

Alzinova AB

Annual Report 2022

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



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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 A β CC 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 the 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. Promising results have been obtained after a study on brain extracts from deceased Alzheimer's patients. The study confirms that Alzinova's unique method of specifically targeting and neutralizing toxic oligomers is effective.

The drug candidate ALZ-101 is a vaccine under clinical development. A phase 1b study

in Alzheimer's patients was initiated in the third quarter of 2021 and was fully recruited in December 2022. Top-line data is expected to be presented in the second half of 2023. The vaccine is being developed as a long-acting drug for the treatment and prevention of Alzheimer's disease.

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 take the antibody into clinical development. Alzinova was founded by researchers who worked at the MIVAC research center at the University of Gothenburg and by GU Ventures AB.

Alzinova's unique solution

- ✓ Targeted treatments that specifically attacks and neutralize the toxic peptides (so-called oligomers) which are central to the onset and development of the disease.
- ✓ Vaccine that stimulates the body to produce antibodies directed against the oligomers (ALZ-101).
- ✓ Fast, effective, and uncomplicated vaccination without long and expensive hospital stays.
- ✓ Specific treatment that is likely to have good efficacy and reduces the risk of serious side effects.
- ✓ Can start treatment early in the disease to slow or stop the course of the disease.
- ✓ 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).



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



Alzinova's lead candidate, ALZ-101, is a therapeutic vaccine to treat Alzheimer's disease. The vaccine is in clinical development with a phase 1b study in Alzheimer's patients.



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



Data show that the unique specificity of Alzinova's vaccine (ALZ-101) and monoclonal antibody (ALZ-201) provides "best-in-class" potential, with ability to provide significantly better efficacy and a more favorable side effect profile.



Preparatory activities are underway for the next clinical development phase for ALZ-101, this together with strong IP and extensive potential in the technology makes Alzinova's candidates attractive for strategic partnership.





A word from our CEO

2022 was a year in which we achieved several important milestones. Recruitment for the ongoing clinical study was completed in December, and we are now looking forward to the study results in the second half of 2023. In addition, during the past year, interesting and important research results have strengthened the Company's strategy – to develop effective and safe amyloid-beta treatments against Alzheimer's disease.

The vaccine ALZ-101 – favorable safety profile and indications of immune response

During the year, the independent Data Safety Monitoring Board, reviewed the safety data from our ongoing phase 1b clinical study. I am very pleased that in the study we see continued good safety and tolerability of the treatment, which is also the goal of the first clinical study. In December, we also conducted a first interim analysis of blinded efficacy and safety data from patients in the study. The information we received from this early interim analysis was very positive, again demonstrating that the treatment is safe and well tolerated. In addition, we received data indicating an immunological response was generated following ALZ-101 administration, that is, antibodies have been formed and this is a sign that ALZ-101 is doing its job!

We ended the year by announcing that the study had fully recruited, that the last patient started the treatment in December was a very important milestone for the study to continue according to plan. We look forward to additional safety and immunological interim data

in the spring as well as top-line data in the second half of 2023. During the year, we have also shown that our vaccine candidate ALZ-101 can be produced at a larger scale. Overall, this lays a strong foundation for the next step in the clinical development of ALZ-101, i.e., phase 2 studies. At the same time, we are preparing for interactions with regulatory authorities, FDA for the US and EMA for the EU, to discuss the development program for the phase 2 study with ALZ-101. The progress we have made during the year strengthens our position on the market and interest in a partnership with Alzinova is increasing from commercial companies.

Unique binding profile – “best-in-class” potential

During the autumn, our antibody ALZ-201's unique binding profile was presented at the large international Alzheimer's Congress CTAD. These data have attracted great interest as have the research results recently published for this antibody in a peer reviewed journal. In a comparative analysis between the oligomer-specific antibody ALZ-201 (which





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Developing the
next generation of
Alzheimer’s drugs

we developed from the vaccine ALZ-101) and copies of the antibodies lecanemab, aducanumab, and gantenerumab, it was found that ALZ-201 binds to a greater extent to the toxic accumulations of amyloid-beta, so-called oligomers.



Our vaccine candidate ALZ-101 can also be given significantly less often than other drug candidates under development, which can contribute to better health economics and make it possible for more people to have access to an effective Alzheimer's treatment.

We are convinced that an oligomer-specific treatment with an antibody such as ALZ-201 or the vaccine ALZ-101, with "best-in-class" potential, has the opportunity to provide significantly better effect with a more favorable side effect profile than what has been observed for other therapies. Our vaccine candidate ALZ-101 can also be given significantly less often than other drug candidates under development, which reduces patient treatment burden and can contribute to better health economics and make it possible for more people to have access to an effective Alzheimer's treatment.

Alzinova's strategy was strengthened – increased interest in the Company

During the autumn, data were presented from Eisai's large phase 3 study in Alzheimer's patients evaluating the efficacy and safety of the monoclonal antibody lecanemab – developed in collaboration with BioArctic. We see these results as positive for both the Alzheimer's field and Alzinova as it once again strengthens our strategy to develop new, effective, and safe amyloid-beta treatments against Alzheimer's disease. This of course

has contributed to an increased interest in Alzinova and our unique portfolio of drug candidates that, with high specificity, have strong potential to become "best-in-class".

Strengthened the organization, positioning of the company, and the financial position

As part of the preparatory work for the clinical phase 2 study, Alzinova has strengthened the organization through recruitment in clinical development and in regulatory operations throughout the year. We have focused on business development and intensified work with partnering activities. An important part is to position the company and its unique technology with the support of recently published data and "best-in-class" potential. During the autumn, we participated in BIO-Europe, among other things, where we met potential licensees and partners for our programs. We noted great interest in our pipeline and the upcoming milestones of our ongoing clinical trial.

We strengthened our financial position through the rights issue carried out in the second quarter of 2022. We are very grateful for the interest in the Company, and I want to thank our existing shareholders for their trust in investing in Alzinova.

Alzinova accelerates work in the fight against Alzheimer's

Over the past year, I have seen firsthand how Alzheimer's breaks people down and how it affects the lives of loved ones. I feel a great commitment and passion for my work in developing drugs against this terrible disease. I am proud to lead this innovative company with a great Alzinova team, partners and the board of directors who all contribute in developing the next generation of Alzheimer's drugs. Now we look forward to continuing to accelerate the work in the fight against Alzheimer's.

Gothenburg in April 2023

Kristina Torfgård

Alzinova AB





This year's milestones

2022 was a very eventful year for Alzinova. The Company continued its journey – to develop a treatment against Alzheimer's disease that enables Alzheimer's patients to live an independent and active life. Several milestones were achieved during the year.

January 2022

The year began with Alzinova announcing that the humanization work on the Company's monoclonal antibody ALZ-201 has been completed, and a lead clinical candidate has been selected for further development.

March 2022

An improved manufacturing process for the vaccine candidate ALZ-101 was developed to meet the requirements for phase 2 studies. CEO Kristina Torfgård commented, *"We are very pleased to have reached this important milestone, which is part of making the therapeutic vaccine, ALZ-101, ready for phase 2 and more attractive to potential partners"*.

April 2022

In April, Alzinova received a positive safety review from the independent Data Safety Monitoring Board ("DSMB") and the phase 1b study continued as planned.

May 2022

Success also continued in the development of the ALZ-201 antibody. In May, Alzinova announced that the Company has started the development of a stable cell line for clinical studies with the monoclonal antibody ALZ-201 in Alzheimer's disease.

June 2022

Alzinova carried out a rights issue which brought the company SEK 34.0 million before transaction related costs. The purpose was to finance the completion of the phase 1b study for ALZ-101, finance the manufacture of drug substance and technical material of ALZ-101 for phase 2, work with strategic marketing, legal processes, patents, operations, and finance the long-term follow-up of the phase 1b study for ALZ-101. In addition, part of the proceeds was intended to be used for the establishment of a manufacturing process for ALZ-201 and preclinical efficacy studies for ALZ-101.

July 2022

As part of the preparations for phase 2 studies with the vaccine candidate ALZ-101, Alzinova established a scaled-up manufacturing process that enables larger production volumes. This process is an important step for the long-term goal of being able to cost-effectively produce and offer a vaccine against Alzheimer's on the global market.

August 2022

In August, the Company reached an important milestone when half of the patients were recruited to the ongoing phase 1b study for the vaccine candidate ALZ-101. The Company had then set the goal that the study would be fully recruited by the end of the year.

September 2022

A new planned safety review of the phase 1b study was carried out in September, which also received a positive assessment from the independent expert group "DSMB". Based on the available data to date, the DSMB recommended continuing as planned with the conduct of the study without adjustments.

October 2022

During the autumn, Alzinova presented its operations and projects to investors and international pharmaceutical companies. The Company also participated in one of the major biotech conferences in Europe, BIO-Europe, which is a gathering place for partner meetings where the Company presented the vaccine candidate ALZ-101 and the antibody ALZ-201.

October 2022

In November, Alzinova presented the unique binding profile of the ALZ-201 antibody at a major international Alzheimer's conference, CTAD, Clinical Trials in Alzheimer's Disease, held in San Francisco.

December 2022

Interim data were presented from Alzinova in December when a new planned safety review was conducted of the phase 1b study with the vaccine candidate ALZ-101. Blinded data showed continued good safety and tolerability of ALZ-101 and also indications of an immunological response, that is, that endogenous antibodies were produced on administration of ALZ-101.

December 2022

The year ended with an important milestone being reached then the Company's Phase 1b study fully recruited by the end of the year. This was achieved in December when the last patient in the ALZ-101 phase 1b study had been recruited and received their first dose.



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 (A β 42), a small protein that also occurs in a healthy brain. When the A β 42 molecule clumps together, stable accumulations are formed in the brain, plaques, but also so-called oligomers.

Oligomers differ structurally from the plaque and, unlike plaque, 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 his own, but requires care and continuous review.


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




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

Alzinova is developing a societal beneficial treatment



 *ALZ-101* – a vaccine under development by Alzinova

 10 min


3 injections per year Administered at home, in a clinic or primary care setting


Cost for society



Decreased costs for society



 Other antibody treatments

 1 h

26 IV treatments per year Administered in a hospital or clinic

Cost for society



Increased costs for society

Alzinova is developing a vaccine candidate to treat Alzheimer’s disease. The vaccine, unlike other treatment methods such as antibodies, only requires a few doses a year instead of 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.

To treat patients with therapeutic antibodies, this sharply increase societal costs and large parts of the budget and 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.

Alzinova's treatments

The market for the treatment of Alzheimer's disease is large as there is currently no effective treatment to slow down or 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 players are developing treatments that target larger accumulations of amyloid-beta, so-called plaques in the brain, which are believed to contain both toxic and harmless protein. It has been shown that this approach is unlikely to provide sufficient treatment effect and may result in serious side effects. Unlike these, Alzinova has succeeded in identifying a treatment method that could specifically target the toxic 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. 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 work in 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. The next milestone is top-line data fall 2023.



About ALZ-201

ALZ-201 is a monoclonal antibody based on Alzinova's A β CC technology developed to specifically attack and neutralize the toxic forms of the peptide amyloid-beta-42 ("A β 42"), 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 A β 42 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.



Alzheimer's
disease affects
someone every
5 seconds



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 secure proof-of-concept, to demonstrate efficacy in patients with Alzheimer's. Based on clinical data, the Company intends to identify one or more strategic partners who can acquire projects for further development 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 global 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. Furthermore, Alzinova has secured a scalable manufacturing process for ALZ-101, which is now being prepared for a Phase 2 study so that a partner can quickly start phase 2. 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 vaccine ALZ-101 when the phase 1b study is complete, and another option is to take this further through phase 2 and then out-license it to a partner at the end of phase 2. 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 precisely on business development with several active 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 percent. 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 2050¹.

The societal costs of dementia diseases are currently estimated at USD 1,300 billion annually. The drug cost of Alzheimer's medications, which are symptom relief alone, amounts to approximately \$6 billion annually. While the first disease-modifying drug has recently

been approved in the United States, 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 were to gain only an initially limited market share. The reason that the estimated sales estimates are initially relatively low compared to other therapeutic areas is that there are currently no good medical alternatives. If effective treatment alternatives were to come to the market, for example Alzinova's drugs, the Company estimates that annual sales could multiply. 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.



¹World Health Organization (WHO) – Alzheimer's facts, September 2021.

Alzinova's collaboration with the Alzheimer Foundation

In January 2022, Alzinova began a collaboration with the Alzheimer Foundation, which is the fundraising organization that contributes the most to research into dementia diseases in Sweden.

Through 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. Alzinova participated, among other things, as a sponsor for the Alzheimer race 2022, and Alzinova's CEO also had the privilege of presenting Alzinova at the Alzheimer Foundation's seminar in September 2022. Both researchers and representatives from the pharmaceutical industry participated in it. Many Alzheimer's patients and their relatives came to listen to the seminar.

Alzheimer
fonden 

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Meeting people with Alzheimer's and conveying that we, and many people with us, are working to crack the Alzheimer's riddle and to urgently develop effective treatments gives hope to both patients and their loved ones.

*Kristina Torfgård
CEO, Alzinova AB*





Living as a relative of someone with Alzheimer's disease

We have had the honor of interviewing Carina Heyner, who has lived as a relative of a person with Alzheimer's disease. Alzheimer's disease is a neurodegenerative disease that affects millions of people worldwide. And even though progress has been made in research, the disease remains one of the biggest challenges in healthcare today. Living close to someone who has the disease means a lot of challenges and pressures, but also opportunities for insight and understanding.

We hope that the interview can contribute to providing an insight into life as a relative of someone with Alzheimer's disease, a deeper understanding of the disease and its impact on both the patient and their family and friends.



What is it like to live as a relative of someone with Alzheimer's disease?

- Living with a relative who has Alzheimer's is really a long sadness over losing a person you know so well but who slowly disappears into his own world. Slowly but surely the memory decreases, the ability to cope with one's life, manage one's home, one's finances, one's self. Eventually, the person becomes like a child again and needs help to dress, eat, take care of their hygiene, and go to the toilet.

How did you adapt your everyday life to accommodate your loved one's changed needs and abilities?

- My everyday life was not affected that much to begin with. It was Dad's partner who had to take the biggest responsibility and who noticed the changes in his behaviour. He received a so-called "symptom-relieving" medication after investigation at the memory clinic, but it made no major difference.

- We have a strong heredity of dementia in our family. My grandmother, aunt, uncle, and father all became demented but quite late in life, after 80. In my father's case it was difficult to judge how he felt because of his impaired hearing which made it difficult to communicate. At first, he could use aids, but all modern technology became incomprehensible over time, i.e., TV, mobiles, computers, banking, and hearing aids.

What are some of the biggest challenges you face when caring for your loved one with Alzheimer's disease, and how do you deal with these challenges?

- We, my brother and I, noticed that Dad's life was shrinking. He was previously socially active but had fewer and fewer contacts. They sold their summer place and the boat. Travels decreased, he could no longer plan, lived mostly in the moment. The driver's license was revoked after several incidents. He continued to drive his partner's car in protest until he was heavily fined. It was a great loss for him.

- We contacted aid workers to try daily activities that could relieve the partner a little. It never worked out very well, dad didn't understand what he was doing there, why he was leaving home.

- When the pandemic broke out, we didn't get to see dad for ten months. They isolated themselves for fear of contagion. It was becoming difficult to talk to him on the phone. The speech became increasingly incoherent. He started doing crazy things with the house. He built it himself 60 years ago and tried to repair and maintain it, but it mostly went

wrong. Water damage and high plumbing bills were usually the result. It turned out that the home insurance had not been paid for several years...

- At the end of 2020, they both got covid. Then dad had tried switch care but that didn't work either, only increasing his confusion. The partner couldn't take it anymore, so I tried to get him to live with us, but there he got even worse. Turned around the clock, didn't sleep at night, packed his bag, and went out in the middle of the night, sometimes to the neighbors. After two weeks of chaos and insomnia, I contacted the welfare officer again and asked for a place in dementia care. It was not a good move during the pandemic with, among other things, a ban on visitors.

Have you sought out any resources or support groups for caregivers of Alzheimer's patients, and if so, how have they helped you in your role as a caregiver?

- I work as a district nurse and have extensive experience with elderly people and dementia. Knowledge about this is a great asset and has helped me a lot in the treatment and all the practical work around dad. He managed two dementia homes before he passed away. It was nice to see him there and how he continued to be an active person, he sought contact with the other residents and the staff. My brother and I had to write a life story which became a nice summary for us of his life. In the last year we made many trips with him. He could still appreciate good food and beautiful surroundings even though he couldn't express it in words.

- Before he got sick, he wrote a power of attorney for the future, which we had a lot of use for when we were going to sell the house, contact the bank, brokers, aid workers, etc. I often recommend that others write at an early stage.

- I have had some use from newsletters for relatives, both from my father's home municipality and my own. There are many good activities and support for relatives. Dad's partner participated in a group with relatives of people who had dementia.

How do you think about Alzheimer's and the future?

- The strong heredity, of course, we think about both my brother, me, and our cousins. We all have a hope for better medicines. But the most important thing is still good, understanding care and loving treatment, concludes Carina Heyner.



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.”

Goals for 2023

- Conduct a second interim analysis in the phase 1b study.
- Interactions with regulatory authorities – FDA and EMA to discuss the development program for the phase 2 study with ALZ-101.
- Present top-line data from the phase 1b study.
- Prepare for the phase 2 study.
- Prepare the antibody ALZ-201 for clinical phase 1b study.

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

Assignment

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

26,000 shares. Warrants giving the right to subscribe: 16,000 shares (warrants of series TO3) 53,000 shares (2020/2023, incentive program).



Anders Sandberg

Assignment

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

167,693 shares. Warrants giving the right to subscribe: 10,500 shares (2020/2023, incentive program).



Håkan Skogström

Assignment

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

16,000 shares. Warrants giving the right to subscribe: 8,000 shares (warrants of series TO3) and 21,000 shares (2020/2023, incentive program).



Stefan Pierrou

Assignment

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

2,025 shares. Warrants giving the right to subscribe: 900 (warrants of series TO3).



Anders Bylock

Assignment

Chief Medical Officer since 2019.

Background

Anders has more than 25 years of experience in drug development in both pre-clinical studies and clinical studies phase I-IV as well as registration work for drugs approved within the EU. Among other things, he has worked at MSD Sweden, held several leading positions within AstraZeneca and worked as Senior Global Director at Boehringer Ingelheim GmbH & Co KG in Germany.

Education

Licensed doctor, specialist in thoracic surgery. Docent and Doctor of Medicine.

Ongoing assignments

No other ongoing assignments.

Holdings in the Company

0 shares and 0 warrants.



Sebastian Hansson

Assignment

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

7,000 shares and 0 warrants.



Board of Directors



Björn Larsson

Assignment

Chairman of the Board since 2011.

Background

Björn has 30 years of experience in international marketing, sales and business development within pharmaceuticals, medical equipment, and biotechnology, including within Novo Nordisk, AstraZeneca, and Medtronic. He has previously been business developer and investment manager at GU Ventures, global marketing and communications manager at ABIGO Medical AB and CEO at Observe Medical. Björn is currently CEO at RLS Global AB.

Education

MSc in engineering at Chalmers University of Technology.

Ongoing assignments

Chairman of the board of Redwood Pharma AB and board member of Medfield Diagnostics AB.

Holdings in the Company

25,005 shares. Warrants giving the right to subscribe: 11,112 shares (warrants of series TO3) and 10,833 shares (2020/2023, incentive program).



Anders Blom

Assignment

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 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 sectors including, but not limited to, Hansa Biopharma AB, Biolamina AB, and Selego AB.

Education

Bachelor's degree in business administration at Uppsala University.

Ongoing assignments

Chairman of the board of Maida Vale Capital AB and board member of Hunterhex AB, Wonderboo AB, Petzbe AB, Terranet AB and PEPTONIC medical AB.

Holdings in the Company

0 shares and 0 warrants.



Per-Göran Gillberg

Assignment

Board member since 2020.

Background

Per-Göran has 35 years of experience in the pharmaceutical industry. He has broad experience in pharmacology and neuropharmacology 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

13,500 shares. Warrants giving the right to subscribe: 6,000 shares (warrants of series TO3) and 10,833 shares (2020/2023, incentive program).



Anders Waas

Assignment

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 assignment

Chairman of the board of Transmed Gothenburg AB, Iscaff Pharma AB, Sobrera Pharma AB, Sortina Pharma AB OligoNova Accelerate AB and SiMSen Diagnostics AB. Board member of Toleranzia AB, Anders Waas AB, Implexion Pharma AB, Ectin Research AB and Nexocure Therapeutics AB.

Holdings in the Company

0 shares and 0 warrants.



Carol Routledge

Assignment

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 was previously Head of Research at Alzheimer's Research UK, and is currently Chief Medical and Scientific Officer at Small Pharma Ltd.

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 Cogentivity Neurosciences Ltd, Vancouver and Honorary Professor & EIR, Exeter University, UK.

Holdings in the Company

0 shares. Warrants giving the right to subscribe: 10,833 shares (2020/2023, incentive program).



Pernilla Sandwall

Assignment

Board member since 2020.

Background

Pernilla has 30 years of experience from the pharmaceutical and biotech industry. She has worked with clinical research activities, including as a project manager and manager, as well as with strategic work in clinical research at Merck & Co. Inc. (MSD). Pernilla was previously Chief Operating Officer at InDex Pharmaceuticals Holding AB, and is currently CEO at WNT Research AB.

Education

Pharmacist.

Ongoing assignments

No other ongoing assignments.

Holdings in the Company

11,900 shares. Warrants giving the right to subscribe: 9,520 shares (warrants of series TO3) and 10,000 shares (2020/2023, incentive program).



Clas Malmeström

Assignment

Board member since 2015.

Background

Clas is chief physician at the MS-Centrum, Neurohealth, and Unit Chief Physician for the Immunology Laboratory in clinical immunology and transfusion medicine 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

10,000 shares. Warrants giving the right to subscribe: 2,000 shares (warrants of series TO3) and 10,000 shares (2020/2023, incentive program).



Lena Degling Wikingsson

Assignment

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 and Biosergen AB.

Holdings in the Company

0 shares. Warrants giving the right to subscribe: 10,833 shares (2020/2023, incentive program).



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 2022. Alzinova is a public limited liability company.

Alzinova is a Swedish biopharmaceutical company specialising in the treatment of Alzheimer's disease – one of our major health scourges, without effective treatment options. The Company's proprietary A β CC-peptide™ technology enables the development of disease modifying therapies that with high precision could target the toxic amyloid beta oligomers involved in the onset and progression of the disease. Alzinova's focus is to develop an oligomer-specific vaccine as a long-acting therapy to treat and prevent Alzheimer's disease. The vaccine candidate, ALZ-101, is in clinical development with a Phase 1b study initiated in the third quarter of 2021. Based on the same technology, the Company is also developing the monoclonal antibody, ALZ-201, which is currently in early preclinical development phase.

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 2022

First quarter

- Alzinova announced in January that the company had completed the humanisation work and selected a humanised lead candidate of its monoclonal antibody ALZ-201. Several backup candidates with promising profiles have also been developed.
- Alzinova announced in February that approximately SEK 2.8 million will be added to the company through the exercise of warrants of series TO2 2020/2022. The exercised warrants corresponded to an exercise rate of approximately 11%.
- Alzinova announced in March that the manufacturing process for the active substance in ALZ-101 has been improved, enabling the supply of ALZ-101 in the amounts required for phase 2 clinical trials. Furthermore, a robust manufacturing process which is beneficial for future cost-effective and reliable manufacturing was obtained.

Second quarter

- The Board of Directors resolved in April on a rights issue of units of approximately SEK 42.5 million upon full subscription. The issue proceeds will primarily be used to finance the completion of the phase 1b study and the long-term study for the vaccine candidate ALZ-101 and to prepare for the phase 1b study of the antibody ALZ-201.
- The company announced in April that an external review of the phase 1b study's safety data shows positive results and that the study with ALZ-101 therefore continues according to plan.
- In April, the company announced continued preclinical development of the antibody candidate ALZ-201, as part of the preparations for clinical studies.

Third quarter

- In July, Alzinova announced that it has successfully verified that the manufacturing process for vaccine doses of ALZ-101, the Company's vaccine candidate against Alzheimer's disease, can be scaled up to deliver the larger production volumes required for Phase 2 clinical trials.
- The company announced in August that 50% of the patients for the ongoing phase 1b study had been recruited.

Fourth quarter

- Alzinova announced in December that the Company received a new positive safety review and interim data from the ongoing phase 1b study with the vaccine candidate ALZ-101. The result indicates an immunological response, that is, antibodies have been formed following administration of ALZ-101, and the study continues as planned.
- In December, Alzinova announced that the phase 1b study had been fully recruited and that the set goal of recruitment before the turn of the year had been achieved.

Significant events after the end of the financial year

- Alzinova announced in January 2023, that a 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. Furthermore, the research shows that ALZ-201 has the potential to become "best-in-class" in the clinic with good efficacy and a more favorable side effect profile than other therapeutic antibody candidates currently in development.

- Alzinova announced in January 2023, that Sebastian Hansson had been recruited to the newly established role of Business Development Director.
- Alzinova announced in March 2023, that a planned external safety review has been conducted of the Company's clinical phase 1b study - with a positive assessment to continue the study as planned. The expert group Data Safety Monitoring Board ("DSMB") has also evaluated the safety data in relation to a possible extension of the study that the Company has announced plans to conduct. Based on the study's included patients, the DSMB recommends that the study continue as planned and that the study can also be extended if the Company decides so.
- Alzinova announced in March 2023 that the Company has submitted 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 the Company's drug candidates.
- Alzinova announced in April 2023 that the Company presented data and studies for the vaccine candidate ALZ-101 at the international AD/PD™ conference held in Gothenburg on March 28 - April 1. The results from the studies show both a long-term effect and that antibodies are found in the central nervous system, where they should have their effect.
- Alzinova announced in April 2023, that all patients participating in the phase 1b study of 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 in April 2023, that the Company received regulatory approval from the Finnish Medicines Agency, Fimea and 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 as well as information on effects on biomarkers and cognitive functions.

- Alzinova announced in April 2023 that the company will receive approximately SEK 26.3 MSEK million before issue costs, through the exercise of warrants of series TO3. The exercised warrants corresponded to a exercise rate of approximately 93.4%.

Revenues and results

During the year, the Company has mainly invested in the development of ALZ-101, a vaccine against Alzheimer's disease, presently in clinical development with a Phase 1b study initiated. The Company has also started the developing of the monoclonal antibody ALZ-201, which is currently in early preclinical development phase, with the aim of treating and also preventing the progression of Alzheimer's disease.

Net sales during 2022 amounted to 0 MSEK (0 MSEK) and the Company is not expected to generate revenues until the Company's products have reached further in their development phase. The operating profit during the year amount to -13.1 MSEK (-7.6 MSEK).

Total costs during the year amounted to 29.7 MSEK (24.8 MSEK), of which 16.6 MSEK (17.3 MSEK) were capitalized as expenditure for development work and were recorded as intangible fixed assets. The increase in development costs has continued according to the Company's plan.

Cash flow

The cash flow from operating activities 2022, including changes in working capital, amounted to -10.3 MSEK (-9.8 MSEK).

The cash flow from investing activities, amounted to -16.6 MSEK (-17.3 MSEK) and consisted of capitalized expenditure for development work.

The cash flow from financing activities 2022 amounted to 30.1 MSEK (0 MSEK) and were generated by 2.8 MSEK from the exercise of warrants of series TO 2020/2022 during the first quarter, in addition with 34.0 MSEK from the preferential rights issue during the third quarter, before issue costs. Issue costs amounted to 6.7 MSEK and consisted of costs connected with the issuance and costs for guarantees.

Financial position

At the turn of the year, the Company had a cash balance of approximately 32 MSEK.

The Company estimates that with the issue proceeds of approximately 26.3 MSEK, before issue costs, which will be added through the exercise of warrants of series TO3 during April 2023, there will be capital to finance planned operations in the coming 12 months. Thus, the board considers that the conditions for continued operation are met. In addition, continuous work is underway on various financing alternatives, to further strengthen the Company's financial position.

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

SEK	2022	2021	2020	2019
Net sales	-	-	-	-
Result after financial items	-13,087,849	-7,552,006	-6,499,557	-6,189,903
Earnings per share (before dilution)	-0.54	-0.48	-0.78	-0.81
Total capital	111,621,075	91,691,392	100,815,659	63,531,184
Average number of full time employees	4	3	3	2
Equity ratio, %	94.5	96.5	95.2	93.0

*Earnings per share: Result for the year, divided by the number of shares at the balance date.
Equity ratio: Total equity divided 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, SEK 22,421,466 be distributed as follows:

To be carried forward	22,421,466 SEK
Total	22,421,466 SEK

The financial result and position of the Company in general is set out in the income statement and balance sheet below.

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 2022,

the number of shares in Alzinova amounted to 32,419,034.

Rights issue

In 2020, the Company carried out a rights issue together with a directed issue, with attached warrants of the TO2 2020/2022 series. Two warrants entitled the holder to subscribe for one new share during the period 24 January - 7 February 2022.

In total, 867,590 warrants were exercised during the exercise period 2022, corresponding to an exercise rate of approximately 11 percent. The number of shares in the Company increased by 443,795 to a total of 16,209,519 with a total share capital of 4,263,103 SEK. In total, the Company was provided with approximately 2.8 MSEK in capital. For existing shareholders who did not exercise any warrants, the dilution amounted to approximately 3 percent based on the number of shares in Alzinova.

In 2022, the Company carried out a preferential rights issue with attached warrants of the TO3 2023 series. 16,209,515 new shares were issued in the rights issue to a total of 32,419,034 shares and with a total share capital of 8,526,206 SEK. In total, the Company received proceeds amounting to 34.0 MSEK

before deduction of issuance and guarantee costs. The attached warrant entitles the holder to subscribe for one new share during the period 11 April – 25 April 2023.

In total during the exercise period 2023, 12,112,231 warrants were exercised, corresponding to an exercise rate of approximately 93.4%. The subscription price per share was set to 2.17 SEK. The exercised warrants will increase the number of shares in the Company by 12,112,231 shares to a total of 44,531,265 shares with a share capital of 11,711,723 SEK. In total, the Company was provided with approximately 26.3 MSEK in capital before issue costs. For existing shareholders who did not exercise any warrants, the dilution amounted to approximately 27.2% based on the number of shares in Alzinova.

Largest owners as per 30 December 2022

Name	No. of shares/votes	Capital %
Maida Vale Capital AB	3,808,226	11.75
Försäkrings AB Avanza Pension	2,600,038	8.02
Nordnet Pensionsförsäkring AB	1,176,147	3.63
Sara Gjertz	898,553	2.77
MIVAC Development AB	761,787	2.35
Ålandsbanken, for owners	709,120	2.19
Patrik Ahlvin	704,000	2.17
UBS Switzerland AG	470,540	1.45
Moll Invest AB	415,440	1.28
Ola Hermansson, with companies	400,000	1.23
Total other owners	20,475,183	63.16
Total all owners	32,419,034	100.00

Long-term incentive program

Through a long-term incentive program, the Company's CEO, other executive managers and some board members have acquired a total of 159,165 warrants of series 2020/2023. The warrants may be exercised for the same number of shares during the period from 1 June 2023 to 31 July 2023. If all warrants are exercised, this corresponds to a dilution of the number of shares and votes in the Company by approximately 2% at the date of issuance, and approximately 0.4% after previous rights issues and the completed TO3 2023 warrant programme.

Risk factors

Alzinova maintains procedures to continuously identify and manage risk factors. The primary risk factors identified by 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 on the 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 shows 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

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. This can lead to the business not being able to be conducted at the planned pace. The Company is continually evaluating its direct and indirect suppliers, and active measures are being taken to mitigate the effect on the Company's operations.

The Company 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 company currently has no exposure to Russia or the situation in Ukraine.

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, safety and efficacy in the treatment of 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 outlicensing, 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 and CHF.

Income statement

SEK	Notes	2022-01-01 2022-12-31 12 months	2021-01-01 2021-12-31 12 months
Net sales		-	-
Own work capitalized	5	16,633,432	17,321,738
		16,633,432	17,321,738
Operating expenses			
Other external expenses	2	-23,032,905	-19,025,906
Personnel expenses	3	-6,686,880	-5,815,184
Operating result		-13,086,353	-7,519,352
Result from financial items			
Interest income		17,905	-
Interest expenses		-19,401	-32,654
Result after financial items		-13,087,849	-7,552,006
Result before tax	4	-13,087,849	-7,552,006
Result for the year		-13,087,849	-7,552,006

Balance Sheet

SEK	Notes	2022-12-31	2021-12-31
ASSETS			
Fixed assets			
<i>Intangible assets</i>			
Capitalized expenditure for development work	5	76,648,660	60,015,227
Patent	6	1,632,086	1,632,086
		78,280,746	61,647,313
Total fixed assets		78,280,746	61,647,313
Current assets			
<i>Short term receivables</i>			
Tax receivables		205,684	129,296
Other receivables		630,186	575,385
Prepaid expenses and accrued income		466,784	503,861
		1,302,654	1,208,542
Cash and cash receivables		32,037,675	28,835,537
Total current assets		33,340,329	30,044,079
TOTAL ASSETS		111,621,075	91,691,392
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital		8,526,206	4,149,015
Fund for development costs		74,585,545	57,946,386
		83,111,751	62,095,401
<i>Unrestricted equity</i>			
Share premium		144,644,792	118,872,676
Retained result		-109,135,477	-84,944,312
Result for the year		-13,087,849	-7,552,006
		22,421,466	26,376,358
Total equity		105,533,217	88,471,759
<i>Long term liabilities</i>			
Other long term liabilities	7	800,000	800,000
		800,000	800,000
<i>Current liabilities</i>			
Accounts payable		3,170,435	792,374
Other current liabilities		722,782	570,137
Accrued expenses and prepaid income		1,394,641	1,057,122
		5,287,858	2,419,633
TOTAL EQUITY AND LIABILITIES		111,621,075	91,691,392

Change in equity

2022-01-01 2022-12-31 12 months	Share capital	Fund for development costs	Share premium	Retained result incl. result for the year	Total equity
At the beginning of the year	4,149,015	57,946,386	118,872,676	-92,496,318	88,471,759
Rights issue	4,377,191	-	32,482,459	-	36,859,650
Transaction costs, rights issue	-	-	-6,710,343	-	-6,710,343
Transfer within equity	-	16,639,159	-	-16,639,159	0
Net result for the year	-	-	-	-13,087,849	-13,087,849
At the end of the year	8,526,206	74,585,545	144,644,792	-122,223,326	105,533,217

2021-01-01 2021-12-31 12 months	Share capital	Fund for development costs	Share premium	Retained result incl. result for the year	Total equity
At the beginning of the year	4,149,015	40,624,648	118,872,676	-67,622,574	96,023,765
Transfer within equity	-	17,321,738	-	-17,321,738	0
Net result for the year	-	-	-	-7,552,006	-7,552,006
At the end of the year	4,149,015	57,946,386	118,872,676	-92,496,318	88,471,759

Cash flow statement

SEK	Notes	2022-01-01 2022-12-31 12 months	2021-01-01 2021-12-31 12 months
OPERATING ACTIVITIES			
Result after financial items		-13,087,849	-7,552,006
Adjustments for items not included in cash flow		-	-
Cash flow from operating activities before change in working capital		-13,087,849	-7,552,006
Cash flow from change in working capital			
Increase (-)/Decrease (+) in operating receivables		-94,112	-695,499
Increase (+)/Decrease (-) in operating liabilities		2,868,225	-1,572,261
Cash flow from operating activities		-10,313,736	-9,819,766
Investing activities			
Acquisition of intangible fixed assets	5,6	-16,633,433	-17,321,738
Cash flow from investing activities		-16,633,433	-17,321,738
Financing activities			
Share issue		36,859,650	-
Transaction costs, share issue		-6,710,343	-
Cash flow from financing activities		30,149,307	0
Cash flow for the year		3,202,138	-27,141,504
Cash and cash equivalents at the beginning of the year		28,835,537	55,977,041
Cash and cash equivalents at the end of the year		32,037,675	28,835,537



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

	2022	2021
Office rent	64,783	41,515
Total	64,783	41,515

Future years' rent is estimated at an annual cost of SEK 66,700.

Note 3, Employees

	2022	2021
Average number of full time employees	4	3
Total	4	3

Note 4, This year's tax expense

	2022	2021
Current tax for the year	-	-
Totalt	-	-

Total unused deferred tax assets amount to SEK 64,191,130.

Note 5, Capitalized expenditure for development work

	2022	2021
<i>Accumulated acquisition values</i>		
Beginning of the year	60,015,227	42,693,489
Capitalized during the year	16,633,433	17,321,738
Capitalized financed by contributions	-	-
Accounted values at end of the year	76,648,660	60,015,227

Acquisition values have been reduced with public contributions from VINNOVA with SEK 240,741 (2013), 206,792 (2014), 75,561 (2015), 10,668 (2016), 307,455 (2017) and 145,497 (2018).

Note 6, Patent

	2022	2021
<i>Accumulated acquisition values</i>		
Beginning of the year	1,632,086	1,632,086
Capitalized during the year	-	-
Capitalization financed by contributions	-	-
Accounted values at the end of the year	1,632,086	1,632,086

Acquisition values have been reduced with public contributions from Innovationsbron with SEK 80,000 (2013) and VINNOVA with SEK 50,145 (2015) and SEK 100,000 (2019).

Note 7, Other long-term liabilities to credit institutes

	2022	2021
Västra Götalandsregionen	-800,000	-800,000
Total	-800,000	-800,000

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

	2022	2021
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

- Alzinova announced in January 2023, that a 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. Furthermore, the research shows that ALZ-201 has the potential to become "best-in-class" in the clinic with good efficacy and a more favorable side effect profile than other therapeutic antibody candidates currently in development.
- Alzinova announced in January 2023, that Sebastian Hansson had been recruited to the newly established role of Business Development Director.
- Alzinova announced in March 2023, that a planned external safety review has been conducted of the Company's clinical phase 1b study - with a positive assessment to continue the study as planned. The expert group Data Safety Monitoring Board ("DSMB") has also evaluated the safety data in relation to a possible extension of the study that the Company has announced plans to conduct. Based on the study's included patients, the DSMB recommends that the study continue as planned and that the study can also be extended if the Company decides so.
- Alzinova announced in March 2023 that the Company has submitted 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 the Company's drug candidates.
- Alzinova announced in April 2023 that the Company presented data and studies for the vaccine candidate ALZ-101 at the international AD/PD™ conference held in Gothenburg on March 28 - April 1. The results from the studies show both a long-term effect and that antibodies are found in the central nervous system, where they should have their effect.
- Alzinova announced in April 2023, that all patients participating in the phase 1b study of 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 in April 2023, that the Company received regulatory approval from the Finnish Medicines Agency, Fimea and 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 as well as information on effects on biomarkers and cognitive functions.
- Alzinova announced in April 2023 that the company will receive approximately 26.3 MSEK before issue costs, through the exercise of warrants of series TO3. The exercised warrants corresponded to a exercise rate of approximately 93.4%.

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

Signatures

Göteborg, April 27, 2023
Alzinova AB

Björn Larsson
Chairman of the Board

Anders Blom
Board member

Per-Göran Gillberg
Board Member

Clas Malmeström
Board member

Carol Routledge
Board member

Pernilla Sandwall
Board member

Anders Waas
Board member

Lena Degling Wikingsson
Board member

Kristina Torfgård
Chief Executive Officer

Our audit report has been submitted
on April 27, 2023

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 2022. This document contains other information on pages 2–25 and 43–44. The company's annual accounts can be found on the pages 26–39 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 2022 and its financial performance and cash flow for the year. The statutory administration report on pages 26–39 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 the pages 2–25 and 43–44 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 2022 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, April 27, 2023
Ernst & Young AB

Linda Sallander
 Authorized Auditor

Definitions and abbreviations

	Definition
Aducanumab	monoclonal antibody developed by Biogen, approved in the US for the treatment of Alzheimer's disease.
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
Blinded analysis of data	The company receives data from the study without being informed about the treatment each patient received.
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.
Clinical study	A study evaluating a medicine, conducted in humans
Disease-modifying treatment	Treatment that targets the underlying cause of the disease
DSMB	Data Safety and Monitoring Board
EMA	European Medicines Agency
FDA	Food and Drug Administration
Gantenerumab	monoclonal antibody developed by Roche
IP	Intellectual properties, for example patents
Lecanemab	monoclonal antibody developed by Eisai, approved in the US for the treatment of Alzheimer's disease.
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
Peptide	Part of a protein (a small chain of amino acids too small to be classified)
Plaque	Local accumulation of clumped insoluble protein, in Alzheimer's mainly consisting of the peptide A β 42

Financial calendar

Event	Date
Interim report 1, 2023	17 May, 2023
AGM 2023	30 May, 2023
Interim report 2, 2023	24 August, 2023
Interim report 3, 2023	2 November, 2023
Year-end report 2023	23 February, 2024

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

For further information

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Alzinova AB (publ)

Alzinova AB is a Swedish clinical-stage biopharma company specializing in the treatment of Alzheimer's disease targeting toxic amyloid beta oligomers. The lead candidate, ALZ-101, is being developed as a therapeutic vaccine for the treatment of Alzheimer's. Alzinova's proprietary A β CC peptide™ technology enables the development of disease-modifying treatments that target the toxic amyloid beta oligomers involved in the onset and progression of the disease with high precision. Alzheimer's is one of the most common and devastating neurological diseases globally, with of the order of 40 million people afflicted today. In addition, the antibody ALZ-201 is in preclinical development, and the ambition is to expand the pipeline further. The company's Certified Adviser on Nasdaq First North Growth Market is Redeye AB. For more information about Alzinova, please visit: www.alzinova.com