ALZECURE PHARMA

First-in-class tablets, team with significant big pharma experience

AlzeCure Pharma is a Swedish-based pharmaceutical company with potentially first-in-class proprietary and novel targeted small molecule (tablets) candidates for neurodegenerative diseases with a primary target on Alzheimer's Disease (AD). AlzeCure's management team has extensive big pharma experience, and formed an integral part of AstraZeneca's CNS department.

First product has started clinical development

AlzeCure's lead asset ACD855, recently started clinical development. By 2020, AlzeCure aims to be in a position where partnering for further clinical development and commersialisation of ACD855 can be explored. Moreover in 2020, it aims to have another tablet product into clinical stage development. The company currently has five product candidates in development that belongs to two product classes with novel mechanism of action; the BDNF/NGF modulators in the NeuroRestore class and the gamma secretase modulators in the Alzstatin class. The market size that AlzeCure's product development targets is fairly significant, an estimated 50 million people today live with neurodegenerative disorders.

Three main reasons for the long-term attraction of the shares

We see three main reasons for the market to see the long-term attraction in the AlzeCure shares. First, the knowledge about early detection and biomarkers for neurodegenerative disorders is developing fast, which could have significant implications for future clinical trials, product development timelines, and approvals in the area. AlzeCure applies a genetically and biomarker driven development, utilizing innovative research to develop the best candidates treating the right patient population with the right disease stage, which potentially could increase the probability of success. Second, in 2018, both FDA and EMA revised their guidelines on clinical trials for Alzheimer's disease medicines, paving the way for approving products on the basis of biomarker data, treating early stage disease. Third, AlzeCure's clinical trials are and will be designed to enable initial efficacy evaluations already during the first stages of clinical development, clinical trials that will report from early 2020 and onwards.

Stepwise approach to valuation

At this early development stage, we believe a stepwise valuation approach is a more reasonable valuation approach for AlzeCure than a very long-term standard discounted cash flow valuation approach. For 2019, we see a reasonable valuation range between SEK17-20 per share (SEK450-650m excluding cash), assuming a year-end cash position of SEK200m. For 2020, we see a range between SEK29-34 per share (SEK0.9-1.1bn excluding cash), assuming that the first efficacy signals with ACD855 is strong, the first product from the Alzstatin product class has started clinical development, and that the earlier stage product portfolio develops as planned.

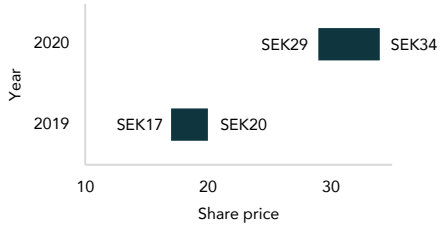
* Source: Factset - Data as per 2019-01-14

OUTPERFORM

Initiating Coverage

We initiate coverage on AlzeCure Pharma with a step wise valuation approach. For 2019, we see a reasonable valuation range between SEK17-20 per share suggesting 102-138% upside to the current share price. For 2020, we see a range between SEK29-34 per share suggesting 245-305% upside to the current share price.

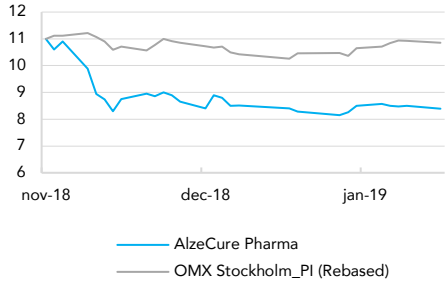
Stepwise valuation approach



Key Data

Ticker	ALZCUR
Share price* (close)	SEK8.398
Free float	71.8%
Market cap*	SEK317.2m
Website	alzecurepharma.se
Average daily volume*	SEK1.66m

Share Price* (SEK)



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The investment case

We initiate coverage on AlzeCure Pharma with an Outperform rating. Based on our step wise valuation approach, we see a reasonable valuation range between SEK17-20 per share suggesting 102-138% upside to the current share price for 2019. For 2020, we see a range between SEK29-34 per share suggesting 245-305% upside to the current share price.

We see three main reasons for the market to see the long-term attraction in the AlzeCure shares.

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Second, in 2018, both FDA and EMA revised their guidelines on clinical trials for Alzheimer's disease medicines, paving the way for approving products on the basis of biomarker data, treating early stage disease.

Third, AlzeCure's clinical trials will be designed to enable initial efficacy evaluations already during the first stages of clinical development, trials that will report from early 2020 and onwards.

The market size that AlzeCure's product development targets is fairly significant, an estimated 50 million people today live with neurodegenerative disorders.

AlzeCure Pharma AB was founded in 2016 and is based at the Karolinska Institute, Stockholm. The people behind the company has extensive background from the pharma industry, and particularly from AstraZeneca (AZN).

By 2020, AlzeCure aims to have one product through phase 1 clinical trials and at a stage where potential partnering can be explored, another product having started clinical stage development, and an extensive portfolio of earlier stage development projects. AlzeCure currently has five identified drug development candidates.

Five products in two tablet based product platforms: NeuroRestore and Alzstatin

Several product candidates in AlzeCure's development portfolio has a background from AZN's research and development. The products are divided into two key project platforms; NeuroRestore and Alzstatin, both being novel and potentially disease modifying therapeutic approaches for the prevention and treatment of neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease and traumatic brain injury.

CHART 1: Key development timelines, AlzeCure

	2012 – 2018	2019 – 2020	2021 – 2022
Neuro Restore	› **ACD 855** Pre-clinical completion and Phase I – Initiation	› **ACD 855** Phase I – Completion › **ACD 856** Phase I – Initiation	› **ACD 855** – Mid-stage trials ongoing › **ACD 856** – Phase I completion
Alzstatin	› **ACD 679** Pre-clinical completion	› **ACD 679** – Phase I ongoing › **ACD 680** – Pre-clinical completion	› **ACD 679** – Phase I completion › **ACD 679** – Phase II/III preparation › **ACD 680** – Follow-up compounds after clinical stage
Pre-Clinical	› Broad program ongoing	› **ACD 857** – Follow-up compounds in pre-clinical research	› Follow-up compounds for NeuroRestore and Alzstatin product classes
Funding	› AZN discovery and pre-clinical investment legacy › Investments from Foundations and Capital from Equity Investors › SEK 350m invested	› NeuroRestore – Potential partnering, one or several development areas	› Alzstatin – Potential partnering, one or several development areas

Source: Company information

Why the interest now?

The scientific knowledge, and regulators' view, is developing fast

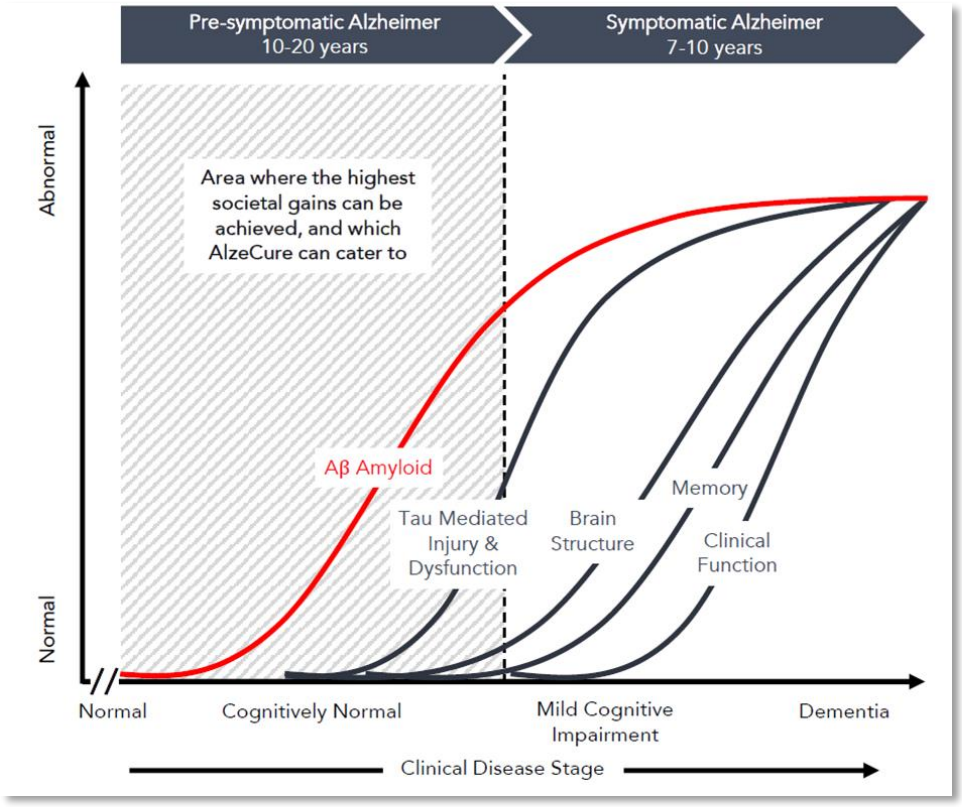
The scientific knowledge about disease biology, diagnostics, biomarkers, importance of early detection and treatment, and potential targets for drug development in the area for neurodegenerative disorders is developing fast. This could have significant implications for the design and follow-up of future clinical trials, product development timelines, and product approvals in the area.

Blood based biomarker tests being developed

In early 2018, researchers published a study ("High performance plasma amyloid-beta biomarkers for Alzheimer's disease", Nature 554, 249-254, 8 February 2018) describing the possibility to distinguish circulating cerebral related amyloid beta in the bloodstream, as opposed to circulating peripheral amyloid beta. Since the measurement of disease biomarkers such as amyloid beta so far been done with cerebrospinal fluid, the development of blood-based biomarker measurements could play a significant role in the efficacy follow-up of future AD trials.

CNS trials ahead will be increasingly driven by biomarker data, we believe, which should have important implications for selection of patients into clinical trials, treatment follow-up, and clinical trial endpoints, which may lead to significantly reduced development timelines in the area.

CHART 2: Alzheimer's disease progression



Source: Company information

New guidelines from FDA as well as EMA regarding Alzheimer's disease trials

Moreover, regulators in the US as well as in Europe issued new guidelines in 2018 about the development of new treatments for early AD, stressing the importance of early detection and treatment, and that effects on biomarkers in principle may serve as the basis for accelerated conditional approvals of new products.

In February 2018, FDA published a draft guideline for the development of new treatments of early AD. These guidelines ("Early Alzheimer's Disease: Developing Drugs for Treatment, Guidance for Industry", U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), February 2018, Clinical/Medical Revision 1) stressed the importance of early detection and treatment, and that an effect on the characteristic pathophysiologic changes of AD, as demonstrated by an effect on various biomarkers, analysed as a primary efficacy measure, may serve as the basis for an accelerated approval.

This means that if the biomarker effects would be found to be reasonably likely to predict a clinical benefit, a post-approval requirement for a study to confirm the predicted clinical benefit would be the follow-up step in such future scenario for AD drug development.

Moreover, in February 2018, EMA (The Europe Medicines Agency) published its "Revised guideline on clinical studies for Alzheimer's disease medicines".

EMA highlighted that "recent progress in understanding the pathophysiology of Alzheimer's disease suggests that the biological changes associated with the disease start to occur as early as 10 to 20 years before clinical symptoms start to appear. Many of the experimental medicines are therefore investigated in earlier disease stages as certain treatments may be more effective at that stage than later in the illness".

CHART 3: February 2018 EMA update

Source: www.ema.europa.eu

The CNS and AD area have seen many failed early and late stage drug development projects, but companies such as Roche, Novartis, Biogen, Lilly, AbbVie and Boehringer Ingelheim continue with broad development efforts and new investments, both in diagnostics and therapeutics, and several earlier stage development companies focusing on the CSN area, including Denali, Alector, AC Immune and Neurimmune are emerging with biomarker driven early-stage and clinical-stage product development.

What makes this case unique?

An estimated 50 million people today live with neurodegenerative dementia related disorders, including 7.5 million in Europe and 5.5 million in the US. In the US, the number of people aged 65 and older with Alzheimer's dementia is projected to reach 7.1 million by 2025, a 29% increase compared with 2018, according to the US Alzheimer's Association, 2018 Alzheimer's Disease Facts and Figures. By 2050, the number of people aged 65 and older, with Alzheimer's dementia may grow to a projected 13.8 million in the U.S., according to Alzheimer's Association.

This should mean that drug regulators, patients and others should have a fair amount of interest in potential disease modifying treatments of neurodegenerative disorders. We believe the recently revised drug development guidelines issued by both FDA and EMA during 2018 is one good example of that.

AlzeCure one of a very few companies with a focus on tablet based products with a novel mechanism of action in the area

While many injectable antibodies are in late-stage development for the treatment of AD, AlzeCure's drug development candidates are based on small molecules, i.e. tablet formulations, which should have several practical advantages. While regulators are increasingly stressing the importance of early detection and early treatment in AD, convenient tablet-based products with benign safety profiles could play a significant role. AlzeCure is one of the few companies with a tablet-based approach in the area with products having a novel mechanism of action.

Also, every ongoing late-stage clinical trial in the area today will assess the clinical efficacy based on evaluation of clinical scores and various symptoms, while clinical trials ahead in CNS increasingly will be driven by biomarker data, we believe.

Phase 1b trials could inform decisions on further testing, including potential registrational trials

As an example, the US based company Denali in December 2018 said that it had enrolled the first patient into a 30-patient phase 1b trial with DNL201 in Parkinson's disease. Following drug dosing in 122 healthy subjects in the phase 1a trial, the results from the first patient trial will provide safety and biomarker data by Q4 2019 which, according to Denali, will inform decisions on further clinical testing of the product, including potential registrational trials.

This should mean that while all late-stage trials that will report in 2019-2020 face the same significant challenges in terms of how the evaluation of clinical efficacy is done, the early clinical stage, biomarker driven, trials that start these days and the years ahead, including AlzeCure's early clinical stage development trials, potentially can inform about design and evaluation of registrational trials, which may enable a significantly shorter route from early development to late-stage development.

Valuation summary

We believe a stepwise valuation approach over time, excluding the development of its cash balance, will be seen as a more reasonable valuation approach for AlzeCure at this stage compared with a very long-term standard discounted cash flow valuation approach, and allow for a reasonable risk/reward profile in the years ahead.

For the near term, until the end of 2019, we see a reasonable valuation range, excluding cash, of SEK450-550m (SEK17-20 per share assuming a year-end net cash position of SEK200m) with:

- One product having entered clinical development
- A second product being in preparation for entering clinical development in late 2019
- Continued development of follow-compounds in pre-clinical development.

The main news updates from AlzeCure this year should be about the progress of the ongoing first clinical trial, and the progress towards the initiation of its second clinical trial.

In the next stage, towards H1 2020, we see SEK0.9-1.1bn as a reasonable equity valuation range (SEK29-34 per share including cash), assuming:

- AlzeCure's recently started first clinical stage development trial with NeuroRestore goes well, demonstrating tolerability and efficacy that will lead to continued clinical development and potentially registrational trials
- The development of the product portfolio elsewhere develops as planned, including initiation clinical development with the first Alzstatin product
- That the company at this stage has seen the first efficacy signal in a clinical trial with the first NeuroRestore product.

Towards early 2021, we see a reasonable equity valuation range of SEK1.7-2.3bn (SEK50-66 per share including cash) assuming:

- AlzeCure has demonstrated its ability to sign a first significant product development partner for the lead candidate within the NeuroRestore product class
- The broader 2020 scenario including advancing the first NeuroRestore product into phase 2 development has been achieved
- The continued phase 1 program with the lead Alzstatin product
- The potential announcement of first efficacy results with Alzstatin.

Towards late 2022, we see a reasonable valuation range of AlzeCure's equity in the range of SEK3.5-4.5bn (SEK98-124 per share including cash), assuming:

- The continued development of a broad and large phase 2 program with the lead NeuroRestore product has resulted in the generation of the first phase 2 data
- The progress of its lead product from the Alzstatin product class through phase 1 and into phase 2 development trials
- The signing of a second collaboration partner
- The broader 2022 scenario has been achieved.

The comparison with other listed development companies is detailed elsewhere in this report.

Background

Significant ongoing industry investments

New investments in the area continue to be very significant

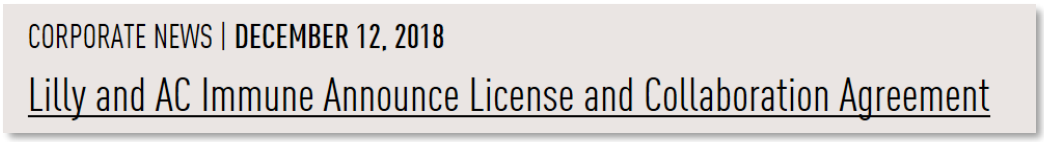
New investments into the AD area continue to be very significant, and several late-stage clinical trials are ongoing. These trials, however, are evaluating the clinical efficacy by means of clinical scores and symptoms, while future clinical trials in the area should be driven by detection and treatment of early disease.

Interestingly, already at the timing of the first patient dosing in phase 1b, a company such as US based Denali mentions that a trial at this early stage will inform about further clinical testing, including potentially registrational trials.

Three recent major industry collaborations

Three recent major announcements of industry collaborations in the area are Lilly's license and collaboration agreement with AC Immune of Switzerland, Sanofi's similar deal with Denali, and a deal between Biogen and C4 Therapeutics.
In mid-December 2018, Lilly said that the collaboration with AC Immune would combine AC Immune's proprietary Morphomer platform technology with Lilly's clinical development expertise and commercial capabilities, and that the collaboration would focus primarily on AC Immune's lead molecule, ACI-3024, which was said to have been demonstrated tau aggregation inhibition in preclinical models.

CHART 4: Lilly CHF60m collaboration announcement with potential CHF1.7bn payments



Source: www.lilly.com

Part of the transaction were that AC Immune will receive an upfront payment of CHF80m as well as USD50m in exchange for a note, convertible to equity at a premium. Moreover, AC Immune is also said to be eligible to receive CHF60m in potential near-term development milestones, and other potential development, regulatory and commercial milestones up to approximately CHF1.7b as well as tiered royalty payments in the low double digits.

CHART 5: Denali and Sanofi collaboration announcement

Source: www.denalitherapeutics.com

In late October 2018, Denali said that its collaboration with Sanofi covering candidate RIPK1 inhibitors have the potential to treat Alzheimer's disease, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS) and systemic inflammatory disease, and that Denali was to receive USD125m upfront payments and future milestone payments that could exceed USD1bn.

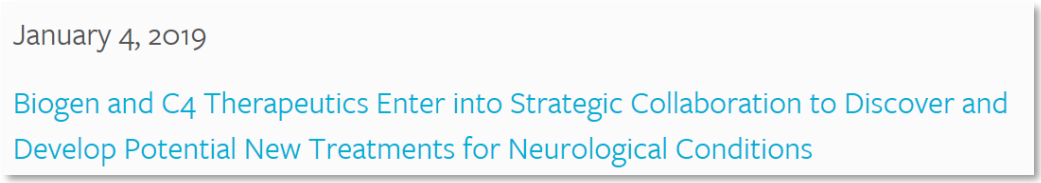
Denali and Sanofi plan to study the product DNL747 in AD, ALS and MS, and DNL758 in systemic inflammatory diseases. At the time of announcing the collaboration, it was added that phase 1b studies with DNL747 in AD and ALS patients are expected to commence in the near-term. Denali will lead phase 2 clinical trials in AD while Sanofi will lead phase 2 trials in MS and ALS. The collaboration was also said to include additional pre-clinical RIPK1 inhibitor molecules.

In January 2019, Denali announced that it had dosed the first patient in the 28-day phase 1b trial with DNL747 in ALS, with the primary purpose to gain safety and biomarker data (measured through blood and cerebrospinal fluid) and to support dose selection. Already in connection to the first dosing of the first patient, Denali added that the results from the study will inform decisions on further clinical testing, including potential registrational trials. DNL747 targets a pathway called RIPK-1, which is said to be a critical signaling protein in the inflammatory TNF receptor pathway. Results from the study is expected during Q4 2019.

Denali has also announced that it has dosed the first patient in a 28-day phase 1b trial with DNL201 in Parkinson's disease, and also here added that the study will inform decisions on further clinical testing, including potential registrational trials. Data from the 30-patient trial is expected during Q4 2019. DNL201 is a small molecule inhibitor of so called leucine-rich repeat kinase 2 (LRRK2). LRRK2 is a regulator of lysosomal function, which is said to be impaired in PD and may be restored by LRRK2 inhibition.

In early January 2019, Biogen and C4 Therapeutics announced that they have entered into a strategic collaboration to investigate the use of C4 Therapeutic's novel protein degradation platform to discover and develop potential new treatments for neurological conditions such as AD and PD. Under the agreement, C4T will provide expertise and research services in targeted protein degradation, while Biogen will provide neuroscience expertise and drug development capabilities.

CHART 6: Biogen and C4 Therapeutics collaboration announcement



Source: www.biogen.com

According to the announcement, Biogen will pay C4 Therapeutics up to a total of USD415m in upfront and potential future milestone payments plus potential future royalties.

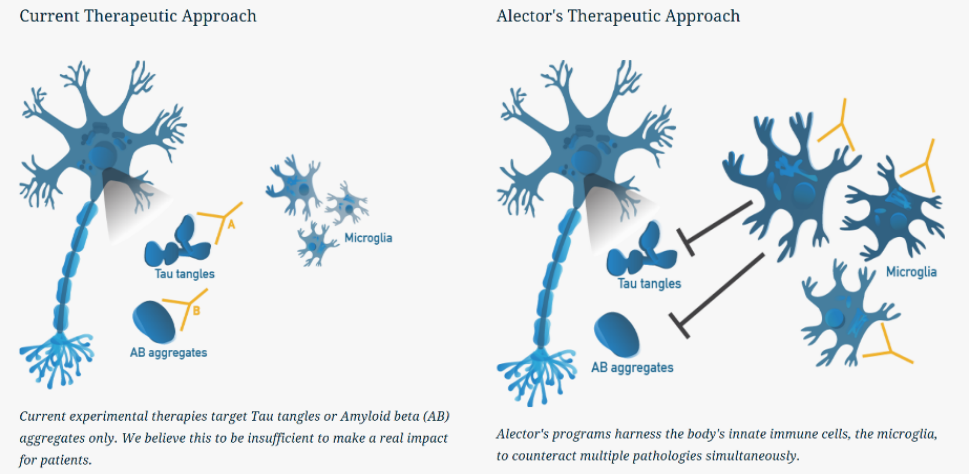
Alector with two products recently having entered clinical development preparing for an IPO; USD400m pre-clinical funding

Another significant industry event is the pending IPO of Alector, San Francisco, US, established in 2013. Alector raised USD133m in 2018 in a series E financing round, and is now aiming to become public. Since its inception, Alector has raised around USD400m, including USD200m from AbbVie in 2017.

Alector has moved ten programs into preclinical research, and advanced two product candidates into clinical development. Its most advanced compound, AL001, was dosed in 42 healthy subjects in a single ascending dose phase 1 study, a drug that will target a genetic subset of patients with frontotemporal dementia in later trials. A phase 1b study is planned for H1 2019, with a phase 2 trial expected in H1 2020.

Alector's other product in clinical stage, AL-002, is targeting a triggering receptor expressed on so called myeloid cells 2 (TREM2), known to contribute to the development of Alzheimer's and other neurodegenerative diseases. AL-003 is targeting a transmembrane receptor, called SIGLEC-3, thought to be involved in the development of neurodegenerative disorders, and is said to move into clinical stage testing during 2019.

CHART 7: Alector's view on its therapeutic approach



Source: www.alector.com

A changed FDA view on AD drug development

Regulators' view: trials should be driven by biomarker data, since there is no clinical outcome to assess

Regarding regulators' view in drug development in the area, in 2018, both FDA and EMA (Europe Medicines Agency) published updates on their guidelines for Alzheimer's disease clinical trials. Both regulators stressed that the knowledge about early signs for neurodegenerative disorders have improved significantly in recent years, and that clinical trials in the future in the area should be driven by biomarker data, since there is no clinical outcome to assess in the earlier stages of the disease.

While all ongoing late-stage clinical trials are based on clinical outcome measures, such as the Clinical Dementia Rating-Sum of Boxes (CDR-SB) Scale Score, Alzheimer's Disease Assessment Scale-Cognition 13 (ADAS-Cog-13) or Clinical Dementia Rating-Global Score (CDR-GS), FDA wrote in its updated guidelines that "because it is highly desirable to intervene as early as possible in AD, it follows that patients with characteristic pathophysiologic changes of AD but no subjective complaint, functional

impairment, or detectable abnormalities on sensitive neuropsychological measures are an important target for clinical trials".

The guidelines are called "Early Alzheimer's Disease: Developing Drugs for Treatment, Guidance for Industry", U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), February 2018, Clinical/Medical Revision 1.

Regarding the efficacy measures in future AD trials, FDA continued to say in the guidelines, as opposed to how the ongoing late-stage clinical trials are being evaluated in terms of efficacy, "a clinically meaningful benefit cannot be measured in these patients because there is no clinical impairment to assess (assuming that the duration of a trial is not sufficient to observe and assess the development of clinical impairment during the conduct of the trial)".

Biomarker data may serve as the basis for accelerated approval

Importantly about the use of biomarkers, FDA stressed that "In Stage 1 (early stage patients, our comment) patients, an effect on the characteristic pathophysiologic changes of AD, as demonstrated by an effect on various biomarkers, may be measured. Such an effect, analyzed as a primary efficacy measure, may, in principle, serve as the basis for an accelerated approval (i.e., the biomarker effects would be found to be reasonably likely to predict clinical benefit, with a post-approval requirement for a study to confirm the predicted clinical benefit)".

FDA concludes with "as with the use of neuropsychological tests, a pattern of treatment effects seen across multiple individual biomarker measures would increase the persuasiveness of the putative effect".

So industry investments in the area for neurodegenerative disorders continue to be very significant, and regulators have opened up for new standards in terms of assessing the efficacy of drugs in development for AD.

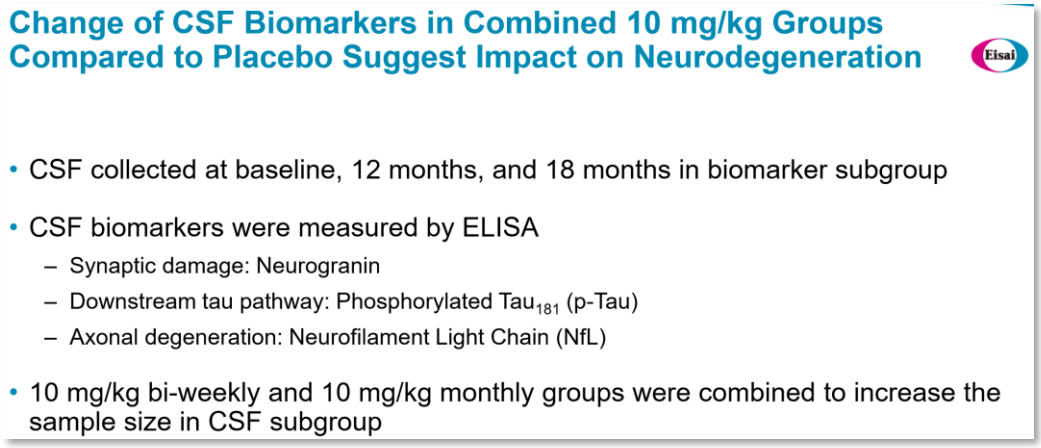
The first late-stage, biomarker driven trial, may be in store

Interestingly, in terms of recent significant new knowledge from clinical trials, in July 2018, it was demonstrated that an antibody based injectable product (BAN2401 developed by BioArctic and Eisai) managed to demonstrate an improvement in clinical symptoms as well as a consistent effect on five different biomarkers through a mechanism of action which focuses on targeting cerebral amyloid beta.

Consistent effect on five different biomarkers in a BAN2401 substudy

The biomarkers (measured with cerebrospinal fluid, CSF) in the BAN2401 study included markers of synaptic damage (neurogranin), tau pathology (phosphorylated-tau, p-Tau), and axonal degeneration (neurofilament light chain, NfL) as well as beta-amyloid 1-42 and total tau.

CHART 8: Biomarker focus in the BAN2401 phase 2b trial



Source: Clinical and Biomarker Updates from BAN2401 Study 201 in Early AD, 11th Clinical Trials on Alzheimer's Disease (CTAD) Conference October 24-27, 2018

These results were achieved despite that the study subjects had AD at an advanced stage. The study was presented at the 2018 Alzheimer's Association International Conference (AAIC), 25 July 2018, in Chicago, Illinois, US, with further details of the study presented in at the 11th Clinical Trials on Alzheimer's Disease (CTAD) conference in Barcelona, Spain, in late October 2018.

Several ongoing clinical trials, particularly from Roche and Biogen, are focusing on similar approaches, while companies such as Novartis and Amgen are conducting major clinical trials testing whether the onset of AD symptoms can be delayed or prevented by drug intervention before the onset of symptoms in patients deemed to be at high risk for the disease.

Some near-term important product developments broadly in the area for product development in the neurodegenerative disease area are as follows:

- 2019: the potential announcement of phase 3 study design and clinical trial initiations with BAN2401, developed by BioArctic, Eisai and Biogen. The details from the phase 2b trial demonstrated a consistent efficacy on five different biomarkers, potentially paving the way for a phase 3 efficacy evaluation to be based on biomarkers as a primary and not secondary outcome measure
- 2019: Denali initiate phase 1 trials with DNL788, targeting Alzheimer's disease
- 2019: phase 3 study enrollment completed into Roche's large gantenerumab, an injectable antibody, phase 3 program
- 2019: phase 3 study enrollment completed into Biogen/Eisai's large 2,700 patient elenbecestat tablet program
- Q1 2019: the US CNS company Alector becomes a publicly listed company
- H1 2019: Alector initiates phase 1b development with AL-001, a drug with orphan drug designation targeting treatment of frontotemporal dementia

(FTD). Around 60,000 people in the US and 110,000 people in Europe lives with FTD, the second most common early-onset form of dementia

- Q4 2019: Denali reports phase 1b trial results with DNL747 in patients with ALS, potentially enabling the initiation of registrational trials
- Q4 2019: Denali reports phase 1b trial results with DNL201 in 30 patients with Parkinson's disease, potentially enabling the initiation of registrational trials
- Q4 2019/2020: AlzeCure initiates clinical development with its first novel gamma secretase modulator, ACD679
- 2019: Alector initiates clinical development of another two compounds.
- 2020: study results from two large 1,600-patient phase 3 trials, ENGAGE and EMERGE, with the injectable antibody aducanumab, developed by Biogen and AC Immune. These trials will be the next significant milestones in terms of the use of injectable amyloid-targeting antibodies for AD treatment
- 2020: phase 3 study results from Roche's two large 24-months studies with crenezumab (CREAD-1 and CREAD-2). These trials have similar design and are scheduled to report after Biogen's ENGAGE and EMERGE studies
- 2023: study results from the DIAN-TU trial, a study of potential disease modifying treatment for individuals at risk for early onset of Alzheimer's disease caused by genetic mutations. Products from Lilly, Roche and JNJ are involved in this 438-patient trial

  2024: study results from the novel GENERATION-S2 trial with Novartis BACE inhibitor tablet CNP520. This large 2,000-patient trial aims to determine the effects of cognition and underlying AD pathology in people at risk for the onset of clinical symptoms of AD based on their age, APOE genotype and amyloid levels. Amgen is collaborating with Novartis on the project, and the novel vaccine CAD106, jointly developed with Karolinska Institute, Stockholm, is involved in the GENERATION-S1 trial.

CHART 9: Summary of ongoing late-stage clinical trials in Alzheimer's disease

Platform	Drug	Study	Primary outcome	Companies	Participants	2019	2020	2021	2022	2023	2024
Early Disease	Aducanumab	ENGAGE	CDR-SB	Biogen	1,605						
	Aducanumab	EMERGE	CDR-SB	Biogen	1,605						
	Crenezumab	CREAD-1	CDR-SB	Roche/AC Immune	813						
	Crenezumab	CREAD-2	CDR-SB	Roche/AC Immune	750						
	Elenbecestat	MISSION AD 1	CDR-SB	Biogen/Eisai	1,330						
	Elenbecestat	MISSION AD 2	CDR-SB	Biogen/Eisai	1,330						
	Gantenerumab	NCT 03443973	CDR-SB	Roche/MorphoSys	760						
	Gantenerumab	NCT 03444870	CDR-SB	Roche/MorphoSys	760						
	BAN2401	TBD	CDR-SB	Biogen/Eisai/ BioArctic							

Source: wwww.clinicaltrials.gov

CHART 10: Summary of major drug development programs in AD disease prevention

Platform	Drug	Study	Primary outcome	Companies	Participants	2019	2020	2021	2022	2023	2024
Disease Prevention	CNP520 CAD106	Generation – S1	Time to Event	**Novartis/Amgen**	1,340						
	CNP520	Generation – S2	Time to Event	**Novartis/Amgen**	2,000						
	Multiple	DIAN-TU	DIAN-TU	**Multiple**	438						

Source: www.clinicaltrials.gov

Valuation: today and onwards

AlzeCure is an early-stage product development company with no expected revenues related to product sales for many years ahead. If phase 1 development with its most advanced product would develop well (phase 1 development started in late 2018) with results in early 2020 and signing a partner already the same year, the first phase 2 development could start in 2021.

Development timelines vary significantly

The timelines for such mid-stage trials can vary significantly: it took six years for BAN2401 (BioArctic/Eisai) to complete a 856-patient phase 2 trial with BAN2401 while other companies such as Biogen's development with aducanumab have been allowed to skip phase 2 based on efficacy signals in phase 1, and to start large scale regulatory trials already after phase 1 results.

It seems that patient enrollment into the larger trials in AD takes at least a year, with two years or more follow-up after the last patient has been treated, so a phase 3 program should typically require 4-5 years from the randomisation of the first patient to the final evaluation of the last participating patient. These future timelines may however be impacted regulators' view on clinical trial design and evaluation, the use of biomarkers, and several other parameters.

We believe at this early stage in AlzeCure's development, to discount the potential value of future revenues, royalties, profits or cash flow that may relate to potential future product sales with such development timelines is not meaningful in our view.

We base our development timelines on these main assumptions:

- NeuroRestore: first product, ACD855, entered clinical stage development in late 2018. Phase 1b results available during H1 2020, including the first signs of a clinical efficacy. Potential signing of a first development partner towards late 2020, or 2021. The initiation of first phase 2 trials around the same timeframe, and report the first mid-stage clinical trial results during 2022

- Alzstatin: first product, ACD679, to enter clinical stage development towards late 2019 or early 2020, with phase 1 results available during H1 2021, including the first signs of a clinical efficacy. Potential signing of a first development

partner towards late 2021. The initiation of the first phase 2 trials around the same timeframe, and report the first mid-stage clinical trial results during 2023

We believe the following stepwise valuation approach over time, excluding the development of its cash balance, will be seen as reasonable for AlzeCure and allow for a reasonable risk/reward profile.

2019: SEK17-23 per share including cash (SEK450-550m equity valuation range, excluding cash balance) with first product having entered clinical-stage development

For the near term, we see a reasonable equity valuation range of SEK450-550m with one product having entered clinical development, a second product being in preparation for entering clinical development in late 2019, and continued development of follow-compounds in pre-clinical development.

H1 2020: SEK29-34 per share including cash (SEK0.9-1.1bn equity valuation range, excluding cash balance) assuming a first successful first clinical stage trial and a first efficacy signal

Assuming that AlzeCure's recently started first clinical stage development trial goes well, demonstrating tolerability and efficacy that will lead to continued clinical development and potentially registrational trials, we see SEK0.9-1.1bn as a reasonable equity valuation range, assuming the development of the product portfolio elsewhere develops as planned. This assumption is based on that the company at this stage has seen the first efficacy signal in a clinical trial with the first NeuroRestore product.

H1 2021: SEK50-66 per share including cash (SEK1.7-2.3bn equity valuation range, excluding cash balance) with the signing of a first significant development partner

Towards early 2021, we see a reasonable equity valuation range of SEK1.7-2.3bn assuming AlzeCure has demonstrated its ability to sign a first significant product development partner for the lead candidate within the NeuroRestore product class, and that the broader 2020 scenario including advancing the first NeuroRestore product into phase 2 development has been achieved as well as the continued phase 1 program with the lead Alzstatin product, and the potential announcement of first efficacy results with Alzstatin.

H2 2022: SEK98-124 per share including cash (SEK3.5-4.5bn equity valuation range, excluding cash balance) with one or two phase 2 programs and two significant industry partners

Towards late 2022, we see a reasonable equity valuation range of AlzeCure's equity in the range of SEK3.5-4.5bn, assuming that the continued development of a broad and large phase 2 program with the lead NeuroRestore product has resulted in the generation of the first phase 2 data, the progress of its lead product from the Alzstatin product class through phase 1 and into phase 2 development trials, the signing of a second collaboration partner, and that the broader 2022 scenario has been achieved.

Comparison with BioArctic

A comparison to BioArctic, and also Irlab, seems most relevant

Compared with other listed drug development companies, AlzeCure is an early-stage company with its most advanced product recently having entered clinical stage development. AlzeCure's valuation will naturally be compared with most other locally listed drug development stage companies, but most particularly with BioArctic since the two companies are active in the same area, i.e. neurodegenerative disorders. We also later in this document compare a bit more in detail with Irlab, since they also focus on CNS disorders, however with Irlab having a clear focus on Parkinson's disease. There are also international peers such as AC Immune, Neurimmune and Denali within CNS that may longer term become important peer comparisons, but we believe the main development and valuation comparison will be based on BioArctic.

Compared with BioArctic, we believe a valuation comparison can be based on the following:

- BioArctic was listed in October 2017 at pre-money valuation of SEK1.2bn, with one product close to phase 2 completion and another product group being partnered with a large pharma company
- Including cash, BioArctic's market cap was around SEK2.2bn until July 2018 when the phase 2 results from its lead product asset were announced
- Following BioArctic's phase 2 results that indicated an efficacy signal with BAN2401, the market cap increased to around SEK9bn, i.e. around SEK8bn excluding the SEK1bn cash position, and is currently around SEK6bn excluding cash

As comparison, these will be, we believe, AlzeCure's overall near-term development targets by 2020, and reaching these targets should be the main catalysts for the future valuation changes:

1. Advance its lead product candidate within the NeuroRestore product class, ACD855, through phase 1 trials by early 2020
2. Sign a collaboration partner for a broader development program with its most advanced product within the NeuroRestore product class during 2020
3. Initiate phase 1 development with its most advanced product within the Alzstatin product class, ACD679, during 2020
4. Broaden the clinical product portfolio in 2020 and onwards

Moreover, these will be, we believe, AlzeCure's overall mid-term development targets by 2022:

1. Continue a broad and large phase 2 program with the most advanced NeuroRestore product
2. Advance its lead product within the Alzstatin product class through phase 1

3. Sign a collaboration partner for a broader development program with its most advanced product within the Alzstatin product class

4. Advance follow-up products into phase 1 development

5. Continue to broaden the pre-clinical product portfolio

We believe the valuation change triggered by the BAN2401 phase 2 study will have an impact on the valuation on future mid-stage development projects in the area, i.e. that the upside from phase 2 trials may not be 6-7x for AlzeCure, but that valuation in advance may be higher than it was for BioArctic, naturally assuming that the signals from the initial stage of clinical trials are strong.

Assuming that AlzeCure may during 2022 be valued towards a range of SEK3.5-4.5bn excluding cash, based on a company and development profile described above, we believe an upside of that magnitude compared to the valuation we see as reasonable near term (SEK450-550m) will be viewed as a reasonable risk/reward profile by the equity market, again assuming that AlzeCure's company and product developments have progressed as described.

A significant upfront payment should be at least USD50m

Overall, we believe up-front payments of at least USD50m are required, if the equity market would see potential partnering agreements as financially significant.

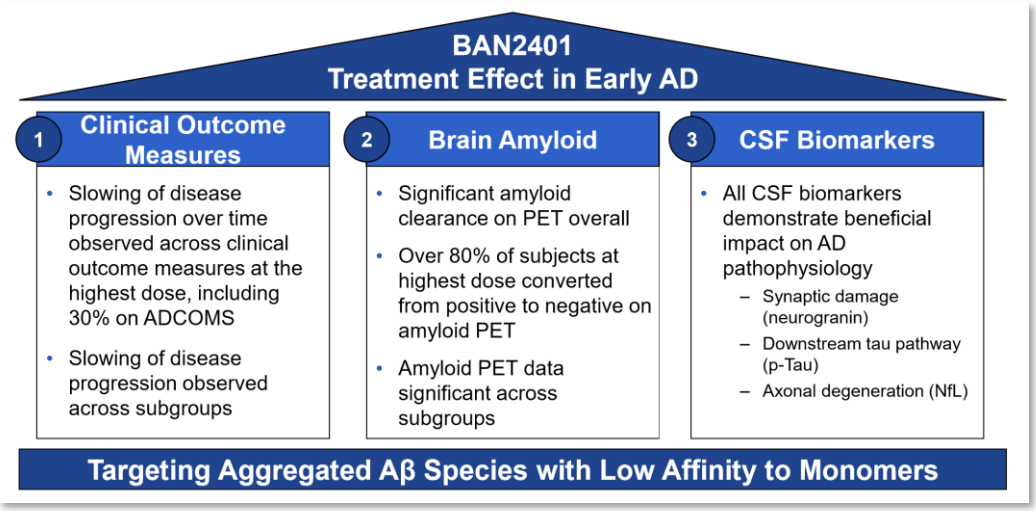
Potentially smaller additional agreements covering niche indications with smaller up-front payments may be signed, but we have not included this into our lists of main catalysts in this valuation scenario. However, such events could be seen important for the case since it could lead to a perception of AlzeCure as being a broader company than being dependent on one disease area.

These simple assumptions naturally disregard that developments in the broader market for AD treatments and emerging opportunities for early disease detection, diagnosis and treatment monitoring may increase or decrease the perceived attraction of doing product development efforts in the area.

Next major late-stage trials will be aducanumab in 2020

In particular, Biogen will report results from two large phase 3 trials in early 2020, trials in fairly advanced disease with a similar risk of missing the efficacy endpoint as most other late stage developments in the area. Also, the novel and long-term disease prevention trial with Novartis CNP520 will later be reported, which together with the DIAN-TU trial program will be the first to report whether pre-symptomatic treatment can delay the onset of clinical symptoms and progression of the disease.

CHART 11: BAN2401 on clinical outcome measures, brain amyloid, and CSF biomarkers



Source: Clinical and Biomarker Updates from BAN2401 Study 201 in Early AD, 11th Clinical Trials on Alzheimer's Disease (CTAD) Conference October 24-27, 2018

Since the valuation of BioArctic increased by around SEK7bn when the results from its major phase 2 trial was announced, this may influence the valuation of earlier stage assets in the area since the significant potential value accretion already in mid-stage development has become visible to the equity market.

Naturally, the valuation of BioArctic could also significantly change over time. In Alzheimer's disease, the industry is targeting an area with 50 million with known disease, a significant portion of this patient pool receives treatment today with medicines that are not regarded as efficacious, treatments that could delay the progression of the disease would be seen as major breakthroughs, and cost savings with such medicines would be significant.

It also seems to use that several treatment opportunities will be available in the future, spanning from tablet treatments with very benign side effects profile for long-term use with the intention of disease prevention, to powerful intravenous medications for plaque eradication in more advanced stages of disease.

As a reminder about the comparison between AlzeCure and BioArctic

- BioArctic's lead asset, BAN2401, has reported promising results from a large prospective 856-patient trial. BioArctic started phase 1 development with BAN2401 in 2010 and the phase 2 trial detailed that were reported in July and October 2018 was launched in 2012. The phase 2 trial design with BAN2401 was indeed complex and time consuming, but anyway gives an indication of the timelines that could be required for product development in the area. AlzeCure starts phase 1 development in 2018.

- BioArctic has two significant commercial collaborations, Eisai and AbbVie, and AlzeCure may be in a position to sign a first significant agreement in 2020.

- BioArctic's collaboration with Eisai was signed as early as 2005, and the agreement with AbbVie within Parkinson's disease that was signed in 2016 included a major USD80m (SEK702m) up-front milestone payment.

- Around SEK350m has been invested by AstraZeneca, foundations, and equity investors, in AlzeCure's projects.

- BioArctic has so far received EUR47m from Eisai out of total potential payments of EUR218m. Regarding the agreement with AbbVie, the total aggregated value may amount to USD755m plus additional royalty payments on product sales.

- BioArctic had SEK1.0bn cash at the end of Q3 2018 with negative cash flow of SEK111m in 9M 2018 (negative SEK90m in 9M 2017).

- BioArctic seems well funded for several years ahead, unless it completely changes its cash consumption profile. Adding to its strong cash position, BioArctic announced in early November 2018 that AbbVie had exercised its option to license BioArctic's portfolio of antibodies targeting alpha-synuclein for PD, upon which a milestone payment of USD50m will be received

- BioArctic's operating expenses were SEK152m in 9M 2018, compared with SEK133m in FY2017. The share issue that BioArctic made in connection to its listing in 2017 was SEK600m in gross proceeds.

- BioArctic has made major development progress in the last two years compared with the situation in Q3 2016, prior to its agreement with AbbVie, at a time when BioArctic had SEK83m in cash, one collaboration partner, and an ongoing phase 2 trial with BAN2401.

Comparison with other listed drug development companies

Other locally and recently listed drug development companies include Oncopeptides, Camurus, Calliditas, Isofol and Asarina. A CNS focused development stage companies that has been listed for a few years is Irlab. The market valuations of these listed companies naturally vary significantly, and we below briefly review the development stage for these companies, as a reference for AlzeCure's development stage and valuation.

Oncopeptides is the most advanced stage companies, since it expects results from its main phase 3 trial in multiple myeloma during Q3 2019. Moreover, it has a broad set of ongoing clinical trials aiming to broaden the long-term use of its lead candidate drug Ygalo (melflufen) that aims to become a backbone treatment in follow-up treatments of multiple myeloma. Oncopeptides has a market cap of around SEK5bn.

Camurus expected to receive its first FDA approval towards end 2018 for its Brixadi (buprenorphine) extended-release injection for subcutaneous use for the treatment of moderate-to-severe opioid use disorder (OUD) in patients who have initiated treatment

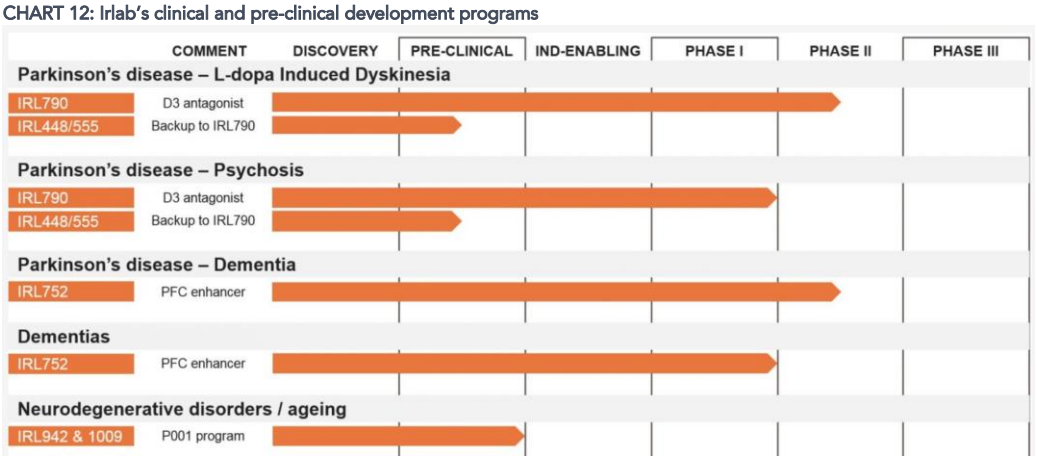
with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. However, FDA instead issued a tentative approval, which means that Brixadi has met all regulatory standards of clinical and non-clinical safety, efficacy and quality for US approval, but final approval of a monthly depot is subject to the expiration of an exclusivity period granted to a marketed product, Sublocade. This may result in a delayed launch for Brixadi of around two years. Camurus has a market cap of around SEK2.5bn.

Irlab's market cap from SEK400m to SEK1.0bn in the months following the first patient data

Irlab's two most advanced products are in phase 2 development for the treatment of Parkinson's disease (PD). IRL752 is aimed to PD related dementia, while IRL790 is aimed at treating levodopa-induced dyskinesia and PD related psychosis. Irlab's main recent development highlights have been as follows:

- October 2015: regulatory approval to start phase 1 development with IRL790
- February 2016: regulatory approval to start phase 1 development with IRL752. At this stage, Irlab's market cap was around SEK400m
- March 2017: positive phase 1 results announced with IRL752 in single-ascending and multiple-ascending dosing studies in healthy volunteers
- May 2017: a 15-patient phase 1b study with IRL790 administered for four weeks in advanced PD. In the four following months after this announcement, Irlab's market cap increased to around SEK1.0bn
- In October 2017, Irlab announced that a phase 2a trial had started with IRL752 in advanced PD
- In January 2018, a UK phase 2a trial was said to have started with IRL790 for the treatment of levodopa-induced dyskynesias, with the ambition to reported top-line data during Q3 2018
- In June 2018, positive headline data from the 32-patient four-week trial with IRL752 were announced. Irlab's market cap at this stage was around SEK1.6bn
- In August 2018, Irlab announced further details from the phase 2a trial with IRL752
- In mid-December 2018, Irlab said that FDA had confirmed that its planned pre-clinical and early clinical package with IRL790 was sufficient to start clinical development in the US, and that the ongoing safety review of the phase 2a trial allowed the trial to continue. Irlab added that FDA gave clear guidance about the design for the planned phase 2b trial with IRL790
- Also in December 2018, 66 patients of the planned 74 were said to have been included in the ongoing phase 2a trial with IRL790, and that recruitment should continue into early 2019. Top-line results were said to be expected within 10 weeks after the inclusion of the last patient in the study, ie during Q2 2019 instead of the earlier plan of Q3 2018

CHART 12: Irlab's clinical and pre-clinical development programs



Source: www.irlab.com

Phase 2b development is also planned for IRL752. Irlab has back-up compounds to IRL752 and IRL790 as well as other novel earlier stage development projects.

Irlab's market cap around SEK2.5bn with two products move into phase 2b

Irlab had SEK152m cash at the end of September 2018 (the latest reported quarterly results), 15 employees, and has a market cap of around SEK2.5bn.

Calliditas main product, Nefocon, is intended for the treatment of a severe chronic autoimmune disease called IgA nephropathy, and the design of the phase 3 trial, which will include 450 patients, is similar to the design of the phase 2b trial. The treatment time in the placebo controlled pivotal trial will be nine months, 150 centres will participate in 19 countries, and top-line data from the first 200 patients is said to be available in H2 2020. These top-line data are said to enable a subsequent submission for regulatory approval. Calliditas has a market cap of around SEK1.5bn.

Isofol's lead drug candidate, arfolitixorin, started phase 3 development in December 2018, with the enrolment of the first patient into a first-line metastatic colorectal cancer trial. The trial has an adaptive design and aim to enrol 440 patients with interim results from treatment of the first 330 patients in Q1 2020 and a planned marketing approval in 2021. If the first phase of the trial will turn out to be too small, up to 660 patients in total can be enrolled in the trial, which would delay head-line trial results to H1 2021 and targeted marketing approval to Q1 2023. Isofol has a market cap of around SEK800m.

Asarina has said that it will initiate a major study of the product sepranolone in menstrual migraine before summer 2019, and added that the pivotal phase 3 trials including the US market for sepranolone will be carried out from 2021, with market launch set for 2023-2024. Asarina's overall ambition is said to become a leading speciality pharma company in women's health, for better understanding, diagnosing and treatment of menstrual related CNS disorders including migraine and depression. Asarina has a market cap of around SEK400m.

Company background

AlzeCure's origin is from AstraZeneca's (AZN) central nervous systems research (CNS). In 2012, AZN divested several CNS product assets to the property company Acturum, which in turn later sold a product portfolio to what today has become AlzeCure. The Alzstatin project is a AZN legacy portfolio, however the NeuroRestore project has been developed entirely in-house by AlzeCure.

During the early years of AlzeCure (2012-16) the development work was supported by grants, support from financial donations, external sources and founders.

According to AlzeCure's estimates, AZN invested around SEK200m in what today is a key part of AlzeCure's product portfolio.

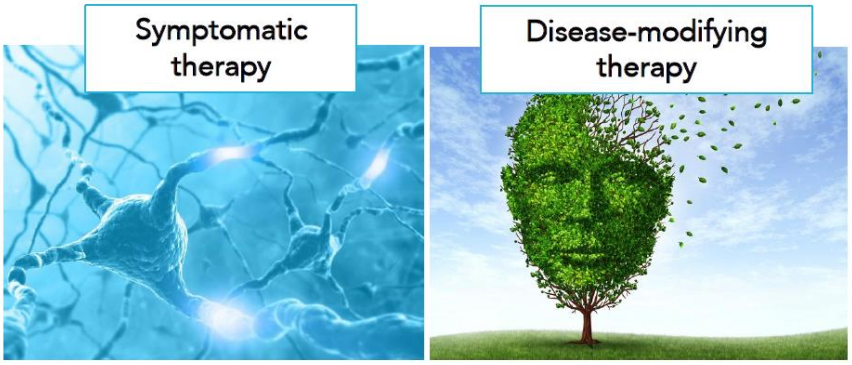
First efficacy signal with NeuroRestore in early 2020

By 2020, AlzeCure's overall ambition is to have completed phase 1 testing with one product, ACD855, and to evaluate whether the product should be partnered or not. Moreover, the company aims to have started clinical trials with other products, and to continue to add new candidates for pre-clinical development, i.e. one product ready for partnering, another one or two in clinical trials, and several follow-up products in the pre-clinical phase.

Alzstatin for early prevention of early disease

AlzeCure's product portfolio is based on two product platforms: NeuroRestore and Alzstatin. While the idea behind NeuroRestore is to develop first-in-class products for the treatment of symptomatic Alzheimer's disease, the intention with Alzstatin is to develop disease-modifying treatments targeting earlier stages of the disease. How broad these medicines eventually will be developed in clinical trials, i.e. whether they will target other CNS areas such as traumatic brain injuries, Parkinson's disease and sleep disorders, will depend on the progress and efficacy and safety signals seen in early clinical trials, and future discussions with development partners.

CHART 13: Illustration of AlzeCure's two tablet product platforms



NeuroRestore	Alzstatin
Novel oral small molecule therapies targeting neuronal dysfunction	Novel oral small molecule therapies targeting amyloid plaque formation

Source: Company information

AlzeCure may decide to partner products after phase 1 trials or continue clinical trials on its own.

Both NeuroRestore and Alzstatin are tablet based product platforms, with NeuroRestore targeting neuronal dysfunction and Alzstatin targeting the formation of amyloid plaques.

AlzeCure's idea is to develop several product candidates in parallel to have back-up candidates, and it currently has five primary product candidates of which the most advanced has just entered clinical stage development.

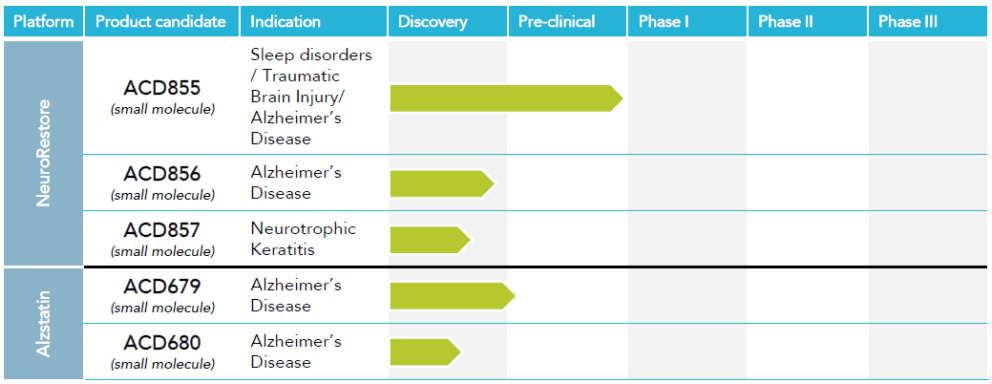
Two tablets, from Novartis and Biogen, undergoing late-stage clinical development today

AlzeCure's focus on small molecule tablet-based products is opposed to the many biologic anti-body drugs (various forms of anti-bodies directed against amyloid beta-42) in late-stage clinical development that requires intravenous administration. Novartis/Amgen's CNP520 and Biogen's elenbecestat are two examples of tablets being in late-stage trials today.

The NeuroRestore platform consists of the product candidates ACD855, ACD856 and ACD857, with ACD855 targeted for clinical stage development from late 2018 and onwards.

The mechanism of action behind the NeuroRestore product platform is to enhance so called neurotrophin signaling, and more specifically to potentiate BDNF (brain derived neurotrophic factor) and NGF (neural growth factor) signaling.

CHART 14: Illustration of AlzeCure's two tablet product platforms



Source: Company information

Potential indication area for NeuroRestore platform is broad

Potential indications to explore for the NeuroRestore product class are within cognitive impairment for example Alzheimer's disease, Parkinson's disease, head trauma and sleep disorders, but also potential areas such as depression and orphan indications in specific eye and ear disorders.

Neurons are the building blocks of both the central (including the brain and spinal cord) and peripheral nervous system. Several different growth factors and signaling molecules are necessary for the development and maintenance of neurons, and impaired functioning are linked to several neurodegenerative diseases including AD, Parkinson's disease and Huntington's disease.

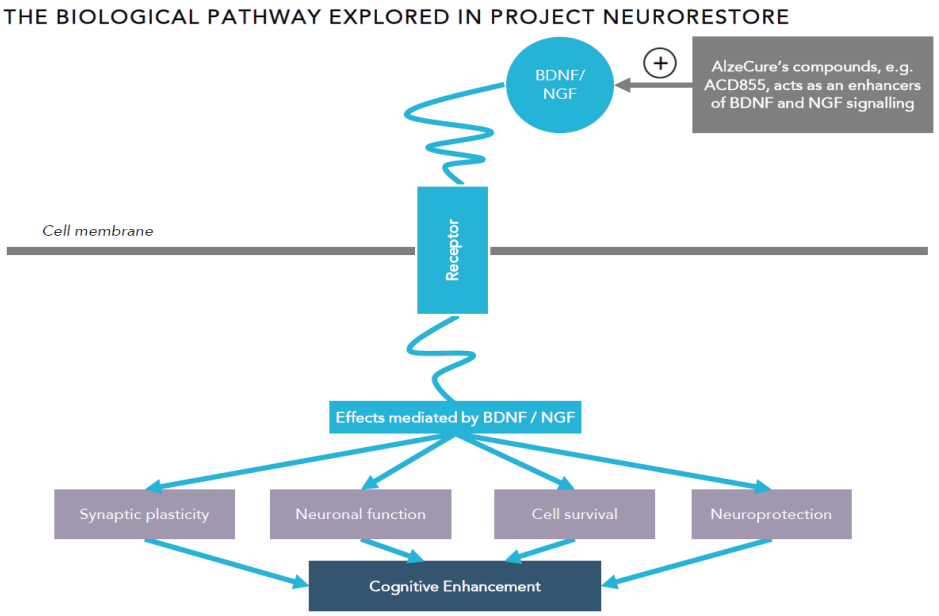
The mechanism of action behind the Alzstatin product platform is based on the knowledge that there is a build-up of amyloid plaques long before the occurrence of any clinical symptoms of Alzheimer's disease, so any disease modifying treatment should be initiated at a pre-symptomatic stage.

Increases shorter amyloid beta peptides, preventing clustering

ACD679 targets and modulates the gamma-secretase enzyme that is involved in the final steps of the production of amyloid beta. It decreases the amount of the aggregation-prone and toxic amyloid beta-42 peptide, and increases shorter amyloid beta peptides which is believed to prevent amyloid beta-42 from clustering, and to interfere with existing amyloid beta-42, the primary form of amyloid beta that is thought to be a major culprit in neurodegenerative disease progression.

The longer-term idea with a tablet based pre-symptomatic AD treatment would naturally be that its use is guided by blood-based tests, both in terms of when to initiate treatment but also to monitor treatment effects.

CHART 15: Illustration of NeuroRestore's mechanism of action



Source: Company information

The modulation of beta-secretase, which similar to gamma secretase is involved in the formation of amyloid beta from APP (amyloid precursor protein) has not been successful in several late-stage clinical trials, but trials continue with new BACE-inhibitors aiming at earlier intervention during the course of the disease. Novartis and Amgen have two major phase 3 trial ongoing with a BACE-inhibitor in pre-symptomatic disease, i.e. testing whether the occurrence of disease symptoms can be delayed or prevented, and Biogen has a BACE inhibitor targeting an early disease population.

The inhibition of gamma-secretase has also been tested in several drug development efforts before without success, however there are always differences between products with similar characteristics despite that they broadly have the same mechanism of action.

Gamma secretase a drug target since long, but more selective products required

With the role of gamma secretase-mediated cleavage of the amyloid precursor protein (APP), resulting in the production of amyloid beta peptides, gamma secretase has since long been a target for drug development. The industry largely lost its appetite for the target early this decade however, following the failure of late-stage product candidates including Lilly's semagacestat and Merck's MRK-560, both being gamma secretase inhibitors.

Gamma secretase however catalyses the proteolysis of more than 50 membrane proteins, so inhibition of the enzymatic activity has been demonstrated to have many different actions beyond amyloid beta formation. For example, the Notch and Eph receptor families (including EphB2 and EphB4) are dependent on gamma secretase activity, and inhibiting these pathways are believed to explain the side effects, such as skin cancer and decreased lymphocyte count, seen with earlier gamma secretase inhibitors. In contrast, gamma secretase modulators do not block the normal physiological function of the enzyme.

Disease area background

Alzheimer's disease is a progressive brain disorder in which the brain gradually degenerates, and it most frequently occurs in people aged above 65–70 years.

The accumulation of amyloid beta in the brain is believed to be one important reason behind brain's degeneration, however the exact underlying mechanism of the build-up and clearance of amyloid beta has not been fully elucidated.

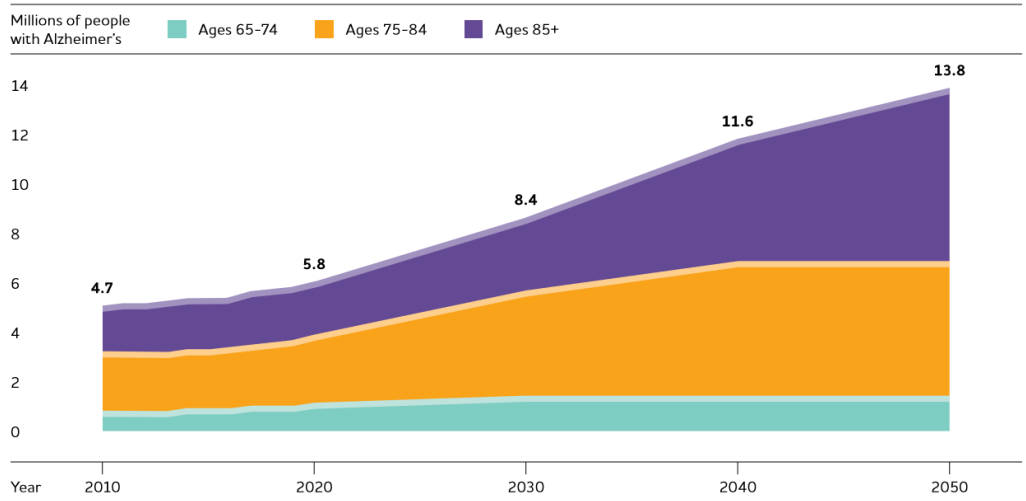
Beta-amyloid plaques are believed to contribute to cell death by interfering with the synaptic communication between cells, while the intracellular tau formations are believed to block transportation of nutrients and other essential molecules inside neurons.

Over the course of the disease, areas of the brain degenerate resulting in cellular loss and dysfunction, a gradual loss of memory, problems with reasoning or judgment, disorientation, difficulty in learning, loss of language skills and decline in the ability to perform routine tasks. As the amount of beta-amyloid increases, a tipping point is reached at which abnormal tau spreads throughout the brain.

Clearance overload leading to chronic inflammation

The presence of toxic beta-amyloid and tau proteins actives cerebral immune system cells called microglia. When this clearance system is overloaded, chronic inflammation is believed to set in, resulting in loss of normal brain functions and a decreased ability of the brain to metabolise its main fuel, glucose.

CHART 16: Projected number of people aged 65 and older in the US with Alzheimer's Dementia, 2010 to 2050



Source: 2018 Alzheimer's disease facts and figures, US Alzheimer's Association

The symptoms of Alzheimer's disease emerge gradually over a period of years and vary from person to person. Typically, the first symptoms to appear are forgetfulness and mild confusion.

Symptoms of AD are normally categorized into cognitive, functional and behavioral/psychological changes.

Cognitive changes include impaired short-term memory, difficulty in making decisions, reduced understanding of the concept of time and space, reduced ability to learn and problems recognizing friends and family.

Functional changes include the reduced ability to perform daily activities such as difficulty handling money, travelling and self-care (eating, getting dressed, maintaining personal hygiene) as well as problems with balance and unsteady movements.

About behavioral and psychiatric changes, patients may also develop behavioral disturbances including withdrawal from social activities, apathy and indifference, depressed mood, anxiety, and agitation. Behavioral changes are particularly difficult for family and caregivers to cope with and are often the reason for patients being moved to institutional care.

The toxicity of amyloid beta to neurons include the balance between intracellular and extracellular amyloid beta, the formation of monomeric, oligomeric and fibrillar forms, and multiple mechanisms including microglial infiltration, generation of reactive oxygen, synaptic damage, and the formation of neurofibrillar tangles.

Change in amyloid beta levels during early disease

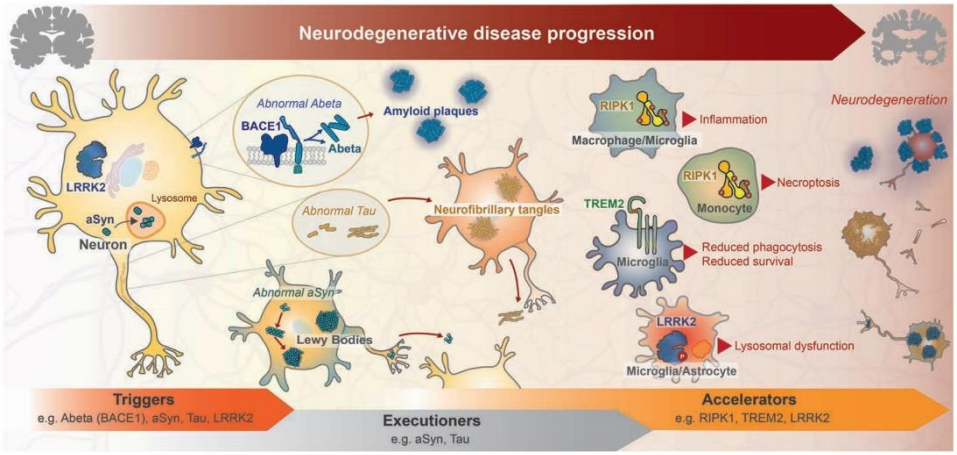
The mechanisms to eliminate extracellular amyloid beta in the brain includes several proteins that either enhance amyloid beta degradation or transport. Early in the disease, the concentration of amyloid beta-42 in the cerebrospinal fluid starts to fall while the concentration in the brain is increasing reflecting reduced transportation of amyloid beta from the brain and increased cerebral accumulation of amyloid beta-42.

Another explanation behind the amyloid beta accumulation among elderly would be a change in the cleavage of APP.

An abnormal form of the tau protein that aggregates in the neurofibrillary tangles has long been linked to Alzheimer's disease, however the exact mechanisms in disease progression are not known.

Recent research suggests that pathological tau impair key parts of the nuclear membrane that acts as the gateway for the exchange of proteins and RNA with the surrounding cytoplasm, and that defects in these pores could further lead to tau accumulation inside neurons.

CHART 17: Illustration of neurodegenerative disease progression



Source: Denali's company presentation

Since tau exists primarily intracellularly, an anti-tau antibody must in addition to the blood brain barrier also be able to transport through the cell membrane. The antibodies currently in development targets extracellular tau, which may still have positive effects since the full range of the functions for tau remains unknown.

Apart from tau, other novel areas of significant interest as targets for drug development include microglial cells and the mTOR pathway. Other cells than neurons are involved in AD pathology and research suggest that microglia may enter a hyperactive state following chronic activation, suggesting that restoring microglia functioning may be beneficial in certain brain regions.

Combination treatments may well developed, targeting different disease mechanisms

Also, the combination of microglia targeting, and antibody treatments could be an attractive combination strategy since research suggests that microglia are believed to be responsible for receptor-mediated antibody activity.

In terms of new diagnostic approaches, plasma neurofilament light (NFL) concentrations may be another area to explore, since research has shown that AD patients have increased plasma NFL concentrations. Increased NFL concentrations are also typically associated with cognitive decline and could provide a tool for early screening of an at-risk asymptomatic population.

Overall, neurodegenerative diseases such as AD is not seen as specific to neural pathology only, but a process also involving many other cell types. Once amyloid

plaques have reached a certain threshold after decades of accumulation, as a consequence of both overexpression and failure of clearance (current research aims to explore the role of the brain's lymphatic system in plaque clearance), the brain's immune system has probably launched a number of inflammatory responses to the amyloid accumulation, processes that may contribute to disease progression and also provide potential future drug targets.

Worldwide, 50 million people have dementia according to WHO. The WHO predicts that the prevalence of dementia will almost double every 20 years, and by the year 2050, 152 million people will have the condition.

Alzheimer's disease is the most common cause of dementia, accounting for 60-80% of dementia cases. Revised US guidelines for diagnosing AD was published in 2011, recommending that AD should be considered a slowly progressive brain disease that begins well before clinical symptoms emerge.

The brain changes of vascular dementia are found in about 40% of brains from individuals with dementia, and about 10% of dementia cases show evidence of vascular dementia alone. It is very common with a mixed pathology in older individuals with AD, about half of whom have pathologic evidence of silent strokes.

People with dementia and Lewy bodies (DLB) have some of the standard AD symptoms but are more likely to have initial or early symptoms of sleep disturbances, hallucinations, slowness and other movement features typically related to Parkinson's disease (PD). Lewy bodies are abnormal aggregations of the protein alpha-synuclein in neurons, and when they develop in the brain cortex, dementia can result. While people with DLB and PD both have Lewy bodies, the onset of the disease is marked by motor impairment in PD and cognitive impairment in DLB.

Several different forms and reasons for AD

Apart from AD, vascular dementia and DLB, there are other reasons for dementia such as mixed dementia (for example AD combined with vascular dementia and AD combined with DLB, frontotemporal lobal degeneration (FTLD), Parkinson's disease, Creutzfeldt-Jakob disease, and normal pressure hydrocephalus. In FTLD, memory is typically intact in the early stages of the disease, in contrast to AD.

Mild cognitive impairment (MCI) is a condition when individuals have mild but measurable changes in thinking abilities that are noticeable to the person affected, and to family members and friends.

An estimated 1% or less of AD develop as a result of mutations to any of three specific genes (the genes for APP, presinilin 1 and 2). People inheriting a mutation to the APP or presinilin 1 genes will develop AD, and those with a mutation to presinilin 2 has a 95% risk of developing the disease. Individuals with any of these three genetic mutations tend to develop symptoms well before the age of 65 and sometimes as young as age 30.

In Down syndrome, an individual is born with an additional copy of chromosome 21, and the early AD development seen in this population is believed to be related to the chromosome 21 includes the gene that encodes for APP production, with an ensuing increased number of beta-amyloid fragments in the brain.

The greatest risk factors for late-onset AD are older age, having a family history of AD and carrying the APOE4 gene, the latter is the reason with APOE4 status is typically evaluated at randomisation of patients into clinical trials.

The APOE gene is involved in cholesterol transportation, and every individual inherits one of three forms of the APOE gene, E2, E3 or E4, from each parent. The E3 form is the most common and E2 the least common. Having the E4 form is believed to increase AD risk, while having the E2 form is believed to decrease the risk compared with having the E3 form. Those who inherit two copies of the E4 form have an 8-12-fold increased risk for developing AD compared to the average risk, and to develop AD at a younger age.

Unlike inheriting a genetic mutation that causes AD, inheriting the APOE4 gene is a risk factor for AD, but it does not necessarily lead to AD. There are also around 20 recently identified genes that increases the risk for AD, but they do not always lead to AD development. Overall, these genes are believed to have only a limited effect on the overall prevalence of AD.

Modifiable risk factors include the risk factors for cardiovascular disease, education, social and cognitive engagement, and avoiding traumatic brain injuries (TBI). An estimated 1.7 million Americans will sustain a TBI in any given year according to "Centers for Disease Control and Prevention. Get the Stats on Traumatic Brain Injury in the United States".

In terms of inherited AD, a major research effort is DIAN (the Dominantly Inherited Alzheimer's Network), which as an ongoing observational study aiming at identifying changes in individuals who carry one of the gene mutations (APP, presenilin-1 or presenilin-2) known to cause dominantly inherited AD (DIAD).

Risk assessment

We would summarise the main development risks in AlzeCure as follows:

- AlzeCure is in an early stage of product development. An IND (investigational new drug) or CTA (clinical trial application) clearance is a major development milestone for a pharmaceutical development company, however the timeline risks and potential hurdles during the various development stages until a potential submission for approval, approval and launch are very significant

- AlzeCure is involved in a particularly difficult and risky product development area. Despite decades of large clinical trials, no effective treatment exists for the slowing, delaying or halting the progression of neurodegenerative disorders such as Alzheimer's disease

- AlzeCure's treatment approaches are novel which may indicate that its product classes in development are particularly risky. Several products have been developed targeting gamma secretases and all of them have failed, however newer product development is focusing on modulating rather than inhibiting the complex gamma secretase enzyme. Products stimulating the BDNF/NGF pathways have not been developed for human use, but do exist in animal health markets

- Medicines for treating or preventing neurodegenerative disorders would typically be used by an elderly population that often have several concomitant disorders, so the safety of any new medicine when used with all other existing medicines used by elderly (such as cholesterol, blood pressure, anti-coagulant and diabetes medications) must be established

- AlzeCure may fail to sign a development partner for its first, larger, phase 2 development, or it may choose to develop its most advanced product on its own, which would increase the financial risk of the company

- Simple, validated, user friendly, blood-based biomarkers for use in diagnostics and treatment monitoring may fail to be developed. This would impact the scope for AD treatments to become mainstay products targeting a broad population

Key personnel

Johan Sandin, CEO. Johan is a neuropharmacologist with 15 years' experience from pre-clinical drug research. At AstraZeneca, he had several positions including team and project leader as well as part of strategic teams. During the latter years at AZN, Johan was Associate Director with a strategic, scientific and managing responsibility for most biology efforts in the neurology area, with a focus on Alzheimer's disease. Johan has a Ph.D. in neuropharmacology from Karolinska Institutet, Stockholm.

Gunnar Nordvall, Director Medicinal Chemistry. Gunnar has held several positions at AZN, and was part of the project generation team and team leader for lead generation computational chemistry, chemistry project leader, and the project leader for two AD projects. He was also principal scientist in medical chemistry with responsibility for drug design. Gunnar has 30 years' experience in medicinal and computational chemistry. Gunnar has a Ph.D. in medical chemistry from Uppsala University.

Pontus Forsell, Director Assay and Screening. Pontus has 18 years of experience from industrial research and drug development in companies including Merck and AZN. At AZN, he had positions as team leader and member of the project generation team and worked extensively with neurotrophins. Pontus has a Ph.D. in medical biochemistry and biophysics from Karolinska Institutet, Stockholm.

Johan Lundkvist, Director Pharmacology. Johan was at AZN during 2004-2012, and held several positions including discovery project leader and scientific team leader for enzyme targets and the amyloid portfolio. Moreover, Johan managed the externalisation outreach team for neurology, and was a strategy team member for the neurology portfolio. Johan has had an academic career on amyloid beta amyloidosis and became Associate Professor in 2005. Johan has a Ph.D. in neurochemistry and neurotoxicology from Stockholm University.

Magnus Hallin, Director ADME and DMPK. Magnus held several positions at AZN during 1985-2012, including Director and Senior principal scientist, DMPK and regulatory science at global DMPK since the year 2000. Magnus was an integral part of the emerging product team in neurology at AZN. He was also scientific reviewer for IND (investigational new drugs) and NDA (new drug applications) of all indications at AZN. Magnus has a M.Sc., Ph.D. in pharmacognosy (the study of medicinal drugs derived from plants or other natural sources), Uppsala University.

Board of Directors

Thomas Pollare, Chairman of the Board. Thomas is a former partner of the venture capital firm 3i. He has held management positions at Pharmacia Corporation and Schering-Plough and was responsible for marketing approval of several products in different therapeutic areas. Thomas has board experience in major corporations as well as start-ups and private equity investments. Thomas is M.D. from Karolinska Institutet, Stockholm, and Ph.D. from Uppsala University.

An van Es-Johansson, Director of the Board. An has held several executive positions in Sobi, Biovitrum, Roche and other companies, and is currently Vice President, Clinical Development, at Sobi. An is M.D. from Erasmus University, Rotterdam.

Ragnar Linder, Director of the Board. Ragnar is co-founder and CEO of Pygargus which was acquired by Quintiles, and previously managing director for Amgen Nordic. Ragnar is Master of Chem Ing., from Royal Institute of Technology, Stockholm.

Ellen Donnelly, Director of the Board. Ellen has extensive experience from big pharma and has held several senior positions at Pfizer. She is currently CEO of Modus Therapeutics AB. At Pfizer, Ellen was responsible for clinical development within neuroscience and pain. Ellen is Ph.D. in pharmacology and neuroscience at Yale University.

Pirkko Sulila Tamsen, Director of the Board. Pirkko has ten years' experience as clinical project leader in larger pharma companies. Further, she has ten years' experience from a full service CRO (as co-owner, Director clinical operation and SVP sales and business development) in addition to eight years' experience as start-up CEO for three life science companies and head of Uppsala University Innovation. Pirkko has a Master's in biology and Chemistry and a Ph.D. in Zoophysiology, Uppsala University.

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I, Lars Hevreng, the author of this report, certify that notwithstanding the existence of any such potential conflicts of interests referred to below, the views expressed in this report accurately reflect my personal view about the companies and securities covered in this report.

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