

# Alzinova

Sector: Biotech

## Ready to ignite – Initiating clinical development

Redeye revisits the Alzinova equity story with the initiation of clinical trials with ALZ-101, its vaccine candidate in Alzheimer's, an indication with a vast unmet medical need. Now is the time when the case could start to heat up. ALZ-101 is a candidate that stands out in a clinical pipeline that is set to gain increasing attention, thus, we have reviewed our financial forecasts and present an updated fair value range.

### Prepare for heated business activity

We believe the approval of Aduhelm (Aducanumab) could mark the beginning of intensified efforts in the Alzheimer's space, focused on research, academia, therapeutics, diagnostic tools, funding, and business interests. Increased funding and business activity would be good news for Alzinova. We still consider the company to be differentiating itself with its approach, focusing on its oligomer-specific vaccine candidate (ALZ-101). This could offer several advantages over passive immunotherapies (such as Aduhelm).

### First-in-human trial in patients

Owing to the high unmet medical need, it is not uncommon for Alzheimer's drug candidates to be trialed directly on patients (rather than healthy volunteers) and this is also true of ALZ-101. Although Alzinova's first-in-human study is a reasonably small phase Ib trial, it could provide important data points, including safety, tolerability, immunogenicity, and biomarker data.

### Valuation – we readjust our Fair Value range

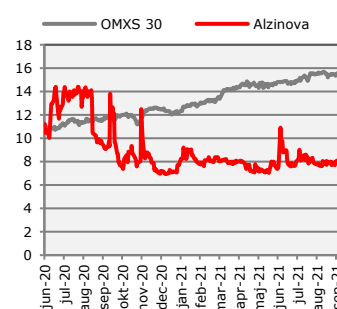
We have reassessed our estimates for ALZ-101 thoroughly, arriving at a revised Base Case of SEK 22 (SEK 20) per share. This offers a significant upside from current share price levels. It is thus important to look at what key catalysts could potentially narrow or even eliminate the gap. We take this opportunity to analyze future inflection points in this update. We find it noteworthy that external news has had the greatest impact on the Alzinova stock in the past, particularly as we foresee several external catalysts in the coming 12-24 months.

Key Financials (SEKm)	2019	2020	2021E	2022E	2023E
Revenues	0	0	0	0	0
EBITDA	-6	-6	-11	-12	-11
EBIT	-6	-6	-11	-12	-11
EBIT Margin (%)	n/a	n/a	n/a	n/a	n/a
Net Income	0	0	0	0	0
EV/EBITDA	-20,0	-20,0	-10,9	-10,0	-10,9
EV/EBIT	-20,0	-20,0	-10,9	-10,0	-10,9

### FAIR VALUE RANGE

BEAR	BASE	BULL
3.0	22.0	38.0

### ALZ.SS VERSUS OMXS30



### REDEYE RATING



### KEY STATS

Ticker	ALZ
Market	First North
Share Price (SEK)	7.0
Market Cap (MSEK)	110
Net Debt 21E (MSEK)	-31
Free Float	83 %
Avg. daily volume ('000)	77

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## Summary of Update

- Prepare for heated business activity
- The vaccine approach offers several advantages
- Ready to explore the vaccine potential in Alzheimer's
- Reassessed valuation

June 2021 saw a momentous event in the Alzheimer's community when Biogen's Aduhelm received FDA approval, the first of an Alzheimer's drug that targets the underlying disease pathology. However, this drug has courted a fair number of controversies in recent years. We still argue that its benefit/risk profile is questionable, at best, and we see the potential for a more favorable benefit/risk profile from drug candidates that are more specific in targeting the A $\beta$  oligomers, such as ALZ-101.

Regardless, we believe the June milestone could prompt increased business interest and more investments in the field, which is good news for Alzinova, which is dependent on Big Pharma to take its vaccine to the market. Aduhelm is far from able to fill the vast unmet medical need on its own.

Alzinova's oligomer-specific vaccine approach could offer a superior administration-friendly and cost-effective alternative targeting this devastating disease. The A $\beta$  oligomers are considered neurotoxic aggregates. Therapies specific towards them should be efficacious. The vaccine- and oligomer-specific approaches are essential factors in why we model peak sales potential for ALZ-101 of around USD 5bn, despite it only being in early development.

The anticipated clinical start for ALZ-101 is a milestone for Alzinova as a biotech company. Moreover, the first-in-human trial is targeting patients directly. Although it is a quite small study (n=26), it could provide important answers on safety, tolerability, immunogenicity, and biomarkers. Alongside this, Alzinova will prepare ALZ-101 for phase II by late 2023.

Given this clinical start, we have reviewed our estimates for the ALZ-101 project. Our key assumptions can be found in the 'Sales Models' section of this report. Based on this review, we adjust our Base Case to SEK 22 per share. This offers a significant upside from current share levels of SEK 7. Key triggers that could narrow this gap are clinical milestones in the phase Ib trial and, as demonstrated earlier, external news that validates the A $\beta$  hypothesis. Such news flow should be on an investor's radar. We discuss this further in the Catalysts section at the end.

## Key Risks

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 financial, development, and partnership risks.

- **Financial risk** – Although the company has no immediate capital need, investors should factor in additional funding. We want to see management working to strengthen the financials and the ownership base.
- **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 attribute the full value to a single project (one-trick-pony characteristics).
- **Partnership risk** – 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.

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### Supportive Analysis: What we talk about when we talk about Alzheimer’s

Increasing life expectancy is a global megatrend. At the same time, age is a determinant factor in developing Alzheimer’s. The worldwide costs for dementia will only continue to rise from the already alarming levels. It was believed that in 2018 the global costs for dementia exceeded USD 1 trillion (ADI World Alzheimer Report, 2018). This figure is expected to double to USD 2 trillion by 2030. What distinguishes dementia from cancer, for example, is the high proportion of direct societal costs (nursing homes, home care, etc.) and informal care costs (e.g., caregiver burden) this disease implies.

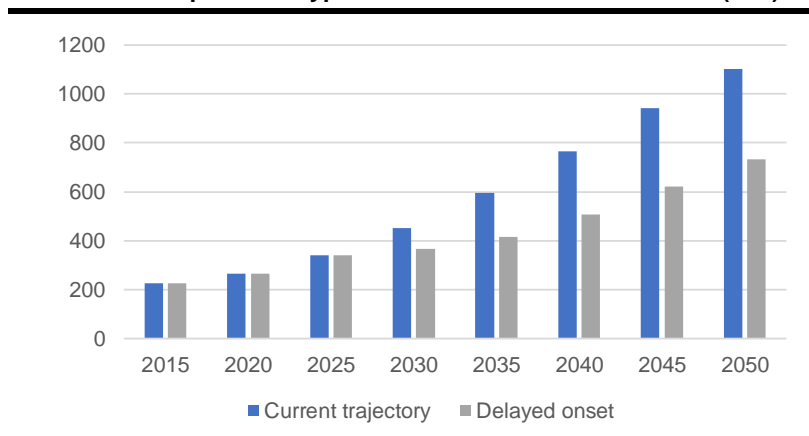
#### Dementia: Global costs of dementia in 2015 (\$bn), by cost category

Direct medical costs		Direct social costs		Informal care costs	
\$bn	% of total	\$bn	% of total	\$bn	% of total
159.2	19.5%	327.9	40.1%	330.8	40.4%

Source: ADI World Alzheimer Report 2015, Redeye Research

To halt this devastating trend, new effective therapies that can alter the course of the disease are needed. The figure below offers a hypothetical scenario for how a treatment that delays the onset of Alzheimer’s by five years impacts total costs in the US if introduced in 2025. Medicare (the US public health insurance system for individuals over 65 years of age) would account for 40% of the savings (Alzheimer’s Association: Changing the Trajectory of Alzheimer’s Disease Report 2015).

#### Alzheimer’s: Impact of a hypothetical treatment on total costs (\$bn)



Source: Alzheimer’s Association: Changing the Trajectory of Alzheimer’s Disease Report 2015, Redeye Research

## ALZ-101 – Alzinova’s Lead Candidate

### Current Status

ALZ-101 is a vaccine candidate for the treatment of early Alzheimer’s disease. It is specific towards a subtype of the A $\beta$  oligomers shown to be the major form of neurotoxic aggregates in the brain of Alzheimer’s patients.

Following a comprehensive preclinical package, which encompasses both transgenic and non-transgenic animal models plus studies on samples from deceased patients, ALZ-101 is now entering the clinical stage with the first dosing of patients. The first-in-human (FIH) study is a phase Ib in early Alzheimer’s patients, i.e., mild Alzheimer’s or MCI (mild cognitive impairment). A summary of the study design can be seen below.

#### ALZ-101: Overall Study Design

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

Source: Alzinova

We believe top-line results can be presented at the second half of 2023. Alongside this study, Alzinova will undertake other activities with the ultimate goal of the vaccine candidate being ready for phase II by 2023. This includes:

- Process optimization of substance manufacturing
- Pharmaceutical development and optimization of ALZ-101
- Long-term toxicology studies with ALZ-101

In addition, Alzinova plans to conduct a long-term extension study with ALZ-101 after the completion of the phase Ib trial. We would encourage this, which is often seen implemented in trials with other disease-modifying drug candidates. It is important to generate such data for intended long-term treatment.

## Market Outlook

### A $\beta$ Vaccine Pipeline

Given the clinical start with ALZ-101, we find it relevant to offer a status update on Alzinova's closest pipeline peers. Even though changes in pharmaceutical pipelines are often slow, we believe an updated pipeline discussion is relevant owing to the delay to ALZ-101 of more than two years.

Our market outlook begins with the peer pipeline we identified when we initiated coverage of Alzinova in 2019. We saw A $\beta$  immunotherapies, especially the active immunotherapies (to which ALZ-101 belongs), as the closest peers. Our proposed pipeline can be seen on page 25 of our initiation report ([link](#)).

Two programs we identified then have since been discontinued: CAD106 (Novartis) and Lu AF20513 (Lundbeck). In 2019, CAD106 was the furthest advanced of the vaccine candidates but was not in any active trials. Novartis announced in its financial report (2019) that the program had been 'retired.' The same applies to Lu AF20513, which Lundbeck decided to discontinue in 2019 following 'increased uncertainty around the biological rationale.'

The suspension of projects is an everyday occurrence in the pharmaceutical industry. Given the timing of the Lu AF20513 discontinuation, we believe the decision possibly relates to aducanumab's abrupt outcome in March 2019. If so, the decision is somewhat irrational, especially considering that aducanumab was later resurrected. The trial for CAD106 enrolled APOE4 homozygotes (a risk factor for developing Alzheimer's) who were healthy, with the time to onset of Alzheimer's symptoms as an efficacy measure. The trial was expected to be lengthy; it started in 2014 with an anticipated readout in 2023. Much can happen over such a long period, not least new strategic initiatives on a corporate level.

Overall, we find these discontinuations neither dramatic nor implying a weakening of the A $\beta$  vaccine approach. As there is increasing evidence that the affinity towards the different A $\beta$  forms matters to achieve a clinical benefit, we find the two active projects, ACI-24 (AC Immune) and UB-311 (Vaxxinity), to be more similar to ALZ-101. However, ALZ-101 should have a higher affinity towards the oligomers (we also stated this in our initiation report – see figure on page 25).

We note that AC Immune and Vaxxinity seem committed to the vaccine approach in neurodegenerative diseases. Data from them is relatively scarce for now, with no single trial above n=100. There have also been 'bumps along the road,' especially for ACI-24, where the formulation was changed following poor responder analysis. Nevertheless, we find it positive that just a few biotech players can jointly drive advancement in this segment.

In addition to our updated clinical pipeline, we see Alzheimer's vaccine efforts taking place at the research/academia level. This is also encouraging and suggests an active research field. Below, we highlight a couple of the papers we have found.

#### University of South Florida, Song et al., 2020

The scientists in this research paper developed a peptide-sensitized dendritic cells vaccine that would target A $\beta$  oligomers, as in the case with ALZ-101, but with a couple of differentiating factors. Firstly, this approach uses dendritic cells rather than an adjuvant to regulate the immune response. The hypothesis is that this could avoid unpleasant autoimmune effects, such as neuroinflammation. This gained attention since the first human trial for active

immunization with the A $\beta$ 42 vaccine AN1792 was halted due to the development of subacute meningoencephalitis (inflammation) in 6 percent of the subjects. In that specific case, however, the development of meningoencephalitis has been linked to an over-activation of the innate immune system with the presumption that the combination of fibrillar A $\beta$ 1-42 and the adjuvant elicited a pro-inflammatory Th1 response (Holmes *et al.*, 2008; Pride *et al.*, 2008). Regulating the immune response is particularly important in patients with impaired immune systems, such as Alzheimer's patients. Secondly, like CAD106 and Lu AF20513, this vaccine targets the N-terminal of the peptide, unlike the oligomer-specific ALZ-101.

However, the results from this study (Song *et al.*, 2020), conducted on transgenic mouse models, suggest that the vaccine candidate activates the 'right' part of immunity, and so it could avoid an autoimmune response. Further findings indicated that the vaccine candidate delayed memory impairment.

This dendritic cell vaccine peptide, which goes under the name AL002, is in preclinical development by Alzamend Neuro Inc. The company recently raised USD 14.4 million through an IPO that listed the shares on Nasdaq Capital Market. The proceeds, however, are planned to fund research and development of both AL002 and its main candidate AL001. AL001 is a lithium-based ionic cocrystal oral therapy, also in preclinical development for Alzheimer's.

#### **Institute for Molecular Medicine and University of California, Irvine (UCI), Davtyan et al., 2020**

The scientists in this paper designed a vaccine approach that concurrently targets the two major pathological hallmarks in Alzheimer's: A $\beta$  and tau. The vaccine was designed using a mixture of two vaccines, AV-1959R and AV-1980R. The hypothesis behind this approach is that A $\beta$  and tau interact synergistically to drive the downstream neurodegenerative cascade. The authors discuss further that, based on the latest clinical findings, A $\beta$  as a monotherapy is probably most suitable as a preventive approach. In this regard, a safe and immunogenic vaccine is most practical.

The vaccine mixture was injected intramuscularly in a bigenic mouse model that develops both A $\beta$  and tau aggregates. The results showed that antibody titers were generated towards both (A $\beta$  and tau). Furthermore, the production of antibodies led to a significant reduction of soluble and insoluble total tau, hyperphosphorylated tau, and A $\beta$ 42.

The vaccine candidate is developed by Capo Therapeutics. We believe it could reach the clinical stage in 2022-23.

That efforts are taking place with Alzheimer's vaccines at both the research and development stages do not surprise us. A therapeutic vaccine is a convenient and cost-effective approach that could result in tremendous health economic benefits in this devastating disorder. It fits well into the overall trend towards more value-based healthcare, with an increasing focus on cure, prevention, and earlier intervention.

#### **Adjacent Approaches**

Passive A $\beta$  immunotherapies dominate the adjacent approaches and have seen considerable progress since our last report. On June 7, 2021, the FDA granted accelerated approval to Aduhelm (aducanumab), a monoclonal antibody (our comment [here](#)). This momentous decision, with conditional approval based on a surrogate endpoint (plaque removal), marks the first drug approved for Alzheimer's that is believed to target the underlying disease pathology. Other monoclonal antibodies in late-stage development have shown modest benefits to cognitive and functional measures, strong reductions of A $\beta$  plaques in the brain, and an effect



on downstream biomarkers. Donanemab, an antibody that also targets plaques, is in late-stage clinical development and could be the next approved therapy within this segment (as early as 2022).

We argue that the passive A $\beta$  immunotherapies that have shown encouraging results validate the amyloid hypothesis and thus further strengthen Alzinova's approach. We have stated before that both active and passive immunotherapies could well complement one another. For instance, vaccines could potentially offer a superior, cost-effective, and administration-friendly (in terms of frequency) approach. However, some argue that they may not be well suited to those with a weakened immune system, such as some elderly patients.

We are also keeping an eye on the non-A $\beta$  vaccine approaches. Closest at hand, in our view, are the tau vaccines: AADVac1 (Axon Neuroscience) and ACI-35.030 (AC Immune). Both are in clinical development phase II. Axon Neuroscience has reported that AADVac1 met the primary endpoint (safety) and that secondary endpoints showed indications of disease modification.

AC Immune, which partnered with Janssen (J&J) in 2015 for its ACI-35 program, initiated clinical studies with its tau-specific vaccine in 2013. The first clinical trial with ACI-35 raised no safety concerns but also suggested a weak immune response. A redesigned version, ACI-35.030, was then prioritized. This includes a second adjuvant and an epitope to activate helper T-cells. ACI-35.030 is currently in phase I/IIb trials, slated for completion in 2023. Interim results have been reported on the second-highest dose (no safety issues). Interim data from the highest dose is expected at the end of 2021. AC Immune and Janssen have also expanded the trial to explore an alternative tau vaccine candidate, JACI-35.054.

On a final note, we recognize that AC Immune and Genentech recently published top-line data from 'Lauriet,' the phase II trial of semorinemab in mild to moderate Alzheimer's. The tau-targeting monoclonal antibody showed first evidence of positive cognitive results, meeting one of its two co-primary endpoints, ADAS-Cog11. The second co-primary endpoint, ADCS-ADL, was not met. Safety data showed that semorinemab is well tolerated with an acceptable safety profile and no unanticipated safety signals.

We see interesting times ahead in the disease-modifying area. The approval of Aduhelm could mark a new era of more disease-modifying therapies coming to market in the decades ahead and intensified investments in the field. It would also correspond to increased business activity and partnership interest from Big Pharma. In this context, it is a true milestone that Alzinova's promising oligomer-specific vaccine has reached clinical phase and is being evaluated directly on patients.

## Alzheimer's – clinical pipeline summary

### Summary of clinical pipeline

Drug Candidate	Company	Phase	Delivery	Comment
<b>A<math>\beta</math> Vaccines</b>				
UB-311	Vaxxinity Inc.	II	Intramuscular (IM)	United Neurosciences formed under a new entity, Vaxxinity Inc. A phase III development plan was presented in 2020.
ABvac40	Araclon Biotech S.L.	II	Intravenous (IV)	Targets A $\beta$ 40. Phase III enrollment has been completed.
ACI-24	AC Immune, Ltd.	II	IM, SQ	Also evaluated for AD in Down's syndrome patients.
<b>ALZ-101</b>	<b>Alzinova AB</b>	<b>I</b>	<b>IM</b>	
AL002	Alzamend Neuro Inc.	Preclinical	Intramuscular (IM)	NEW
AV-1959R/AV-1980R	Capo Therapeutics	Preclinical	Intramuscular (IM)	NEW
<b>A<math>\beta</math> Immunotherapies</b>				
Aduhelm	Biogen/Eisai	Approved	Intravenous	FDA granted accelerated approval in June 2021
Lecanemab	Eisai/Biogen	III	Intravenous	Ph III data expected in H2'22
Gantenerumab	Roche	III	Intravenous	Ph III data expected in 2022 (GRADUATE). Roche is running an ambitious program with gantenerumab, which is also evaluated as a prevention approach (together with solanezumab, this study did not meet the primary endpoint but is ongoing in an open-label study). Roche is also developing a modified form of gantenerumab that has the potential to increase the levels of the antibody in the brain.
ACU-193	Acumen Pharmaceuticals, Inc.	I	Intravenous	Ph I data expected in H2'22
Donanemab	Eli Lilly	III	Intravenous	Ph II results met the primary endpoint (the composite scale iADRS). Ongoing phase 3 study (TRAILBLAZER-ALZ 2) with top-line results anticipated in 2023.
<b>Tau Vaccines</b>				
AADVac1	Axon Neuroscience	II	Subcutaneous	
ACI-35.030	AC Immune	II		

\* The list does not claim to represent the entire pipeline.

Source: Biomedtracker, company websites, Redeye Research

## Financials

### Financial Forecasts

So far, Alzinova has operated as a semi-virtual organization and its cash burn has been relatively low. We expect that to change gradually in tandem with Alzinova's plans to take the next step to becoming a biotech company with key resources in-house. This change has already started. Moreover, as ALZ-101 moves into the clinic, investors should factor in a higher burn rate. We showcase our financial forecasts for the coming years below.

<b>Alzinova: Financial Forecasts</b>					
<b>(SEKm)</b>	<b>2019</b>	<b>2020</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>
Net income	0.0	0.0	0.0	0.0	0.0
<b>Operating expenses</b>					
Other external costs	-8.8	-17.2	-30.5	-37.3	-17.5
Personnel costs	-4.2	-4.2	-5.7	-5.8	-7.4
Other operating expenses	0.0	0.0	0.0	0.0	0.0
Capitalization	6.8	14.9	25.0	30.6	14.4
<b>Total operating costs</b>	<b>-6.2</b>	<b>-6.5</b>	<b>-11.1</b>	<b>-12.5</b>	<b>-10.5</b>
<b>Operating profit (EBIT)</b>	<b>-6.2</b>	<b>-6.5</b>	<b>-11.1</b>	<b>-12.5</b>	<b>-10.5</b>
<b>Free cash flow</b>	<b>-10.9</b>	<b>-21.2</b>	<b>-36.1</b>	<b>-42.1</b>	<b>-24.9</b>

Source: Redeye Research

In its Q3'21 report, Alzinova reported SEK 34.3m cash at hand. We judge that to be sufficient to fund its operations until the back end of H1 2022. In addition, Alzinova has outstanding warrants, with redemption from January 24, 2022, to February 7, 2022. The warrants (TO2 2020/2022) could bolster Alzinova's cash account with SEK 25-42m, assuming full subscription. The variable component is the exercise price. It is determined as 70% on VWAP during the ten (10) trading days immediately preceding January 19, 2022. However, there is a floor at SEK 6.5 per share and a ceiling at SEK 11 per share. The maximum that Alzinova could achieve is SEK 42m. Given an unfavorable stock development, Alzinova would receive less, and there is also a risk that TO2 2020/2022 trades out-of-the-money.

### Sales Model Assumptions

Our sales models can be found at the end of this section. Before that, there are a few key assumptions we want to highlight:

- Top-down sales:
  - Targeted population
  - The distinction between priming and booster shots
  - Pricing – especially given the WAC for aducanumab
- Timing for out-licensing and deal conditions
- Probability rate

We follow the 'the earlier intervention, the better' approach for the targeted population. As we do not find it reasonable to model in presymptomatic individuals yet, we base our top-down sales model on MCI and mild Alzheimer's patients – considered early population groups. Those will be enrolled in Alzinova's phase Ib study. Moreover, Vaxxinity, the company developing UB-311, the furthest advanced A $\beta$  vaccine in the pipeline, presented a phase III development plan at CTAD 2020. Its intention is to enroll MCI and mild Alzheimer's patients, further strengthening our conviction.

We want to highlight that the vaccine approach is highly relevant as a prevention treatment. Targeting presymptomatic individuals could, for instance, include those who are at genetic risk of developing symptomatic Alzheimer's. If Alzinova manages to out-license ALZ-101, we would find it especially positive if it was to partner with a strong and global 'Big Pharma' player with the in-house capabilities to assess its treatment potential fully. A prevention label in Alzheimer's would allow for far higher commercial potential but would also require significant development efforts.

The anticipated administration frequency for vaccines in Alzheimer's is challenging as there is no vaccine approved for this progressive indication. The vaccine approach is common in infectious diseases, but we do not anticipate a necessarily clear correlation in neurodegenerative diseases. Regardless, we separate priming and annual booster (maintenance) doses and emphasize that both could encompass several shots. Note that Alzheimer's primarily affects elderly individuals, who often have a weakened immune system, and so several shots might be necessary, to kick-start and then maintain an immune response.

Even though there is a long way to market for ALZ-101, we find it relevant to discuss pricing. We have looked at the USD 56,000 annual price tag (WAC) disclosed by Biogen for Aduhelm, which is essentially a monopoly price. We consider this a highly controversial price level given that we do not really know if Aduhelm provides any clinical benefits. But we do know that it has significant side effects.

We foresee a more competitive environment if/when ALZ-101 reaches the market. The vaccine approach could offer a more cost-effective treatment to passive immunotherapies, as the body itself elicits antibodies towards the antigen. Both these aspects have guided us in our applied price range for priming and maintenance shots. We believe, however, there are a number of factors (such as the immunogenicity profile, clinical benefits, etc.) that will ultimately determine the price. For now, we apply a minor price increase compared to when we initiated coverage in 2019, driven by a higher price level than expected for the first drug on the market to target the underlying pathology (Aduhelm).

In our Base Case, we factor in that Alzinova first demonstrates proof-of-concept (PoC) in a larger patient group before out-licensing. We believe that Big Pharma wants to see PoC efficacy and would rather pay a higher upfront price. This also entails the possibility for Alzinova to increase the value of the project in-house. To offer guidance for investors on what the timing of partnering could mean for our valuation, we use our scenario modeling.

We apply a low double-digit probability rate of ten percent, which reflects a still prominent development risk.

## ALZ-101 – Sales Models

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

### ALZ-101: Priming shots sales model

	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
	Launch					Peak				
<b>MCI-AD &amp; Mild AD prevalence (m)</b>										
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
<b>MCI-AD &amp; Mild AD treatment rate (m)</b>										
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
<b>Market penetration per year, ALZ-101</b>										
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%
<b>Newly treated patients, ALZ-101 (m)</b>										
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
<b>Price - Primer shots, ALZ-101 (\$)</b>										
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
<b>Sales - Primer shots, ALZ-101 (\$m)</b>										
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
<b>Total</b>	<b>291</b>	<b>500</b>	<b>818</b>	<b>1,985</b>	<b>3,006</b>	<b>3,402</b>	<b>3,137</b>	<b>1,364</b>	<b>923</b>	<b>0</b>

\* 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

	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
	Launch					Peak				
<b>Patients in the need for booster doses (m)</b>										
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
<b>Compliance rate (m)</b>										
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
<b>Price - annual booster dose, ALZ-101 (\$)</b>										
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
<b>Sales - booster doses, ALZ-101 (\$m)</b>										
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
<b>Total</b>	<b>0</b>	<b>70</b>	<b>210</b>	<b>430</b>	<b>960</b>	<b>1,760</b>	<b>1,670</b>	<b>2,180</b>	<b>2,420</b>	<b>2,570</b>

Source: Datamonitor, Redeye Research

### ALZ-101: Total sales estimates

	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
	Launch					Peak				
<b>Total sales, ALZ-101 (\$m)</b>										
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
<b>Total</b>	<b>291</b>	<b>570</b>	<b>1,028</b>	<b>2,415</b>	<b>3,966</b>	<b>5,162</b>	<b>4,807</b>	<b>3,544</b>	<b>3,343</b>	<b>2,570</b>

Source: Datamonitor, Redeye Research

## Valuation

### Valuation Summary

Below we show our project valuation for ALZ-101 – a net present value (NPV) model based on our sales models and the underlying key assumptions:

#### Project valuation: NPV model

(\$m)	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
	Launch					Peak				
Sales	291	570	1028	2415	3966	5162	4807	3544	3343	2570
Royalty Rate	16%	16%	16%	16%	16%	16%	16%	16%	16%	16%
Royalty	46	91	164	386	635	826	769	567	535	411
Probability	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
<b>Risk adj. Royalty</b>	<b>4.5</b>	<b>8.9</b>	<b>16.0</b>	<b>37.6</b>	<b>61.7</b>	<b>80.3</b>	<b>74.8</b>	<b>55.1</b>	<b>52.0</b>	<b>40.0</b>
In SEK	39.3	77.1	139.0	326.8	536.6	698.4	650.4	479.5	452.4	347.7
Milestone Payments	60	0	0	0	60	0	60	0	60	0
Probability	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
<b>Risk adj. Milestones</b>	<b>5.8</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>5.8</b>	<b>0.0</b>	<b>5.8</b>	<b>0.0</b>	<b>5.8</b>	<b>0.0</b>
In SEK	50.7	0.0	0.0	0.0	50.7	0.0	50.7	0.0	50.7	0.0
<b>Risk adj. R&amp;D Expenditure</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
In SEK	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>Risk adj. Value, Pre-tax</b>	<b>10.4</b>	<b>8.9</b>	<b>16.0</b>	<b>37.6</b>	<b>67.5</b>	<b>80.3</b>	<b>80.6</b>	<b>55.1</b>	<b>57.8</b>	<b>40.0</b>
Tax		-1.8	-3.3	-7.7	-13.9	-16.5	-16.6	-11.4	-11.9	-8.2
<b>Risk adj. Value, Post-tax</b>	<b>10.4</b>	<b>7.0</b>	<b>12.7</b>	<b>29.8</b>	<b>53.6</b>	<b>63.7</b>	<b>64.0</b>	<b>43.8</b>	<b>45.9</b>	<b>31.7</b>
Discount Factor	0.26	0.23	0.20	0.18	0.16	0.14	0.12	0.10	0.09	0.08
<b>Risk adj net present value (rNPV)</b>	<b>2.7</b>	<b>1.6</b>	<b>2.6</b>	<b>5.3</b>	<b>8.3</b>	<b>8.7</b>	<b>7.6</b>	<b>4.6</b>	<b>4.2</b>	<b>2.6</b>

<b>Total rNPV</b>	<b>42.8</b>
In SEKm	372.4
Per share	23.6
Cash (21/08/26)	2.6
Shared costs	-3.9
<b>Base Case</b>	<b>22</b>

\* The table above only shows numbers from expected launch year and on. However, the model and valuation do include the years prior to 2031 as well.

### Scenario Analysis

To provide a dynamic view of our valuation, we also model both a pessimistic scenario (Bear Case) and an optimistic scenario (Bull Case) in addition to our Base Case. The differences in estimates between scenarios are based on modifications of the assumptions used in the valuation process (see below).

#### Bear Case 3.0 SEK

A Bear Case scenario would include additional delays to ALZ-101 and an unfavorable stock development with TO 2020/2022 becoming out-of-the-money. We then see a risk that Alzinova has to conduct a rights issue in 2022 with a hefty rebate.

#### Base Case 22.0 SEK

We refer to the 'Project Valuation' (NPV figure) for our Base Case.

#### Bull Case 38.0 SEK

Our Bull Case is based on a 24-month horizon and factors in positive results from phase Ib, success in preparing ALZ-101 for phase II, and out-licensing in H2'23 with a USD 20 million upfront payment to a strong Big Pharma partner.

## Catalysts

Our Base Case of SEK 22 per share offers significant upside from current share levels. When that is the case, investors should direct their attention to catalysts that could narrow or even eliminate this gap. In this section, we analyze upcoming catalysts and break them down into internal and external catalysts. Interestingly, as top-line results from the phase Ib trial might be some 18-24 months in the future, we pay equal attention to the external news flow in the Alzheimer's community. As seen in the past, the Alzinova stock tends to react significantly to external news flow related to A $\beta$  as a therapeutic target.

### External

Below we list the external catalysts that could significantly impact the stock in the coming 12-18 months.

#### **ACI-24 (AC Immune)**

We believe phase II results (24-month data) could be presented at the end of 2021 or in early 2022.

Strength: Minor

#### **Aduhelm (Biogen/Eisai)**

All eyes are on Aduhelm (as always). But from now on, investors will redirect their focus towards the commercial aspects, such as market uptake in the US. In Europe, we expect a CHMP (Committee for Medicinal Products for Human Use) opinion in the near future.

Strength: Moderate

#### **Lecanemab (Eisai/Biogen)**

Eisai and Biogen recently initiated a rolling submission to the FDA of a BLA (Biologics License Application) for lecanemab under the accelerated approval pathway. Lecanemab is the furthest advanced monoclonal antibody after Aduhelm, and is currently in phase III trials (Clarity AD). The results from the study are anticipated in H2'22 and could prove a major catalyst for the Alzinova stock (as evident in the past).

Strength: Moderate

#### **Gantenerumab (Roche)**

Phase III results are expected in 2022 from the GRADUATE trial. Although relevant, we see more promise for lecanemab and a higher resemblance to ALZ-101.

Strength: Minor

#### **Donanemab (Eli Lilly)**

Eli Lilly intends to seek fast approval (under the accelerated approval pathway) during the second half of 2021 based on phase II data for donanemab. Meanwhile, donanemab is in an ongoing phase III trial, with expected top-line results in H1'23.

Strength: Moderate

## Internal

Below we list the internal catalysts that could significantly impact the stock in the coming 12-18 months.

### ALZ-101 – Progression of phase Ib in early Alzheimer’s patients (Ongoing)

With the company now having initiated clinical phase Ib trials, we see the study progression as the most important catalyst for Alzinova this year. During the study, we believe investors could expect updates from recruitment milestones.

<b>IMPACT</b>				
<b>Downside</b>		<b>Upside</b>		<b>Time Frame</b>
Significance:	Likelihood:	Significance:	Likelihood:	
<b>Major</b>	<b>Unlikely</b>	<b>Moderate</b>	<b>Possible</b>	<b>Short</b>

### ALZ-201 – Preclinical progress

In the latest equity issue, Alzinova raised capital to humanize ALZ-201, it's preclinical monoclonal antibody candidate. 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 Alzinovas clinical portfolio.

<b>IMPACT</b>				
<b>Downside</b>		<b>Upside</b>		<b>Time Frame</b>
Significance:	Likelihood:	Significance:	Likelihood:	
<b>Minor</b>	<b>Possible</b>	<b>Moderate</b>	<b>Possible</b>	<b>Short</b>

### ALZ-101 – Phase Ib results in early Alzheimer’s patients

We believe top-line results from the phase Ib trial could be presented in the second half of 2023. This will, of course, be a significant value-defining inflection point for Alzinova and its shareholders.

<b>IMPACT</b>				
<b>Downside</b>		<b>Upside</b>		<b>Time Frame</b>
Significance:	Likelihood:	Significance:	Likelihood:	
<b>Major</b>	<b>Possible</b>	<b>Major</b>	<b>Possible</b>	<b>Long</b>



## 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**

CEO Kristina Torfgård (appointed in 2019) has extensive experience from the pharma industry and possesses good communication and project leadership skills. CSO Anders Sandberg is the co-inventor of the A $\beta$ CC technology and the co-founder of the company. During 2019-20, the appointments of a CFO, a CMO, and a Project Director have bolstered the management team. We had sought a strengthened in-house organization when we initiated coverage of Alzinova. When the organization gets itself established and has proven its execution capabilities, there could be a rationale to review this rating.

We want to see institutional ownership within the next year or two. Until now, Alzinova has primarily been a retail stock. The lack of any major, active shareowner impacts our rating.

#### **Business: 2**

The sales potential for disease-modifying therapies in Alzheimer's cannot be emphasized enough. If ALZ-101 were to demonstrate clear clinical efficacy and make it to market, it would undoubtedly have blockbuster potential. At present, however, Alzinova is a biotech company years from achieving recurrent revenues.

#### **Financials: 1**

Alzinova reported a cash position of SEK 49.4m in its latest interim report. Although it has no immediate cash need, investors need to factor in additional equity funding when considering an investment. The TO 2020/2022 (redemption in January 2022-February 2022) could bolster the cash position by a further SEK 25-42 million.

	2020	2021E	2022E	2023E					
<b>INCOME STATEMENT</b>					<b>DCF Valuation Metrics</b>				<b>Sum FCF (SEKm)</b>
Revenues	0	0	0	0	Initial Period (2021–2040)				283
Cost of Revenues	0	0	0	0	Momentum Period (2041–2040)				32
Gross Profit	0	0	0	0	Stable Period (2041–)				57
Operating Expenses	6	11	12	11	Firm Value				372
EBITDA	-6	-11	-12	-11	Net Debt				-31
Depreciation & Amortization	0	0	0	0	Equity Value				341
EBIT	-6	-11	-12	-11	Fair Value per Share				22
Net Financial Items	0	0	0	0					
EBT	-6	-11	-12	-11					
Income Tax Expenses	0	0	0	0	<b>CAPITAL STRUCTURE</b>				
Non-Controlling Interest	0	0	0	0	Equity Ratio	1.0	0.9	0.7	0.5
Net Income	-6	-11	-12	-11	Debt to equity	0.0	0.0	0.3	0.8
					Net Debt	-56	-20	22	47
					Capital Employed	97	86	73	63
					Working Capital Turnover	0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>									
<b>Assets</b>					<b>GROWTH</b>				
<b>Current assets</b>					Revenue Growth	0%	0%	0%	0%
Cash & Equivalents	56	20	0	0	Basic EPS Growth	n/a	n/a	n/a	n/a
Inventories	0	0	0	0	Adjusted Basic EPS Growth	-49%	71%	12%	-16%
Accounts Receivable	0	0	0	0					
Other Current Assets	1	1	1	1	<b>PROFITABILITY</b>				
Total Current Assets	56	20	1	1	ROE	n/a	n/a	n/a	n/a
					ROCE	-7%	-13%	-17%	-17%
<b>Non-current assets</b>					ROIC	-16%	-18%	-14%	-9%
Property, Plant & Equipment, Net	0	0	0	0	EBITDA Margin (%)	n/a	n/a	n/a	n/a
Goodwill	0	0	0	0	EBIT Margin (%)	n/a	n/a	n/a	n/a
Intangible Assets	44	69	100	114	Net Income Margin (%)	n/a	n/a	n/a	n/a
Right-of-Use Assets	0	0	0	0					
Shares in Associates	0	0	0	0	<b>VALUATION</b>				
Other Long-Term Assets	0	0	0	0	Basic EPS	-0.4	-0.7	-0.8	-0.7
Total Non-Current Assets	44	69	100	114	Adjusted Basic EPS	-0.4	-0.7	-0.8	-0.7
					P/E	-18.7	-9.9	-9.7	-12.6
Total Assets	101	90	100	115	EV/Revenue	n/a	n/a	n/a	n/a
					EV/EBITDA	-18.7	-9.9	-9.9	-13.2
<b>Liabilities</b>					EV/EBIT	-18.7	-9.9	-9.9	-13.2
<b>Current liabilities</b>					P/B	1.3	1.3	1.7	2.1
Short-Term Debt	0	0	22	47					
Short-Term Lease Liabilities	0	0	0	0	<b>SHAREHOLDER STRUCTURE</b>				<b>CAPITAL % VOTES %</b>
Accounts Payable	2	0	0	0	Avanza Pension			11.4%	11.4%
Other Current Liabilities	2	4	5	5	Maida Vale Capital AB			11.0%	11.0%
Total Current Liabilities	4	4	27	52	Nordnet Pensionsförsäkring			4.9%	4.9%
					GU Ventures			4.4%	4.4%
<b>Non-current liabilities</b>					Ola Hermansson			2.5%	2.5%
Long-Term Debt	0	0	0	0					
Long-Term Lease Liabilities	0	0	0	0	<b>SHARE INFORMATION</b>				
Other Long-Term Liabilities	1	1	1	1	Reuters code				ALZ.SS
Total Non-current Liabilities	1	1	1	1	List				First North
					Share price				7
Non-Controlling Interest	0	0	0	0	Total shares, million				15.8
Shareholder's Equity	96	85	72	62					
Total Liabilities & Equity	101	90	100	115	<b>MANAGEMENT &amp; BOARD</b>				
					CEO				Kristina Torfgård
<b>CASH FLOW</b>					CFO				Håkan Skogström
NOPAT	-6	-11	-12	-11	Chairman				Björn Larsson
Change in Working Capital	0	0	1	0					
Operating Cash Flow	-6	-11	-11	-11	<b>ANALYSTS</b>				
Capital Expenditures	0	0	0	0					Redeye AB
Investment in Intangible Assets	-15	-25	-31	-14	Kevin Sule				Mäster Samuelsgatan 42, 10tr
Investing Cash Flow	-15	-25	-31	-14	Fredrik Thor				111 57 Stockholm
Financing Cash Flow	43	0	22	25					
Free Cash Flow	-21	-36	-42	-25					

## 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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## Disclaimer

### Important information

Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redeye.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.

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### Redeye Rating (2021-11-01)

Rating	People	Business	Financials
5p	33	15	4
3p - 4p	137	123	42
0p - 2p	5	37	128
Company N	175	175	175

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### CONFLICT OF INTERESTS

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.