No one-trick pony – advancing a novel platform-based CNS company

AlzeCure has with its seven-project portfolio multiple shots at goal where each, while early stage, represents a potential multibillion-dollar opportunity.

It goes without saying that the past year’s achievements mark management’s extensive experience and competence in drug development and how to sophisticatedly run a research and development company. This is an important asset to recognize, and it should provide the market confidence in the company’s ability to drive the company successfully forward and limit the risk-profile to biological risk factors.

By leveraging its solid financial position and broad drug development strategy - derived from management’s Big Pharma experience - AlzeCure has quickly advanced into early clinical stage and expanded its diversified project portfolio. The company wisely raised sufficient capital in its IPO to fund a development strategy that is de-risked in the high-risk CNS disease area, building a company that is far from being a “one-trick pony”.

With ACD856 (NeuroRestore) and the in-licensed ACD440 (Painless) positioned for further clinical development to begin by the end of the year, we update our valuation of the company to reflect the de-risking progress. We set a 10% likelihood of approval (LOA) for ACD856 and a 15% LOA for ACD440.

We update our rating to Outperform and raise the target price to SEK 16 per share, corresponding to an equity value of approximately SEK 600m non-diluted, derived from risk-adjusted DCF valuation of ACD856 and ACD440.

Given the early stage of the Alzstatin platform and TrkA-NAM project (Painless), and the inherently high-risk profile, we currently consider these to add significant upside to our base case with ACD856 and ACD440.
ACD856 cleared for further clinical development

AlzeCure has confirmed a suitable half-life of ACD856 in humans from its first clinical study. This is a significant de-risking milestone achieved since the set-back with the candidate’s predecessor, enabling further clinical development for the treatment of cognitive dysfunction in Alzheimer's Disease (AD). We believe that this achievement supports an initial validation of the NeuroRestore platform. Furthermore, it demonstrates the value of AlzeCure’s development strategy, i.e. to advance follow-on candidates in parallel to evaluate several indications and ensure selection of an optimal candidate to pursue for each indication. Hence, spreading the risk among candidates mitigate the often-time-consuming consequences from clinical trial setbacks. The company wisely raised sufficient capital in its IPO to fund such a development strategy that is de-risked in a high-risk disease area, building a company that is far from being a “one-trick pony”. Preparations are ongoing to continue clinical development with Phase I studies, planned to start by the end of 2020, to evaluate the safety, tolerability, and initial efficacy of ACD856. The upcoming study is fully funded with existing funds.

The NeuroRestore platform consists of first-in-class symptomatic therapies by novel oral small molecules targeting cognitive dysfunction in multiple neurodegenerative disorders such as AD. The drug candidates are selective enhancers of neurotrophin signaling that mediates promoting effects on synaptic plasticity, neuronal function, cell survival and neuroprotection – all which stimulates neuronal function and communication crucial for cognition and memory. The BDNF/NGF pathway is recognized scientifically, but the holy grail in the area has been to enhance the pathway to drive neuronal survival and function safely and selectively. Moreover, an interesting observation in the space is that Athira Pharma recently reeled in USD 85m from institutions and specialized life science investors including (among others) Sofinnova, Venrock, Viking and Perceptive Advisors to fund a phase II/III study of their lead drug NDX-1017, targeting the repair pathway HGF-MET for treatment of cognitive dysfunction in AD1. Although the target pathway is different from NeuroRestore, with the BDVF/NGF pathway benefitting from more solid scientific support, the transaction is one of several that highlights an increasing appetite in the field for new approaches and hypotheses beyond amyloid beta and tau.

We set a 10% LOA for ACD856 on the back of a solid scientific rational, with the target pathway being genetically linked to disease, and promising preclinical results.

Research platforms expanded with clinical stage ACD440-project

AlzeCure has expanded its portfolio of drug candidates against CNS disorders through the exclusive in-licensing of ACD440 - a clinical stage project targeting neuropathic pain. Together with the rapid progress of ACD856, the company has advanced and diversified its portfolio, hence balancing the overall development risk in it. ACD440 and the discovery phase project TrkA-NAM, against osteoarthritic pain, constitute the first-

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in-class Painless research platform, adding to the NeuroRestore and Alzstatin research platforms.

Neuropathic pain is a chronic condition caused by damage or injury to the nerves that transfer information between the brain and spinal cord from the skin and other parts of the body. Today, about 8% of the global adult population are suffering from neuropathic pain and it is often associated with impaired quality of life. 50% of patients do not respond to existing first-line treatments and this exploits an opportunity for AlzeCure to fill a demand gap.

AlzeCure’s project has the potential to approach neuropathic pain in a new way through VR1 receptors, which has an established key role in pain signaling. VR1 receptors are upregulated in the skin in various neuropathic pain conditions, and ACD440 is a topical VR1 antagonist targeting pain sensory neurons – optimized for local delivery and shows strong scientific support for peripheral treatment. The candidate emanates from Big Pharma with approximately 200 MSEK already invested in project development, and the mode of action has been confirmed in Phase 1 clinical trials. The project thus benefits from extensive preclinical and clinical documentation on safety, tolerability, and initial efficacy, which increases the likelihood of continued success from its current phase. AlzeCure plans to begin a clinical proof-of-mechanism Phase Ib study in the latter part of 2020 and the cost to fund this through readout up until Phase II is estimated to SEK 10-15m- fully funded with existing funds. It is important to note that this is a relatively low cost for preparatory clinical activities and a Phase Ib study, which upon successful outcome positions the project for deal opportunities and a significant upside.

We set a 15% LOA for ACD440, which is roughly 5% higher than the LOA for a novel phase I therapeutic in neurology. We believe that this is motivated by the fact that the candidate already has extensive preclinical and clinical documentation with target-engagement demonstrated. In addition, the target benefits from strong scientific support for peripheral treatment.

Execution is everything

It goes without saying that the past year’s achievements mark management’s extensive experience and competence in drug development and how to sophisticatedly run a research and development company. This is an important asset to recognize, and it should provide the market confidence in the company’s ability to drive the company successfully forward and limit the risk-profile to biological risk factors.

Along with AlzeCure’s progression into clinical stage, management has been strengthened with business development expertise to ramp-up commercial activities and position the pipeline projects for attractive deal opportunities. The CEO Martin Jönsson brings extensive deal-making and business development experience from the global pharmaceutical industry, providing AlzeCure with commercial know-how to position itself and its pipeline on potential partners’ radar screen. We expect the

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Marketing material commissioned by AlzeCure Pharma AB – July 07, 2020

business development activities to increase, with partnerships to be initiated subject to continued clinical progress through phase I with early efficacy signals. We also see potential for partnerships concerning the earlier pipeline candidates, particularly for the TrkA-NAM project (painless platform) where the mechanism of action has strong clinical validation from clinical trials with novel antibodies.

Outlook

Below follow short-term events that we forecast in 2020.

- Q4 2020: Initiate next clinical study for NeuroRestore ACD856
- H2 2020: Preclinical efficacy data for pain project TrkA-NAM
- Q4 2020: Initiate Phase 1b study for neuropathic pain project ACD440 (VR1)

Valuation

We update our rating to Outperform and raise the target price to SEK 16 per share. Our target price is based on a risk-adjusted DCF valuation of future proceeds from the clinical stage projects ACD856 and ACD440.

We presently consider the preclinical/discovery pipeline assets as upside to our base case, where we deem particularly Alzstatin platform and TrkA-NAM to offer substantial value-generating potential.

We expect that AlzeCure Pharma will enter partnerships and receive royalties from sales of ACD856 and ACD440. We forecast AlzeCure to generate risk-adjusted peak proceeds of SEK 844m and SEK 108m in 2034 from ACD856 and ACD440 respectively. The following key parameters are applied as basis for our forecast:

ACD856

- Our assumptions for ACD856 are based on epidemiology data and penetration scenarios in the market for moderate and severe Alzheimer’s Disease (AD). Our assumptions are made from year 2027 when ACD856 is expected to launch. We include EU5, US and Japan.
- 10% LOA
- We estimate a peak market share of 18%
- We assume a price of USD 12 000 per treatment per year in the US and USD 7 200 in EU5 and Japan. We have benchmarked the price against other small molecule therapeutics in the disease area.
- License partner secured on the back of positive Phase II data, although we note that this can be achieved earlier based on early efficacy demonstrated in phase I.

3 GlobalData 2020
Based on the average of deal values for comparable deals\(^4\), we assume a total deal value of USD 250m, excluding royalties on sales, structured as follows:

- USD 15m in upfront (2024)
- USD 35m upon initiation of Phase III (2025)
- USD 100m in total based on regulatory filing and approval (2027)
- USD 50m in 2028 and 2029 in sales-based milestones.
- 10% royalty rate
- Developments costs from phase III onwards covered by partner

**ACD440**

- Our assumptions for ACD440 are based on epidemiology data and penetration scenarios in the market for neuropathic pain in diabetic neuropathy and postherpetic neuralgia\(^5\). Our assumptions are made from year 2027 when ACD856 is expected to launch. We include EU5, US and Japan.

- 15% LOA
- We estimate a peak market share of 20%
- We assume a price of 5 000 USD per treatment per year in the US and USD 3 500 in EU5 and Japan. We have benchmarked the price against other treatments in the area.
- License partner secured on the back of positive Phase II data, although we note that this can be achieved earlier based on early efficacy demonstrated in phase I.

Based on the average of deal values for comparable Neuropathic pain deals\(^6\), we assume a total deal value of USD 330m, excluding royalties on sales, structured as follows:

- USD 20m in upfront (2024)
- USD 35m upon initiation of Phase III (2025)
- USD 150m in total based on regulatory filing and approval (2027)
- USD 50m in 2028 and USD 75m in 2029 in sales-based milestones.
- 10% royalty rate
- Developments costs from phase III onwards covered by partner

**Other**

- Gradual sales decline towards 10% y/y upon key patent expiry
- Research and development costs driven by clinical trials of ACD440 and ACD856.
- AlzeCure has a lean operation of some ten full-time equivalent employees as of end June 2019. We expect a modest cost increase based on a partner strategy for both ACD440 and ACD856.
- Only costs related to ACD440 and ACD856 are included
- We model two equity issues of SEK 200m in 2022 and SEK 100m in 2024

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\(^4\) GlobalData 2020

\(^5\) GlobalData 2020

\(^6\) GlobalData 2020
Risk-adjusted P&L (SEK m)

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Source: Vator Securities. Probability adjusted revenues include licensing fees.

We use a discount rate (WACC) of 19.3%, as well as 1.5% terminal growth rate (in line with GDP growth) and a 80% life cycle adjustment of the terminal value. The risk-free rate is 0%, based on the Swedish government ten-year bond, and the risk premium is 10.7%, based on a size and market risk premium of 3.5% and 7.2% respectively. Lastly, we use an equity beta value of 2.2 reflecting high underlying volatility. We have also included a net present value of the cumulative tax shield. With our estimates and DCF input variables, our DCF model indicates an equity value for AlzeCure Pharma of approximately SEK 600m, equivalent to SEK 16 per share (based on approximately 37.8m outstanding shares).

DCF valuation (SEK m)

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Source: Vator Securities

SEK million

- Terminal value: 3 653
- Life cycle adjustment TV: 80%
- Adjusted Terminal value: 2 923
- Net Present Terminal Value: 225
- Net Present Value FCF: 339
- NPV of FCF incl. TV: 564
- Tax shield value, NPV: 33
- Interest bearing net debt: 0
- Equity Value: 597
- Number of shares, non-diluted, million: 37.8

SEK/Share: 16

Key metrics

- Terminal value/DCF: 40%
Our project-based, risk-adjusted implied DCF valuation highlights that the current market value in comparison does not reflect our perception of future risk-adjusted revenue streams.

The main risks in this case currently pertains to biological and clinical trial aspects of drug development. Both candidates are in early clinical stages, where the drug development risk is inherently high, and the area of neurodegenerative disorders is one of the most challenging fields. Therefore, it is important to establish development strategies, as AlzeCure Pharma does, to reduce risk and spread it among multiple candidates and therapeutic indications. With its seven-project portfolio, AlzeCure Pharma has multiple shots at goal where each represents a potential multibillion-dollar opportunity.

In reality, the risk-adjusted sales will not materialize as the outcome of each project is binary, meaning it will either reach the market or not. The forecast cost base, which currently only considers two projects, is dependent on AlzeCure’s R&D strategy and ability to secure a partner for late stage clinical development, regulatory approval and commercialization.
Key personnel

Martin Jönsson, CEO. Martin has more than 20 years’ experience in the global pharmaceutical industry, working for Roche and Ferring Pharmaceuticals, with senior positions in several different areas. He has worked with business development, sales, marketing, alliance management and medical affairs. Martin has a MSc in business from University of Lund, and with studies at University of Freiburg, Germany and University of Ottawa, Canada.

Johan Sandin, CSO. Johan is a neuropharmacologist with 17 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.

Birgitta Lundvik, CFO. Birgitta Lundvik has more than 25 years of experience from software development, life science and real estate companies. She has taken part in several M&A projects and has a broad experience of venture capital companies. Birgitta Lundvik has an MSc in business from Uppsala University and an eMBA in finance from Stockholm Business school.

Pontus Forsell, Head of Discovery. Pontus has 20 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.

An van Es-Johansson, Head of Development. An has previously held various executive positions relating to clinical development, medical affairs, business development and marketing at Sobi, Eli Lilly, Roche, Pharmacia & Upjohn and biotechnology companies in the USA, the Netherlands, Switzerland and Sweden. She is currently An van Es Johansson holds an M.D. (physician) from Erasmus University Rotterdam (the Netherlands).

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.

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, Felicia Rittemar, 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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