Alzinova AB (publ)
Annual Report 2023

alzinova

We will make it possible for Alzheimer's patients to live an *independent and active life.*

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The terms "Company" or "Alzinova" refer to Alzinova AB (publ) with organization number 556861-8168. The information in the annual report regarding markets, competition and future growth represents Alzinova's assessment, mainly based on material internally within the Company and from external sources. The Swedish krona (SEK) is the currency used consistently and unless otherwise stated, figures in brackets refer to operations in 2022. Some figures have been rounded, which may mean that tables and calculations do not always add up exactly. The formal annual report can be found on pages 29-46.

Please note that this is an English translation of the Annual Report written in Swedish by Alzinova AB (publ), in the event of any inaccuracies, the Swedish version applies.

About Alzinova

Alzinova AB is a Swedish biopharmaceutical company that specializes in the treatment of Alzheimer's disease.

The Company's patented AβCC peptide technology™ enables the development of disease-modifying treatments that target and neutralize the toxic accumulations of the peptide amyloid-beta, so-called oligomers, which are central to the onset and development of Alzheimer's disease. Using this technology, we can develop effective treatments which at the same time have a favourable safety profile with a lower risk of side effects compared to other treatments. Promising results have been obtained after a study on brain extracts from deceased Alzheimer's patients demonstrated proof of mechanism of these treatments.

Alzinova's primary focus is the development of a vaccine that specifically targets and neutralizes the toxic oligomers. The vaccine is being developed as a long-acting treatment and prevention of Alzheimer's disease. The vaccine candidate ALZ-101 is in clinical development and part A of the phase 1b study in Alzheimer's patients started in Q3 2021. Based on positive interim data from part A, the Company decided in May 2023 to initiate an extension, part B, to the ongoing clinical study.

Part A of the study was completed at the turn of the year 2023/2024 with a positive outcome where ALZ-101 shows good safety and tolerability as well as a clear immunological response. The results from the complete analysis from part A opens up the possibility of evaluating a higher dose. Alzinova therefore applied in early 2024 for an additional extension of the study (A2) to evaluate treatment with 400 µg, which has been approved by regulatory authorities. Part A2 is expected to be completed in 2024. Overall, the results from preclinical and clinical studies, show that Alzinova has the opportunity to develop a treatment that is superior to other treatments against Alzheimer's.

Based on the same technology, the Company is also developing the antibody ALZ-201, which is currently in preclinical development. The project portfolio for the development of disease-modifying treatments is broadened as the Company prepares to progress the antibody into clinical development. Alzinova was founded by researchers who have worked at the MIVAC research centre at the University of Gothenburg, and by GU Ventures AB.

Alzinova's unique solution

- ✓ Targeted treatment that specifically targets and neutralizes the toxic peptides (so-called oligomers) that are central to the onset and development of Alzheimer's disease.
- ✓ A vaccine that stimulates the body to produce its own antibodies against oligomers (ALZ-101).
- ✓ Specific treatment that is predicted to have good efficacy and reduces the risk of serious side effects.
- ✓ Fast, effective and uncomplicated vaccination without long and expensive hospital stays.
- ✓ Can start treatment early in the disease to prevent progression.
- ✓ Monoclonal antibody (ALZ-201) that neutralizes the toxic oligomers and can be used as a stand-alone or as a complement to the vaccine (ALZ-101).

Other actors within the field

- — Developing treatments that target large accumulations of amyloid-beta, known as plaques, in the brain which are believed to contain both toxic and harmless protein.
- — Non-specific treatments which therefore do not target and neutralise the toxic oligomers.
- — Often complicated drug treatments that require costly hospitalisation.
- — Targeting plaques is unlikely to provide sufficiently good clinical efficacy and can result in serious side effects.

Investment highlights

Vaccine with potential to treat Alzheimer's

Alzinova's lead candidate, ALZ-101, is a therapeutic vaccine to treat Alzheimer's disease. Positive results from part A of the ongoing study demonstrate good safety and tolerability and a clear immunological response.

Supplementary treatment with antibody

Based on the same technology, Alzinova is also developing a monoclonal antibody, ALZ-201, as a complementary treatment to the vaccine to combat Alzheimer's disease.

Best-in-class potential with favourable safety profile

Data show that the unique specificity of Alzinova's vaccine (ALZ-101) and monoclonal antibody (ALZ-201) provides "best-in-class" potential with a more favourable side effect profile compared to other treatments.

Regulatory progress boost collaborations

Positive feedback from the FDA and EMA as well as other ongoing activities for the next clinical development phase, make Alzinova's candidates attractive for strategic partnerships.

Robust product pipeline

Strong product pipeline and upcoming trigger events backed by a proprietary scientific foundation and well-thought-out studies.

Enabling an independent and active life

Alzinova's goal is to enable Alzheimer's patients to live an independent and active life.

A word from our CEO Kristina Torfgård

2023 was a year of many achievements in which we reached our goals. What I am particularly proud of is that we, in November, could report positive top-line data for Alzinova's phase 1b study in Alzheimer's patients. The full analysis of part A of the phase 1b study, that we presented in January 2024, confirms that ALZ-101 is a promising vaccine candidate against Alzheimer's disease. Strong safety and tolerability data and an increased immune response with increasing numbers of doses puts us in a good position for clinical development and continued partnering activities. Our main focus for 2024 is to sign a partnering agreement to accelerate the continued clinical and commercial development of ALZ-101.

Positive phase 1b results for the vaccine candidate ALZ-101

This year's, and one of the Company's most important milestones so far, is the positive top-line results from our clinical phase 1b study with the vaccine candidate ALZ-101 in Alzheimer's disease. The main goal of the study is to show that the vaccine candidate is well tolerated and safe, which we have confirmed with strong data. At the same time, the results show that we also achieved the study's secondary goal of generating an immune response where the results show a high frequency of immune response. In January, we finally received all the data from part A of the study and conducted a full analysis which confirmed the positive topline results from November. The fact that we have now reached the goals of the study is a sign of the strength of the Company, and we are now taking the opportunity to gather further information for future studies.

With all the data and information we now have, we can proudly state that we have successfully reached the goals of the phase 1b study and obtained positive data that is crucial for the future development of our promising vaccine candidate. We look forward with excitement and anticipation to present these great results to potential partners and at upcoming international conferences, while continuing the preparations to initiate the next clinical phase.

» Our main focus for 2024 is to sign a partnering agreement to accelerate the continued clinical and commercial development of ALZ-101 «

Strong results allow for optimised treatment effect with ALZ-101

Both doses of ALZ-101 investigated in the phase 1b study, showed good safety and tolerability and were shown to stimulate the immune system. Based on these results, we now want to investigate a higher dose of ALZ-101 to optimise the design of phase 2. We have therefore applied, and received approval from FIMEA, to make an addition to the study, part A2, where six patients will be treated with a higher dose of ALZ-101 for 16 weeks. This part of the study started in early 2024.

I am very pleased with how we are working adaptively in this early phase, building on the ongoing study as new data emerges. This allows us to gather a lot of valuable information which will enable us to gain a deeper understanding and knowledge about our drug candidate ALZ-101 and thereby optimise the design and implementation of future studies.

In parallel, the extension part (part B) of the study continues; we chose to add this extension to learn more about the vaccine candidate's profile for phase 2. Our current view is that we can obtain information on long term safety and tolerability when applying to start the phase 2 study, i.e. before part B is fully reported.

Regulatory interactions in the US and Europe

As part of the preparations for the phase 2 study, we have during the year conducted a pre-IND meeting with the US Food and Drug Administration (FDA) and received scientific advice from the European Medicines Agency (EMA). With the positive and clear feedback we have received from the FDA and EMA regarding the planned development program for ALZ-101, we can now ensure that the development plan for ALZ-101 meets the regulatory requirements in both the US and Europe. In addition, we can more quickly reach important milestones in the development process with the goal of offering a new treatment for patients suffering from Alzheimer's disease. These are also important steps for the commercial development and future partnerships for ALZ-101.

In the summer of 2023, we signed an agreement with PolyPeptide, a leading peptide manufacturer, which secures our production capacity for future clinical studies. A robust multi-manufacturer production of the peptide is important for drug development and, at a later stage, for commercial production. We will have a great advantage in having already secured and completed this.

Strengthened patent position and "best in class" potential

In parallel with the vaccine candidate ALZ-101, we continue to develop the monoclonal antibody ALZ-201. This work resulted in a patent application for a further developed form of the antibody, and we continue with preclinical development in order to bring the antibody into the clinic. Both of our drug candidates

are oligomer-specific, which means that our candidates are developed to specifically target what is believed to be behind the onset and progression of the disease, and are therefore expected to provide a more favourable efficacy and side effect profile compared to other amyloid-beta targeted therapies. Strong phase 1 data for ALZ-101 gives us "best in class" potential.

Expanded team and focus on visibility
During the year, Alzinova strengthened its organisation by recruiting Kirsten Harting to the role of Chief Medical Officer and Sebastian Hansson as Business Development Director. We have a strong focus on clinical development with the goal of starting phase 2. Furthermore, we have optimised our business development strategy and positioning of the Company, which has been further intensified after positive data from the phase 1b study. We have strengthened our brand and increased our visibility with more investor meetings and partnering activities.

During the year, we participated in the international Alzheimer's conference AD/PD, BIO US and BIO-Europe where we were able to present the excellent data for ALZ-101 and for ALZ-201. Overall, we noted great interest in our project portfolio and the ongoing clinical study. Our top priority for 2024 is now to harness this interest with the main goal of signing a partnering agreement that takes the clinical and commercial development further.

I am very proud of everything we achieved in 2023. Alzinova's progress gives me hope and a sense that we are on the way to solving the puzzle to stop, and even cure, this terrible disease. Alzheimer's affects not only millions of people worldwide, but also so many of their loved ones.

With the great results we have achieved with ALZ-101, a strengthened Alzinova team and the support of the Board of Directors, I have great confidence that the Company will successfully continue this exciting journey even after my departure. I look forward to seeing the Alzinova team take ALZ-101 into the next clinical phase and thus one step closer to the goal - a unique vaccine against Alzheimer's disease.

Kristina Torfgård,
CEO of Alzinova AB

This year's milestones

2023 was a very eventful year with many accomplishments and where we reached our goals. Alzinova has had notable achievements with the vaccine candidate ALZ-101, participated in several conferences and worked actively with the Company's visibility in the sector. A selection of the events that were important for the Company in 2023 is presented below.

January

Alzinova began the year with announcing that a new scientific article was published in the prestigious journal Alzheimer's Research & Therapy, with preclinical results demonstrating that the ALZ-201 antibody has specificity for the toxic oligomers that are considered to be the cause of Alzheimer's disease.

Later that month, on 24 January, Alzinova announced that the Company had strengthened its management team by appointing Sebastian Hansson as Business Development Director.

April

Alzinova received regulatory approval from the Finnish Medicines Agency, Fimea, and the Finnish National Ethics Committee, to initiate an extension part (Part B) of the phase 1b study. The extension part aims to provide information on long-term safety and tolerability, immune response and also information on effects on biomarkers and cognitive functions.

Alzinova announced that all patients participating in the phase 1b study of the ALZ-101 Alzheimer's disease vaccine candidate had received their fourth and final dose of the ALZ-101 vaccine or placebo.

March

A planned external safety review of the Company's clinical phase 1b study in Alzheimer's patients was conducted - with a positive assessment to continue the vaccine study as planned.

Alzinova filed a new patent application for a further developed form of the Company's monoclonal antibody ALZ-201. The patent application is part of Alzinova's strategic further development of the patent portfolio for drug candidates.

The Company presented studies and data for the vaccine candidate ALZ-101 at the international conference AD/PD™, held in Gothenburg on 28 March - 1 April.

May

May began with Alzinova announcing the completion of a second planned interim analysis of the ongoing clinical phase 1b study with the vaccine candidate ALZ-101 against Alzheimer's disease. The analysis showed positive data with continued good safety and tolerability and a clear immunological response, i.e. the formation of specific antibodies. Based on this positive second interim analysis, the Company made a decision to conduct an extension part (B part) of the study.

Later that month, part B of the phase 1b study with the vaccine candidate ALZ-101 was initiated, and the first patient was dosed.

June

The Company announced in June that an application was submitted for a pre-IND meeting with the US Food and Drug Administration (FDA) and an application for Scientific Advice from the European Medicines Agency (EMA).

August

Alzinova recruited Kirsten Harting to the role of Chief Medical Officer (CMO).

Alzinova conducted a pre-IND meeting with the FDA and received positive feedback on the planned clinical development programme for the vaccine candidate ALZ-101.

Later in August, Alzinova signed an agreement with PolyPeptide Laboratories Holding (PolyPeptide) to manufacture Alzinova's peptide (AβCC) for future clinical studies.

September

Alzinova announced that the Company has received a positive response from the EMA regarding the planned clinical development programme for the vaccine candidate ALZ-101. This represents a significant step in the preparations to include European study centres in future clinical studies.

November

In November, Alzinova participated in Europe's largest life science conference, BIO-Europe. The conference, which is a venue for partner meetings, gave Alzinova the opportunity to present the vaccine candidate ALZ-101, and the antibody ALZ-201 to potential partners.

In November, Alzinova announced positive phase 1b results with the vaccine candidate ALZ-101 against Alzheimer's disease. Topline results showed that the vaccine candidate ALZ-101 meets the study's primary objectives regarding safety and tolerability. Furthermore, patients treated with ALZ-101 responded to treatment with antibody levels increasing with the number of doses given.

About Alzheimer's

Alzheimer's, which is the most common dementia disease, usually starts with mild symptoms, worsens over time, and ends with severe brain damage and death. Alzheimer's causes problems with, among other things, memory, thinking, behavior, and personality changes. Symptoms generally develop slowly, get worse over time, and interfere with daily activities. In the end, the body's physiological functions are also affected, and the patient usually dies within about seven years of the established diagnosis.

What causes Alzheimer's?
In Alzheimer's disease, the nerve cells in the brain are damaged by abnormal protein deposits that mainly consist of amyloid-beta 42 (Aβ42), a small protein that also occurs in a healthy brain. When the Aβ42 molecule clumps together, stable accumulations are formed in the brain, plaques, but also so-called oligomers.

Oligomers differ structurally from the plaque and, unlike plaques, are highly toxic to brain cells. They damage important functions that cause the contact surfaces between nerve cells, the synapses, to stop functioning normally. The synapses are the places in the brain where electrical and chemical signals are transmitted from one nerve cell to another, and its function is critical for us to be able to remember, react, think, and act. Eventually the nerve cells die.

The disease first affects the parts of the brain that handle short-term memory, but eventually the disease spreads over the entire brain and the patient finds it increasingly difficult to carry out daily tasks. In the end, the patient cannot manage on their own, but requires care and continuous monitoring.

Alzheimer's is a disease that basically anyone can get, and which is strongly age dependent. Over 95% of all cases affect those over 65, and in these cases, there is not a strong genetic component driving the disease.

Alzheimer's is most common in the elderly population, with 1 in 9 people over 65 affected, 65% of whom are women. However, about 5% of cases are diagnosed at an earlier age.


Every 5th
second, someone
is affected by
Alzheimer's
disease

Alzinova's treatments

The market for the treatment of Alzheimer's disease is large as there is currently no effective treatment to cure the disease. Alzinova's approach, to develop a therapeutic vaccine that specifically targets the toxic accumulations of amyloid-beta in the form of oligomers in the brain, has several advantages over other treatment methods. Other actors have developed or are developing treatments that target larger accumulations of amyloid-beta, known as plaques in the brain, which are believed to contain both toxic and harmless protein. It has been shown that these are unlikely to provide sufficient treatment effect and can result in serious side effects.

In contrast, Alzinova has managed to identify a treatment method that could specifically target the toxic protein in the brain, amyloid-beta oligomers, one of the underlying causes of Alzheimer's disease.

About ALZ-101

ALZ-101 is an active therapeutic oligomer-specific vaccine. A vaccination with ALZ-101 means that the body generates its own antibodies, specific against toxic accumulations of amyloid-beta oligomers in the brain. These toxic peptides are then expected to be rendered harmless, and in this way the brain's synapses are protected from being damaged, which could prevent the development of Alzheimer's disease. The treatment method is also expected to have a lower risk of side effects such as bleeding and edema which are associated with treatments that target plaques. The Company therefore believes that it is likely to be more successful in contrast to other broader beta-amyloid treatment approaches to Alzheimer's disease. Alzinova's process for developing and producing pharmaceutical drug substance for the oligomer-specific vaccine ALZ-101 is currently carried out on an industrial scale, which results in a robust and quality-assured production of ALZ-101.

In November 2023, Alzinova announced positive topline results from its clinical phase 1b study with the vaccine candidate ALZ-101. A first analysis of the study data showed that ALZ-101 continues to have good tolerability, an acceptable safety profile and a high immunological response. Furthermore, the results demonstrated that patients treated with ALZ-101 responded with antibody levels that increased with the number of doses given.

A complete analysis of the dataset from part A of the phase 1b study, announced in January 2024, confirms the favourable safety and tolerability profile observed in all dose groups, a high frequency of immune responses, and that patients treated with ALZ-101 responded with antibody levels that increased with the number of doses given. The analysis also showed that the patients dosed with the highest dose of the vaccine, 250 µg, had a higher response rate compared to those who received the lower dose of 125 µg.

Alzinova continues with the extension part (part B) of the phase 1b study, where all patients from part A are offered active treatment with 250 µg of ALZ-101 over a 20-week period. The patients are then followed for 48 weeks. Part B of the study aims to provide information on long-term safety and tolerability, the long-term immune response, as well as signs of effects in biomarkers and cognitive functions.

The strong results from the complete data analysis from part A part opens up the possibility of evaluating a higher dose of ALZ-101. Alzinova therefore applied in early 2024 for an extension of the study (A2) to evaluate treatment with 400 µg of ALZ-101, which has since been approved by regulatory authorities. The extension is designed as an open-label part to the study and includes six patients treated with 400 µg of ALZ-101 over a 16-week period with four treatment sessions. Patients will then be followed up after a period of 4 weeks. Alzinova has chosen to investigate an additional dose level of ALZ-101 in this study to optimise the dose for phase 2 and thus maximise the treatment effect.

About ALZ-201

ALZ-201 is a monoclonal antibody based on Alzinova's AβCC technology developed to specifically attack and neutralize the toxic forms of the peptide amyloid-beta-42 ("Aβ42"), so-called oligomers which are considered to be the underlying cause of Alzheimer's disease. The antibody ALZ-201 does not bind to other, harmless, forms of amyloid-beta such as fibrils and plaques as proven in pre-clinical studies on human material. The pre-clinical results indicate that it is a small amount of Aβ42 oligomers that accounts for the main toxic effect in Alzheimer's disease, and that specificity for this form is likely necessary to obtain a good therapeutic effect of an antibody treatment. The pre-clinical results provide support that ALZ-201 has the potential to halt or slow the progressive decline in cognition seen in patients with Alzheimer's disease.

Alzinova is currently developing a humanized version of ALZ-201 for clinical phase 1 study in patients with Alzheimer's disease. The study is planned to start in 2024. A passive immunotherapy with ALZ-201 can be developed into an effective complement and a disease-modifying alternative to the therapeutic vaccine ALZ-101. The Company's research shows that both ALZ-201 and the vaccine ALZ-101 have "best-in-class" potential, and clinical results from other players in the field strengthen the Company's strategy.

ALZ-101 phase 1b clinical study

Alzinova's vaccine candidate, ALZ-101, is in a phase 1b clinical trial. The primary objective of the study is to evaluate the safety and tolerability of repeated doses of ALZ-101 in patients with early Alzheimer's disease. The study also includes secondary and exploratory endpoints related to immune response and biomarkers.

The phase 1b study, which is divided into two parts, part A and B, is investigating two different dose strengths of ALZ-101 - 125 and 250 µg and placebo. In part A of the study, 20 patients were treated with the ALZ-101 vaccine and six patients with placebo. In November 2023, Alzinova announced topline results from this first treatment arm (part A) when all patients had received four doses over a 20-week period. These results were then confirmed in a full analysis published in January 2024.

Based on the positive data from part A, Alzinova has applied for and received approval to evaluate a higher dose (400 µg) of ALZ-101 (part A2). This part was initiated in spring 2024 and includes 6 patients treated with ALZ-101 (400ug) for 16 weeks.

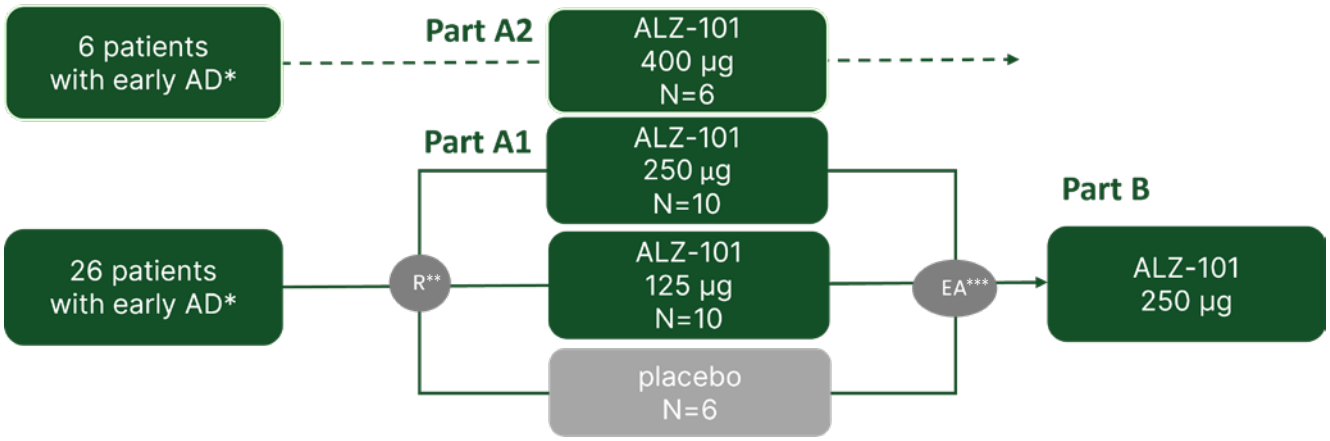
The B part, which is an extension of the phase 1b study, is ongoing and involves all patients from the A part being offered active treatment with ALZ-101 (250 ug) for a 20-week period. The patients are then followed for 48 weeks. Part B aims to provide information on long-term safety and tolerability, the long-term immune response, as well as information on the effect on biomarkers and signals on cognitive functions following administration of ALZ-101.

Phase 1b study: Double-blind, randomized, placebo-controlled study on safety, tolerability and immunogenicity.

Part A: ALZ-101 (125 and 250 µg) or placebo, given at weeks 0, 4, 8 and 16, if not eligible for Part B, follow-up for additional 48 weeks.

Part A2: ALZ-101 (400 µg), given at weeks 0, 4, 8 and 16, follow up 4 weeks.

Part B: ALZ-101 (250 µg), given at week 0, 4, 8 and 16 and for additional 48 weeks.

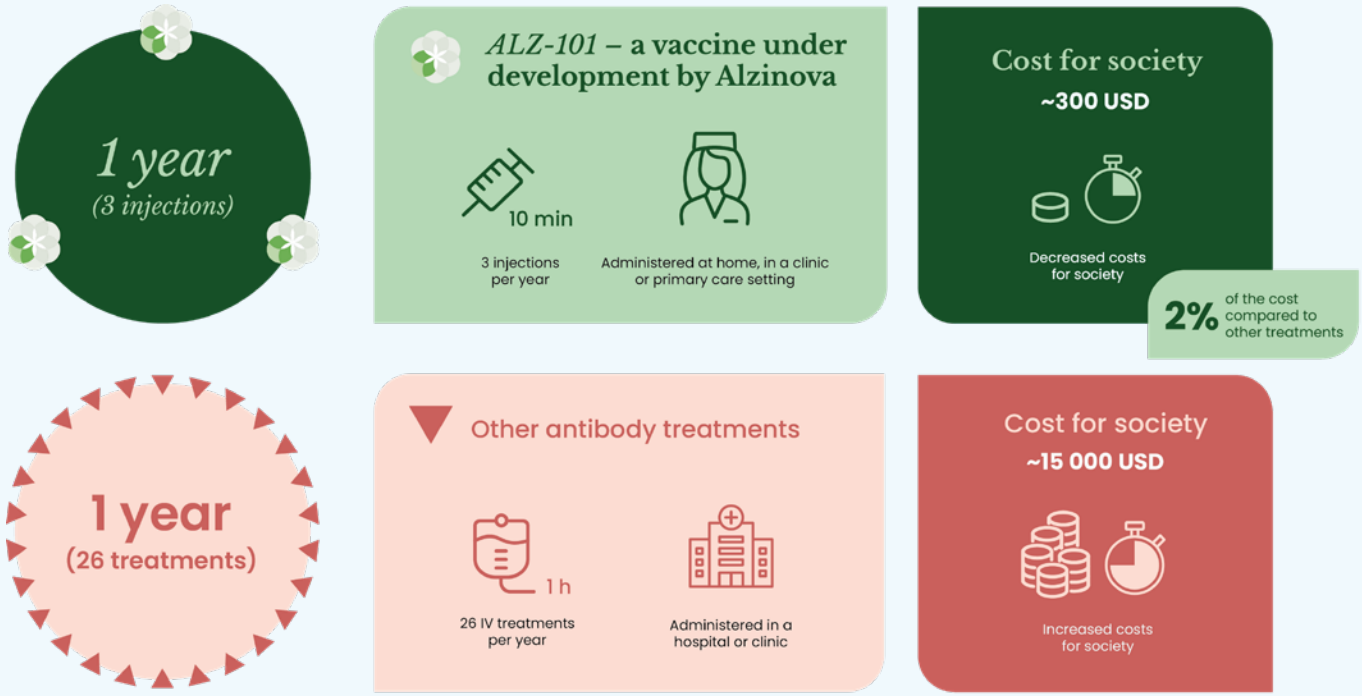


**According to National Institute of Aging – Alzheimer's Association (NIA-AA). MCI – Mild Cognitive Impairment; AD – Alzheimer's Disease; CSF – Cerebrospinal fluid; Aβ– amyloid-beta*

***Randomisation*

****Eligibility Assessment*

Alzinova's competetive advantages



Based on statistics from Statistics Sweden on the Swedish healthcare system, and that the two treatments have equivalent clinical efficacy, total treatment time and drug cost.

Alzinova is developing a vaccine candidate to treat Alzheimer's disease. The vaccine, unlike other treatments such as antibodies, is expected to require only a few doses a year rather than as often as every two weeks. In addition, it can be given to patients in a very time-efficient way through a simple injection in primary care or at home by a nurse. Other treatments are time-consuming and require hospital care.

Treating patients with therapeutic antibodies, sharply increases societal costs, resulting in fewer patients being treated with an antibody treatment. With Alzinova's vaccine, compared to antibody treatment, healthcare and societal costs can be reduced, which creates the opportunity for more people to receive care.

Business model

Alzinova's business model is to drive projects into clinical development with the aim of documenting that the drug candidates are safe and well tolerated as well as demonstrating proof-of-concept, i.e. that they exhibit efficacy in patients with Alzheimer's disease. Based on clinical data, the Company intends to identify one or more strategic partners who have the resources and expertise to conduct the studies needed for registration and commercialization. This can be done through out-licensing with a partnership where the Company jointly brings the drug to the market with the collaboration partner, or through a complete acquisition of the drug candidate for further development.

Out-licensing
A common alternative for development companies like Alzinova is to out-license projects to one or more regional pharmaceutical companies. Either these can get exclusivity in a limited market, and you agree with several partners to cover the market globally, or you have a global partner who takes the drug to the entire market. A typical arrangement for out-licensing is initial compensation and then future installments linked to pre-defined milestones during further development, the regulatory process and commercialization with high revenues linked to future drug sales.

The Company has so far taken several important steps towards out-licensing and commercialization. The data shows "best-in-class" potential, which is very attractive for partnering. With positive results in the Company's two drug projects, ALZ-101 and ALZ-201, there are several options. One is to out-license the ALZ-101 vaccine to a major pharmaceutical company, and another option is for the Company to take ALZ-101 through phase 2 and then out-license it to a partner. For the antibody ALZ-201, this could be out-licensed immediately during the preclinical phase, or alternatively after phase 1b studies. The Company's focus going forward is on business development with several ongoing dialogues in parallel with clinical development of the project portfolio.

The market for Alzheimer's drugs

Every year around 10 million people in the world become ill with some form of dementia, of which Alzheimer's disease accounts for around 60–70 %. Today, it is estimated that there are approximately 55 million patients with dementia in the world, but it is difficult to diagnose dementia today at early stages of disease. Therefore, it is expected that this figure is significantly higher. In addition, this number is expected to increase to more than 130 million by 2050. It is estimated that more than 30 million people in the world today have Alzheimer's disease and the number is expected to triple by 2050[1].

The societal costs of dementia diseases are currently estimated at $1,300 billion annually[2]. The drug cost of Alzheimer's medications, which are symptom relief alone, amounts to approximately $6 billion annually. While the first disease-modifying drugs has recently been approved in the United States, Japan and China there is still a very long way to go to truly treat and prevent the progression of Alzheimer's disease.

The sales and revenue potential of a new effective disease-modifying drug is therefore significant even if it would only have an initially limited market share. By 2026, drugs for Alzheimer's disease are expected to be represented among 2 out of 7 expected top sellers (pharmaceutical companies), with an expected annual turnover of USD 1.7–4.5 billion[3]. The reason why the initial sales estimates are relatively low is that there have been no good medical alternatives. With effective treatment options coming to the market, such as Alzinova's drug, the Company estimates that annual sales can be multiplied several times compared to today.

The research firm Global Data estimates that annual sales for disease-modifying drugs for Alzheimer's disease will reach roughly $13 billion by 2028 in the largest markets: the United States, Germany, France, the United Kingdom, Italy, Spain, Japan, China, and India. An approved disease-modifying treatment for Alzheimer's disease has the potential to generate peak annual sales in excess of USD 10 billion[4].

[1] World Health Organization (WHO) – Facts about Dementia, March 2023.
[2] World Alzheimer's Report, 2021.
[3] Drugs to watch report, 2022.
[4] US, Germany, France, UK, Italy, Spain, Japan, China. GlobalData, Pharma, June 7, 2023.

Alzinova's collaboration with the Alzheimer foundation

In January 2022, Alzinova initiated a collaboration with the Alzheimer's Foundation, the fundraising organisation that contributes the most to dementia research in Sweden. Through the collaboration, Alzinova and the Alzheimer's Foundation can together increase understanding and interest in the disease and support research with the ultimate goal - to stop Alzheimer's disease. In 2023, Alzinova participated in and sponsored the Alzheimer's race.
At the end of 2023, after Alzinova presented positive topline results from its phase 1b study with the vaccine candidate ALZ-101, the Alzheimer's Foundation conducted an interview with Alzinova's CEO Kristina Torfgård.

What will the results, which you have now presented from the phase 1b study, mean for patients with Alzheimer's and when do you think a vaccine will be available for sufferers in the future?
— It is very positive that we, in the first clinical study, have been able to show that the vaccine is safe and well tolerated and that patients show an immune response with specific antibodies against toxic oligomers. A clinical development phase in drug development usually takes 8-10 years for this type of drug, but it is hoped to shorten the time with the help of new technology, new research findings and shorter regulatory processes (Fast Track in the US). Despite the long lead times, we feel that we have taken a significant and important step forward with our latest results.

What does a vaccine (therapeutic vaccine) mean in the fight against Alzheimer's disease?
— A therapeutic vaccine that specifically targets and neutralises the toxic accumulation of amyloid-beta oligomers is unique. Alzinova's vaccine candidate ALZ-101 is being developed as a long-acting drug for the treatment and prevention of Alzheimer's disease by causing the body to develop antibodies against the harmful oligomers, thus preventing the progression of the disease. We are at an early stage, but the initial results we have obtained show that the patients who have received the vaccine are tolerating it well and that they show elevated antibody levels.

How does it differ from other disease-modifying approaches?
— The vaccine, unlike other treatments such as antibodies, is expected to require only a few doses per year instead of as often as every two weeks. Moreover, it can be administered to patients in a very time-efficient way through a simple injection in primary care or at home by a nurse. Other treatments are time-consuming and require hospitalisation. The cost to society of treating patients with an antibody treatment increases significantly, resulting in fewer patients being treated. Compared to antibody treatment, Alzinova's vaccine can reduce healthcare and social costs, making it possible for more people to receive treatment.

For those who are diagnosed with Alzheimer's today and are concerned that their children may carry the APOE4 risk gene, could vaccines be available for those with a hereditary risk in the future?
— Our goal is to develop effective and safe treatments for Alzheimer's disease with the vaccine being developed first as a therapeutic vaccine to treat patients with a confirmed Alzheimer's diagnosis. If we can dream and hope, the ultimate goal is, of course, that it can also be developed into a vaccine to prevent Alzheimer's disease.

The Alzheimer's Foundation has conducted further interviews with Alzinova which are available at: https://www.alzinova.com/news/.

Alzinova's regulatory work – *An interview with Head of Regulatory Affairs Margareth Jorvid*

In the dynamic world of drug development, navigating regulatory frameworks is a crucial aspect of bringing innovative treatments to market. Alzinova, with its breakthrough vaccine candidate ALZ-101, has been at the forefront of constructive dialogues with regulatory authorities. We had the privilege of sitting down with Margareth Jorvid, Head of Regulatory Affairs at Alzinova, to explore the meaning of these dialogues and what it entails from a regulatory perspective.

In 2023, Alzinova had positive dialogues with both the FDA and EMA. What does this mean for Alzinova and specifically for the vaccine candidate ALZ-101, from a regulatory perspective?
— With our innovative vaccine candidate ALZ-101, it is particularly important to have an early dialogue with the regulatory authorities. Through this dialogue, the authorities receive information about new thinking in the treatment of diseases, in this case Alzheimer's disease, where patients and the healthcare system are in great need of new treatments. Furthermore, Alzinova gets clarity on the regulatory requirements and expectations that the authorities have, while it is also a good opportunity to check that Alzinova is on the right track with our development programme for ALZ-101.

»By navigating these regulatory processes, we can continue Alzinova's quest to make a real difference for patients battling this difficult disease.«

What is a pre-IND meeting or Scientific Advice Procedure, and why has Alzinova had these?
— In the US, IND stands for Investigational New Drug and Pre-IND is a meeting with the FDA prior to submitting an IND to the FDA. At Pre-IND, the company can check and get answers from the FDA on questions about manufacturing, pre-clinical studies and how the planned clinical study in the US is intended to be carried out. Alzinova received clear and positive answers to the questions in written form, which is common for Pre-IND meetings during and after the pandemic.

Similarly, in Europe, a Scientific Advice Procedure (SAP) with the EMA is a good way to get answers to important questions about manufacturing, pre-clinical studies, and the design of the next planned clinical trial. A Rapporteur/Co-rapporteur is appointed among the EU member states, but all EU countries are represented in the procedure and support the answers the company receives. Here too, Alzinova received clear and positive answers to the questions.

Alzinova chose to conduct Pre-IND with FDA and SAP with EMA as an important part of the preparation work for the planned phase 2 study. In both these procedures, we compiled information material for the authorities in order to get good and clear answers to the questions asked. The authorities' answers were a good reconciliation and a solid basis for the planned phase 2 study.

What are Alzinova's next steps on the regulatory front?
— The next regulatory step for Alzinova is to plan for and compile the material needed for the clinical trial application (phase 2 study) in the relevant countries in Europe, and to compile an IND application for the US. By navigating these regulatory processes, we can continue Alzinova's quest to make a real difference for patients battling this difficult disease. ●

About Margareth Jorvid

Margareth Jorvid has over 30 years of experience in Regulatory Affairs and has worked at the Swedish Medical Products Agency as well as at large and small pharmaceutical companies, such as Roussel Nordiska, Hoechst Marion Roussel (Stockholm and Paris, France) and Neopharma. Since 2006 she is a consultant in regulatory affairs and QA for pharmaceuticals, advanced therapies and medical devices through her company Methra Uppsala AB, LSM group. She is a member and honorary member of TOPRA (Organisation for Professionals in Regulatory Affairs), board member and president of TOPRA between 2005-2006. She is a pharmacist and holds an MSc in Medical Technology Regulatory Affairs from Cranfield University, UK, and an Executive Master of Business Administration (MBA) from the Stockholm School of Economics. Margareth joined Alzinova in 2022 and is responsible for regulatory affairs in the role as Head of Regulatory Affairs.

Our vision

»To enable patients to live independent and active lives without the impact of Alzheimer's disease by developing new treatments that modify the disease.«

Our goals

Goals for 2024

- Present the results of part A1 of the phase 1b study at international scientific meetings.
- Conduct analysis of and present part A2 of the phase 1b study.
- Apply to the FDA for Fast Track status.
- Conduct initial analysis of part B of the phase 1b study.
- Prepare and apply to start the phase 2 study.
- Prepare the ALZ-201 antibody for phase 1b clinical trials.

Our long-term goal

»Our long-term goal is to develop a disease-modifying therapeutic vaccine for the treatment and prevention of the development of Alzheimer's disease.

A long-acting drug will make it possible for patients to live an active and independent life without the influence of the disease.«

Management

Kristina Torfgård

Position
Chief Executive Officer since 2019.

Background
Kristina has 30 years of experience from leading roles in the pharmaceutical and biotech industry. She previously worked at AstraZeneca with research and development in both early and late phase and was globally responsible for marketed products. Kristina has also worked at the biotech company Albireo AB/Pharma Inc.

Education
Pharmacist and doctor of medicine in clinical pharmacology.

Ongoing assignments
Board member of GU Ventures.

Holdings in the Company
50,000 shares privately as of 28 March 2024.

Anders Sandberg

Position
Chief Scientific Officer since 2015.

Background
Anders is one of Alzinova's founders and was also the Company's CEO during a transition period. He has over 20 years of experience in protein research with an emphasis on neurotoxic peptide aggregates. As former operations manager, he has run much of the Company's operations. Anders is a co-inventor of Alzinova's AβCC technology and has been deputy board member since 2011.

Education
PhD in chemistry - specializing in biochemistry.

Ongoing assignments
No other ongoing assignments.

Holdings in the Company
135,144 shares privately as of 28 March 2024.

Håkan Skogström*

Position
Chief Financial Officer since 2020.

Background
Håkan has 20 years of experience from leading finance positions in the shipping industry. He has previously worked as CFO and CEO at a privately owned Swedish shipping company with international operations where he was involved in building up the company's economy and finance function. Håkan has worked as CFO for Safe at Sea AB.

Education
Bachelor's degree small business economics.

Ongoing assignments
No other ongoing assignments.

Holdings in the Company
37,751 shares privately as of 28 March 2024.

**CHANGES IN MANAGEMENT*
After the end of 2023, CFO Håkan Skogström retired and thus ended his employment. Alzinova has appointed Erik Kullgren as interim CFO from March 2024 while the process of recruiting a permanent CFO continues.

Kirsten Harting

Position
Chief Medical Officer since 2023.

Background
Kirsten has more than 30 years of experience in medicine, clinical studies and drug development as well as business development and bringing products to market from Lundbeck, Pfizer, ALK and Novo Nordisk, among others. She is currently CMO at SynAct Pharma and Tetra Pharm Technologies and is Medical & Compliance Manager at Sandoz.

Education
MD and Executive MBA.

Ongoing assignments
No other ongoing assignments.

Holdings in the Company
0 shares as of 28 March 2024.

Stefan Pierrou

Position
Development Project Director since 2021.

Background
Stefan has 25 years of experience in drug discovery and development. He has worked as a preclinical research leader and early clinical project leader to develop substances for clinical testing and more. Stefan has worked at AstraZeneca in various project leading and managing roles within research and development. He also works as a senior consultant supporting smaller biotech and drug development companies.

Education
MSc in Chemical Engineering, PhD in Molecular Biology.

Ongoing assignments
CEO, ESP Life Science Consulting AB.

Holdings in the Company
16,925 shares privately and through company as of 28 March 2024.

Sebastian Hansson

Position
Business Development Director since 2023.

Background
Sebastian has more than 15 years of experience in drug development and clinical development, CROs and GMP production of APIs (Active Pharmaceutical Ingredients). He has extensive experience in startups and business development. Before joining Alzinova, he was Chief Operating Officer at SWIPP AB, Project Manager and Key Account Manager at Polypeptide Group and Business Development Manager at Solve R&C.

Education
MSc in chemistry, PhD in molecular biophysics, MBA, certified board member.

Ongoing assignments
Board member of Bulb Intelligence AB, Tyto Competitive Intelligence Solutions AB and Scientific Intelligence Consulting Öresund AB.

Holdings in the Company
29,000 shares privately and through company as of 28 March 2024.

Board of Directors

Julian Aleksov

Position
Chairman of the Board since 2023.

Background
Julian has more than 25 years of experience in finance and international business development within the pharmaceutical and technology industries, including Oasmia Pharmaceutical AB. Julian is an entrepreneur who ran his own companies for many years in several different business areas, primarily pharmaceutical development. He is an active investor and, through companies, also a major owner in a number of listed companies.

Education
Economist.

Ongoing assignments
Board member of Maida Vale Capital AB and Hunterhex AB.

Holdings in the Company
6,748,920 shares through company as of 28 March 2024.

Anders Blom

Position
Board member since 2021.

Background
Anders has more than 25 years of experience in international finance and business development within the pharmaceutical and medical technology industry. His experience includes Pharmacia & Upjohn, Q-Med AB, partner and CEO at the venture capital company Nexttobe AB and EVP and CFO at Oasmia Pharmaceutical AB. In addition, Anders has extensive board experience from the pharmaceutical and technology sector.

Education
Bachelor's degree in business administration at Uppsala University.

Ongoing assignments
Chairman of the board of Maida Vale Capital AB, Globopetz AB and Peptonic Mecical AB, board member of Terranet AB, Rosland Nordic AB, Hunterhex AB and Wonderboo Holding AB.

Holdings in the Company
6,748,920 shares through company as of 28 March 2024.

Clas Malmeström

Position
Board member since 2015.

Background
Clas is senior physician at the MS Center, Neurohealth, and at the Laboratory in clinical immunology at Sahlgrenska University Hospital in Gothenburg. Since 2001, he has conducted research in Multiple Sclerosis (MS) at the hospital's MS Center and the Department of Clinical Neuroscience, University of Gothenburg. In addition to academic research, he has participated in several MS clinical drug trials led by Biogen-Idec, Merck, Novartis, Roche, and Sanofi, several of which resulted in today's standard treatments for MS.

Education
Medical doctorate, senior physician Neurology and Clinical Immunology.

Ongoing assignments
No other ongoing assignments.

Holdings in the Company
12,000 shares privately as of 28 March 2024.

Per-Göran Gillberg

Position
Board member since 2020.

Background
Per-Göran has 35 years of experience in the pharmaceutical industry. He has broad experience in pharmacology and neuro-pharmacology from Kabi/Kabi Pharmacia, Pharmacia/Pharmacia & Upjohn and AstraZeneca. Per-Göran is the founder of Albireo AB and was previously VP Development for Albireo Pharma Inc. He is also affiliated with the department of translational Alzheimer's neurobiology at the Karolinska Institutet in Stockholm.

Education
PhD in medical science, adjunct professor in neuroscience at Uppsala University.

Ongoing assignments
Board member of Dicot AB. Adjunct to the Center for Alzheimer Research at Karolinska Institutet.

Holdings in the Company
19,500 shares privately as of 28 March 2024.

Carol Routledge

Position
Board member since 2018.

Background
Carol has over 30 years of experience in pharmaceutical and biotechnology companies. She has had a key role in GSK Biopharmaceuticals, in the areas of immunoinflammatory diseases and neuroscience. She recently managed a dementia fund focusing on disease-modifying mechanisms for the treatment of all different types of dementia. Carol also Headed the Research Department at Alzheimer's Research UK, and was previously the Chief Medical and Scientific Officer at Small Pharma Ltd. She is now an independent consultant in the biomedical research space.

Education
PhD in neuropharmacology.

Ongoing assignments
Steering Committee member and Advisor of EDoN, Alzheimer's Research UK, Advisory Board of Ro5.AI, London, UK, Advisory Board of Cognetivity Neurosciences Ltd, Vancouver and Honorary Professor & EIR, Exeter University, UK.

Holdings in the Company
0 shares as of 28 March 2024.

Anders Waas

Position
Board member since 2018.

Background
Anders has held several senior roles in Astra, AstraZeneca, CV Therapeutics, Actogenics and Tikomed AB. He has previous experience in business management, business development and pharmaceutical development.

Education
Dentist (DDS).

Ongoing assignments
Chairman of the Board of Sobrera Pharma AB, and SiMSen Diagnostics AB. Board member of Transmed Gothenburg AB, Toleranzia AB, Anders Waas AB, Nexocure Therapeutics AB, Xandrax AB, and CerInvent AB.

Holdings in the Company
0 shares as of 28 March 2024.

Lena Degling Wikingsson

Position
Board member since 2020.

Background
Lena has 25 years of experience from the pharmaceutical industry. She has broad experience in regulatory affairs and development of biological medicines and vaccines from, among others, Dilafor AB, Avaris AB, Independent Pharmaceutica AB, SBL Vaccines, Accuro Immunology, and the Swedish Medicines Agency. Lena is currently CEO of Dilafor AB.

Education
Pharmacist and PhD in pharmaceutical science.

Ongoing assignments
Chairman of the Board of Simplexia AB, and Dilafor Incentive AB. Board member of XNK Therapeutics.

Holdings in the Company
0 shares as of 28 March 2024.

Administration report

The Board of Directors and the Chief Executive Officer of Alzinova AB (corporate identity number: 556861-8168) hereinafter referred to as Alzinova or the Company, hereby submit the Annual Report for the financial year 2023. Alzinova is a public limited liability company.

Alzinova is a Swedish biopharmaceutical company specialising in the treatment of Alzheimer's disease. The Company's proprietary AβCC-peptide™ technology enables the development of disease modifying therapies that with high precision could target the toxic accumulations of the peptide amyloid-beta, so-called oligomers, which are central to the onset and development of the disease.

The vaccine candidate ALZ-101 is under clinical development and part A of the phase 1b study with Alzheimer patients started Q3 2021. Part A of the study was completed at the turn of the year 2023/2024 with a positive outcome where ALZ-101 shows good safety and tolerability as well as a clear immunological response. Based on positive interim data from Part A, the Company decided in May 2023 to initiate an extension part, Part B, of the ongoing clinical study. The results of the full analysis from Part A open up the possibility of evaluating an additional higher dose. An addition to the study (A2) has been approved by the regulatory authority and evaluates treatment with a higher dose. The A2 part is expected to be completed in 2024. Based on the same technology, the Company is also developing the antibody ALZ-201, which is currently in the preclinical development phase. Alzinova is currently developing a humanized version of ALZ-201 for clinical phase 1 studies in patients with Alzheimer's disease.

Alzinova was founded by researchers from the MIVAC research center at the University of Gothenburg, in collaboration with GU Ventures.

The Company has its registered office in Gothenburg.

Significant events during the financial year 2023

First quarter

- Alzinova announced on January 3 that a new scientific article has been published in the respected journal Alzheimer's Research & Therapy with preclinical results demonstrating that the antibody ALZ-201 has specificity for the toxic oligomers believed to be the cause of Alzheimer's disease.
- On January 24, Alzinova announced that the Company has strengthened its management team by appointing Sebastian Hansson as Business Development Director.
- On March 16, Alzinova announced that a planned external safety review has been carried out of the Company's clinical phase 1b study in Alzheimer patients - with a positive assessment to continue the vaccine study as planned.

Second quarter

- During April, the exercise period for the Company's warrants of series TO3 began, where the subscription price was set at SEK 2.17 per share with a subscription period of 11 - 21 April. The warrants were subscribed to a utilization rate corresponding to approximately 93.4% and the Company thereby received approximately 26.3 MSEK, before issue costs.
- On April 12, Alzinova announced that all patients participating in the phase 1b study with the vaccine candidate ALZ-101 against Alzheimer's disease have received their fourth and final dose of the vaccine ALZ-101 or placebo.
- Alzinova announced on April 18 that the Company received regulatory approval from the Finnish Medicines Agency, Fimea, as well as the Finnish National Ethics Committee to initiate an extension part of the phase 1b study. The extension part aims to provide information on long-term safety and tolerability, immune response and information on signals of effect on biomarkers and cognitive functions.
- On April 24, Alzinova announced that the Company has terminated the agreement with Mangold Fondkommission AB regarding the assignment as liquidity guarantor. The last day for liquidity support trading of Mangold was April 28, 2023.
- On April 27, Alzinova announced a change in the management team, Chief Medical Officer (CMO) Anders Bylock is leaving the Company for personal reasons on May 28, 2023. The Company has already initiated a recruitment process to find a replacement.
- On May 4, the Company announced that a second planned interim analysis had been completed of the ongoing phase 1b clinical study with the vaccine candidate ALZ-101 against Alzheimer's disease. The analysis showed positive data with continued good safety and tolerability as well as a clear immunological response, i.e. that specific antibodies have been produced after dosing with ALZ-101. Based on this positive second interim analysis, the Company made a decision to conduct an extension to the study.
- On May 29, the Company announced that the extension of the phase 1b study with the vaccine candidate ALZ-101 had been initiated by dosing the first patient.
- The Company's annual general meeting was held on 30 May 2023 and all proposed decisions were adopted by the general meeting. The minutes for the meeting are available on the Company's website, www.alzinova.com. At the annual general meeting, Björn Larsson resigned as chairman of the board and the meeting thanked him for his far-reaching commitment and efforts for Alzinova during his 10 years on the board. Julian Aleksov was elected as the new chairman of the board.
- On June 13, the Company announced that it has submitted an application for a pre-IND meeting with the US FDA (Food and Drug Administration) and an application for EMA Scientific Advice from the European Medicines Agency (EMA).

Third quarter

- Alzinova announced on August 3 that the Company has recruited Kirsten Harting to the role of Chief Medical Officer (CMO). Kirsten Harting, who assumed her position on August 14, is also part of the Company's management team.
- On August 8, Alzinova announced that the Company has conducted a so-called pre-IND meeting with the US Food and Drug Administration (FDA) and received positive feedback on the planned clinical development program for the vaccine candidate ALZ-101. This represents significant steps in preparation to include US study centers in future clinical studies.

- On August 25, Alzinova announced that the Company has signed an agreement with PolyPeptide Laboratories Holding (PolyPeptide) for the production of Alzinova's peptide (AβCC) intended for future clinical studies.
- Alzinova announced on September 26 that the Company has received a positive response from the European Medicines Agency (EMA) regarding the planned clinical development program for the vaccine candidate ALZ-101. This means significant steps have been taken in the preparations to include European study centers in future clinical studies.

Fourth quarter

- On October 5, Alzinova announced that the Company will participate in Europe's largest Life science conference BIO-Europe during the autumn. The conference is a gathering place for partner meetings where the Company presented the vaccine candidate ALZ-101 and the antibody ALZ-201 to potential partners. Furthermore, the Company announced that they would present at Redeye's theme day on neurology, which was held on 11 October.
- On October 24, Alzinova announced that the Company engaged Erik Penser Bank as liquidity guarantor from and including November 1, 2023.
- On November 29, Alzinova announced positive phase 1b results with the vaccine candidate ALZ-101 against Alzheimer's disease. Top-line data show that the vaccine candidate ALZ-101 meets the study's primary safety and tolerability objectives. Furthermore, the patients treated with ALZ-101 responded to the treatment producing antibody levels which increased with the number of doses given.
- On December 1, Alzinova announced that the Company's CFO intends to retire in 2024 and that recruitment of a replacement had begun.

Significant events after the end of the financial year 2023

- On January 30, Alzinova announced that the full analysis of data from Part A of the phase 1b clinical trial, with the vaccine candidate ALZ-101, has confirmed the positive results previously reported. Given the favourable safety profile, the Company applied for an addition to the study to evaluate a higher dose level. The addition is being made to optimize the design of the upcoming phase 2 study.
- On February 13, Alzinova announced that the Company received approval from regulatory authorities to evaluate a higher dose of the vaccine candidate ALZ-101 in the ongoing phase 1b study.
- On March 8, Alzinova announced that the Company is appointing Erik Kullgren as interim CFO due to the fact that the Company's current CFO, Håkan Skogström, will retire on March 27. The process of recruiting a permanent CFO continues.
- On April 4, Alzinova announced that all patients participating in the extension part (part B) of the phase 1b study with the vaccine candidate ALZ-101 against Alzheimer's disease, have received their last dose of ALZ-101.
- On April 11, Alzinova announced that an in-depth analysis of data from part A of Alzinova's phase 1b study with the vaccine candidate ALZ-101 has been completed. The analysis indicates that patients with the higher antibody levels after vaccination have a positive effect on biomarkers associated with Alzheimer's disease.
- On April 25, Alzinova's CEO, Kristina Torfgård, announced that she had informed the Board of her wish to resign as CEO of the Company.
- On April 26, Alzinova announced that the Board of Directors of the Company had decided, with the support of the authorisation from the Annual General Meeting 2023, on a rights issue of shares of approximately SEK 34.4 million.
- On April 26, the shareholders of Alzinova were invited to the Annual General Meeting on 29 May 2024 at 13:00 in Chalmersska Huset in Gothenburg.

Revenues and results

During the year, the Company mainly invested in the development of ALZ-101, a vaccine against Alzheimer's disease, which is in clinical phase 1b. The Company has also started development for clinical studies of the antibody ALZ-201, with the goal of treating, and also preventing, the progression of Alzheimer's disease.

Net sales in 2023 were 0.3 MSEK (0.0), and the Company is not expected to generate revenue until the Company's products are further along in their development phase. Operating profit during the year amounted to approximately -16.5 MSEK (-13.1).

During the year, the Company's total costs amounted to approximately 36.4 MSEK (29.7), of which approximately 19.6 MSEK (16.6) were capitalized as development costs relating to the Company's products and recorded as intangible fixed assets. The increase in development costs has continued according to the Company's plan.

Cash flow

Cash flow from current operations, including changes in working capital for the year, amounted to approximately -15.2 MSEK (-10.3).

Cash flow from investment activities amounted to approximately -19.6 MSEK (-16.6) and consisted of capitalized development costs.

Cash flow from financing activities amounted to approximately 24.8 MSEK (30.1), and was generated through the warrants that were exercised during the second quarter with approximately 26.3 MSEK before expenses. Total issue costs of around 1.5 MSEK were deducted from this.

Financial Position

At the turn of the year, the Company had a cash balance of approximately 22.0 MSEK (32.0).

The financial information has been prepared based on the assumption of continued operations. When preparing the annual report, the management and the board have based their assumptions on existing liquid assets and expected financing.

At the time of publication of the annual report, a rights issue of shares has been decided, which, if fully subscribed, could provide the Company with 34.4 MSEK before issue costs. The rights issue is guaranteed by subscription commitments and guarantee commitments to 100%. During the first quarter of 2024, the Company has also received a loan commitment on market terms of 5 MSEK from one of the Company's major owners, Maida Vale Capital AB.

The clinical development requires continued and significant financing for Alzinova. The Board of Directors believes that there are good conditions for this and that the rights issue decided in April, together with the loan commitment received, creates the conditions for continued operations for the financial year 2024. The Company also has the opportunity to reprioritise operations based on the capital available in the Company, which is why the Board of Directors believes that the conditions for continued operations are met. The management is aware that there are uncertainties in the estimate of future cash flows, but considers this risk to be manageable and works continuously to overcome it.

Development of the Company's operations, profit/loss and position

KSEK	2023	2022	2021	2020
Net sales	270	-	-	-
Result after financial items	-16,480	-13,088	-7,552	-6,500
Earnings per share before/after dilution, SEK	-0.41	-0.54	-0.48	-0.78
Total capital	123,189	111,621	91,691	100,816
Average number of full time employees	5	4	3	3
Equity ratio, %	92.4	94.5	96.5	95.2

Earnings per share: Result for the year, divided by the number of shares at the balance date
Equity ratio: Total equity diveded by total capital

Proposed appropriations of the Company's profit or loss

The Board of Directors and the Chief Executive Officer of Alzinova AB propose that available profits, 7,956 KSEK as follows:

KSEK	
Retained result	-141,828
Share premium	166,264
Result for the year	-16,480
Total	**7,956**
To be carried forward	7,956
Total	**7,956**

As regards the Company's results and position in general, reference is made to the subsequent income and balance sheets with accompanying notes.

Corporate structure and shareholding

Alzinova has no subsidiaries and is not part of any group. Neither does the Company hold any shares.

The Share

The Alzinova share was listed on the Spotlight Stock Market on 25 November 2012. As of 11 March 2019, the Company was listed on Nasdaq First North Growth Market. There is one class of shares in the Company. The share entitles to one (1) vote per share. Each share has equal right in shares in the Company's assets and profits. As of 31 December 2023, the number of shares in Alzinova amounted to 45,531,256. The share's quota value amounts to SEK 0.263/share.

Rights Issues

During 2022, the Company carried out a rights issue with connected warrants of the series TO3 2023. During April 2023, these warrants expired and a total of 12,112,231 warrants of the series TO3 were used to subscribe for shares, which meant that the Company's shares increased by 12,112,231 shares to a total of 44,531 265 shares and with a total share capital of SEK 11,711,723. In total, approximately 24.8 MSEK was added to the Company after deduction for issue costs of approximately 1.5 MSEK. For shareholders who did not exercise their warrants, the dilution amounted to approximately 27.2% based on the total number of shares in the Company.

Largest owners as per 29 December 2023

Owner	No. of shares/ votes	Capital, %
Maida Vale Capital AB	6,747,686	15.15
Försäkrings AB Avanza Pension	3,099,897	6.96
Nordnet Pensionsförsäkring AB	1,864,018	4.19
Patrik Ahlvin	1,004,750	2.25
Sara Gjertz	766,015	1.72
MIVAC Development AB	711,787	1.60
Özlem Erdogdu Gül	684,916	1.54
MGC Capital Ltd.	604,171	1.36
Moll Invest AB	600,080	1.35
Ålandsbanken, i ägares ställe	596,476	1.34
Total other owners	27,851,469	62.54
Total all owners	**44,531,265**	**100.00**

Long-term share-based incentive programs

There are currently no outstanding long-term incentive programs in the Company.

Risk factors

Alzinova maintains procedures to continuously identify and manage risk factors. The primary risk factors that affect the Company are set out below.

Market and business-related risks

The Company's drug candidates
The Company's primary focus is the vaccine candidate ALZ-101 and the antibody ALZ-201.

ALZ-101 is presently undergoing a clinical phase 1b study in humans. If the clinical study shows that ALZ-101 is not well tolerated, causes unexpected side effects or if the vaccine does not give satisfactory results in terms of generating an immune response immune response, it may mean that the Company must terminate the project.

The Company is developing the antibody ALZ-201 which is in the early preclinical phase and based on the same technology as the vaccine candidate ALZ-101. There is a risk that the development of ALZ-201 may be hindered if the clinical phase 1b study that ALZ-101 undergoes shows that ALZ-101 has insufficient safety or tolerability in humans. There is also a risk that studies of ALZ-201 in themselves will not give satisfactory results. The realization of the risk may mean that the Company must terminate the development of ALZ-201.

If one or both projects had to be terminated, the Company would not be able to generate income from the projects, which would have a negative impact, primarily on the Company's sales, earnings and financial position.

Commercialization
The Company has not yet commercialized its projects, for example through licensing agreements, partnerships or independently developed or launched any drugs and has therefore not conducted any sales or generated any revenue. There is thus a risk that the Company will not succeed in commercializing its projects. If the Company does not successfully succeed in commercializing its projects, the Company will not be able to generate income and is then still completely dependent on externally provided capital. If the Company does not successfully succeed in commercializing its projects, it may have a negative impact, primarily on the Company's sales and earnings.

Key people and recruitment
When commercializing its projects, the Company is dependent on the organization maintaining the competence to carry out all steps in the development of the projects. As the Company's organization is limited, the Company is particularly sensitive to the loss of its employees. Loss of certain specific key people as well as failure to recruit people with sufficient competence for the clinical studies may make it more difficult to carry out the necessary studies and achieve commercialization of the projects.

Suppliers and manufacturers
The Company is dependent on collaborations with suppliers and manufacturers. The part of the business that is carried out by partners is judged not to be able to be carried out by the Company. There is a risk that the Company's cooperation partners will be forced to discontinue cooperation with the Company. There is also a risk that the Company's suppliers and manufacturers do not fully meet the quality requirements set by the Company. If the Company's collaborations could no longer continue, or if they do not live up to the quality requirements set by the Company, it would cause delays in the development program. The Company continuously evaluates its direct and indirect suppliers and conducts active work to minimize and, as far as possible, eliminate external influences on the Company's operations.

The Company today operates in an environment with a very uncertain geopolitical world situation, and it is difficult to say how this will affect the Company's long-term development.

The general global economic situation is a major challenge for all companies to manage, mainly through inflationary cost increases. This risk is continuously monitored through a high awareness of costs.

Legal and regulatory risks

Preclinical and clinical studies
Before a drug can be launched on the market, the safety and efficacy of a treatment for humans must be ensured for each individual indication, which can often be demonstrated through preclinical studies in animals and clinical trials in patients. Alzinova may need to conduct more extensive studies than the Company currently assesses. There is also a risk that the partners conducting the preclinical and clinical trials will not be able to maintain the clinical and regulatory quality required for any future out-licensing, partnership, sale or regulatory approval.

If the Company needs to conduct more extensive studies than what the Company currently assesses, this may lead to increased costs or delayed revenues. If the partners who carry out the preclinical and clinical studies are unable to maintain the clinical and regulatory quality required for any future out-licensing, partnership, sale or approval from authorities, this may lead to delays in preclinical and clinical studies for the Company and thus no commercialization.

Immaterial rights
The value of the Company is largely dependent on the ability to obtain and defend patents. There is a risk that the Company's patents will not be granted on patent-pending inventions, that patents will be circumvented by, above all, generic companies, that patents will be annulled in court, or that the patent period expires before successful commercialization has taken place. If the Company does not obtain or succeed in defending its patents, the Company's competitors will be given the opportunity to commercialize their own products without prejudice to patent rights and thus affect the Company's sales potential.

Financial risks

Liquidity risk
Even if the Company succeeds in commercializing its projects, the revenue potential of the Company and the future commercialized projects is uncertain. If the Company does not reach a satisfactory revenue potential, there is a risk that revenue will be completely or partially absent. If the revenues do not exceed the Company's costs, the Company will continue to be dependent on externally supplied capital. If the Company cannot obtain external capital to a sufficient extent, it will have a negative impact on the Company's financial position, which means that the Company's operations will not be able to be conducted at the planned pace. The Company manages this risk by preparing in good time for external financing in the form of issues, grants or other capital. Furthermore, the Company continuously monitors the cash flow to reduce the liquidity risk.

Financial market risk
The financial market risk mainly consists of currency risks which arise through business transactions in foreign currency. The Company's currency risk is affected by flows from purchases mainly in EUR.

Income Statement

KSEK	Notes	Jan-Dec 2023 12 months	Jan-Dec 2022 12 months
Net sales		270	-
Own work capitalized	5	19,604	16,633
		19,874	**16,633**
Operating expenses			
Other external expenses	2	-27,097	-23,033
Personnel expenses	3	-9,299	-6,687
Operating result		**-16,522**	**-13,087**
Result from financial items			
Interest income		140	18
Interest expenses		-98	-19
Result after financial items		**-16,480**	**-13,088**
Result before tax	4	**-16,480**	**-13,088**
Result for the year		**-16,480**	**-13,088**

Balance Sheet

KSEK	Notes	31 December 2023	31 December 2022
ASSETS			
Fixed assets			
Intangible assets			
Capitalized expenditure for development work	5	96,253	76,649
Patent	6	1,632	1,632
		97,885	**78,281**
Total fixed assets		**97,885**	**78,281**
Current assets			
Short term receivables			
Tax receivables		257	206
Other receivables		378	630
Prepaid expenses and accrued income		2,643	466
		3,278	**1,302**
Cash and cash receivables		**22,026**	**32,038**
Total current assets		**25,304**	**33,340**
TOTAL ASSETS		**123,189**	**111,621**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		11,712	8,526
Fund for development costs		94,190	74,586
		105,902	**83,112**
Unrestricted equity			
Share premium		166,264	144,645
Retaind result		-141,828	-109,136
Result for the year		-16,480	-13,088
		7,956	**22,421**
Total equity		**113,858**	**105,533**
Long term liabilities			
Other long term liabilities	7	800	800
		800	**800**
Current liabilities			
Accounts payable		2,493	3,170
Other current liabilities		3,413	723
Accrued expenses and prepaid income		2,625	1,395
		8,531	**5,288**
TOTAL EQUITY AND LIABILITIES		**123,189**	**111,621**

Change in equity

Jan-Dec 2023 12 months KSEK	Share capital	Fund for development costs	Share premium	Retained result incl. result for the year	Total equity
At the beginning of the year	**8,526**	**74,586**	**144,645**	**-122,224**	**105,533**
Rights issue	3,186	-	23,098	-	26,284
Transaction costs, rights issue	-	-	-1,479	-	-1,479
Transfer within equity	-	19,604	-	-19,604	0
Net result for the year	-	-	-	-16,480	-16,480
At the end of the year	**11,712**	**94,190**	**166,264**	**-158,308**	**113,858**

Jan-Dec 2022 12 months KSEK	Share capital	Fund for development costs	Share premium	Retained result incl. result for the year	Total equity
At the beginning of the year	**4,149**	**57,947**	**118,873**	**-92,497**	**88,472**
Rights issue	4,377	-	32,482	-	36,859
Transaction costs, rights issue	-	-	-6,710	-	-6,710
Transfer within equity	-	16,639	-	-16,639	0
Net result for the year	-	-	-	-13,088	-13,088
At the end of the year	**8,526**	**74,586**	**144,645**	**-122,224**	**105,533**

Cash flow statement

KSEK	Notes	Jan-Dec 2023 12 months	Jan-Dec 2022 12 months
OPERATING ACTIVITIES			
Result after financial items		-16,480	-13,088
Adjustments for items not included in cash flow		-	-
Cash flow from operating activities before change in working capital		**-16,480**	**-13,088**
Cash flow from change in working capital			
Increase (-)/Decrease (+) in operating receivables		-1,976	-94
Increase (+)/Decrease (-) in operating liabilities		3,243	2,868
Cash flow from operating activities		**-15,213**	**-10,314**
Investing activities			
Acquisition of intangible fixed assets	5, 6	-19,604	-16,633
Cash flow from investing activities		**-19,604**	**-16,633**
Financing activities			
Share issue		26,284	36,860
Transaction costs, share issue		-1,479	-6,710
Cash flow from financing activities		**24,805**	**30,150**
Cash flow for the year		**-10,112**	**-3,203**
Cash and cash equivalents at the beginning of the period		**32,038**	**28,835**
Cash and cash equivalents at the end of the period		**22,026**	**32,038**

Notes

Note 1, Accounting principles

All amounts in SEK unless otherwise specified.

General accounting principles
This annual report is prepared in accordance with the Swedish Annual Accounts Act and pursuant to the general recommendations of the Swedish Accounting Standards board BFNAR 2012:1 Annual Accounts and Consolidated Financial Statements (K3).

The accounting principles are unchanged compared to previous years. No new accounting principles that had any significant impact on results or position have been adopted during the year.

Valuation policies, etc.
Assets, provisions and liabilities are measured at cost unless otherwise specified below.

Intangible fixed assets

Research and development costs
Development costs are recognized according to the capitalization model. That means expenditures arising during the development phase are reported as assets when all of the following prerequisites are met:

- It is technically possible to complete the intangible fixed asset for use or sale.
- The intention is to complete the intangible fixed asset and to use it or sell it.
- There are prerequisites for using or selling the intangible fixed asset.
- It is likely that the intangible fixed asset will generate future economic benefits.
- Sufficient and adequate technological, financial and other resources are available to complete the development and use or sell the intangible asset.
- The costs that are attributable to the intangible asset can be calculated reliably.

Other intangible fixed assets
Other intangible fixed assets acquired by the Company are recognized at cost less accumulated amortization and impairment losses.

Amortization
Amortization is recognized on a straight-line basis over the asset's estimated useful life, and as an expense in the income statement. No amortizations have been recorded during the year. Amortization will be recognized when the products are commercialized.

Depreciation of intangible fixed assets
At each balance sheet date, an assessment is made as to whether there is any indication that an asset value is lower than its carrying amount. If such an indication exists, the asset's recoverable amount is calculated.

The recoverable amount is the highest of the fair value less costs to sell and the value in use.

The value in use is calculated as the present value of future cash flows that the asset is expected to generate in the operating activities as well as when it is sold or scrapped. The discount rate applied is before tax and reflects assessments, based on market conditions, of the time value of money and the risks associated with the asset.

An impairment loss recognized in prior periods is only reversed if there has been a change in the estimates used to determine the asset's recoverable amount since the last recognition of impairment loss.

Receivables
Receivables are recognized at the amount that is considered to be collectable based on an individual assessment.

Revenue
Revenue is measured at the fair value of the consideration received or receivable. It is recognized as revenue when it can be reliably calculated, when it is likely that the financial benefits arising from it will be available to the Company, and when the costs incurred or expected to be incurred in respect of the transaction can be measured reliably.

Public grants
Public grants that are not contingent on future performance are recognized as revenue when the conditions for the award of the grant are satisfied. Public grants that are contingent on future performance are recognized as revenue when the performance is delivered. If the grant has been received before the satisfaction of the associated conditions, the grant is recognized as a liability.

A public grant attributable to the acquisition of a fixed asset is recognized as a decrease in the acquisition cost of the asset.

Note 2, Operational leasing - lessee

KSEK	2023	2022
Office rent	67	65
Total	**67**	**65**

Future years' rent is estimated at an annual cost of SEK 67.

Note 3, Employees

	2023	2022
Average number of full-time employees	5	4
Total	**5**	**4**

Note 4, This year's tax expense

	2023	2022
Current tax for the year	-	-
Total	**-**	**-**

Total unused deferred tax assets amount to 82,254 KSEK.

Note 5, Capitalized expenditure for development work

KSEK	2023	2022
Accumulated acquisition values		
Beginning of the year	76,649	60,016
Capitalized during the year	19,604	16,633
Capitalized financed by contributions	-	-
Accounted values at end of the year	**96,253**	**76,649**

Acquisition values have been reduced with public contributions from VINNOVA with 241 KSEK (2013), 207 KSEK (2014), 76 KSEK (2015), 11 KSEK (2016), 307 KSEK (2017) and 145 KSEK (2018).

Note 6, Patent

	2023	2022
Accumulated acquisition values		
Beginning of the year	1,632	1,632
Capitalized during the year	-	-
Capitalization financed by contributions	-	-
Accounted values at end of the year	**1,632**	**1,632**

Acquisition values have been reduced with public contributions from Innovationsbron with 80 KSEK (2013) and VINNOVA with 50 KSEK (2015) and 100 KSEK (2019).

Note 7, Other long-term liabilities to credit institutes

	2023	2022
Västra Götalandsregionen	-800	-800
Total	**-800**	**-800**

The loan is conditional and is not subject to an amortization schedule. Obligation to repay the debt arises in conjunction with the exploitation of projects. The creditor may also cancel the debt if the result for which financing has been requested is not achieved.

Note 8, Pledged assets and contingent liabilities

	2023	2022
Pledged assets	None	None
Contingent liabilities	None	None

Note 9, Definitions of key figures

Total balance sheet: Total assets

Solvency: Total equity, including equity part of untaxed reserves, divided with total assets.

Note 10, Significant events after the balance sheet date

- On January 30, Alzinova announced that the full analysis of data from part A of the phase 1b clinical trial, with the vaccine candidate ALZ-101, has confirmed the positive results previously reported. Given the favourable safety profile, the Company applied for an addition to the study to evaluate a higher dose level. The addition is being made to optimize the design of the upcoming phase 2 study.
- On February 13, Alzinova announced that the Company received approval from regulatory authorities to evaluate a higher dose of the vaccine candidate ALZ-101 in the ongoing phase 1b study.
- On March 8, Alzinova announced that the Company is appointing Erik Kullgren as interim CFO due to the fact that the Company's current CFO, Håkan Skogström, will retire on March 27. The process of recruiting a permanent CFO continues.
- On April 4, Alzinova announced that all patients participating in the extension part (part B) of the phase 1b study with the vaccine candidate ALZ-101 against Alzheimer's disease, have received their last dose of ALZ-101.
- On April 11, Alzinova announced that an in-depth analysis of data from part A of Alzinova's phase 1b study with the vaccine candidate ALZ-101 has been completed. The analysis indicates that patients with the higher antibody levels after vaccination have a positive effect on biomarkers associated with Alzheimer's disease.
- On April 25, Alzinova's CEO, Kristina Torfgård, announced that she had informed the Board of her wish to resign as CEO of the Company.
- On April 26, Alzinova announced that the Board of Directors of the Company had decided, with the support of the authorisation from the Annual General Meeting 2023, on a rights issue of shares of approximately SEK 34.4 million.
- On April 26, the shareholders of Alzinova were invited to the Annual General Meeting on 29 May 2024 at 13:00 in Chalmersska Huset in Gothenburg.

No significant events leading to adjustments have occurred between the balance sheet date and the date of approval for this report.

Signatures

Gothenburg on May 6, 2024
Alzinova AB (publ)

Julian Aleksov
Chairman of the board

Anders Blom
Board member

Per-Göran Gillberg
Board member

Clas Malmeström
Board member

Carol Routledge
Board member

Anders Waas
Board member

Lena Degling Wikingsson
Board member

Kristina Torfgård
Chief Executive Officer

Our audit report has been submitted
on May 6, 2024

Ernst & Young AB

Linda Sallander
Authorized Auditor

Auditor's report

To the general meeting of the shareholders of Alzinova AB, corporate identity number 556861 – 8168.

Report on the annual accounts

Opinions

We have audited the annual accounts of Alzinova AB for the financial year 2023. This document contains other information on pages 2 - 28 and 47 – 49. The company's annual accounts can be found on pages 29 – 43 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Alzinova AB as of 31 December 2023 and its financial performance and cash flow for the year. The statutory administration report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Alzinova AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Information other than the annual accounts

It is the Board of Directors and the CEO who are responsible for the other information. The other information can be found on pages 2 – 28 and 47 - 49 but does not include the annual accounts and our auditor's accounts regarding it.

Our statement regarding the Annual Accounts does not include this information and we do not make a statement confirming this other information.

In connection with our audit of the Annual Accounts, it is our responsibility to read the information identified above and consider whether the information is materially inconsistent with the Annual Accounts. In this review, we also take into account the knowledge we have otherwise acquired during the audit and assess whether the information otherwise appears to contain material misstatements.

If, based on the work that has been done regarding this information, we conclude that the other information contains a material misstatement, we are obliged to report this. We have nothing to report in that regard.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting.

Auditor's responsibility

Our objectives are to obtain reasonable

assurance about whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and the Managing Director of Alzinova AB for the financial year 2023 the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent

of Alzinova AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Gothenburg on May 6, 2024
Ernst & Young AB

Linda Sallander
Authorized Public Accountant

Glossary and abbreviations

Term	Definition
Aβ42 - amyloid-beta 42	A peptide (part of a protein) produced by the body that can aggregate in the brain and cause Alzheimer's disease
ApoE (Apolipoprotein E)	A protein that transports fats in the blood and comes in three variants. People who express ApoE4 are more likely to develop Alzheimer's disease
"Best-in-Class"	A product that is considered superior to other competitors in its class, can be compared to 'first-in-class', which refers to being first to market with a product
Biomarker	A measurable indicator of a state of disease
Disease-modifying treatment	Treatment of the underlying cause of the disease
EMA	European Medicines Agency
Fast Track Process	FDA process designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fill an unmet medical need
FDA	The United States Food and Drug Administration
Immunogenicity	The ability of a foreign substance, such as an antigen, to provoke an immune response in the body of, for example, a human being
Interim analysis	A statistical analysis carried out during the course of the study and may aim to make a recommendation about the study
IP	Intellectual properties, for example patents.
Monoclonal antibody	A type of antibody produced by a single clone of cells
Neurotoxic	Dangerous or poisonous to the brain
Oligomers	Proteins or peptides, clumped together, used to designate soluble peptide clumps

Glossary and abbreviations

Term	Definition
Peptide	Part of a protein (a small chain of amino acids too small to be classified)
Phase 1 study	Study of the safety and tolerability of a drug candidate in a limited number of healthy persons or patients
Phase 2 study	Study the safety of a drug candidate and usually also in a limited number of patients
Placebo-controlled study	Study design in which some of the patients receive an inactive drug candidate in order to have a relevant comparison group
Plaque	Local accumulation of clumped insoluble protein, in Alzheimer's mainly consisting of the peptide Abeta42
Preclinical phase	Preparatory studies of drug candidates
Pre-IND meeting	Regulatory advice from the FDA regarding product development programs
Randomised study	The randomisation of subjects into predetermined groups that are assigned to an active treatment or placebo in a clinical trial
SAP	Scientific Advice Procedure, i.e. a scientific advice procedure at the EMA
Tolerability	The degree of side effects from a medicine that can be tolerated by a patient
Therapeutic vaccine	A vaccine used to treat a disease

Financial calendar

Event	Date
Interim report 1, 2024	28 May 2024
Annual Gerneral Meeting 2024	29 May 2024
Interim report 2, 2024	22 August 2024
Interim report 3, 2024	14 November 2024
Year-end report, 2024	27 February 2025

Financial reports are available on the Company´s website www.alzinova.com from the day they are made public.

For further information, please contact:

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Alzinova AB (publ)

Alzinova AB is a Swedish clinical-stage biopharma company specializing in the treatment of Alzheimer's disease, which focuses on targeting toxic amyloid-beta oligomers. The lead candidate, ALZ-101, is a therapeutic vaccine against Alzheimer's disease. Alzinova's patented AβCC peptide™ technology makes it possible to develop disease-modifying treatments that accurately target the toxic amyloid-beta oligomers that are central to the onset and progression of the disease. From a global perspective, Alzheimer's disease is one of the most common and devastating neurological diseases. It is estimated that more than 30 million people in the world today have Alzheimer's disease and the number is expected to triple by 2050. Based on the same technology, the Company is also developing the antibody ALZ-201, which is currently in preclinical development, and the goal is to further expand the pipeline. The Company's Certified Adviser on Nasdaq First North Growth Market is Redeye AB. For more information about Alzinova, please visit: www.alzinova.com

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alzinova