, aiming to develop a month-long depot formulation of liraglutide, a GLP-1 peptide for treating type 2 diabetes. More specifically, the market development is extraordinary and increasingly compelling as is the potential for liraglutide and other GLP-1 peptides marketed by big pharma companies, which could be considered for a PharmaShell technology license. Our goal is to create convenient and long-acting treatments for type 2 diabetes, serving the varied needs of patients in this area.

In December of last year, we signed the exclusive evaluation agreement with Novo Nordisk where they will evaluate our PharmaShell system to make a one-month depot formulation of one specific substance which they currently market. For this exclusivity and the evaluation project Novo Nordisk paid in total 4.4 MUSD and also decided to invest another 1.6 MUSD in Nanexa in a directed share issue.

Both NEX-22 and the Novo Nordisk project have been at the forefront of our daily operations, receiving high priority during the first half of 2023.

I would like to stay with the NEX-22 project and elaborate on the market for GLP-1 receptor agonists. It is a huge and rapidly growing market, in which it is a clear logic in launching a one-month depot GLP-1 product. We have gathered some interesting facts and own reflections on the market potential that I would like to share with you.

The GLP-1 RAs (Glucagon-Like Peptide-1 Receptor Agonist), indicated for treatment of both type-2 diabetes (first indication) and obesity, is currently gaining tremendous growth. In my 30 plus years in the pharmaceutical industry, I have never seen such a fast growth for one class of pharmaceuticals. This gives us extra energy to focus our resources on NEX-22, which we see as a door opener for building the one-month segment in type-2 diabetes. It could also be an entry into the obesity market, since the needs for improved compliance via a once-per-month injection is foreseen to be even higher in obesity.

Supported by sales numbers from the dominating companies in the GLP-1 RA class, Novo Nordisk and Eli Lilly, in combination with forecasts from Global Data, we are confident that Nanexa is very well positioned in the right market segment with NEX-22. According to the forecasts, the total value of the GLP-1 and GLP-1/GIP (Glucose-dependent Insulinotropic Polypeptide) segment is forecasted to reach 90 BUSD in 2029 (71 BUSD in type-2 diabetes and 20 BUSD in obesity). Some analysts project it to an even higher number reaching 150 BUSD. During the second half of 2023 we will continue the optimization of the formulation, perform pre-clinical studies, and submit the Clinical Trial Application, supporting a start of the study late 2023 or early 2024.

In type-2 diabetes, GLP-1 and GLP-1/GIP sales of 71 BUSD represents over 50% of the expanding global type-2 diabetes market, which is expected to reach \$136B by 2029, with a compound annual growth rate (CAGR) of 11.5% from 2019. Please see chart 1 in Appendix to this letter.

The obesity market is forecasted for an even stronger growth during the upcoming period and will reach 37 BUSD in 2031. In this segment the GLP-1 and GLP-1/GIP products are expected to dominate even more than in type-2 diabetes and will reach a 70% share and 26 BUSD in sales. Please see chart 2 in Appendix to this letter.

With these market projections of the GLP-1 sales in the coming years, even a normal technology license agreement for our drug delivery system PharmaShell, with royalty numbers of about 2-3% of net sales, would give very substantial yearly revenues for Nanexa. We believe and hope this will be a reality, not only because it will be very pleasant for Nanexa, but it will also give all type-2 diabetes and potentially also obesity patients taking GLP-1 receptor agonists a much better treatment and quality of life.

It is hard to beat these market size numbers for almost any other indication, but even so, both NEX-20 for multiple myeloma and NEX-18 for myelodysplastic syndrome also provide substantial opportunities for Nanexa. The markets are smaller, but there are clear unmet medical needs for both these indications that we will be able to meet with long-acting PharmaShell based products and substantial market opportunities are definitely there.

I would like to point out a very important aspect of our project portfolio. You know the saying that the devil is in the details, which is absolutely true also for our projects. Therefore, it is of critical essence to have experts within the respective indication fields linked to our projects, and we have been able to gather international Key Opinion Leaders (KOL) to all our projects to engage in our advisory boards. They are KOLs that could well be advisory board members at global big pharma companies. This gives us great strength, both in understanding the details of the unmet medical needs in the indications, the critical target product profiles, etc., and in our contacts with potential partners.

In summary, our own projects have progressed according to plan during the first half of 2023, we have completed the recruitment to the NEX-20 clinical study and are now looking forward to evaluating the results later this year. Knowing how much work is behind it, I am very satisfied and would like to take the chance to officially thank our great team for an excellent performance.

I have already talked about the Novo Nordisk project as being on top of our priorities. With that said, we have also succeeded in delivering PharmaShell coated active substances in our other partner projects during this first half of 2023. Some of these are now in the hands of our capable partners where they evaluate the performance of our compositions in their labs and in animal studies. We hope that some of these evaluations will lead to deeper collaborations and ultimately license agreements. My own thinking is that we are getting closer to such deals, even though it's hard to predict when. One thing is already true and that is the fact that we now receive higher fees for the evaluations, which is usually a very good sign.

We have also had the opportunity to meet and discuss the PharmaShell opportunity with many companies when attending different conferences, both in Europe and in the US. It's clear to me that the interest in our technology has increased a lot over the last year. Most prominently in the field of formulating large molecules, biologics, such as peptides and monoclonal antibodies, where we already have promising data. Our own NEX-22 project is based on a peptide, which is also the case in a few of the partner projects we work on right now. We have also started an evaluation study together with a big pharma partner in the field of long-acting monoclonal antibodies, where there are several needs to address, and we see that our PharmaShell coating has the potential to provide solutions to the challenges.

I can also mention that our business development team is constantly in discussions with several companies, and we hope this will lead to even more interesting evaluations, development agreements as well as license agreements where we see larger signings, milestones and royalty fees coming our way. I feel very confident that we are progressing in the right direction towards such critical agreements.

I hope this letter has provided a good status update and that you agree with me when it comes to priorities in the company, given the enormous potential and strong development in the GLP-1 market, and huge revenue potential for the NEX-22 project.

With that, it leaves me with wishing you a wonderful summer.

All the best,

David

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About Nanexa AB (publ)

Nanexa is a pharmaceutical company developing injectable drug products based on the proprietary and innovative drug delivery system PharmaShell® – the high drug load delivery system enabling the next generation long-acting injectables through atomic layer precision. Nanexa develops its own products and also has collaboration agreements with several pharma companies, among others Novo Nordisk and AstraZeneca.

Nanexa's share is listed on Nasdaq First North Growth Market in Stockholm (NANEXA).

Attachments

[Summer letter from Nanexa](#)
[Appendix To Nanexa Summer Letter](#)