Alzinova

Sector: Biotech

Q4 report: Right on track

Redeye provides a research update of Alzinova following the company's recent Q4 report and clinical progress with lead candidate ALZ-101. We make some slight adjustments to our overall estimates following a revision of our model. However, we reiterate our previous fair value range (SEK1 – SEK20) with a base case valuation of SEK10 as we continue to have a positive outlook on the case.

Summary of the Q4 report

We note that Alzinova's Q4 report came in line with our expectations and without any major surprises. The company reported an operating profit (loss) of SEK-4.7m (-2.4), while Free cash flow for the period amounted to SEK-6.8m (-5.5). While being a slightly higher OPEX than our expectations, this is not a significant difference in the long run. The company also reported a cash position at quarter-end of SEK32.0m (28.8). Assuming full subscription in the upcoming exercise period for the company's TO3 warrants, we expect that Alzinova will have sufficient funds to finance operations well into 2024.

Clinical progress

Alzinova's lead candidate, ALZ-101, is currently in phase Ib clinical trials, where it is being developed as a potential first-in-class oligomer-specific vaccine treatment against Alzheimer's disease (AD). Following study initiation in October 2021, Alzinova recently released an updated positive safety review and initial interim data from the trial. Blinded data from half of the subjects (13 patients), who have received three doses of the ALZ-101 or placebo, suggest continued good safety and tolerability, with evidence of immunological response and antibody formation.

Valuation – Base case of SEK10

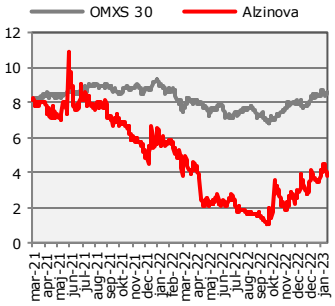
We value Alzinova using a discounted cash flow (DCF) model based on our sales model and our underlying assumptions. We reiterate our fair value range of SEK1-20 per share with a base case of SEK10, bull case: SEK20; bear case: SEK4. This demonstrates a significant upside potential from current share price levels of SEK c.3.9 as we believe the share will continue its newfound upwards momentum. Looking ahead, we see multiple inflection points that could further narrow the valuation gap, primarily the topline data from the phase Ib study with ALZ-101.

Key Financials (SEKm)	2019	2020	2021	2022	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	-13.1	-15.3
EBIT	-6.2	-6.5	-7.5	-13.1	-15.3
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)	3.9
Market Cap (MSEK)	128
Net Debt 23E (MSEK)	-33
Free Float	84 %
Avg. daily volume ('000)	170

ANALYSTS

Kevin Sule

Kevin.sule@redeye.se

Fredrik Thor

Fredrik.thor@redeye.se

Investment case

Case: Unique offering in blockbuster indication

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

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

Evidence: Rooted in Innovation

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

Supportive analysis: Toxicity specifically stem from Aβ42

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

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

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

Challenge I: Partnership dependent

Operating in such a huge indication as Alzheimer's, Alzinova is highly dependent on Big Pharma's resources to take ALZ-101 through the more extensive clinical trials and to the market. However, we believe that a strong safety profile being displayed in the 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 SEK10. Having adjusted for the last year's rights issue along with the 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, data readout from the phase Ib trial and preclinical advancements with the company's antibody candidate, ALZ-201. As been demonstrated following the recent success with Lecanemab, however, external news that validates the Aβ hypothesis could also have an effect on the Alzinova 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 last year's rights issue (and outstanding warrants), investors should factor in additional funding needs before any recurring revenue streams.

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

Key Catalysts

ALZ-101 – phase Ib study results

Top-line results from the ongoing phase Ib trial are expected to be presented in the second half of 2023, with an interim data readout planned in in H1 2023. We believe that these will be significant value-defining inflection points for Alzinova and its shareholders.

Timeframe: 0-9 months
Impact: Major

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 Alzinova's clinical portfolio in the coming years.

Timeframe: 6-18 months
Impact: Moderate

Licensing deal

Should ALZ-101 demonstrate proof-of-concept (PoC) in the ongoing phase Ib trial, we believe it is possible that the candidate could catch the eye of Big Pharma companies. Accordingly, we project a licensing deal being struck prior to phase II trials. This could act as a major catalyst for the stock.

Timeframe: 12-24 months
Impact: Major

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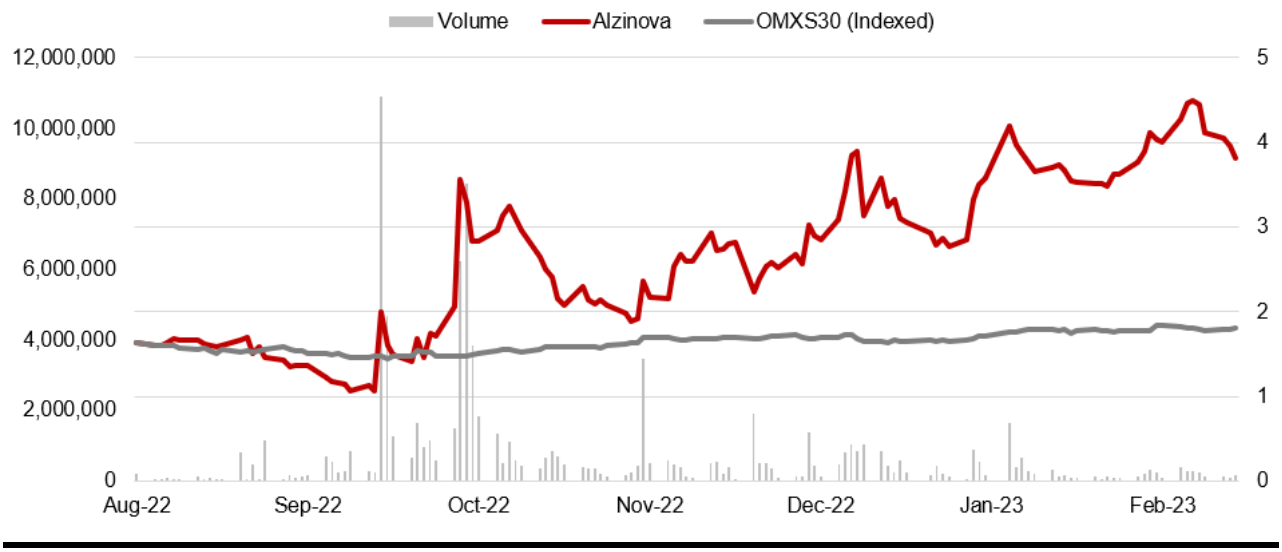
Stock Performance

Following the rights issue last summer, the share price dropped heavily, reaching its lowest point in September. However, with the company having secured funding and saturated its capital need, we argued in our previous update that Alzinova had set a starting point for long-term value creation. Accordingly, bolstered by encouraging interim updates from the ongoing phase Ib study with ALZ-101 and positive external news in the AD treatment sphere, the share turned its trend and has rallied almost 300% since. We believe that the Alzinova stock will continue its newfound momentum with top-line results from the phase Ib trial (H2 2023) and preclinical progress with ALZ-201 constituting the main inflection points in the coming year.

Share Price Performance (6 months)



Source: Redeye Research, Alzinova

Ownership Structure

The top shareholders in the company are summarized in the table below. However, note that the table could change following the coming exercise period of the outstanding TO3 warrants.

Top 10 Shareholders – Alzinova*

Alzinova: Top 10 shareholders				
Owners	Number of shares	Value (mSEK)	Capital	Votes
Maida Vale Capital AB	3,808,226	14.8	11.75%	11.75%
Avanza Pension	2,600,038	10.1	8.02%	8.02%
Nordnet Pensionsförsäkring	1,176,147	4.6	3.63%	3.63%
GU Ventures	1,139,337	4.4	3.51%	3.51%
Sara Gjertz	898,553	3.5	2.77%	2.77%
Patrik Ahlvin	704,000	2.7	2.17%	2.17%
Moll Invest AB	415,440	1.6	1.28%	1.28%
Ola Hermansson	400,000	1.6	1.23%	1.23%
Ing-Marie Fraim	359,955	1.4	1.11%	1.11%
Marcus Milerud	328,000	1.3	1.01%	1.01%
Other shareholders	20,589,338	80.1	63.51%	63.51%
Total	32,419,034	126.1	100.00%	100.00%

Source: Holdings, Redeye Research
*Correct as of February 20, 2023.

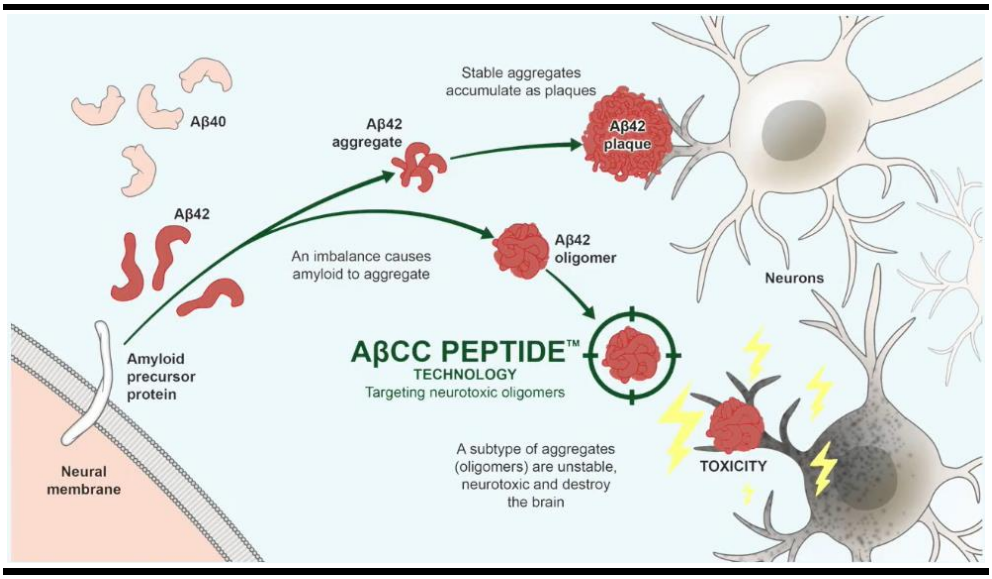
However, based on the current information at hand, we believe the ownership situation could be strengthened further. We primarily want to see three things happen regarding the company's ownership base:

- An increased ownership among 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.

ALZ-101 – The vaccine candidate

Alzinova's drug candidates utilize the company's patented AβCC peptide technology, which aims to stabilize the oligomeric form of Aβ42, preventing the formation of amyloid fibrils. Among these candidates, ALZ-101 stands out as a promising vaccine therapy for the treatment of early Alzheimer's disease. ALZ-101 generates antibodies targeted specifically towards a subtype of Aβ oligomers known to be a major form of neurotoxic aggregates in brain extracts from Alzheimer's patients. This unique oligomer stabilization positions ALZ-101 as an attractive vaccine candidate. The hypothesis is that intramuscular injections of ALZ-101, along with an aluminum hydroxide adjuvant, will trigger the body's immune system to recognize the substance as potentially harmful, thus stimulating the production of antibodies against it.

AβCC Technology – Mode of Action



Source: Alzinova

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). The overall design and characteristics of the study are summarized in the table below:

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

Following study initiation in October 2021, Alzinova released an updated positive safety review and initial interim data from the trial in Q4 2022. The company has analyzed blinded data from half of the subjects (13 patients) who have received three doses of the ALZ-101 or placebo. The results indicate continued good safety and tolerability, with no perceived severe adverse events (SAE).

Furthermore, the interim analysis shows evidence of immunological response and antibody formation, as increases in antibody levels have been observed. While the data is still in the early stages of analysis, the ability to elicit an immune response is a promising first indication of a potential desired effect in patients. It is important to note, however, that the analysis of antibody levels is fully blinded, including results from patients who received placebo instead of treatment, making it difficult to draw any definitive conclusions from the data.

This was closely followed up by another important milestone as Alzinova also announced in December 2022 that the study had been fully recruited. A second interim analysis in all 26 patients is anticipated in H1 2023. This is set to generate additional data on which a decision on the extension of the study will be based upon. Top-line data for the study is expected in H2 2023, and we believe it will constitute a significant inflection point for the company.

Upcoming events

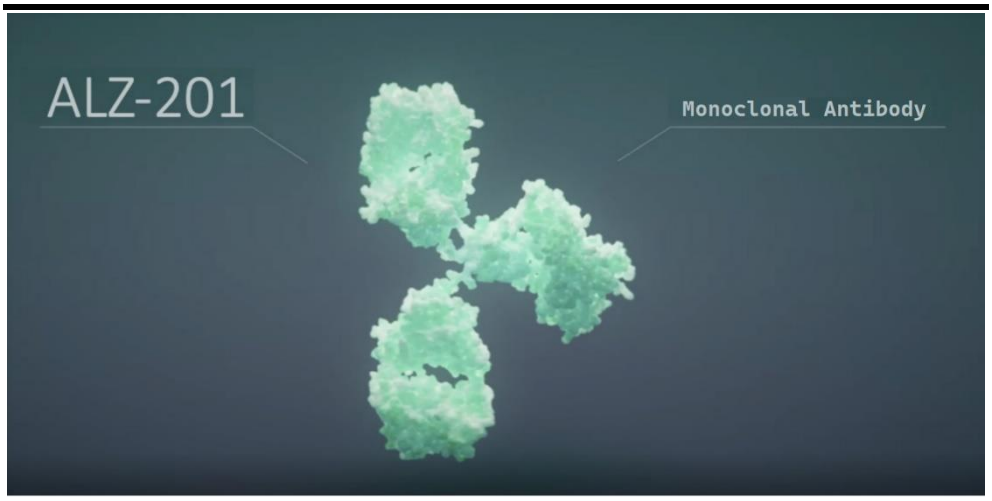
Alzinova has announced plans to conduct a long-term extension of the phase Ib study with ALZ-101, aiming to generate additional information on the candidate's long-term safety, tolerability, immune response, and effects on biomarkers and cognitive functions. We endorse this approach, as it is a commonly adopted strategy in trials with other disease-modifying drug candidates, and crucial for establishing the safety and efficacy of long-term treatments.

In parallel, Alzinova is undertaking further preparations to optimize the conditions for an upcoming clinical phase II study. These efforts involve improving the manufacturing process for the compound and optimizing its pharmaceutical development. The company is also in continuous discussions with potential strategic partners to facilitate the next phase of clinical development, enabling a seamless transition without the need for extensive preparations on their part.

ALZ-201 – A monoclonal antibody

In addition to ALZ-101, Alzinova is developing another promising drug candidate, ALZ-201, a monoclonal antibody that is designed to specifically neutralize the harmful soluble oligomeric forms of amyloid-β42. Utilizing the same proprietary AβCC peptide technology as ALZ-101, ALZ-201 has a unique mechanism of action that selectively targets the toxic form of amyloid-β42. This selectivity is expected to translate into a higher degree of binding to the target across the blood-brain barrier, potentially leading to a highly effective treatment option.

ALZ-201 – Illustrated



Source: Alzinova

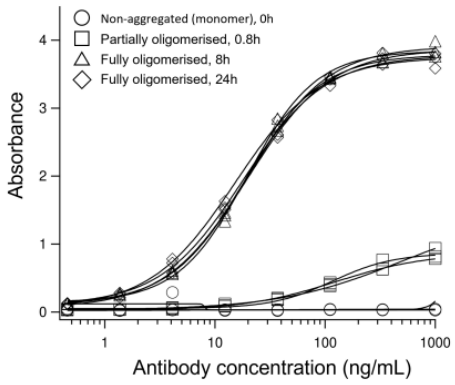
Through the development of ALZ-201, Alzinova is broadening its business area and portfolio of disease modifying Alzheimer's treatments. Given the complex and multifaceted nature of Alzheimer's disease, we posit that there is a potential need for both vaccine treatments and antibody alternatives.

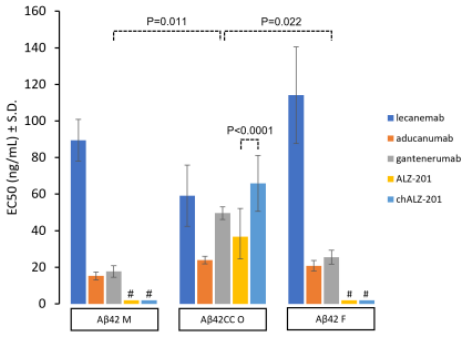
While we believe that the vaccine approach is better suited for lifelong indications, such as Alzheimer's, and could be more cost-effective in the long run, an antibody treatment could also serve as an adjunctive therapy for patients who require high levels of antibodies or have a weakened immune system. Thus, we see a compelling rationale for the simultaneous development of both ALZ-101 and ALZ-201. This strategy has the potential to offer patients a more comprehensive and effective treatment regimen, addressing multiple aspects of the disease and improving overall clinical outcomes.

Current Status

At the beginning of 2023, an article, published in the "Alzheimer's Research & Therapy" journal, presented new preclinical data on Alzinova's monoclonal antibody candidate ALZ-201. The data suggest that the candidate has a strong specificity toward the most toxic form of the peptide amyloid-β42 (oligomers). In contrast, aducanumab, lecanemab, and gantenerumab had similar affinities for all different conformations of the peptide. The oligomeric form of Aβ42 is widely thought to be the primary driver of Alzheimer's disease. We believe that the unique binding profile of ALZ-201 indicates a potential to elicit a solid neutralizing effect on toxic Aβ with a reduced risk of side effects.

ALZ-201 – Antibody dose-response curves





Source: Sandberg et al., 2022.

Figure 1. Antibody dose-response curves of ALZ-201 against non-aggregated (0h), partially aggregated (0.8h), and fully aggregated (8h and 24h) Aβ42CC peptides. The Half maximal effective concentration rate (EC50) was taken from a 4-parameter logistic equation fitted to the experimental data. N=3 for each antigen. Control antibody 6E10 exhibited no preference for any form of Aβ (not shown).

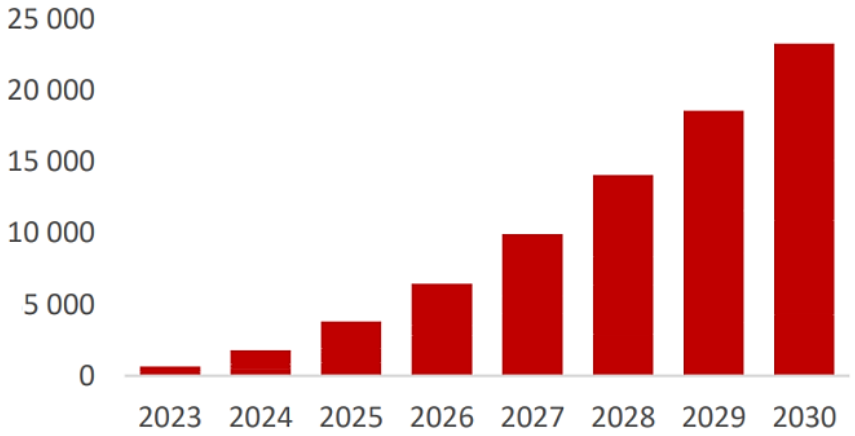
Figure 2. The EC50 (taken from a 4-parameter logistic equation fitted to the experimental data) from antibody dose-response curves against monomeric non-aggregated Aβ42 peptides ("M"), Aβ42CC oligomers ("O"), and fibrillar forms of the Aβ42 peptide for which the Mw is unknown ("F") . #: No binding detected

We see these research results as exciting, adding to the promising scientific rationale of Alzinova's candidates. However, it is essential to note that this is preclinical data. Alzinova is currently developing a humanized version of ALZ-201 for clinical trials. A potential phase 1 trial with ALZ-201 in patients with Alzheimer's disease is expected to be initiated in 2024.

Market outlook – Alzheimer's treatment

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

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



Source: Biomedtracker, Redeye research

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

Looking at the scope of clinical activities and recent progress in the field of Alzheimer research, we saw some important advancements over the past months. Primarily, the focus has been on Lecanemab, which earlier this year received conditional approval in the US following the positive topline results from the phase III trial "Clarity AD". From the perspective of Alzinova, the breakthrough of Lecanemab should also be seen as significant as it highlights the amyloid beta theory as a leading approach in finding a cure for Alzheimer's disease, we argue.

We have previously emphasized external news within the amyloid-beta space as potential short-term catalysts for the Alzinova stock. This was made evident following the announcement of the Clarity AD topline results, which caused the share to double in price due to the similarities between Lecanemab and Alzinova's own ALZ-101.

Disease Modifying Treatments – Clinical Pipeline Summary

Summary of clinical pipeline			
Drug Candidate	**Company**	**Phase**	**Delivery**
Aβ Vaccines			
UB-311	Vaxxinity Inc.	II	Intramuscular (IM)
ABvac40	Araclon Biotech S.L.	II	Intravenous (IV)
ACI-24	AC Immune, Ltd.	II	IM, SQ
ALZ-101	**Alzinova AB**	**I**	**IM**
AL002	Alzamend Neuro Inc.	I	IM
AV-1959R/AV-1980R	Capo Therapeutics	Preclinical	IM
Aβ Immunotherapies			
Aduhelm	Biogen/Eisai	Conditionally approved*	IV
Lecanemab	Eisai/Biogen	Conditionally approved	IV
Donanemab	Eli Lilly	III	IV
ACU-193	Acumen Pharmaceuticals, Inc.	I	IV
ALZ-201	**Alzinova AB**	**Preclinical**	**IM**
Gantenerumab	Roche	Suspended	Subcutaneous
Tau Vaccines			
AADVac1	Axon Neuroscience	II	Subcutaneous
ACI-35.030	AC Immune	I/II	

Source: Datamonitor, Redeye research

***Only in the US, with limited reimbursement coverage.**

****The list does not claim to comprehend the whole pipeline.**

Looking ahead, we foresee exciting developments in the field of Alzheimer's research and treatment. Specifically, we anticipate that the expected first full approvals of disease-modifying treatments could usher in a new era of Alzheimer's therapies that will have a transformative impact for years to come. Notably, we believe that this could stimulate increased business activity, as we anticipate more significant investments in the field and an intensified interest in licensing opportunities from leading pharmaceutical companies. Such developments wouldbe particularly beneficial for Alzinova and the ongoing development of its unique vaccine candidate, ALZ-101. Overall, these exciting prospects highlight the tremendous potential for transformative advancements in the field of Alzheimer's research and underscore the critical need for continued investment and innovation in this area.

Financials

Operating expenditures for the period amounted to SEK-8.1m (-5.2m). While being somewhat higher than our expectations of SEK-6.5m, this is not a significant difference in the long run as patient recruitment for the phase Ib study is now completed. Similarly, the Q4 EBIT of SEK-4.7m (-2.4m) was lower in than our expectations of SEK-2.9m.

Alzinova: Q4 Financial estimates (SEKm)

Alzinova: Actual vs. Estimates (SEKm)				
SEKm	Q4 21	Q4 22a	Q4 22e	Diff (%)
Net sales	0.0	0.0	0.0	0%
Sales growth Y/Y	N/A	N/A	N/A	N/A
OPEX	-5.2	-8.1	-6.5	-21%
Capitalization	2.7	3.4	3.6	-5%
EBITDA	-2.4	-4.7	-2.9	-39%
EBITDA margin (%)	N/A	N/A	N/A	N/A
EBIT	-2.4	-4.7	-2.9	-39%
EBIT margin (%)	N/A	N/A	N/A	N/A
Free cash flow	-5.5	-6.8	-5.6	-19%
Cash & Equivalents	28.8	32.0	33.3	-4%

Source: Redeye Research

We argue that the company is in a healthy cash position at SEK 32m, following the rights issue in 2022. Furthermore, in our financial forecast and valuation of Alzinova, we assume a full exercise of the enclosed TO3 warrants. The exercise period for subscription of shares th rough 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.

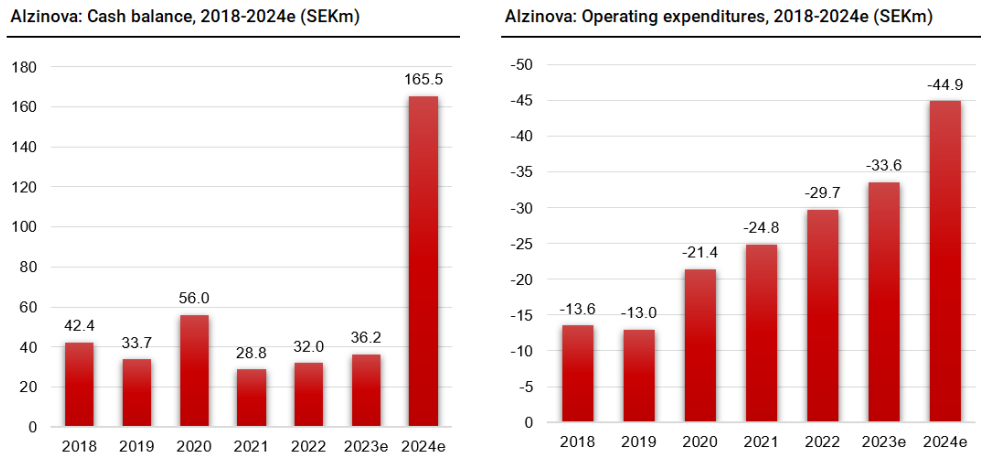
Alzinova: Financial Estimates, 2020-2024e, risk-adjusted (SEKm)

Alzinova: Financial Forecasts (SEKm)					
SEKm	2020	2021	2022	2023e	2024e
Net income	0.0	0.0	0.0	0.0	144.6
Capitalization	14.9	17.3	16.6	18.3	20.1
Revenue	14.9	17.3	16.6	18.3	164.7
Other external costs	-17.2	-19.0	-23.0	-26.6	-37.2
Personnel costs	-4.2	-5.8	-6.7	-7.0	-7.7
Other operating expenses	0.0	0.0	0.0	0.0	0.0
Operating expenses	-21.4	-24.8	-29.7	-33.6	-44.9
EBITDA	-6.5	-7.5	-13.1	-15.3	119.8
EBIT	-6.5	-7.5	-13.1	-15.3	119.8
Free cash flow	-21.2	-27.2	3.2	4.2	129.3

Source: Redeye Research

Accordingly, we estimate an additional capital injection of some SEK 35-40m (before the deduction of transaction costs) in Q2 2023. We believe that this would provide the company with sufficient funding of its operations for well into 2024.

Operating Expenditures and Cash Balance, 2018-2024e, risk-adjusted (SEKm)



Source: Redeye Research, Alzinova

Sales Model

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

Assumptions Summary

Targeted population, treatment frequency and pricing

When delineating the target population for ALZ-101, our approach is to employ a top-down sales model, centered on individuals with mild cognitive impairment (MCI) and mild Alzheimer's disease. Given that it is not yet feasible to model in presymptomatic individuals, we refrain from doing so. Notably, the patient population currently enrolled in Alzinova's phase Ib study with ALZ-101 falls under this umbrella.

The frequency of ALZ-101's administration poses a challenge as there is no existing clinical data or approved vaccine for Alzheimer's to serve as a benchmark. Notwithstanding, we advocate for a dichotomous approach of priming and annual booster (maintenance) doses, with each potentially requiring multiple injections. This is due to the fact that Alzheimer's predominantly impacts the elderly population, who often exhibit a diminished immune response, necessitating multiple dosages.

Similarly, it's difficult to predict a precise pricing for treatment with ALZ-101. We foresee a more competitive environment when the candidate potentially reaches the market (2031e). Thus, we chose to adopt a more conservative pricing approach. 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) in the ongoing phase Ib trial before out-licensing ALZ-101. Accordingly, we factor in a licensing deal being struck prior to phase II trials in late 2024 with an upfront payment in the regions of USD 20m, taking into account the current market trends and historic industry standards.

Likelihood of Approval

We apply an overall likelihood of approval (LoA) of 11% for ALZ-101, which is our estimated probability of the candidate reaching market approval. This is based on a 70% probability rate of ALZ-101 progressing through the ongoing phase Ib trial. Accordingly, should the candidate demonstrate encouraging results in the data readout expected later this year, we will raise our estimated LoA.

ALZ-101: 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 – calculated through a discounted cash flows (DCF) model based on our sales models and the underlying key assumptions – and our valuation of Alzinova as a whole:

Valuation: DCF model

Valuation summary (SEKm) - Base case						
Program	Indication	Stage	Launch	Peak sales ($m)	Probability (LoA)	Value, r-adj (SEKm)
ALZ-101	Alzheimer's	Phase I	2031	5162	11%	606
				Tech Value (SEKm)		**606**
				Est. net cash		31.1
				Shared costs		-193.7
				Equity Value		**443**
				Shares outstanding		32.4
				Est. Capital raise from warrants (SEKm)		35.8
				Est. Increase in shares from warrants		13.0
WACC: 15%				Base case		10.0

Source: Redeye Research

Summary of changes in valuation

- We change the risk-free rate to 2.5% (previously 2.0%) according to Redeye policy.
- We update the SEK/USD exchange rate to 10.725 (a running average for the period 1/10-30/12, 2022) according to Redeye policy.
- We include an estimated capital injection of SEK 35-40m (before the deduction of transaction costs) from the outstanding TO3 warrants in Q2 2023.
- We have updated our Redeye Rating for Alzinova according to our new Redeye Rating 2.2.
- We make some slight adjustments to our overall estimates following a revision of our model.

Bear Case SEK 1

We factor in negative results from the ALZ-101 phase Ib trial 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 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.

Appendix

Patents

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

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

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

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

Summary Redeye Rating

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

Rating changes in the report

People: 3
(No changes)

Business: 3
(No changes)

Financials: 1
(No changes)

	2021	2022	2023E	2024E
INCOME STATEMENT				
Revenues	0	0	0	145
Cost of Revenues	0	0	0	0
Gross Profit	0	0	0	145
Operating Expenses	8	13	15	25
EBITDA	-8	-13	-15	120
Depreciation & Amortization	0	0	0	0
EBIT	-8	-13	-15	120
Net Financial Items	0	0	0	0
EBT	-8	-13	-15	120
Income Tax Expenses	0	0	0	6
Non-Controlling Interest	0	0	0	0
Net Income	-8	-13	-15	114
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	29	32	36	166
Inventories	0	0	0	0
Accounts Receivable	0	0	0	0
Other Current Assets	1	1	2	3
Total Current Assets	30	33	38	168
Non-current assets				
Property, Plant & Equipment, Net	0	0	0	0
Goodwill	0	0	0	0
Intangible Assets	62	78	115	168
Right-of-Use Assets	0	0	0	0
Shares in Associates	0	0	0	0
Other Long-Term Assets	0	0	0	0
Total Non-Current Assets	62	78	115	168
Total Assets	92	112	153	336
Liabilities				
Current liabilities				
Short-Term Debt	0	0	0	0
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	2	3	5	7
Other Current Liabilities	2	2	3	5
Total Current Liabilities	3	5	8	11
Non-current liabilities				
Long-Term Debt	0	0	0	0
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	1	1	1	1
Total Non-current Liabilities	1	1	1	1
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	87	106	144	324
Total Liabilities & Equity	92	112	153	336
CASH FLOW				
NOPAT	-8	-13	-15	114
Change in Working Capital	-1	2	2	3
Operating Cash Flow	-10	-10	-14	122
Capital Expenditures	0	0	0	0
Investment in Intangible Assets	-17	-17	-16	-17
Investing Cash Flow	-17	-17	-16	-17
Financing Cash Flow	0	30	35	24
Free Cash Flow	-27	-27	-30	105

DCF Valuation Metrics	**Sum FCF (SEKm)**
Initial Period (2023–2030)	-29
Momentum Period (2031–2040)	415
Stable Period (2041–)	123
Firm Value	509
Net Debt (last quarter)	-32
Equity Value	477
Fair Value per Share	10

	2021	2022	2023E	2024E
CAPITAL STRUCTURE				
Equity Ratio	1.0	0.9	0.9	1.0
Debt to equity	0.0	0.0	0.0	0.0
Net Debt	-29	-32	-36	-166
Capital Employed	88	106	145	325
Working Capital Turnover	0.0	0.0	0.0	-17.0
GROWTH				
Revenue Growth	n/a	n/a	n/a	n/a
Basic EPS Growth	16%	-16%	-17%	-720%
Adjusted Basic EPS Growth	16%	-16%	-17%	-720%
PROFITABILITY				
ROE	-8%	-14%	-12%	49%
ROCE	-9%	-12%	-11%	37%
ROIC	-15%	-20%	-17%	85%
EBITDA Margin (%)	n/a	n/a	n/a	83%
EBIT Margin (%)	n/a	n/a	n/a	83%
Net Income Margin (%)	n/a	n/a	n/a	79%
VALUATION				
Basic EPS	n/a	-0.4	-0.3	2.1
Adjusted Basic EPS	n/a	-0.4	-0.3	2.1
P/E	n/a	neg	neg	1.8
EV/Revenue	n/a	n/a	n/a	0.3
EV/EBITDA	n/a	neg	neg	0.3
EV/EBIT	n/a	neg	neg	0.3
P/B	n/a	0.9	1.2	0.6

SHAREHOLDER STRUCTURE	**CAPITAL %**	**VOTES %**
Maida Vale Capital AB	11.7%	11.7%
Avanza Pension	8.0%	8.0%
Nordnet Pensionsförsäkring	3.6%	3.6%
GU Ventures	3.5%	3.5%
Sara Gjertz	2.8%	2.8%

SHARE INFORMATION	
Reuters code	ALZ
List	First North
Share price	3.76
Total shares, million	45.3866

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

ANALYSTS
Kevin Sule
Fredrik Thor

Redeye AB
Mäster Samuelsgatan 42, 10tr
111 57 Stockholm

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.

Redeye Equity Research team

Management

Björn Fahlén
bjorn.fahlen@redeye.se

Tomas Otterbeck
tomas.otterbeck@redeye.se

Technology Team

Hjalmar Ahlberg
hjalmar.ahlberg@redeye.se

Henrik Alveskog
henrik.alveskog@redeye.se

Alexander Flening
alexander.flening@redeye.se

Douglas Forsling
douglas.forsling@redeye.se

Forbes Goldman
forbes.goldman@redeye.se

Jessica Grünewald
jessica.grunewald@redeye.se

Jesper von Koch
jesper.vonkoch@redeye.se

Anton Hoof
anton.hoof@redeye.se

Rasmus Jacobsson
rasmus.jacobsson@redeye.se

Viktor Lindström
viktor.lindström@redeye.se

Fredrik Nilsson
fredrik.nilsson@redeye.se

Jacob Svensson
jacob.svensson@redeye.se

Danesh Zare
danesh.zare@redeye.se

Editorial

Joel Karlsson
joel.karlsson@redeye.se

Mark Siöstedt
mark.siostedt@redeye.se

Life Science Team

Oscar Bergman
oscar.bergman@redeye.se

Christian Binder
christian.binder@redeye.se

Filip Einarsson
filip.einarsson@redeye.se

Mats Hyttinge
mats.hyttinge@redeye.se

Ethel Luvall
ethel.luvall@redeye.se

Gustaf Meyer
gustaf.meyer@redeye.se

Erik Nordström
erik.nordstrom@redeye.se

Richard Ramanius
richard.ramanius@redeye.se

Kevin Sule
kevin.sule@redeye.se

Fredrik Thor
fredrik.thor@redeye.se

Johan Unnerus
johan.unnerus@redeye.se

Disclaimer

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Redeye Rating (2023-02-23)

Rating	People	Business	Financials
5p	7	6	2
3p - 4p	144	142	38
0p - 2p	23	26	134
Company N	174	174	174

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.