REDEYE

Update

Equity Research

21 June 2022

Alzinova

Sector: Biotech

Setting the Conditions for Success

Redeye revisits the Alzinova equity story following the company's continued pipeline progress and recent rights issue. We continue to see the lead candidate, ALZ-101, as a candidate that stands out from other Alzheimer's treatments. We argue that Alzinova offers an exciting investment opportunity and see an attractive entry point for the long-term oriented investor.

Promisingly Positioned

With secured funding and its lead candidate, ALZ-101, continuing making development progress as the phase I study is in full swing, Alzinova has now optimized its conditions for clinical success. The candidate's vaccine approach is potentially highly cost-effective and long-lasting, a perfect fit for the life-long disease of Alzheimer's. We judge its mechanism of action as scientifically and empirically strong, specifically targeting the neurotoxic amyloid beta (Aβ) oligomers. Accordingly, we see ALZ-101 as one of the more promising drug candidates for disease-modification in Alzheimer's.

Preclinical Progress

Following promising preclinical progress – including a recent project in collaboration with Amsterdam University Medical Centers which confirmed the unique specificity and therapeutic effect of the candidate – Alzinova has now completed the humanization work and selected a lead candidate for its monoclonal antibody, ALZ-201. This allows the company to broaden its scope of activities and potentially expand its clinical portfolio with an additional program in the coming years.

Valuation – we readjust following recent rights issue

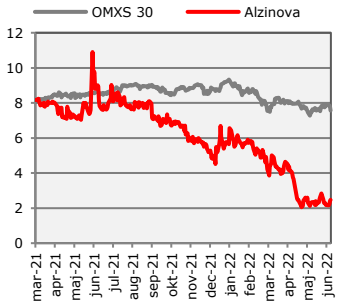
Following the recently finalized rights issue of 34 SEK, we have reassessed our fair value range for Alzinova. In our reevaluation, we take into account both the rights issue and the associated warrants. Having adjusted for the dilution effect, we arrive at a revised **Base Case of SEK 10** (SEK 22) per share (Bear 1, Bull 20). This demonstrates a significant upside from current share price levels of SEK c2.2 as we believe the share will bounce back from the recent downwards pressure. Looking ahead, we have identified some key short- and long-term catalysts that could potentially narrow, or even eliminate, our valuation gap.

Key Financials (SEKm)	2019	2020	2021	2022E	2023E
Revenues	0	0	0	0	0
Revenue growth	n/a	n/a	n/a	n/a	n/a
EBITDA	-6.2	-6.5	-7.5	-8.8	-9.7
EBIT	-6.2	-6.5	-7.5	-8.8	-9.7
EBIT Margin (%)	n/a	n/a	n/a	n/a	n/a

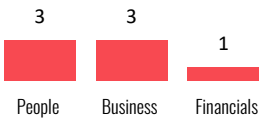
FAIR VALUE RANGE

BEAR	BASE	BULL
1	10	20

ALZ.SS VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	ALZ
Market	First North
Share Price (SEK)	2.2
Market Cap (MSEK)	75
Net Debt 22E (MSEK)	-48
Free Float	84 %
Avg. daily volume ('000)	77

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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 disease-modifying therapies for Alzheimer's disease in clinical development. With the company now having secured a financial runway until 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 USD 5 billion, 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 ongoing 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 SEK 10. Having adjusted for the recent rights issue along with associated warrants, this still offers a significant upside from current share price levels. Key triggers that could narrow the valuation gap in both the short- and long-term are, primarily, clinical milestones in the phase Ib trial and preclinical advancements with the company's antibody candidate, ALZ-201. As demonstrated earlier, however, external news that validates the Aβ hypothesis could also have an effect on the stock.

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 recent rights issue, investors should factor in additional funding needs (from 2024 and onwards) 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. 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 – Progression of phase Ib in early Alzheimer's patients (Ongoing)

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

Timeframe: 3-9 months
Impact: Minor

ALZ-201 – Preclinical progress

In the latest equity issue, Alzinova 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 Alzinovas clinical portfolio.

Timeframe: 6-18 months
Impact: Moderate

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.

Timeframe: 12-18 months
Impact: Major

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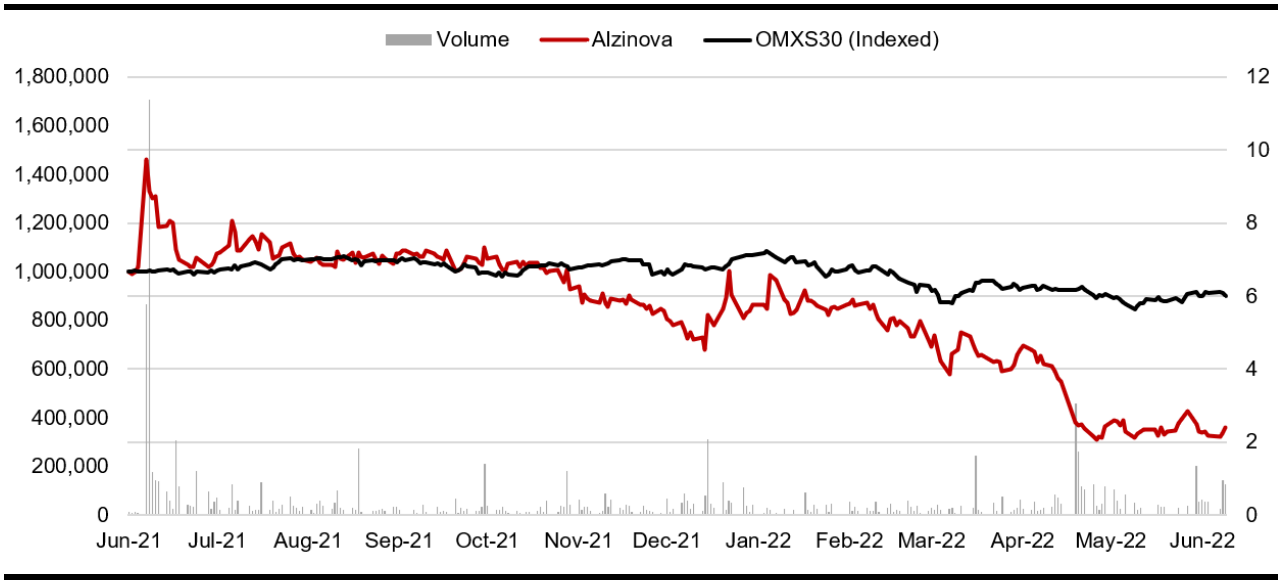
Stock Performance

An untimely negative sentiment towards the biotech segment caused an unfavorable stock development over the past six months, which in turn meant that the TO 2020/2022 warrants traded out-of-the-money. Consequently, Alzinova had to find alternative options to conduct a capital raise and announced the recent rights issue in April 2022. Following the announcement, the share price dropped some 30% as an immediate reaction and has since traded sideways. With the company now having secured funding and saturated its capital need, we believe that Alzinova has set a starting point for long-term value creation. Top-line results from the phase Ib trial with ALZ-101 (H2 2023) and continued preclinical preparations with ALZ-201 constitutes the main inflection points in the coming 12-18 months and could induce share price re-ratings.

Share Price Performance (12 months)



Source: Redeye Research, Alzinova

Ownership Structure

The top shareholders in the company are summarized in the table below. However, note that the table is not updated following the recent rights issue, and is thus subject to change.

Top 10 Shareholders – Alzinova*

Alzinova: Top 10 shareholders		Total amount of shares: 16.2M	
Owners	Number of Shares	Value (MSEK)	% of capital
Avanza Pension	1,762,513	3.88	10.87%
Maida Vale Capital	1,734,332	3.82	10.70%
Nordnet Pensionsförsäkring	677,792	1.49	4.18%
MIVAC Development	531,312	1.17	3.28%
Ola Hermansson	400,000	0.88	2.47%
Sara Gjertz	323,784	0.71	2.00%
Ålandsbanken	311,170	0.68	1.92%
Patrik Ahlvin	300,000	0.66	1.85%
Özlem Erdogdu Gül	254,154	0.56	1.57%
Jan Löngårdh	200,000	0.44	1.23%
Other shareholders	9,714,462	21.37	59.9%
Total	16,209,519	35.66	100%

Source: Holdings, Redeye Research

*** Correct as of Mars 31, the table is not updated following the recent rights issue and is subject to change.**

However, based on the current information at hand, we believe the ownership situation could be strengthened further. We primarily want to see three things happen regarding the company's ownership base:

- An increased ownership among the Board of Directors (CEO included).
- An increased ownership among management.
- A broadened base of investors. Specifically, an increased institutional ownership. In mid- to long-term, we also hope to see an investor base that includes international capital and life science specialist investors.

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 causation 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.

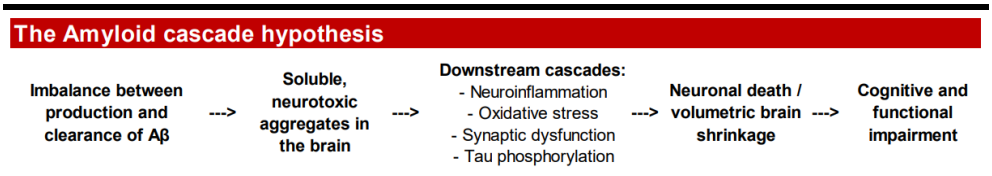
The Amyloid Beta Peptide

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



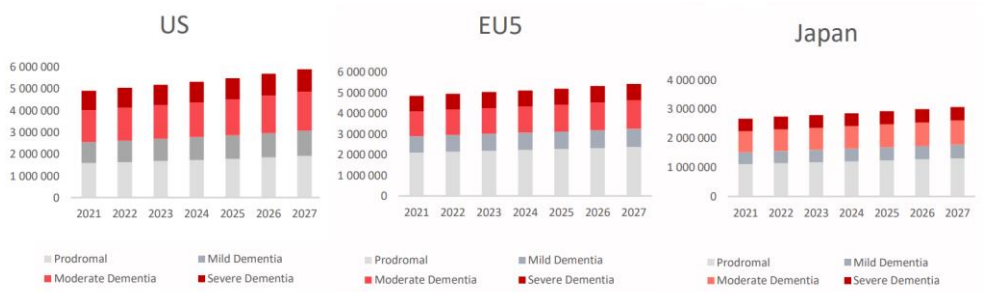
Source: Redeye Research

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.

Prevalence

In terms of prevalence, the number of patients diagnosed with Alzheimer's disease in the key markets (the US, EU5, and Japan) is currently a total of 13 million, according to Datamonitor. Driven primarily by an aging population, this is expected to grow annually by three percent in the US and two percent in EU5 and Japan during 2020-2029.

Prevalence – Diagnosed Alzheimer's



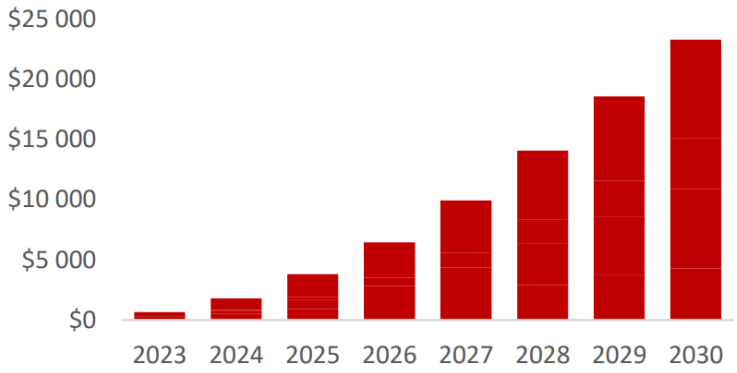
Source: Datamonitor, Redeye Research

In terms of disease burden and addressable market, we argue that a disease-modifying treatment for Alzheimer's is one of the most urgent unmet medical needs of modern society. The current disease burden of Alzheimer's has been estimated at USD 300bn in the US alone, according to the Alzheimer's Association, and is expected to reach nearly USD 1tn by 2050. As of today, it is the seventh most common cause of death in the US. Alzheimer's disease stands out from other leading causes of death as Alzheimer's related fatalities have more than doubled in number over the past 20 years. Consequently, new innovations are desperately needed to handle the increasing strain on healthcare systems worldwide.

Market Outlook

In comparison to the societal cost burden, the current treatment and prescription drug market for Alzheimer's is remarkably limited. We judge it to be valuated at a modest USD 2-4bn, stemming from the difficulties in developing innovative treatments along with currently marketed drugs mainly being generics with limited efficacy and problematic side effects. Given the high and increasing disease burden and the innovative treatments in the pipeline, we expect the market to grow rapidly in the upcoming decade.

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



Source: Biomedtracker, Redeye Research

Current market estimates from Informa/Datamonitor assume that Biogen's and Eisai's Lecanemab (in-licensed from Bioarctic) will contribute the most to the growth in the upcoming years, followed by Eli Lilly's Donanemab, pending market authorization (all of which are currently in phase III).

Disease Modifying Treatments – Clinical Pipeline Summary

Summary of clinical pipeline				
Drug Candidate	**Company**	**Phase**	**Delivery**	**Comment**
Aβ Vaccines				
UB-311	Vaxxinity Inc.	II	Intramuscular (IM)	Recently granted Fast Track designation by the FDA.
ABvac40	Araclon Biotech S.L.	II	Intravenous (IV)	Interim ph II data suggest that it meets the primary objectives on safety and efficacy of the first part.
ACI-24	AC Immune, Ltd.	II	IM, SQ	Also evaluated for AD in Down's syndrome patients.
ALZ-101	**Alzinova AB**	**I**	**IM**	
AL002	Alzamend Neuro Inc.	Preclinical	IM	Expected to soon enter clinical trials following positive pre-IND response from the FDA.
AV-1959R/AV-1980R	Capo Therapeutics	Preclinical	IM	Expected to soon enter clinical trials.
Aβ Immunotherapies				
Aduhelm	Biogen/Eisai	Conditionally approved	IV	FDA granted accelerated approval in June 2021.The CMS has since decided against national reimbursement.
Lecanemab	Eisai/Biogen	III	IV	Ph III data expected in H2'22
Gantenerumab	Roche	III	Subcutaneous	Ph III data expected in H2'22
ACU-193	Acumen Pharmaceuticals, Inc.	I	IV	Ph I data expected in H2'22. Recent preclinical data suggest that ACU193 is not expected to elicit ARIA side effects due to its high selectivity for Aβ oligomers.
Donanemab	Eli Lilly	III	IV	Ph III data expected in 22/23.
Tau Vaccines				
AADVac1	Axon Neuroscience	II	Subcutaneous	
ACI-35.030	AC Immune	I/II		

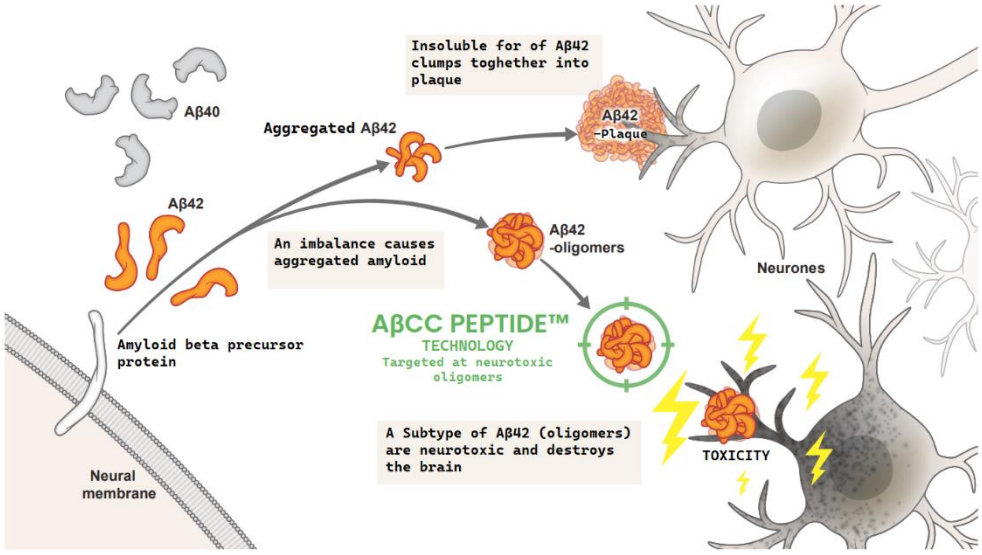
Source: Redeye Research, Datamonitor

We see interesting times ahead in the field of Alzheimer's disease treatment. The anticipated first full approvals of potentially disease-modifying treatments could mark a new era of Alzheimer's therapies coming to the market in the decades ahead and intensified investments in the field. We believe that it could also generate increased business activity and partnership interest from Big Pharma. With this in mind, it is truly exciting to follow Alzinova's promising oligomer-specific vaccine, ALZ-101's, continued clinical progress.

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]

[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.

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.

Current Status

Following comprehensive preclinical development, ALZ-101 is currently being evaluated in an ongoing phase Ib trial in early Alzheimer's patients, i.e., mild Alzheimer's or MCI (mild cognitive impairment). We believe that top-line results are likely to be presented in the second half of 2023.

ALZ-101: Overall 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

In addition, Alzinova also plans to conduct a long-term extension of the phase Ib study with ALZ-101. This long-term follow-up will be able to provide additional information on long-term safety and tolerability of ALZ-101, and study immune response and effects on biomarkers and cognitive functions. We highly encourage this kind of study, it is often seen implemented in trials with other disease-modifying drug candidates as well. We believe that it is important to generate such data for intended long-term treatments.

In parallel, Alzinova is carrying out further preparations in an attempt to optimize the conditions for the start of an upcoming clinical phase II study. This includes:

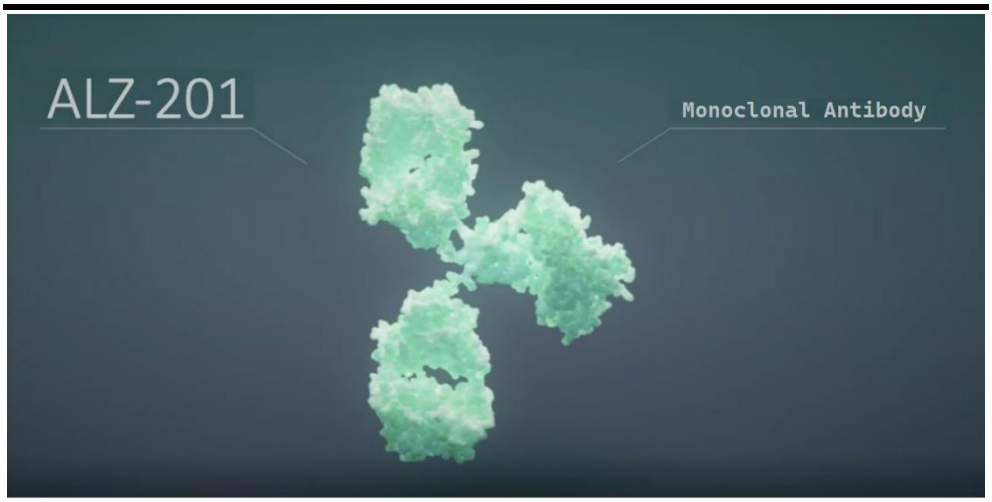
- Process optimization of substance manufacturing
- Pharmaceutical development and optimization of ALZ-101

Discussions are continuously taking place with potential strategic partners, who would then be able to quickly start the next phase of clinical development without extensive preparations of their own.

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.

Preclinical progress

At the end of 2021, Alzinova communicated the conclusion of a preclinical research project in collaboration with Amsterdam University Medical Centers. The collaborative study assessed ALZ-201 as a potential novel therapy to specifically target toxic forms of the Aβ peptide. This was observed by evaluating the antibody on toxic Aβ aggregates from deceased Alzheimer's patients. The results confirmed the unique specificity and therapeutic effect of the candidate as it demonstrated an ability to effectively neutralize the toxicity of the brain extracts. It lacks affinity for monomers and fibrils, including plaques, and all forms of the much less toxic amyloid-β40. Despite its unique binding profile, it has a strong effect on the toxicity of brain extracts from deceased Alzheimer's patients. The study provides additional evidence suggesting that soluble aggregates of The Aβ42 peptide (oligomers) in Alzheimer's disease truly are the toxic forms.

Following this, the company announced earlier this year that it had successfully completed the humanization work initiated in Q2 2021, and selected a humanized lead candidate of ALZ-201 This is a process which modifies the antibody with an aim to make it tolerated by humans.

Alzinova's aim is to conduct preclinical efficacy and toxicology studies with ALZ-201, and develop and scale up the production of the antibody during the period 2022-2024. The goal is to make the candidate ready for phase I clinical trials in Alzheimer's patients in a couple of years' time.

Financials

Financial Forecasts

Before entering clinical development, Alzinova operated as a semi-virtual organization with a quite modest cash burn. We expected 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, however, with operating expenses (OPEX) for 2021 coming in lower than our expectations, we have somewhat reduced our forecasted OPEX.

Alzinova: Financial Estimates, 2019-2023E (SEKm)

Alzinova: Financial Forecasts					
(SEKm)	**2019**	**2020**	**2021**	**2022E**	**2023E**
Net income	0.0	0.0	0.0	0.0	0.0
Operating expenses					
Other external costs	-8.8	-17.2	-19.0	-24.7	-19.8
Personnel costs	-4.2	-4.2	-5.8	-8.1	-10.6
Other operating expenses	0.0	0.0	0.0	0.0	0.0
Capitalization	6.8	14.9	17.3	21.6	18.4
Total operating results	**-6.2**	**-6.5**	**-7.5**	**-11.2**	**-11.9**
Operating profit (EBIT)	**-6.2**	**-6.5**	**-7.5**	**-11.2**	**-11.9**
Free cash flow	**-10.9**	**-21.2**	**-27.1**	**-29.5**	**-30.3**

Source: Redeye Research

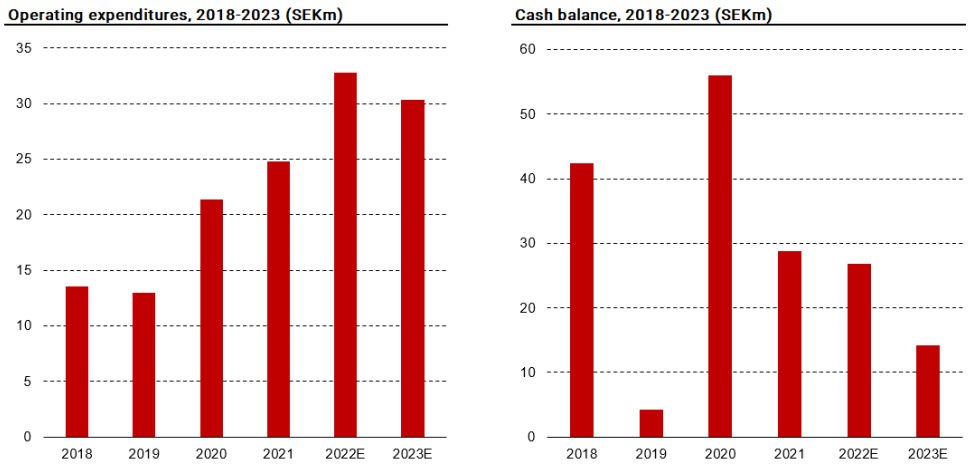
The company's previous outstanding warrants (TO2 2020/2022), with redemption from January 24, 2022, to February 7, 2022, did not provide the anticipated boost to Alzinova's cash account due to the share trading at levels below the predetermined floor at SEK 6.5 per share. As a result, Alzinova received SEK 2.8m through the exercise of the warrants, in comparison to a potential SEK 42m had there been a full exercise of all warrants at the ceiling price of SEK 11 per share.

In its Q1'22 report, Alzinova reported a cash position at the end of the period of SEK 26.8m. However, since then, the company has conducted a rights issue which was subscribed for a total of 80 percent and provided Alzinova with approximately SEK 34m before issuing costs. Thus, the number of shares increased by 16,209,515 shares, from 16,209,519 shares to a total of 32,419,034 shares. Correspondingly, this has caused a dilution effect of approximately 50 percent for shareholders who did not participate in the offering.

Furthermore, each subscribed unit in the offering entailed the right to an associated warrant of series TO3. The exercise period for subscription of shares through exercising warrants will run from 11 April to 25 April 2023. Each warrant of series TO3 entails a right to subscribe for one new share in the company to a subscription price corresponding to 70 percent of the volume weighted average share price (VWAP) for the share during the period 23 March to 5 April 2023.[2] Should all warrants be exercised, the number of shares will increase additionally by 12,967,612 shares (45,386,646 in total), corresponding to an additional dilution effect of approximately 28.6 percent.

[2] However, not less than the quota value for the share (which amounted to SEK 0.263 as of today) and not more than SEK 3.15.

Operating Expenditures and Cash Balance, 2018-2023E (SEKm)



Source: Redeye Research, Alzinova

In our financial forecast and valuation of Alzinova, we assume a full exercise of the TO3 warrants. Accordingly, we estimate an additional capital injection of some SEK 25-30m in 2023. We believe that this would provide the company with sufficient funding of its operations for well into 2024.

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.

Sales Model

As has been stated by the company, Alzinova's primary focus is the development of lead candidate ALZ-101. Accordingly, until we see a clear and funded path for the clinical development of ALZ-201, we refrain from including it in our valuation model.

Assumptions Summary

Targeted Population and Treatment Frequency

When defining the target population for ALZ-101, we base our top-down sales model on MCI and mild Alzheimer's patients as we do not find it realistic to model in presymptomatic individuals yet. This is also the patient population being enrolled in Alzinova's current phase Ib study with ALZ-101.

The anticipated administration frequency for the candidate is challenging as there is no clinical data or other approved vaccine (for Alzheimer's) to base this on. Regardless, we separate priming and annual booster (maintenance) doses and emphasize that both could encompass several shots. Alzheimer's primarily affects elderly individuals, who often have a weakened immune system, and so several shots might be necessary.

Pricing

As expected, the initial USD 56,000 annual price tag (WAC) disclosed by Biogen for Aduhelm was not well received by the public. It was considered a highly controversial price level given the uncertainties surrounding the treatment's safety profile and clinical benefits, and ultimately Biogen responded by decreasing its list price.

As explained in previous updates, we foresee a more competitive environment when ALZ-101 potentially reaches the market. For now, we do not make any adjustments to our previous pricing estimates.

Licensing Deal

We assume that Alzinova first demonstrates proof-of-concept (PoC) before out-licensing ALZ-101. Accordingly, we factor in a licensing deal being struck prior to phase II trials in 2024 with an upfront payment in the regions of USD 20m.

Likelihood of Approval

We previously applied a 60% probability rate of ALZ-101 progressing through phase Ib development and an overall likelihood of approval (LoA) of 10%. However, following encouraging progression in the ongoing phase Ib study, we make an upwards adjustment to its probability of success (PoS). Primarily, the Data and Safety Monitoring Board (DSMB) completed a planned assessment of the study earlier this year and recommended continuation of the study. The DSMB is an independent group of experts who periodically review and examine data accumulated during progress of the study to assess if action is necessary regarding the safety and execution of the study. Accordingly, we raise our estimates for the phase Ib PoS to 70% (60%), which in turn slightly increases the overall LoA for ALZ-101 to 11% (10%).

ALZ-101: Likelihood of Approval

ALZ-101: Est development risk per phase					
Preclin	Ph I	Ph II	Ph III	NDA	Market
100%	70%	30%	60%	90%	**11%**

Source: Redeye Research

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

Valuation

Valuation Summary

Below we show our project valuation for ALZ-101 – a discounted cash flows (DCF) model based on our sales models and the underlying key assumptions:

Project valuation: DCF model

($m)		2031E Launch	2032E	2033E	2034E	2035E	2036E Peak	2037E	2038E	2039E	2040E
Sales		291	570	1028	2415	3966	5162	4807	3544	3343	2570
Royalty Rate	16%	16%	16%	16%	16%	16%	16%	16%	16%	16%	16%
Royalty		46	91	164	386	635	826	769	567	535	411
Probability	11%	11%	11%	11%	11%	11%	11%	11%	11%	11%	11%
Risk adj. Royalty		**5.1**	**10.0**	**18.0**	**42.2**	**69.3**	**90.2**	**84.0**	**61.9**	**58.4**	**44.9**
In SEK		50.8	99.6	179.5	421.9	692.8	901.7	839.8	619.1	584.1	449.0
		Milestone				Milestone		Milestone		Milestone	
Milestone Payments		60	0	0	0	60	0	60	0	60	0
Probability		11%	11%	11%	11%	11%	11%	11%	11%	11%	11%
Risk adj. Milestones		**6.6**	**0.0**	**0.0**	**0.0**	**6.6**	**0.0**	**6.6**	**0.0**	**6.6**	**0.0**
In SEK		65.5	0.0	0.0	0.0	65.5	0.0	65.5	0.0	65.5	0.0
Risk adj. Value, Pre-tax		**11.6**	**10.0**	**18.0**	**42.2**	**75.8**	**90.2**	**90.5**	**61.9**	**65.0**	**44.9**
Tax			-2.1	-3.7	-8.7	-15.6	-18.6	-18.6	-12.8	-13.4	-9.2
Risk adj. Value, Post-tax		**11.6**	**7.9**	**14.3**	**33.5**	**60.2**	**71.6**	**71.9**	**49.2**	**51.6**	**35.6**
Discount Factor		0.26	0.22	0.19	0.17	0.14	0.12	0.11	0.09	0.08	0.07
Risk adj net present value (rNPV)		**3.0**	**1.7**	**2.7**	**5.6**	**8.7**	**8.9**	**7.8**	**4.6**	**4.2**	**2.5**

Total rNPV	**50.6**
In SEKm	*506.4*
Cash* (15/06/22)	49.5
S/O (post warrants)	45.4
Shared costs (per share)	-2.0
Base Case	**10**

*** Our estimate of the company's cash position following the recent rights issue.**
**** 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.**

Summary of changes in valuation

- We slightly increase the LoA of ALZ-101 following progress in ongoing phase Ib study and a favorable opinion from the DSMB.
- We increase risk-free rate to 2% (1%) per our policy to account for higher market rates.
- We include two capital injections of SEK 34m and SEK 26m (before issuing costs) for the rights issue and linked warrants, respectively, in 2022.
- We update the USD/SEK exchange rate to 10 (8.75).

Bear Case SEK 1

We factor in negative results from the ALZ-101 phase Ib trials and see limited prospects in the candidate. The company's cash position and the untapped potential in ALZ-201 constitute the company's remaining value.

Base Case SEK 10

We refer to the 'Project Valuation' (DCF model) for our Base Case.

Bull Case SEK 20

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 2024 with a USD 20 million upfront payment to a strong Big Pharma partner.

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 experience from the pharma industry and possesses effective communication and project leadership skills. CSO Anders Sandberg is the co-inventor of the AβCC technology and the co-founder of the company. The appointments of a CFO, a CMO, and a Project Director have also bolstered the management team. When the organization gets itself established and has proven its execution capabilities, there could be a rationale to review this rating.

Business: 3

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 undoubtably 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 26.8m in its latest interim report. However, since then, the company has performed a rights issue securing some well-needed funding. Although this entails no immediate additional cash need, investors need to factor in further equity funding when considering an investment. Primarily, If all warrants from the rights issue are exercised, the number of shares will increase additionally by 12,967,612 shares (45,386,646 in total) in April 2023, a dilution of approximately 28.6 percent.

	2020	2021	2022E	2023E
INCOME STATEMENT				
Revenues	0	0	0	0
Cost of Revenues	0	0	0	0
Gross Profit	0	0	0	0
Operating Expenses	6	8	9	10
EBITDA	-6	-7	-9	-10
Depreciation & Amortization	0	0	0	0
EBIT	-6	-7	-9	-10
Net Financial Items	0	0	0	0
EBT	-6	-7	-9	-10
Income Tax Expenses	0	0	0	0
Non-Controlling Interest	0	0	0	0
Net Income	-6	-7	-9	-10
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	56	29	37	26
Inventories	0	0	0	0
Accounts Receivable	0	0	0	0
Other Current Assets	1	1	1	1
Total Current Assets	56	30	38	27
Non-current assets				
Property, Plant & Equipment, Net	0	0	0	0
Goodwill	0	0	0	0
Intangible Assets	44	62	74	81
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	44	62	74	81
Total Assets	101	92	112	108
Liabilities				
Current liabilities				
Short-Term Debt	0	0	0	0
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	2	1	0	0
Other Current Liabilities	2	2	5	5
Total Current Liabilities	4	2	5	5
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	96	88	123	139
Total Liabilities & Equity	101	92	129	145
CASH FLOW				
NOPAT	-6	-7	-9	-10
Change in Working Capital	0	-2	3	0
Operating Cash Flow	-6	-10	-6	-10
Capital Expenditures	0	0	0	0
Investment in Intangible Assets	-15	-17	-22	-24
Investing Cash Flow	-15	-17	-22	-24
Financing Cash Flow	43	0	36	22
Free Cash Flow	-21	-27	-27	-34

DCF Valuation Metrics	**Sum FCF (SEKm)**
Initial Period (2022–2030)	-66
Momentum Period (2031–2040)	595
Stable Period (2041–)	160
Firm Value	529
Net Debt	-48
Equity Value	481
Fair Value per Share	10

	2020	2021	2022E	2023E
CAPITAL STRUCTURE				
Equity Ratio	1.0	1.0	1.1	1.3
Debt to equity	0.0	0.0	0.0	0.0
Net Debt	-56	-29	-37	-26
Capital Employed	97	89	107	103
Working Capital Turnover	0.0	0.0	0.0	0.0
GROWTH				
Revenue Growth	0%	0%	0%	0%
Basic EPS Growth	n/a	n/a	n/a	n/a
Adjusted Basic EPS Growth	n/a	n/a	n/a	n/a
PROFITABILITY				
ROE	n/a	n/a	n/a	n/a
ROCE	-7%	-8%	-8%	-9%
ROIC	-16%	-14%	-13%	-12%
EBITDA Margin (%)	n/a	n/a	n/a	n/a
EBIT Margin (%)	n/a	n/a	n/a	n/a
Net Income Margin (%)	n/a	n/a	n/a	n/a
VALUATION				
Basic EPS	-0.4	-0.5	-0.2	-0.2
Adjusted Basic EPS	-0.4	-0.5	-0.2	-0.2
P/E	-18.7	-14.7	-31.7	-45.5
EV/Revenue	n/a	n/a	n/a	n/a
EV/EBITDA	-18.7	-14.8	-14.0	-14.3
EV/EBIT	-18.7	-14.8	-14.0	-14.3
P/B	1.3	1.2	2.3	3.2

SHAREHOLDER STRUCTURE	**CAPITAL %**	**VOTES %**
Avanza Pension	10.9%	10.9%
Maida Vale Capital AB	10.7%	10.7%
GU Ventures	4.3%	4.3%
Nordnet Pensionsförsäkring	4.2%	4.2%
Ola Hermansson	2.5%	2.5%

SHARE INFORMATION	
Reuters code	ALZ.SS
List	First North
Share price	2.4
Total shares, million	36.06

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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Disclaimer

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Redeye Rating (2022-06-21)

Rating	People	Business	Financials
5p	32	15	4
3p - 4p	157	139	48
0p - 2p	5	40	142
Company N	194	194	194

Duplication and distribution

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.