

ALZECURE

First clinical stage read-out in late 2021 instead of early 2020

AlzeCure's lead product asset, ACD855, started clinical development in late 2018 with the ambition to generate first clinical trials by early 2020. However, early human exposure with the tablet product demonstrated that the concentration of the substance would require significantly longer dosing intervals than once daily, so the future development of the substance will now only be pursued with a formulation targeting ophthalmologic disorders. Instead, AlzeCure will move another substance, ACD856, that belongs to the same NeuroRestore substance class, into clinical stage development towards late 2019, targeting results towards H2 2021. The single and multiple ascending dose parts of the trials with ACD856 will have around 60 participants in each.

Six compounds in two product classes in development

In total, the company currently has six compounds in development that belongs to two product classes with novel mechanism of action; the BDNF/NGF modulators in the NeuroRestore class to which ACD855 and ACD856 belongs, and the gamma secretase modulators in the Alzstatin class. The first product from the Alzstatin class will move into clinical trials during the coming year.

Continued strong industry activity in the area

Despite several recent phase 3 clinical trial failures in Alzheimer's disease (AD), the pharma and diagnostics industries continue to invest heavily in the area, targeting products with novel mechanisms of action and diagnostics that could enable treatments during earlier disease. A large 1,600-patient study with a blood-based biomarker (neurofilament light) during different disease stages was recently published, and the US company Alector has reported progress in three different clinical trials programs since early April, all programs evaluating Alzheimer's disease products with novel mechanism of action. Another US company, Denali, recently started patient dosing with a product with novel mechanism of action targeting AD treatment. In contrast to the medicines that have been and are being tested in ongoing large phase 3 trials, early-stage clinical trials in the area are being monitored according to biomarker changes in plasma and cerebrospinal fluid, and we believe AlzeCure's future clinical trials will be evaluated in a similar way. Both Alector and Denali went public in a late pre-clinical or very early clinical stage.

Stepwise approach to valuation

The clinical trial news that we had expected within a one-year timeframe, i.e. early 2020, is now not expected until H2 2021. While we earlier saw a reasonable valuation range of SEK 29-34 per share in early 2020, we now see a reasonable range of SEK 20-24 (SEK 750-900m market cap) per share during late 2021, assuming that the first efficacy signals with ACD856 are strong, the first product from the Alzstatin product class has started clinical development, and that the earlier stage portfolio develops as planned. Towards late 2020, we see a reasonable range of SEK 12-14 per share, assuming two products are in clinical development. For the coming year however, the valuation may reflect the cash balance, which is around SEK 5 per share we believe, unless any significant corporate activity including development collaborations are announced.

NEUTRAL

Company update

For the coming year, we believe the share's valuation will reflect its cash balance of SEK 5 per share. Towards late 2020, we see a range between SEK 12-14 per share suggesting 153-195% upside to the current share price. Towards late 2021, we see a range between SEK 20-24 per share, suggesting 321-405% upside.

Stepwise valuation approach



Key Data	
Ticker	ALZCUR
Share price* (close)	SEK4.75
Free float	71.8%
Market cap*	SEK179.4m
Website	alzecurepharma.se
Average daily volume*	SEK0.70m

Share Price (SEK)



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^{*} Data as per 2019-05-08



Marketing material commissioned by AlzeCure Pharma AB – 9 May 2019

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Marketing material commissioned by AlzeCure Pharma AB – 9 May 2019

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