



Alzinova Interim Report

JANUARY – MARCH 2022

alzinova 

www.alzinova.com



Alzinova at a glance

- Alzinova's goal is to enable patients with Alzheimer's disease to live an independent and active life.
- Alzinova's lead candidate, ALZ-101, is as a therapeutic vaccine for the treatment of Alzheimer's disease. The vaccine is in clinical development with a Phase 1b study in Alzheimer's patients.
- Based on the same technology, Alzinova is also developing a monoclonal antibody, ALZ-201, as a complementary treatment to fight 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.
- Preparation work ahead of the next clinical development phase is also ongoing to ensure Alzinova's candidates are more attractive to strategic partners.
- Alzinova was listed on Nasdaq First North Growth Market in March 2019 (ALZ).

Summary of events during January-March 2022

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 present the interim report for the period January-March 2022.



Three months, January-March 2022

- Net sales amounted to 0 SEK (0 SEK).
- Result after financial items amounted to -2,282,156 SEK (-1,461,253 SEK).
- Earnings per share amounted to -0.14 SEK (-0.09 SEK).
- Equity ratio amounted to 91.4% (93.6%).

Result per share: Result for the period divided by 16,209,519 shares as of 2022-03-31 (15,775,724 shares as of 2021-03-31)

Equity ratio: Total equity divided by total capital.

Amounts in brackets: Corresponding period in previous year.

Significant events during January – March 2022

- Alzinova announced in January 2022 that the company had completed work on adapting the antibody to humans and selected a main candidate for its monoclonal antibody for ALZ-201 and that several backup candidates with promising profiles had also been developed.
- Alzinova announced in February 2022 that the Company will receive approximately SEK 2.8 million 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 had been improved, thus enabling supply of ALZ-101 in the amounts required for Phase 2 clinical trials. Furthermore, a more robust manufacturing process is beneficial for future reliable, cost-effective and GMP (Good Manufacturing Practice) compliant manufacturing.

Significant events after the end of the period

- No significant events.



CEO comments

Our continued focus is on the vaccine candidate, ALZ-101, and the ongoing clinical study in patients with Alzheimer's disease. It is pleasing that a Swedish biopharma company such as Alzinova is now on the international map of companies that have ongoing studies in Alzheimer's patients.

ALZ-101 - recruitment for the Phase 1b study is ongoing

The recruitment of patients for the phase 1b study is ongoing and we are proud to now have patients being treated with our therapeutic vaccine, ALZ-101, which is being developed into a disease-modifying treatment against Alzheimer's disease. The study is blinded and being managed by our partner, Clinical Research Services Turku, in Finland so we cannot provide any detailed updates, but patients are being continuously recruited into the study and we have not received any reports that the vaccine is harmful to or not well tolerated in humans.

Improved manufacturing process ahead of Phase 2


Preparing for the next clinical development phase – Phase 2 – is also an important part of the development of ALZ-101. We have just finished

work on improving the manufacturing process of the active peptide in the ALZ-101 vaccine. The new manufacturing process meets the higher quality requirements placed on therapies in clinical phase 2. It generates representative material with higher purity and in larger quantities, which is promising for future cost-effective manufacturing ahead of Phase 2.

ALZ-201 – humanised lead candidate

During the first quarter, we selected a humanised lead candidate for the oligomer-specific antibody, ALZ-201. The monoclonal antibody has a unique and specific binding profile and strong preclinical efficacy data. The fact that it has now been modified to be tolerated by humans now makes it possible to develop further as a potential treatment for patients with Alzheimer's.

We see several potential uses for the antibody, ALZ-201. For example, as adjunctive therapy to the vaccine ALZ-101 in patients who, for some reason, initially need high levels of antibodies, as well as in Alzheimer's patients with weakened immune systems who have difficulties producing antibodies themselves.



Kristina Torfgård
CEO, Alzinova AB

Strengthened portfolio with best-in-class potential

I am pleased that we now have a new candidate in the form of a monoclonal antibody that we can progress and prepare for clinical development.

This also means that we have a stronger product portfolio in dialogue with potential partners.

I am convinced that both the vaccine, ALZ-101, and the antibody, ALZ-201, have "best-in-class" potential and that they could make a significant impact in future disease treatments for Alzheimer's disease.

I look forward to an exciting new year where our most important goal is to complete patient recruitment for the ongoing clinical study with ALZ-101 before the end of this year so we can finalise the study in the second half of next year.

“Our goal is to have recruited all patients for the ongoing clinical study with the *oligomer-specific* vaccine ALZ-101 in 2022.”



About Alzheimer's and the Market

Every year, around 10 million people globally fall victim to dementia; Alzheimer's disease accounts for approximately 60-70 percent of that number. The incurable dementia disorders represent a growing problem as life expectancy increases. It is estimated that dementia afflicts around 55 million patients worldwide. The number is projected to rise to more than 130 million people in 2050. It is estimated that more than 30 million people around the world are suffering from Alzheimer's disease today, and the number is set to triple by 2050¹. The cost to society of the disease is estimated today to be approximately USD 1.3 trillion annually. The annual pharmaceutical expenditure related to just symptom-relief drugs for Alzheimer's disease amounts to approximately USD 6 billion.

Although the first drug for disease modification was recently approved in the USA, there is still a very long way to go to fully treat and prevent the progression of Alzheimer's disease. The sales and revenue potential of a new effective drug is therefore substantial even if it only obtains an initially limited market share. According to Global Data, the annual sales volume of disease modifying therapies for Alzheimer's disease in the major markets US, Germany, France, UK, Italy, Spain, Japan, China and India will amount to USD 13 billion in 2028.

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

About Alzinova

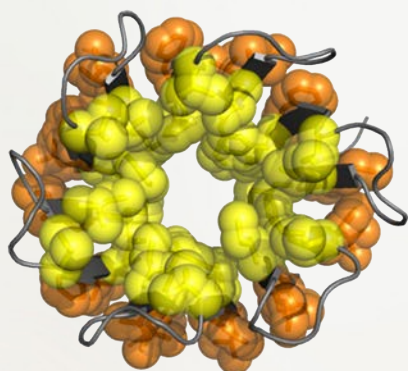
Alzinova AB is a Swedish biopharmaceutical company specialising in the treatment of Alzheimer's disease – one of our major health scourges, without effective treatment options. The Company's proprietary A β CC-peptide™ technology enables the development of disease modifying therapies that, with high precision, target the neurotoxic amyloid beta oligomers that are involved in the onset and progression of the disease. Using this technology, we can develop effective treatments that also have a favourable safety profile. 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. A Phase 1b study in Alzheimer's patients was 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. The aim is to broaden Alzinova's scope of activities and develop ALZ-201 within Alzinova's portfolio of disease modifying therapies. Alzinova was founded by researchers from the MIVAC research center at the University of Gothenburg, in collaboration with GU Ventures AB

Risk factors

Alzinova maintains procedures to continuously identify and manage risk factors. A detailed assessment of the Company's uncertainty factors was included in the Annual Report 2021, as well as in the Prospectus Alzinova Rights Issue 2020.



Illustrative model of oligomers.

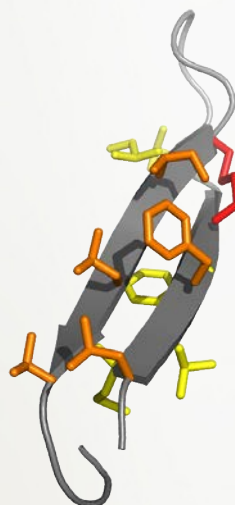


Illustration of Alzinova's patented A β CC molecule.

Illustrations courtesy of Prof. Torleif Härd, SLU, Sweden.

Financial information

Corporate structure and shareholding

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

The share, share capital and owner structure

The share

The Alzinova share was listed on Spotlight Stock Market on 25 November 2015. As of 11 March 2019, the Company is listed on Nasdaq First North Growth Market. There is one class of shares in the Company. The share entitles to one (1) vote.

Each share has equal right in shares in the Company's assets and profits. As of 31 March 2022, the number of shares in Alzinova amounted to 16,209,519.

Largest owners per 31 March 2022

Owner	No. of shares	Capital %
Försäkrings AB Avanza Pension	1,762,513	10.87%
Maida Vale Capital AB	1,734,332	10.70%
Nordnet Pensionsförsäkring AB	677,792	4.18%
MIVAC DEVELOPMENT AB	531,312	3.28%
Ola Hermansson with company	400,000	2.47%
Sara Gjertz	323,784	2.00%
Ålandsbanken, for owner	311,170	1.92%
Patrik Ahlvin	300,000	1.85%
Özlem Erdogdu Gül	254,154	1.57%
Jan Löngårdh	200,000	1.23%
Total 10 largest owners	6,495,057	40.07%
Total other owners	9,714,462	59.93%
Total all owners	16,209,519	100.00%

Share-based incentive programs

Through a long-term incentive program, the Company's CEO, other executive managers and some board members were invited to acquire warrants of series 2020/2023. A total of 159,165 warrants were acquired the Company's CEO and other executive managers. 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 1% after previous rights issues and the completed T02 2020/2022 share option programme.

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, corresponding to an exercise rate of approximately 11 percent. The subscription price per share was defined as 70% of the volume-weighted average price prior to the subscription period (set at SEK 6.61), with a minimum of SEK 6.50.

For comparison, the share price during the subscription period varied between approximately 6.00 and 6.60. 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 their warrants, the dilution amounted to approximately 3 percent based on the number of shares in Alzinova.

Financial development

During the year, the Company has mainly invested in the development of ALZ-101, a vaccine to treat and prevent the progression of Alzheimer's disease. Other external costs have increased during the period compared to previous quarter (but still according to plan) and amounted to 7.6 MSEK. The majority of this amount, 6.9 MSEK, are costs for research and development which has been capitalised in the balance sheet, and refers among others to the optimization and upscaling of the manufacturing process for ALZ-101.

Personnel expenses 1.6 MSEK are lower than previous quarter however as per budget. At the end of the reporting period (31 March 2022), the Company's equity amounted to 89 MSEK with an equity ratio of 94.4% (95 MSEK and 93.6% respectively as per 31 March 2021). The Company had a cash balance of approximately 27 MSEK (49 MSEK as per 31 March 2021).

Auditor's review

This report has not been reviewed by the Company's auditors.

Policies for the preparation of the interim financial report

The interim financial report is prepared in accordance with the Swedish Annual Accounts Act as well as the Swedish Accounting Standards Board BFNAR 2012:1 annual report and consolidated (K3).

The Board of Directors and the Chief Executive Officer hereby confirm that this interim report provides a true and fair view of the Company's operations, financial position and earnings, and describes significant risks and uncertain factors the Company is facing.

Gothenburg, 19 April 2022

Alzinova AB



Upcoming financial reports

Interim Report 2, 2022 25 August 2021

Interim Report 3, 2022 27 October 2021

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

For further information, please contact:

Kristina Torfgård, CEO, kristina.torfgard@alzinova.com, telephone +46 708 467975

Håkan Skogström, CFO, hakan.skogstrom@alzinova.com, telephone +46 705 850859

or mail directly to info@alzinova.com

Income statement

SEK	Jan-Mar 2022 3 months	Jan-Mar 2021 3 months	Jan - Dec 2021 12 months
Net sales	-	-	-
Own work capitalized	6,922,971	6,959,904	17,321,738
	6,922,971	6,959,904	17,321,738
Operating expenses			
Other external expenses	-7,571,191	-7,248,660	-19,025,906
Personnel expenses	-1 627 269	-1,172,497	-5,815,184
Operating result	-2,275,489	-1,461,253	-7,519,352
Result from financial items			
Interest expenses	-6,667	-	-32,654
Result after financial items	-2,282,156	-1,461,253	-7,552,006
Result before tax	-2,282,156	-1,461,253	-7,552,006
Result for the period	-2,282,156	-1,461,253	-7,552,006

Balance sheet

SEK	31 Mar 2022	31 Mar 2021	31 Dec 2021
ASSETS			
Fixed assets			
<i>Intangible assets</i>			
Capitalized expenditure for development work	66,938,198	49,653,393	60,015,227
Patent	1,632,086	1,632,086	1,632,086
	68,570,284	51,285,479	61,647,313
Total fixed assets	68,570,284	51,285,479	61,647,313
Current assets			
<i>Short term receivables</i>			
Tax receivables	105,064	67,267	129,296
Other receivables	546,303	108,528	575,385
Prepaid expenses and accrued income	1,170,474	126,135	503,861
	1,821,841	301,930	1,208,542
Cash and cash receivables	26,776,502	49,426,470	28,835,537
Total current assets	28,598,343	49,728,400	30,044,079
TOTAL ASSETS	97,168,627	101,013,879	91,691,392
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	4,263,104	4,149,015	4,149,015
Fund for development costs	64,869,352	47,584,552	57,946,386
	69,132,456	51,733,567	62,095,401
<i>Unrestricted equity</i>			
Share premium	121,414,772	118,872,676	118,872,676
Retained result	-99,419,284	-74,582,478	-84,944,312
Result for the year/period	-2,282,156	-1,461,253	-7,552,006
	19,713,332	42,828,945	26,376,358
Total equity	88,845,788	94,562,512	88,471,759
<i>Long term liabilities</i>			
Other long term liabilities	800,000	800,000	800,000
	800,000	800,000	800,000
<i>Current liabilities</i>			
Accounts payable	5,878,154	4,145,760	792,374
Other current liabilities	537,013	505,318	1,143,281
Accrued expenses and prepaid income	1,107,672	1,000,289	483,978
	7,522,839	5,651,367	2,419,633
TOTAL EQUITY AND LIABILITIES	97,168,627	101,013,879	91,691,392

Change in equity, condensed

Jan-Mar 2022 3 months	Share capital	Fund for deve- lopment 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
Share issue	114,089		2,705,579		2,819,668
Transaction costs rights issue			-163,483		-163,483
Transfer within equity		6,922,966		-6,922,966	0
Net result for the period				-2,282,156	-2,282,156
At the end of the period	4,263,104	64,869,352	121,414,772	-101,701,440	88,845,788

Jan-Mar 2021 3 months	Share capital	Fund for deve- lopment cost	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		6,959,904		-6,959,904	0
Net result for the period				-1,461,253	-1,461,253
At the end of the period	4,149,015	47,584,552	118,872,676	-76,043,731	94,562,512


Jan-Dec 2021 12 months	Share capital	Fund for deve- lopment cost	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, condensed

SEK	Jan-Mar 2022 3 months	Jan-Mar 2021 3 months	Jan - Dec 2021 12 months
OPERATING ACTIVITIES			
Result after financial items	-2 282 156	-1 461 253	-7 552 006
Adjustments for items not included in cash flow	-	-	-
Cash flow from operating activities before change in working capital	-2 282 156	-1 461 253	-7 552 006
Cash flow from change in working capital			
Increase (-)/Decrease (+) in operating receivables	-613 298	211 113	-695 499
Increase (+)/Decrease (-) in operating liabilities	5 103 206	1 659 473	-1 572 261
Cash flow from operating activities	2 207 752	409 333	-9 819 766
Investing activities			
Acquisition of intangible fixed assets	-6 922 971	-6 959 904	-17 321 738
Cash flow from investing activities	-6 922 971	-6 959 904	-17 321 738
Financing activities			
Share issue	2 819 667	-	-
Transaction costs share issue	-163 483	-	-
Cash flow from financing activities	2 656 184	0	0
Cash flow for the period	-2 059 035	-6 550 571	-27 141 504
Cash and cash equivalents at the beginning of the period	28 835 537	55 977 041	55 977 041
Cash and cash equivalents at the end of the period	26 776 502	49 426 470	28 835 537

Definitions and abbreviations

amyloid beta	a peptide (part of a protein) produced by the body that can aggregate in the brain and cause Alzheimer's disease
aggregated	clumped together
biomarker	a measurable indicator of a disease
clinical studies	a study of a medicine conducted on humans
disease modifying treatment	impacts the underlying cause of a disease
monoclonal antibody	one type of antibody made by cloning a unique white blood cell
neurotoxic	dangerous or poisonous to the brain
oligomers	aggregated proteins or peptides, used to designate soluble peptide clumps
peptide	part of a protein (a small chain of amino acids too small to be classified)



Alzinova AB is a Swedish clinical-stage biopharma company specialising in the treatment of Alzheimer's disease by targeting neurotoxic *amyloid-beta-oligomers*. The lead candidate, ALZ-101, is a therapeutic vaccine for the treatment of Alzheimer's. Alzinova's proprietary A β CC peptide™ technology enables the development of disease-modifying therapies 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 around 40 million people afflicted today. In addition, the antibody ALZ-201, in early preclinical development, was generated with the same A β CC peptide™ technology and the ambition is to further expand the pipeline.

Alzinova AB

(corporate identity number: 556861-8168)

AstraZeneca BioVentureHub
Pepparedsleden 1
SE-431 83 Mölndal
Sweden

alzinova 

www.alzinova.com