



# Alzinova Year end report

JANUARY – DECEMBER 2020

alzinova 

[www.alzinova.com](http://www.alzinova.com)



## Alzinova at a glance

- Alzinova is an innovative Swedish biopharma company specialized in the development of disease-modifying treatments for Alzheimer's disease.
- Alzinova's lead candidate, ALZ-101, is in late preclinical development as a therapeutic vaccine for the treatment of Alzheimer's disease.
- Alzinova's proprietary A $\beta$ 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.
- Alzinova's therapies are being developed to demonstrate safety and efficacy in Alzheimer's disease. In parallel, preclinical and pharmaceutical development is ongoing to ensure the candidates are ready for Phase II development together with a strategic partner.
- Listed on Nasdaq First North Growth Market in March 2019 (ALZ).

# Summary of events during January-December 2020

The Board of Directors and the Chief Executive Officer of Alzinova AB, hereby present the report for the period January-December 2020.



## Twelve months, January-December 2020

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- Net sales amounted to 0 SEK (0 SEK).
- Result after financial items amounted to -6,499,557 SEK (-6,189,903 SEK).
- Earnings per share amounted to -0.41 SEK (-0.81 SEK).
- Equity ratio amounted to 95.2 % (93.0 %).

## Three months, October-December 2020

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- Net sales amounted to 0 SEK (0 SEK).
- Result after financial items amounted to -2,361,085 SEK (-2,844,273 SEK).
- Earnings per share amounted to -0.15 SEK (-0.37 SEK).

**Result per share:** Result for the period divided by 15,775,724 shares as of 2020-12-31 (7,633,415 shares as of 2019-12-31)

**Equity ratio:** Total equity divided by total capital.

**Amounts in brackets:** Corresponding period in previous year.

**"The Company"** or **"Alzinova"** refers to Alzinova AB reg.no./org.no. 556861-8168.



## Significant events during October – December 2020

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- Alzinova carried out a 95 percent guaranteed preferential rights issue of units of MSEK 49.6 with attached warrants. The warrants can provide additional proceeds of approximately MSEK 25-42 in January 2022 (upon full exercise).
- The rights issue was oversubscribed to approximately MSEK 86 including subscription commitments, corresponding to a subscription rate of 173 percent, 95 percent of which with preferential rights. Alzinova was provided MSEK 49.6 in proceeds before issuance and guarantee costs.
- Alzinova received positive feedback in scientific advice from the Finnish Medicines Agency Fimea, for the forthcoming clinical trial application of the Alzheimer's vaccine ALZ-101.

## Significant events during January - September 2020

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- The Company announced in January that it had ensured a robust and validated process to manufacture API that meets the quality standards required to conduct the clinical Phase 1b study with the vaccine ALZ-101 on Alzheimer's disease patients. It was further announced that the study would commence during the fourth quarter with the initial dosing of the first patient planned for the turn of the year 2020/2021.
- In February, Alzinova AB made changes to the composition of the Board of Directors, as Björn Löwenadler stepped down from the board on personal grounds.
- An extraordinary general meeting was held on 27 February 2020. The general meeting passed resolutions regarding the number of board members of the Company and the appointment of Pernilla Sandwall as new board member.
- In March, Håkan Skogström took up appointment as Chief Financial Officer.
- During the period, Alzinova initiated an active risk analysis effort of Covid-19-related hazards. The Company is working closely with its partners to minimize the impact of Covid-19.
- The annual general meeting held on May 14 resolved to establish long-term incentive schemes for the Board of Directors and key personnel by issuing subscription warrants.
- Alzinova strengthened its Board of Directors with two new members, Lena Degling Wikingsson and Per-Göran Gillberg.
- Alzinova presented preclinical data on the Company's candidates at the Alzheimer's Association International Conference (AAIC). The preclinical data support the continued development of the Company's lead candidate, ALZ-101.
- The manufacture of the ALZ-101 vaccine drug substance for the Phase 1b clinical trial in Alzheimer's disease patients was delayed due to additional analytical work. The study is expected to commence with the first patient's first dose during the second quarter of 2021.

## Significant events after the end of the period

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- Alzinova announced in January that the drug substance for the vaccine ALZ-101 is manufactured and meets the requirements for the upcoming Phase Ib clinical study in patients with Alzheimer's disease, expected to start during the second quarter of 2021.



# CEO comments

**2020** was an important year and our goal-oriented work has ensured that we are well prepared for the start of our upcoming clinical study in 2021 in patients with Alzheimer's disease, despite the challenges of the Covid-19 pandemic.


During the fourth quarter, we progressed the work on the manufacturing of the drug substance for the ALZ-101 vaccine and, at the start of 2021, we secured materials for the Phase 1b clinical study. The drug substance has a high purity and meets the requirements of the clinical study. For us, this is an important milestone ahead of the study start and the continued development of the vaccine. We are now working to optimize the drug substance manufacturing process to ensure we can meet the requirements of the next stage of the development process, which is a Phase 2 study.

Preparations for the start of the Phase 1b clinical study in Finland have, during the year, featured two important regulatory interactions. As previously communicated, we received positive feedback in scientific advice from the Finnish Medicines Agency Fimea.

During 2020, we also submitted an application to the National Ethics Committee in Finland and received their favorable opinion in February 2021. With these positive outcomes and according to plan, we will now submit our application to Fimea to obtain approval to start the clinical study with our therapeutic vaccine, ALZ-101, during the second quarter 2021.

ALZ-101 is a therapeutic *oligomer-specific* vaccine being developed to treat patients with Alzheimer's disease. The vaccine is unique because its *oligomer-specificity* means that the body generates its own antibodies that only target the neurotoxic *oligomers of amyloid- $\beta$* , which are believed to be one of the causes of Alzheimer's disease.

During the year, data from clinical trials conducted with a number of other *amyloid- $\beta$*  drug candidates were presented. The results show that high *oligomer-specificity* is important both to obtain a good effect, and to avoid side effects. This supports our strategy to develop *oligomer-specific* treatment of Alzheimer's and that ALZ-101 can succeed in clinical trials.



**Kristina Torfgård**  
CEO, Alzinova AB



In November, Alzinova presented the study design for the vaccine candidate ALZ-101 at the scientific congress, Clinical Trials in Alzheimer's Disease (CTAD). The planned study will be conducted in patients with early Alzheimer's disease. The study is the first in humans and the aim is to demonstrate if the vaccine candidate, ALZ-101 is well tolerated and doesn't result in any unexpected side-effects. Moreover, the study will also include analyses of the immune response, i.e. levels of antibodies generated by the vaccine after repeated dosing, as well as a number of biomarkers that are linked with Alzheimer's disease.

As part of the ongoing preparations for the upcoming clinical study, Alzinova has established a research collaboration with Sahlgrenska University Hospital in Gothenburg, Sweden, focused on biomarkers that are used to track neurodegenerative change related to Alzheimer's disease.

We strengthened our financial position during the fourth quarter through a preferential rights issue of units of MSEK 49.6 with attached warrants. The warrants can provide additional proceeds of approximately MSEK 25-42 in January 2022 (upon full exercise). The new capital will primarily be used to finance preparations for clinical Phase 2 and thereby strengthen our ability to make ALZ-101 even more attractive to potential partners.

During the year, we have been affected by Covid-19, but thanks to actively implementing safety precautions, the pandemic hasn't had any major impact on our operations.

I am proud to lead this innovative company and, together with colleagues, board members and collaboration partners, to be developing a therapeutic vaccine that can potentially improve the lives of people suffering from Alzheimer's disease. We are now looking forward to starting our first clinical study with patients.

**“Our vision is to enable patients to live an independent and active life without any impact of Alzheimer's disease, by developing novel disease-modifying treatments.”**



# About Alzheimer's Disease

Every year, about 10 million people globally fall victim to dementia; Alzheimer's disease accounts for approximately 60-80 percent of that number.

The incurable dementia disorders represent a growing problem as life expectancy increases. It is estimated that dementia afflicts in the order of 50 million patients worldwide today and the number of cases is currently growing by nearly 10 million every year. The number is projected to rise to approximately 95 million people in 2025. 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 2050. The cost to society of the disease is estimated today to be approximately USD 1 trillion annually.

The annual pharmaceutical expenditure related to Alzheimer's disease drugs alone amounts to approximately USD 6 billion. There are no treatments available that are capable of providing anything more than temporary symptom relief. The sales and revenue potential of a new drug is therefore substantial even if it would obtain only a very 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 and Spain, Japan, China and India will reach up to USD 13 billion in 2028. An approved disease-modifying therapy for Alzheimer's disease has the potential to generate annual peak sales of more than USD 10 billion.



# About Alzinova

Alzinova AB is a Swedish biopharmaceutical company specializing in the treatment of Alzheimer's disease – one of our major health scourges, without effective treatment options. The Company's proprietary A $\beta$ 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 for treatment and prevention of

Alzheimer's disease. The candidate drug ALZ-101 is in late preclinical development and human clinical trials are estimated to initiate during the second quarter of 2021. Based on the same technology, the Company is also developing the ALZ-201 antibody which currently is in early preclinical development phase. The aim is to broaden Alzinova's scope of activities and develop ALZ-201 in 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.

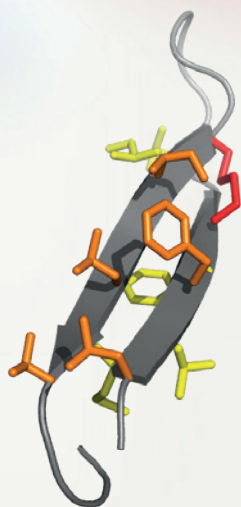
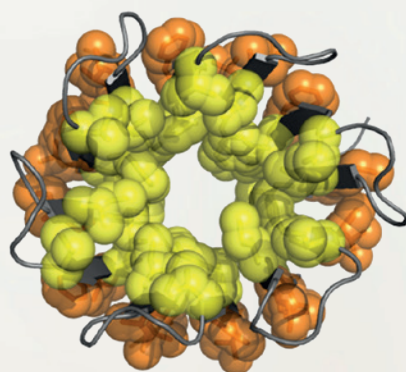


Illustration of Alzinova's patented A $\beta$ CC molecule.



Illustrative model of oligomers.

## Future outlook

Alzinova continues to focus primarily on development of the candidate drug vaccine ALZ-101. Our aim is to obtain approval to initiate the clinical study during the second quarter of 2021. The Company's assessment is that there is sufficient capital to finance operations throughout the second quarter 2022.

During the first quarter of 2021, the Company will also initiate studies for humanization of the ALZ-201 antibody. There may be opportunities for the Company to develop the antibody into a disease-modifying therapy. However, our focus is on the *oligomer-specific* vaccine, ALZ-101.

## Risk factors

Alzinova maintains procedures to continuously identify and manage risk factors.

At present times, it is still very difficult to assess how the Covid-19 pandemic will develop and what impact it will have on the Company and its risk factors. The Company has implemented a number of measures to protect its employees and we continue to follow the situation closely. We will take further precautions as necessary to limit the impact on the Company's operations.

Since Alzinova has not yet launched any pharmaceuticals or diagnostic medical devices, neither individually nor through cooperation, the Company has not made any sales or generated any revenue. Assessing the Company's sales potential may therefore be difficult; there is a risk that revenue is forgone, in whole or in part. The pre-clinical, clinical and registration phases are all associated with risks that may prevent the Company's products from resulting in commercial therapies, and thereby from generating revenue, fully or partially.

Alzinova still has no revenue. Depending on when the Company is able to generate a positive cash flow, the Company may therefore find itself forced to raise additional external capital in the future. Both the amount and timing of the Company's future capital requirements are dependent on a number of factors, such as the commercial success of the Company's products.

Alzinova has multiple collaboration agreements with suppliers and manufacturers. The Company is continually evaluating its direct and indirect suppliers, and active measures are being taken to mitigate any negative effects on the Company's operations. A detailed assessment of the Company's uncertainty factors was included in the Annual Report 2019, as well as in the Prospectus Alzinova Rights Issue 2020. The Board of Directors finds that Covid-19 thus far has not had any material impact on the operations. The Company monitors the development of the pandemic continuously and is working proactively to manage any long-term risk.

# 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

per share. Each share has equal right in shares in the Company's assets and profits. As of 31 December 2020, the number of shares in Alzinova amounted to 15,775,724.

### Largest owners per 30 December 2020

Owner	No. of shares	Capital %
Försäkrings AB Avanza Pension	1,970,313	12.49%
Maida Vale Capital AB	1,542,453	9.78%
Nordnet Pensionsförsäkring AB	772,344	4.90%
MIVAC Development AB	531,312	3.37%
Ola Hermansson med bolag	400,000	2.54%
Ålandsbanken, för ägare	303,478	1.92%
Gjertz, Sara	250,000	1.58%
Ahlvin, Patrik	206,300	1.31%
Löngårdh, Jan	200,000	1.27%
Sandberg, Anders	185,193	1.17%
<b>Total 10 largest owners</b>	<b>6,361,393</b>	<b>40.32%</b>
Total other owners	9,414,331	59.68%
<b>Total all owners</b>	<b>15,775,724</b>	<b>100.00%</b>

### Share-based incentive programs

Through a long-term incentive plan, the Company's CEO, other executive managers and board members were invited to acquire warrants of series 2020/2023. A total of 159,165 warrants were acquired at fair market value. 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 the rights issue and directed issue described below.



## Rights issue

During the autumn, the Company carried out a preferential rights issue with attached warrants of series TO2 2020/2022. 7,633,415 new shares were issued in the preferential rights issue and the Company received proceeds amounting to MSEK 49.6 before deduction of issuance and guarantee costs.

In connection with the preferential rights issue, a directed issue was also carried out which was settled by set-off against part of the cash liability to guarantors for guarantee commitments made in the preferential rights issue.

Through the directed issue, 508,894 new shares were issued, with the same attached warrants of series TO2 2020/2022, amounting to MSEK 3.5.

Every two warrants entitle the holder to subscribe for one new share during the period 24 January 2022 – 7 February 2022.

The directed issue resulted in an initial dilution of approximately 3% of the total number of shares in the Company after the preferential rights issue and the directed issue. If all warrants are exercised in series TO2 2020/2022, the directed issue will result in a combined dilution of approximately 5% of the total number of shares in the Company after the preferential rights issue and the directed issue.

## 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. At the end of the reporting period

(31 December 2020), the Company had a cash balance of approximately MSEK 56. The equity ratio at the end of the year was 95.2%.

## Proposal for the allocation of profits

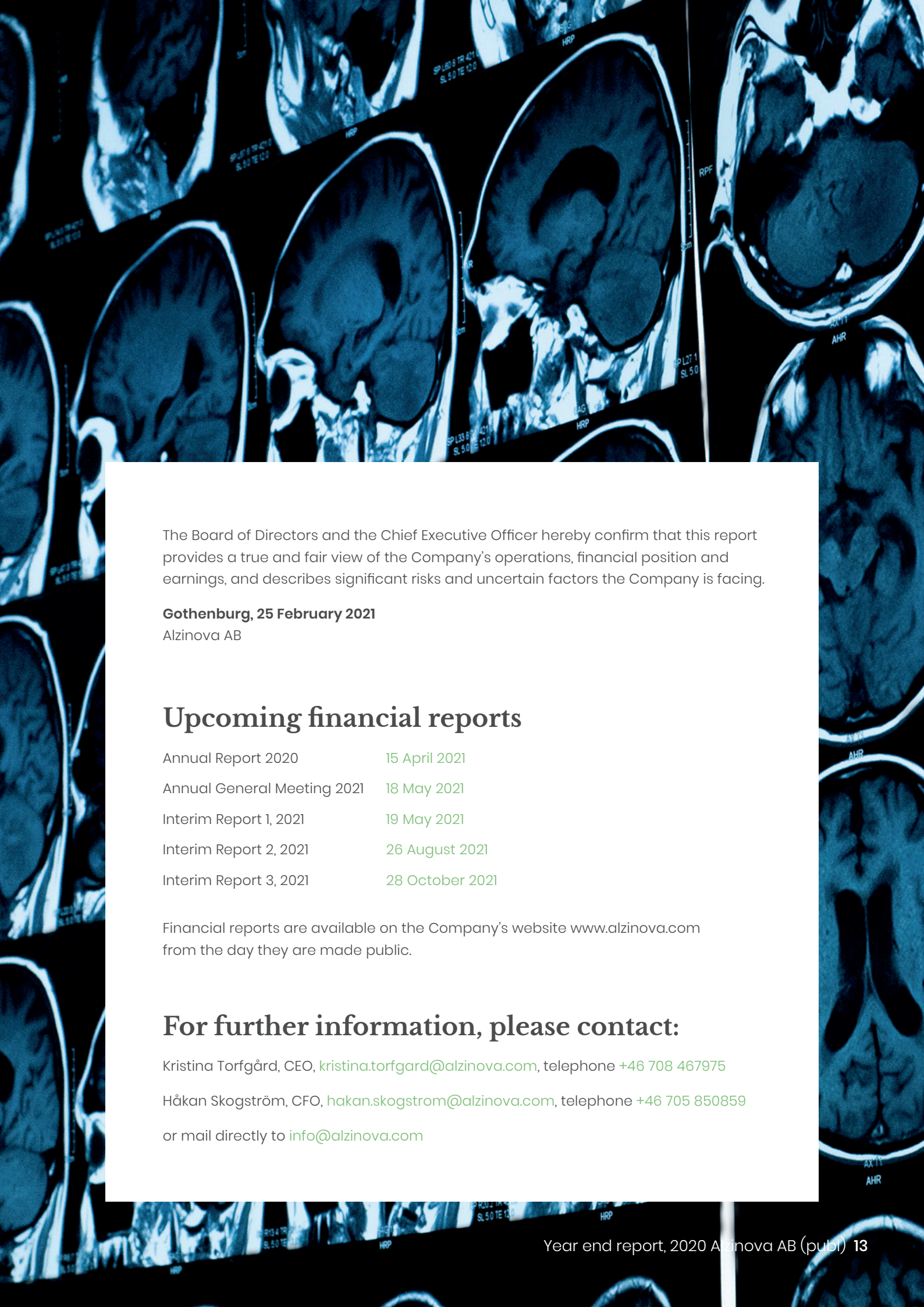
The CEO and Board of Directors propose that no dividend is paid for the financial year 01 January 2020 to 31 December 2020.

## 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 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, 25 February 2021**

Alzinova AB

## Upcoming financial reports

Annual Report 2020	15 April 2021
Annual General Meeting 2021	18 May 2021
Interim Report 1, 2021	19 May 2021
Interim Report 2, 2021	26 August 2021
Interim Report 3, 2021	28 October 2021

Financial reports are available on the Company's website [www.alzinova.com](http://www.alzinova.com) from the day they are made public.

## For further information, please contact:

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# Income statement

SEK	Oct-Dec 2020 3 months	Oct-Dec 2019 3 months	Jan - Dec 2020 12 months	Jan - Dec 2019 12 months
Net sales	-	-	-	-
Own work capitalized	3,630,082	2,152,970	14,898,034	6,808,837
	<b>3,630,082</b>	<b>2,152,970</b>	<b>14,898,034</b>	<b>6,808,837</b>
<b>Operating expenses</b>				
Other external expenses	-4,686,108	-2,755,970	-17,233,465	-8,764,417
Personnel expenses	-1,304,140	-2,235,173	-4,163,207	-4,221,897
<b>Operating result</b>	<b>-2,360,166</b>	<b>-2,838,173</b>	<b>-6,498,638</b>	<b>-6,177,477</b>
<b>Result from financial items</b>				
Interest expenses	-919	-6 100	-919	-12,426
<b>Result after financial items</b>	<b>-2,361,085</b>	<b>-2,844,273</b>	<b>-6,499,557</b>	<b>-6,189,903</b>
<b>Result before tax</b>	<b>-2,361,085</b>	<b>-2,844,273</b>	<b>-6,499,557</b>	<b>-6,189,903</b>
<b>Result for the period</b>	<b>-2,361,085</b>	<b>-2,844,273</b>	<b>-6,499,557</b>	<b>-6,189,903</b>



# Balance sheet

SEK	31 Dec 2020	31 Dec 2019
<b>ASSETS</b>		
<b>Fixed assets</b>		
<i>Intangible assets</i>		
Capitalized expenditure for development work	42,693,488	27,795,456
Patent	1,632,087	1,626,732
	<b>44,325,575</b>	<b>29,422,188</b>
<b>Total fixed assets</b>	<b>44,325,575</b>	<b>29,422,188</b>
<b>Current assets</b>		
<i>Short term receivables</i>		
Tax receivables	102,510	49,026
Other receivables	338,076	216,420
Prepaid expenses and accrued income	72,457	109,942
	<b>513,043</b>	<b>375,388</b>
<b>Cash and cash receivables</b>	<b>55,977,041</b>	<b>33,733,608</b>
<b>Total current assets</b>	<b>56,490,084</b>	<b>34,108,996</b>
<b>TOTAL ASSETS</b>	<b>100,815,659</b>	<b>63,531,184</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
<i>Restricted equity</i>		
Share capital	4,149,015	2,007,588
Fund for development costs	40,624,648	25,726,620
	<b>44,773,663</b>	<b>27,734,208</b>
<i>Unrestricted equity</i>		
Share premium	118,872,676	77,601,555
Retained result	-61,123,017	-40,035,086
Result for the year	-6,499,557	-6,189,903
	<b>51,250,102</b>	<b>31,376,566</b>
<b>Total equity</b>	<b>96,023,765</b>	<b>59,110,774</b>
<i>Long term liabilities</i>		
Other long term liabilities	800,000	800,000
	<b>800,000</b>	<b>800,000</b>
<i>Current liabilities</i>		
Accounts payable	1,911,584	425,367
Other current liabilities	511,453	558,992
Accrued expenses and prepaid income	1,568,857	2,636,051
	<b>3,991,894</b>	<b>3,620,410</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>100,815,659</b>	<b>63,531,184</b>

## Change in equity, condensed


Jan-Dec 2020 12 months	Share capital	Share capital, non- registered	Fund for development costs	Share premium	Retained result incl. result for the year	Total equity
<b>At the beginning of the year</b>	<b>2,007,588</b>	<b>0</b>	<b>25,726,620</b>	<b>77,601,555</b>	<b>-46,224,989</b>	<b>59,110,774</b>
Share issue	2,141,427			50,941,338		53,082,765
Transaction costs share issue				-9,950,347		-9,950,347
Subscription warrants				280,130		280,130
Transfer within equity			14,898,028		-14,898,028	0
Net result for the year					-6,499,557	-6,499,557
<b>At the end of the year</b>	<b>4,149,015</b>	<b>0</b>	<b>40,624,648</b>	<b>118,872,676</b>	<b>-67,622,574</b>	<b>96,023,765</b>

Jan-Dec 2019 12 months	Share capital	Rights issue	Fund for development cost	Share premium	Retained result incl. result for the year	Total equity
<b>At the beginning of the year</b>	<b>1,440,819</b>	<b>539,524</b>	<b>18,917,780</b>	<b>76,081,120</b>	<b>-33,226,246</b>	<b>63,752,997</b>
Registered new share issue	539,524	-539,524				0
Subscription warrants	27,245			1,520,435		1,547,680
Transfer within equity			6,808,840		-6,808,840	0
Net result for the year					-6,189,903	-6,189,903
<b>At the end of the year</b>	<b>2,007,588</b>	<b>0</b>	<b>25,726,620</b>	<b>77,601,555</b>	<b>-46,224,989</b>	<b>59,110,774</b>

## Cash flow statement, condensed

SEK	Oct-Dec 2020 3 months	Oct-Dec 2019 3 months	Jan - Dec 2020 12 months	Jan - Dec 2019 12 months
<b>OPERATING ACTIVITIES</b>				
Result after financial items	-2,361,085	-2,844,273	-6,499,557	-6,189,903
Adjustments for items not included in cash flow	-	-	-	-
<b>Cash flow from operating activities before change in working capital</b>	<b>-2,361,085</b>	<b>-2,844,273</b>	<b>-6,499,557</b>	<b>-6,189,903</b>
<b>Cash flow from change in working capital</b>				
Increase (-)/Decrease (+) in operating receivables	771,652	-11,039	-137,655	128,542
Increase (+)/Decrease (-) in operating liabilities	1,537,195	2,040,770	371,484	2,085,626
<b>Cash flow from operating activities</b>	<b>-52,238</b>	<b>-814,542</b>	<b>-6,265,728</b>	<b>-3,975,735</b>
<b>Investing activities</b>				
Acquisition of intangible fixed assets	-3,370,115	-2,169,660	-14,903,387	-6,891,854
<b>Cash flow from investing activities</b>	<b>-3,370,115</b>	<b>-2,169,660</b>	<b>-14,903,387</b>	<b>-6,891,854</b>
<b>Financing activities</b>				
Subscription warrants	-	-	280,130	2,247,656
Share issue	53,082,765	-	53,082,765	-
Transaction costs share issue	-9,950,347	-	-9,950,347	-
<b>Cash flow from financing activities</b>	<b>43,132,418</b>	<b>0</b>	<b>43,412,548</b>	<b>2,247,656</b>
<b>Cash flow for the period</b>	<b>39,710,065</b>	<b>-2,984,202</b>	<b>22,243,433</b>	<b>-8,619,933</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>16,266,976</b>	<b>36,717,810</b>	<b>33,733,608</b>	<b>42,353,541</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>55,977,041</b>	<b>33,733,608</b>	<b>55,977,041</b>	<b>33,733,608</b>





**Alzinova AB** is a Swedish biopharma company specializing in the treatment of Alzheimer's disease by targeting neurotoxic *amyloid- $\beta$  oligomers*. The lead candidate, ALZ-101, is in late preclinical development as a therapeutic vaccine for the treatment of Alzheimer's. Alzinova's proprietary A $\beta$ 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 of the order of up to 40 million people afflicted today. In addition, the antibody ALZ-201, in early preclinical development, was generated with the A $\beta$ CC peptide™ technology and the ambition is to expand the pipeline further.

For further information,  
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## Visiting address

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