Alzinova

Sector: Biotech

Positive topline results

Redeye provides a short research update following the positive phase Ib results with lead candidate ALZ-101 published by Alzinova last week. Overall, we are encouraged to learn that the candidate met the primary endpoint of safety and tolerability while demonstrating a clear immunological response related to treatment. We raise our base case valuation to SEK12 as we see an increased likelihood of approval (LoA) for ALZ-101 following the results.

Encouraging phase Ib data

Last week, Alzinova announced positive initial findings from the phase Ib study with its vaccine candidate ALZ-101. The topline data show good tolerability, an acceptable safety profile, and a clear immunological response related to treatment with ALZ-101. While the full data analysis is still pending (expected in Q1 2024), these results reinforce our confidence in the candidate. Accordingly, we raise our overall LoA to 15% (11%) for ALZ-101 as we argue that the risk related to the development of the program has been reduced.

Attract new interest

Having proven itself in the clinical setting, we argue that this propels ALZ-101 as a serious candidate in the disease-modifying AD treatment space. Consequently, amidst increased interest in the field following the market approval of Lecanemab, we believe that this could attract the eyes of Big Pharma and will benefit Alzinova immensely in achieving a potential licensing deal in conjunction with the upcoming phase II trial.

Valuation – Revised base case of SEK12

We value Alzinova using a discounted cash flow (DCF) model based on our sales model and our underlying assumptions. Following the recent encouraging phase Ib study results, we raise our fair value range to SEK2-24 per share with a base case of SEK12 (10), bull case: SEK24 (20); bear case: SEK2 (1). Accordingly, our base case represents a significant upside potential from current share price levels as we continue to have a positive outlook on the case.

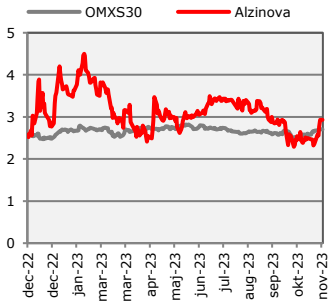
Key Financials (SEKm)*	2020	2021	2022	2023e	2024e
Revenues	0	0	0	0	202
Revenue growth	N/A	N/A	N/A	N/A	N/A
EBIT	-6,5	-7,5	-13,1	-15,1	182,6
EBIT Margin (%)	N/A	N/A	N/A	N/A	0,9
Net Income	-6,5	-7,6	-13,1	-15,1	156,2
EV/Revenue	neg	neg	neg	neg	27%
EV/EBIT	neg	neg	neg	neg	31%

*Risk-adjusted estimates.

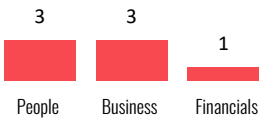
FAIR VALUE RANGE

BEAR	BASE	BULL
2	12	24

ALZ VS OMXS30 – LAST 12 MONTHS



REDEYE RATING



KEY STATS

Ticker	ALZ
Market	First North
Share Price (SEK)	3.2
Market Cap (MSEK)	143
Net Debt 23E (MSEK)	-32
Free Float	82%
Avg. daily volume ('000)	130

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Important information: All information regarding limitation of liability and potential conflicts of interest can be found at the end of the report
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Investment case

Case: Unique offering in blockbuster indication

Alzinova offers a rare investment opportunity in the Scandinavian equity markets as its main candidate, ALZ-101, is one of the very few oligomer-specific disease-modifying therapies for Alzheimer's disease in clinical development. With the company having secured a financial runway into 2024 and saturated its capital need, we believe that Alzinova has set a starting point for long-term value creation.

Furthermore, we view ALZ-101's vaccine approach as unique in the Alzheimer's pipeline. It suits well for a life-long indication, such as Alzheimer's, and is potentially superior in cost-effectiveness to its peers. We believe that ALZ-101 is in a promising position to become a vital part of the future toolbox for treating Alzheimer's disease. Accordingly, we forecast ALZ-101's potential annual peak sales at more than USD5bn, in 2036.

Evidence: Rooted in Innovation

Amyloid-β (Aβ) will continue to be a key target in the perpetual aim of achieving disease modification within Alzheimer's disease, and we argue that Alzinova's approach of targeting a specific type of Aβ aggregates (Aβ oligomers/Aβ42) is the best supported in the field. The company's drug candidates are based on the patented proprietary AβCC peptide technology, which can accurately attack the harmful substances that are central to the origin and development of the disease. With the AβCC technology, Alzinova has exciting potential to further expand its portfolio of innovative projects within Alzheimer's in the long run – as is evident with the emergence of its monoclonal antibody, ALZ-201.

Supportive analysis: Toxicity specifically stem from Aβ42

In a recent study comparing the effect of a Aβ42-specific monoclonal antibody (ALZ-201) with an all Aβ-binding antibody (4G8) and a non-Aβ-binding isotype control it was demonstrated that all of the Aβ toxicity observed in human-derived brain extracts stem specifically from soluble Aβ42 aggregates (Sandberg, A. et al., 2021).

Brain tissue samples from ten individuals were collected, seven cases confirmed as Alzheimer's and three as non-Alzheimer's. Extracts were prepared and immunodepleted with either the antibody 4G8, ALZ-201 or the isotype control to ALZ-201. Fractions were then biochemically characterized, and toxicity assays were performed in primary mouse neuronal cultures using an automated cell imaging platform.

The results from the study demonstrated that very small amounts of soluble aggregated Aβ42 likely account for a large part of the overall toxicity in Alzheimer's patients. The unique antibody, ALZ-201 (and ALZ-101), is capable of specifically depleting these without targeting other forms of Aβ. Since this natural toxic form of Aβ is extremely low in abundance, this could be a critical attribute for achieving an adequate therapeutic effect in actual Alzheimer's patients as well.

Challenge I: Partnership dependent

Operating in such a huge indication as Alzheimer's, Alzinova is highly dependent on Big Pharma's resources to take ALZ-101 through the more extensive clinical trials and to the market. However, we believe that a strong safety profile being displayed in the phase Ib trial could attract interest from the big industry players.

Challenge II: Historically, a challenging Indication

Alzheimer's disease is undeniably a heterogeneous and complex indication within drug development. Even though significant scientific effort over the last decade has increased the public knowledge of the disease, Alzheimer's remains a tough nut to crack. The specificity of Alzinova's candidates could, however, be the key to overcoming this hurdle.

Valuation: Attractive upside

In our valuation of Alzinova, we use a DCF based on our sales model and our underlying assumptions to generate our revised fair value Base Case of SEK12. While the positive phase Ib study results triggered an initial ~30% rise in the share price, our base case suggests a significant further upside potential in the stock. Key triggers that could narrow the valuation gap in both the short- and long-term are, primarily, the full data analysis from the phase Ib trial, a potential licensing deal for ALZ-101 and preclinical advancements with the company's antibody candidate, ALZ-201.

Counter Points

Alzinova is a biotech company in early-stage development. Investors should be aware of the high risks when considering such an investment. In Alzinova's case, we want to draw specific attention to the development, partnership and patent risks.

- Development risk – ALZ-101 is in early-stage development in Alzheimer's, an indication that has proven a hard nut to crack. Moreover, we emphasize that we currently attribute the full company value to a single project.

- Financial risk – Although the company has no immediate capital need following the last year's rights issue (and the TO3 warrants), investors should factor in additional funding needs before any recurring revenue streams.

- Patent risk – The AβCC technology (ALZ-101) is protected on the most important markets (most of Europe, US, and Japan) - until 2029 and the company is pursuing an active patent strategy. However, there is a risk that Alzinova will not be granted extensions to its key patents.

Key Catalysts

ALZ-101 – phase Ib full data analysis

A full analysis of the study data is expected to be completed in the first quarter of 2024, where we will see more detailed outcomes on several different endpoints.

Timeframe: 2-4 months
Impact: Moderate

ALZ-201 – Preclinical progress

In the latest equity issue, Alzinova partly raised capital for the establishment of a manufacturing process for the ALZ-201. ALZ-201 is built on the same theoretical approach as ALZ-101. Sufficient preclinical progression and data could position ALZ-201 as the second asset in Alzinova's clinical portfolio in the coming years.

Timeframe: 4-16 months
Impact: Moderate

Licensing deal

Now that ALZ-101 has demonstrated a good tolerability and safety profile in the phase Ib trial, we believe it is possible that the candidate could catch the eye of Big Pharma companies. Accordingly, we project a licensing deal being struck prior to phase II trials. This could act as a major catalyst for the stock.

Timeframe: 3-12 months
Impact: Major

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ALZ-101 – Encouraging phase Ib results

Phase Ib – Study design

Alzinova's lead candidate, ALZ-101, is being developed as a potential first-in-class oligomer-specific vaccine treatment against Alzheimer's disease (AD). The phase Ib study is a placebo-controlled, double-blind, randomized First in Human (FIH) trial in patients diagnosed with early AD. The study have two parts. In part A, the main part of the study, patients received four doses of either ALZ-101 or placebo, during a treatment period of 20 weeks. The study investigates two different dose levels of ALZ-101, 125 and 250 µg. Participants in part A were followed up in week 30 and either continued in the extension part of the study, Part B, or complete Part A. Participant not eligible to Part B are followed up until week 68 with no further dosing. Patients eligible for Part B are treated with 2 doses of ALZ-101 in an open-label study over 16 weeks and followed up during in total 68 weeks (Part A and B).

In total, 26 patients are included in the study, where the primary endpoint is to evaluate the safety and tolerability of repeated doses of ALZ-101. However, the study also includes secondary and exploratory (efficacy) endpoints related to immune response and biomarkers.

ALZ-101: Overall phase Ib study design

ALZ-101: Phase Ib Study Design	
Site	Clinical Research Service Turku (CRST) Finland
Subjects	26 patients - mild AD or MCI due to AD
Study design	Randomized, placebo controlled, double-blind
Treatment	Two doses ALZ-101 and placebo
Study duration	20 weeks treatment; 48 weeks follow-up
Primary endpoint	Safety and tolerability
Secondary endpoint	Immunogenicity (Aβ-specific)
Exploratory endpoints	Biomarkers (CSF & blood) and cognition

Source: Alzinova, Redeye research

Phase Ib – Topline data

Last week, Alzinova announced topline results from the study, based on analysis after the first part (A) of the trial where all patients received four doses over 20 weeks of treatment. Results from part A show good tolerability, an acceptable safety profile and a high immune responder rate. Similar to what was seen in the interim analysis of the study, the topline data suggests that there is a clear immunological response related to treatment with ALZ-101 as treated patients exhibited a heightened level of (Aβ-) specific antibodies. Notably, antibody levels escalated with each administered dose.

All patients underwent magnetic resonance imaging to detect amyloid-related imaging abnormalities, i.e., ARIA-E (localized brain swelling) and ARIA-H (micro bleeding). These types of side effects can occur with antibody treatment against the peptide Aβ. However, no patients developed ARIA-E during treatment, while one patient who entered the study with a history of ARIA-H had a symptom-free increase in size. A full analysis of the study data is expected to be completed in the first quarter of 2024, where we will see more detailed outcomes on several different endpoints.

These results represent a significant milestone for Alzinova and stand as the most pivotal development in the company's history yet. These results reinforces our confidence in the company's proprietary AβCC peptide technology and the rationale behind the vaccine-based approach in AD. Although the comprehensive trial data analysis is still pending, the positive

outcome results proves the possibility of targeting Aβ42 in its oligomeric form in a safe and effective way to achieve clinically relevant results. Having proven itself in the clinical setting, we argue that this propels ALZ-101 as a serious candidate in the disease modifying AD treatment space. Consequently, amidst increased interest in the field following the market approval of Lecanemab, we believe that this could attract the eyes of Big Pharma and will benefit Alzinova immensely in achieving a potential licensing deal in conjunction with the upcoming phase II trial.

Following these initial results, we choose to raise our probability of success (PoS) for the phase I development of ALZ-101 to 95% (70%), and the overall likelihood of approval (LoA) to 15% (11%). We argue that the risk related to the development of the ALZ-101 program has been reduced and that the results warrant further clinical advancement of the asset.

Probability of Success & Likelihood of Approval

PoS (%)	Phase I	Phase II	Phase III	NDA/EMA	LoA (Phase I)
Old	70%	30%	60%	90%	**11%**
New	**95%**	30%	60%	90%	**15%**

Source: Alzinova, Redeye research

Furthermore, Alzinova is currently proceeding with the ongoing extension part (B) of the phase Ib study, providing active treatment with ALZ-101 to all patients over a 20-week span. Subsequently, patients are monitored for 48 weeks. Part B aims to offer insights into the long-term safety and tolerability of the treatment, assess the extended immune response, and gather data on its impact on biomarkers and cognitive functions.

We will return with an extended take on the phase Ib trial results and the ALZ-101 program following the release of the final study data analysis from and the announcement of a more detailed development plan ahead for the candidate.

Valuation

Valuation Summary

Below we show our project valuation for ALZ-101 – calculated through a discounted cash flows (DCF) model based on our sales models and the underlying key assumptions – and our valuation of Alzinova as a whole. We apply a weighted average cost of capital (WACC) of 15.5%, based on our Redeye Rating model, using a risk-free rate of 3%.

Valuation: DCF model

Valuation summary (SEKm) - Base case						
Program	Indication	Stage	Launch	Peak sales ($m)	Probability (LoA)	Value, r-adj (SEKm)
ALZ-101	Alzheimer's	Phase I	2031	5162	15%	909
				Tech Value (SEKm)		**909**
				Est. net cash		28,6
				Shared costs		-392,6
				Equity Value		**545**
				Shares outstanding		44,5
WACC: 15,5%				Base case		12,0

Source: Redeye Research

Summary of changes in valuation

- We update the ALZ-101 phase Ib PoS to 95% (70%), and the overall LoA to 15% (11%).

Bear Case SEK 2

We factor in disappointing findings from the full analysis of the phase Ib trial data, as well as a delayed phase II study and a dilutive rights issue due to difficulties in finding a partner for ALZ-101.

Base Case SEK 12

We refer to the DCF model for our Base Case.

Bull Case SEK 24

Our Bull Case factors in further supporting positive results from the full analysis of the phase Ib data, success in preparing ALZ-101 for phase II, and out-licensing in 2024 with a USD 20 million upfront payment to a strong Big Pharma partner.

Sensitivity Analysis

Our valuation of Alzinova is highly affected by the WACC we attribute to the company. WACC plays an essential part in calculating the discounted cash flow and reflects the uncertainties related to the company and the market. We illustrate the impact of applying changes to WACC on our fair value range (Base Case, Bull Case, and Bear Case) valuation in a sensitivity analysis below.

Initiator Pharma: Sensitivity analysis

Sensitivity analysis: WACC						
		13,5%	14,5%	**15,5%**	16,5%	17,5%
Value (SEK/share)	Bull	2,5	2,2	**2**	1,8	1,7
	Base	14,8	13,4	**12**	11,0	10,0
	Bear	29,6	26,8	**24**	22,0	20,0

Source: Redeye Research

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General summary

Disease Overview: Alzheimer's Disease

Alzheimer's disease is the most common form of neurodegenerative disorder and the leading cause of dementia. Approximately 70 percent of all dementia cases are due to Alzheimer's. It is manifested clinically as deterioration of cognitive and functional abilities. The disease is characterized by a long pre-symptomatic stage (up to 20 years) followed by a relatively rapid process of increasing morbidity. As the deterioration is progressive, eventually fatal (average survival after diagnosis is four to eight years, Datamonitor), and lacks a cure – it is a devastating disease, both for the patient and the caregivers. It is currently the only disease among the top ten causes of death that lacks (a fully approved) disease modifying treatment.

Although the cause of Alzheimer's disease is subject to ongoing debate, the pathological hallmarks of the disease are well understood. At a molecular level, Alzheimer's arises due to protein misfolding in the brain. Misfolded proteins tend to get sticky and form aggregates. In Alzheimer's, two pathological hallmarks have been identified: extracellular senile plaques of Aβ and intracellular fibrillary tangles of Tau.

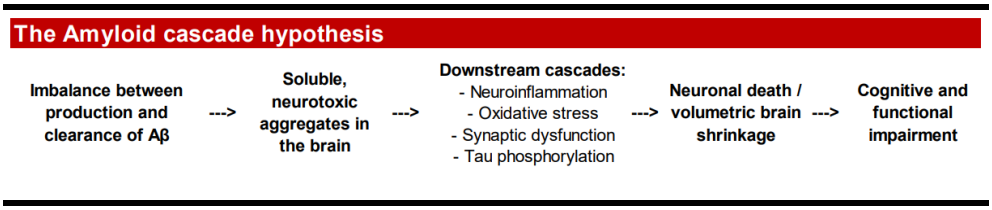
The Amyloid Beta Peptide

The most established theory revolves around the Aβ protein playing a central role in Alzheimer's disease pathology. Aβ is a peptide that is generated through cleavage of the amyloid precursor protein (APP) by β- and γ-secretases into different sizes. The most common Aβ peptides comprise 40-42 amino acids. Since the discovery of Aβ as the major constituent in the pathology of AD brains, the research has come to a more sophisticated stage. Several research findings suggest that the different sizes of the Aβ is of great relevance. For instance, the longer Aβ42 peptide is more prone to form neurotoxic aggregates than its shorter Aβ counterparts.

The strongest supporters of the Aβ field has attributed it not only as the major pathological hallmark but as the causative agent of the neurodegenerative process. The approach is known as "The amyloid cascade hypothesis" and can be summarized as follows:

1. Due to genetic factors and increasing age, there is an imbalance in the production and clearance of Aβ in the brain. The Aβ42 peptide tends to have a sticky character in the brain and readily form aggregates as it accumulates.
2. However, not all Aβ aggregates are neurotoxic; the revised amyloid cascade hypothesis focuses on the soluble oligomer aggregates.
3. Soluble oligomers are the initiating agent in the downstream cascade of the neurodegenerative process.

Neurodegenerative Process – The Amyloid Cascade Hypothesis



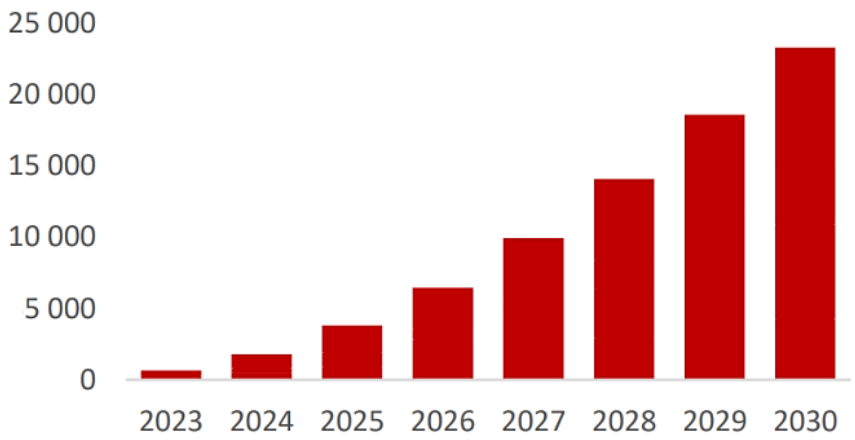
Source: Redeye Research

Aβ will continue to be a key target in the perpetual aim of achieving disease modification within Alzheimer's. We argue that ALZ-101, Alzinova's oligomer-targeting vaccine candidate, is in a promising position to become a vital part of the future toolbox for treating Alzheimer's disease.

Market outlook – Alzheimer's treatment

When comparing the current treatment and prescription drug market for Alzheimer's with the extensive societal cost burden of the disease, it becomes clear that the market is severely constrained. The present valuation of USD 2-4 billion is seemingly meagre and can be attributed to the manifold challenges encountered in developing novel and efficacious treatments, especially in the context of the limited options available currently, comprising mainly of generics that are riddled with efficacy issues and unfavourable side effects. Nevertheless, the disease burden is ever-increasing, and the encouraging advancements in innovative treatments offer much hope for the market to undergo rapid expansion in the near future.

Estimated Sales, US, EU5 and Japan – Disease Modifying Antibodies (USDm), 2023E-2030E



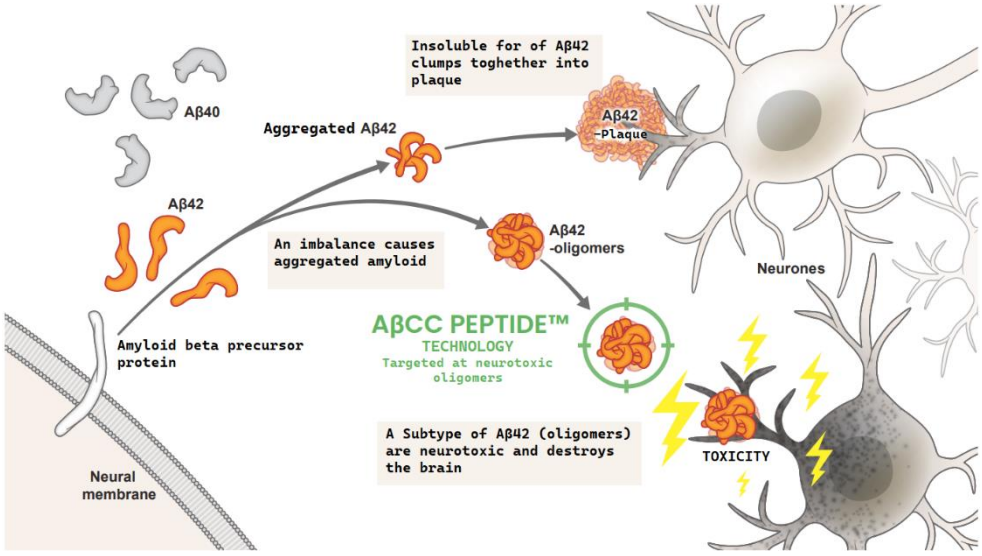
Source: Biomedtracker, Redeye research

Based on current market analyses conducted by Informa/Datamonitor, it is projected that the greatest contribution to the growth of the Alzheimer's treatment and prescription drug market in the upcoming years will be attributed to Lecanemab, a drug jointly developed by Biogen and Eisai, which was in-licensed from Bioarctic. This is expected to be followed by the market entry of Donanemab, a drug being developed by Eli Lilly.

ALZ-101 – Alzinova's Lead Candidate

Alzinova's drug candidates are based on the company's patented proprietary AβCC peptide technology. The idea behind the technology is to stabilize Aβ42 in its oligomeric form so that it does not form amyloid fibrils. Alzinova's lead candidate, ALZ-101, is a vaccine therapy for the treatment of early Alzheimer's disease. It generates antibodies specifically towards a subtype of the Aβ oligomers shown to be a major form of neurotoxic aggregates in brain extracts from Alzheimer's patients. The stabilized oligomers position ALZ-101 attractively for development as a vaccine. By intramuscular injections of ALZ-101 together with an aluminum hydroxide adjuvant, the hypothesis is that the body's own immune system will recognize it as a potentially harmful substance and thus start to produce antibodies against it.

AβCC Technology – Mode of Action



Source: Alzinova

Preclinical Evidence

Preclinical studies using a transgenic mouse model of Alzheimer's disease (genetically modified mice that overproduces Aβ in the brain) showed that a six month-treatment with ALZ-101 led to a significant reduction in the number of eliminated synapses — the junctions between two nerve cells that allow them to communicate — in the brain of treated animals compared to controls.

However, the animal models of Alzheimer's disease commonly used in efficacy studies of potential drugs are not particularly useful for the evaluation of oligomer-specific drugs. Alzheimer's disease is a unique human disease that has not been able to be recreated in any model animal. Therefore ALZ-101 (and ALZ-201) is also evaluated in new models based on biological material from deceased humans.

In a collaboration with a research group at the University of Gothenburg in 2019, it was shown that ALZ-101 (and ALZ-201) have a completely unique ability to specifically neutralize the causes of the toxic effect in the brain. Zebrafish were exposed to toxic human brain extracts, and researchers assessed the vaccine's ability to rescue zebrafish embryos' startle response.[1]

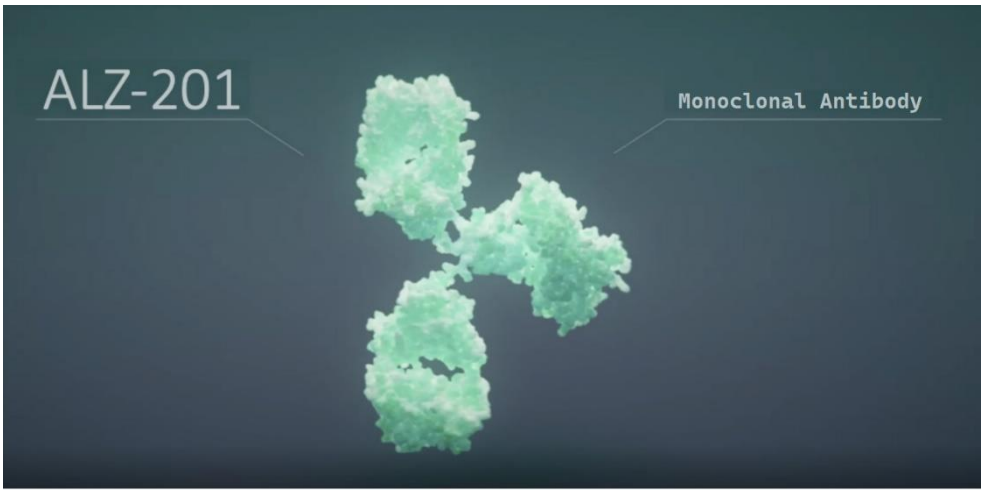
The results showed the vaccine was well-tolerated in non-human primates, with no signs of toxicity or inflammation. Moreover, it improved the ability of zebrafish embryos to learn the startle response after being challenged with toxic human brain extracts. This effect was demonstrated despite the fact that these oligomer-specific antibodies are completely devoid of the ability to bind to aggregated Aβ and plaque. Based on the findings, the researchers suggest that ALZ-101 is well suited as a long-term treatment option for preclinical and prodromal Alzheimer's disease to prevent or delay the onset of dementia.

[1] This is a rapid, generalized extreme response to a sudden, surprise stimulus and has been used as a readout for motor function, sensory physiology and basic forms of learning.

ALZ-201 – A Monoclonal Antibody

Alzinova is also developing ALZ-201, a monoclonal antibody developed to specifically neutralize harmful soluble oligomeric forms of amyloid-β42. Similar to ALZ-101, this candidate is also based on the company's proprietary AβCC peptide technology. By only neutralizing the toxic form of amyloid-β42, ALZ-201 is expected to express a higher degree of binding to the target across the blood-brain barrier in comparison with other amyloid antibodies. In turn, we argue that this could result in a treatment with considerable efficacy.

ALZ-201 – Illustrated



Source: Alzinova

Through the development of ALZ-201, Alzinova is broadening its business area and portfolio of disease modifying Alzheimer's treatments. Given the nature of Alzheimer's disease, we argue that there is potentially a need for both vaccine treatments and antibody alternatives. While we believe that the vaccine approach suits well for a life-long indication (such as Alzheimer's) and is potentially superior in cost-effectiveness, an antibody treatment can also act as adjunctive therapy for patients who initially need to be treated with high levels of antibodies or suffer from a weakened immune system. Thus, we see a rationale for the development of both ALZ-101 and ALZ-201.

Sales Model

As has been stated by the company, Alzinova's primary focus is the development of lead candidate ALZ-101. Accordingly, until a well-defined and well-resourced pathway for the clinical development of ALZ-201 is established, it remains outside the scope of our current valuation model for Alzinova.

Likelihood of Approval

We apply an overall likelihood of approval (LoA) of 15% for ALZ-101, which is our estimated probability of the candidate reaching market approval. This is based on a 95% probability rate of ALZ-101 progressing through the ongoing phase Ib trial. Accordingly, should the candidate demonstrate encouraging results in the data readout expected later this year, we will raise our estimated LoA.

ALZ-101 – Sales Models

Below we show our peak sales models for ALZ-101:

ALZ-101: Priming shots sales model

	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E	2040E
	Launch					Peak				
MCI-AD & Mild AD prevalence (m)										
US	7.792	8.032	8.264	8.490	8.715	8.956	9.179	9.390	9.592	9.799
5EU	8.708	8.904	9.088	9.261	9.428	9.614	9.776	9.926	10.078	10.231
Japan	4.563	4.629	4.689	4.746	4.800	4.842	4.872	4.896	4.914	4.932
MCI-AD & Mild AD treatment rate (m)										
US	3.117	3.213	3.306	3.396	3.486	3.583	3.672	3.756	3.837	3.920
5EU	3.483	3.561	3.635	3.704	3.771	3.846	3.910	3.971	4.031	4.092
Japan	2.281	2.314	2.345	2.373	2.400	2.421	2.436	2.448	2.457	2.466
Market penetration per year, ALZ-101										
US	1.0%	1.5%	2.5%	6.0%	7.5%	8.0%	6.0%	3.0%	2.0%	0.0%
5EU	0.5%	1.0%	1.5%	3.5%	6.5%	7.5%	8.0%	3.0%	2.0%	0.0%
Japan	0.5%	1.0%	1.5%	3.5%	6.5%	7.5%	8.0%	3.0%	2.0%	0.0%
Newly treated patients, ALZ-101 (m)										
US	0.031	0.048	0.083	0.204	0.261	0.287	0.220	0.113	0.077	0.000
5EU	0.017	0.036	0.055	0.130	0.245	0.288	0.313	0.119	0.081	0.000
Japan	0.011	0.023	0.035	0.083	0.156	0.182	0.195	0.073	0.049	0.000
Price - Primer shots, ALZ-101 ($)										
US	6,000	6,000	6,000	6,000	6,000	6,000	6,000	6,000	6,000	6,000
5EU	3,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000
Japan	4,500	4,500	4,500	4,500	4,500	4,500	4,500	4,500	4,500	4,500
Sales - Primer shots, ALZ-101 ($m)										
US	187	289	496	1,223	1,569	1,720	1,322	676	460	0
5EU	52	107	164	389	735	865	938	357	242	0
Japan	51	104	158	374	702	817	877	330	221	0
Total	**291**	**500**	**818**	**1,985**	**3,006**	**3,402**	**3,137**	**1,364**	**923**	**0**

* Datamonitor data over MCI-AD prevalence lasts to 2037. From 2038, we estimate a conservative prevalence increase of 1-2% annually between the different regions. Please also note that totals may not add up due to rounding.
Source: Datamonitor, Redeye Research

ALZ-101: Booster shots sales model

	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E	2040E
	Launch					Peak				
Patients in the need for booster doses (m)										
US	0.000	0.031	0.079	0.162	0.366	0.627	0.914	1.134	1.247	1.324
5EU	0.000	0.017	0.053	0.108	0.237	0.482	0.771	1.084	1.203	1.283
Japan	0.000	0.011	0.035	0.070	0.153	0.309	0.490	0.685	0.759	0.808
Compliance rate (m)										
US	0.000	0.025	0.063	0.130	0.293	0.502	0.457	0.567	0.623	0.662
5EU	0.000	0.014	0.042	0.086	0.190	0.386	0.385	0.542	0.601	0.642
Japan	0.000	0.009	0.028	0.056	0.122	0.247	0.245	0.343	0.379	0.404
Price - annual booster dose, ALZ-101 ($)										
US	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000
5EU	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000
Japan	1,400	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500
Sales - booster doses, ALZ-101 ($m)										
US	0	50	130	260	590	1,000	910	1,130	1,250	1,320
5EU	0	10	40	90	190	390	390	540	600	640
Japan	0	10	40	80	180	370	370	510	570	610
Total	**0**	**70**	**210**	**430**	**960**	**1,760**	**1,670**	**2,180**	**2,420**	**2,570**

Source: Datamonitor, Redeye Research

ALZ-101: Total sales estimates

	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E	2040E
	Launch					Peak				
Total sales, ALZ-101 ($m)										
US	187	339	626	1,483	2,159	2,720	2,232	1,806	1,710	1,320
5EU	52	117	204	479	925	1,255	1,328	897	842	640
Japan	51	114	198	454	882	1,187	1,247	840	791	610
Total	**291**	**570**	**1,028**	**2,415**	**3,966**	**5,162**	**4,807**	**3,544**	**3,343**	**2,570**

Source: Datamonitor, Redeye Research

Appendix

Patents

Alzinova has two patent families, each consisting of both composition-of-matter- and method patents.

- The first patent family covers the protection for the AβCC technology and ALZ-101.
- The second patent family covers the monoclonal antibody, ALZ-201.

The AβCC technology (ALZ-101) is protected on the most important markets – that is, most of Europe, US, and Japan - until 2029. Patents for the AβCC technology are also approved in China, India, Australia, and Canada. Furthermore, ALZ-201 is patent protected until 2032 in the US and a large part of Europe. In addition, registered medicinal products can receive prolonged protection with up to five years in all of these markets.

Alzinova has an active patent strategy and aims to strengthen the patent situation further and prolong the expiration dates.

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3
(No changes)

Business: 3
(No changes)

Financials: 1
(No changes)

	2021	2022	2023E	2024E
INCOME STATEMENT				
Revenues	0	0	0	202
Cost of Revenues	0	0	0	0
Gross Profit	0	0	0	202
Operating Expenses	8	13	15	20
EBITDA	-8	-13	-15	183
Depreciation & Amortization	0	0	0	0
EBIT	-8	-13	-15	183
Net Financial Items	0	0	0	0
EBT	-8	-13	-15	183
Income Tax Expenses	0	0	0	26
Non-Controlling Interest	0	0	0	0
Net Income	-8	-13	-15	156
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	29	32	26	217
Inventories	0	0	0	0
Accounts Receivable	0	0	1	1
Other Current Assets	1	1	0	1
Total Current Assets	30	33	28	219
Non-current assets				
Property, Plant & Equipment, Net	0	0	0	0
Goodwill	0	0	0	0
Intangible Assets	62	78	101	149
Right-of-Use Assets	0	0	0	0
Shares in Associates	0	0	0	0
Other Long-Term Assets	0	0	0	0
Total Non-Current Assets	62	78	101	149
Total Assets	92	112	129	367
Liabilities				
Current liabilities				
Short-Term Debt	0	0	0	0
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	2	3	2	3
Other Current Liabilities	2	2	5	8
Total Current Liabilities	3	5	8	11
Non-current liabilities				
Long-Term Debt	0	0	0	0
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	1	1	1	1
Total Non-current Liabilities	1	1	1	1
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	87	106	121	303
Total Liabilities & Equity	92	112	129	314
CASH FLOW				
NOPAT	-8	-13	-15	156
Change in Working Capital	-1	2	2	3
Operating Cash Flow	-10	-10	-13	185
Capital Expenditures	0	0	0	0
Investment in Intangible Assets	-17	-17	-17	-18
Investing Cash Flow	-17	-17	-17	-18
Financing Cash Flow	0	30	25	24
Free Cash Flow	-27	-27	-30	167

DCF Valuation Metrics	**Sum FCF (SEKm)**
Initial Period (2023–2030)	23
Momentum Period (2031–2040)	521
Stable Period (2041–)	28
Firm Value	572
Net Debt (last quarter)	-32
Equity Value	540
Fair Value per Share	12

	2021	2022	2023E	2024E
CAPITAL STRUCTURE				
Equity Ratio	1,0	0,9	0,9	0,8
Debt to equity	0,0	0,0	0,0	0,0
Net Debt	-29	-32	-26	-217
Capital Employed	88	106	122	356
Working Capital Turnover	0,0	0,0	0,0	-21,8
GROWTH				
Revenue Growth	n/a	n/a	n/a	n/a
Basic EPS Growth	16%	-16%	-16%	-960%
Adjusted Basic EPS Growth	16%	-16%	-16%	-960%
PROFITABILITY				
ROE	-8%	-14%	-13%	74%
ROCE	-9%	-12%	-12%	51%
ROIC	-15%	-20%	-18%	133%
EBITDA Margin (%)	n/a	n/a	n/a	90%
EBIT Margin (%)	n/a	n/a	n/a	90%
Net Income Margin (%)	n/a	n/a	n/a	77%
VALUATION				
Basic EPS	n/a	-0,4	-0,3	2,9
Adjusted Basic EPS	n/a	-0,4	-0,3	2,9
P/E	n/a	neg	neg	1,3
EV/Revenue	n/a	n/a	n/a	neg
EV/EBITDA	n/a	neg	neg	neg
EV/EBIT	n/a	neg	neg	neg
P/B	n/a	0,9	1,4	0,7

SHAREHOLDER STRUCTURE	**CAPITAL %**	**VOTES %**
Maida Vale Capital AB	11,7%	11,7%
Avanza Pension	8,0%	8,0%
Nordnet Pensionsförsäkring	3,6%	3,6%
GU Ventures	3,5%	3,5%
Sara Gjertz	2,8%	2,8%

SHARE INFORMATION	
Reuters code	ALZ
List	First North
Share price	3,165
Total shares, million	44,5313

MANAGEMENT & BOARD	
CEO	Kristina Torfgård
CFO	Håkan Skogström
Chairman	Björn Larsson

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Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories: PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Redeye Rating (2023-12-02)

Rating	People	Business	Financials
5p	7	6	2
3p - 4p	163	155	38
0p - 2p	26	35	156
Company N	196	196	196

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Kevin Sule owns shares in the company : No
Fredrik Thor owns shares in the company :No
Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.