

# AlzeCure Pharma

R&amp;D update

## Catalysts on the horizon

Pharma &amp; biotech

1 June 2021

**Price** **SEK7.77**  
**Market cap** **SEK294m**

Net cash (SEKm) at end-Q121 94.2  
 Shares in issue 37.8m  
 Free float 63%  
 Code ALZCUB  
 Primary exchange Nasdaq First North Growth  
 Secondary exchange N/A

### Share price performance



% 1m 3m 12m  
 Abs 6.4 3.5 35.5  
 Rel (local) 7.3 (7.6) (6.7)  
 52-week high/low SEK11.60 SEK5.30

### Business description

AlzeCure Pharma is a clinical-stage biotech company based in Sweden focused on developing small molecule drugs for the treatment of Alzheimer's (symptomatic and disease modifying) and pain (neuropathic and osteoarthritis).

### Next events

PDUFA date for aducanumab 7 June 2021  
 ACD856 Phase I SAD data Mid-2021  
 Filing for Phase IIa ACD440 study H221

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AlzeCure remains on track with its evolution into a mid-stage biotech, having recently reported [positive headline data](#) from its Phase Ib trial for ACD440, topical TRPV1 antagonist for pain. The company also held an R&D event for its Painless platform highlighting assets for pain ACD440 and TrkA-NAM (preclinical). Upcoming Phase I data for ACD856, a cognitive enhancer for Alzheimer's disease (AD), are expected in the coming months, while details about the start of a Phase IIa trial with ACD440 should be clarified later this year. We value AlzeCure at SEK826m or SEK21.9 per share (vs SEK19.3 per share previously).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/19	0.0	(50.9)	(1.35)	0.0	N/A	N/A
12/20	0.0	(71.4)	(1.89)	0.0	N/A	N/A
12/21e	0.0	(82.0)	(2.17)	0.0	N/A	N/A
12/22e	0.0	(86.1)	(2.28)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

## Positive Phase Ib data for ACD440

In April 2021, AlzeCure announced headline findings from its placebo-controlled, Phase Ib study (n=24) with ACD440 in healthy volunteers. The drug candidate was well tolerated and demonstrated an initial signal of analgesic potential (statistically significant effect compared to placebo). Full results are due to be presented at the upcoming IASP World Congress on Pain in June 2021, but the company has already indicated that the data allow planning the next study. We expect an update on the details of trial design and timelines during H221.

## Data from Phase I with ACD856 in AD imminent

Phase I results for ACD856 are expected in the coming months and should provide initial safety and tolerability data from the single ascending dose part of the study. The results from the multiple ascending dose part of the study will follow thereafter, while an extension phase is expected to investigate early cognitive effects of ACD856, with data expected sometime in 2022. We also note the upcoming FDA decision (7 June) on whether to approve Biogen's AD drug candidate aducanumab is a key near-term catalyst for the stock and for the AD drug development industry in general. Both AlzeCure's platforms in AD are differentiated from Biogen's antibody approach, so the direct read across is limited. However, this will be a landmark event in AD research, so there should be a sentiment effect either way for all players in the AD area.

## Valuation: SEK826m or SEK21.9 per share

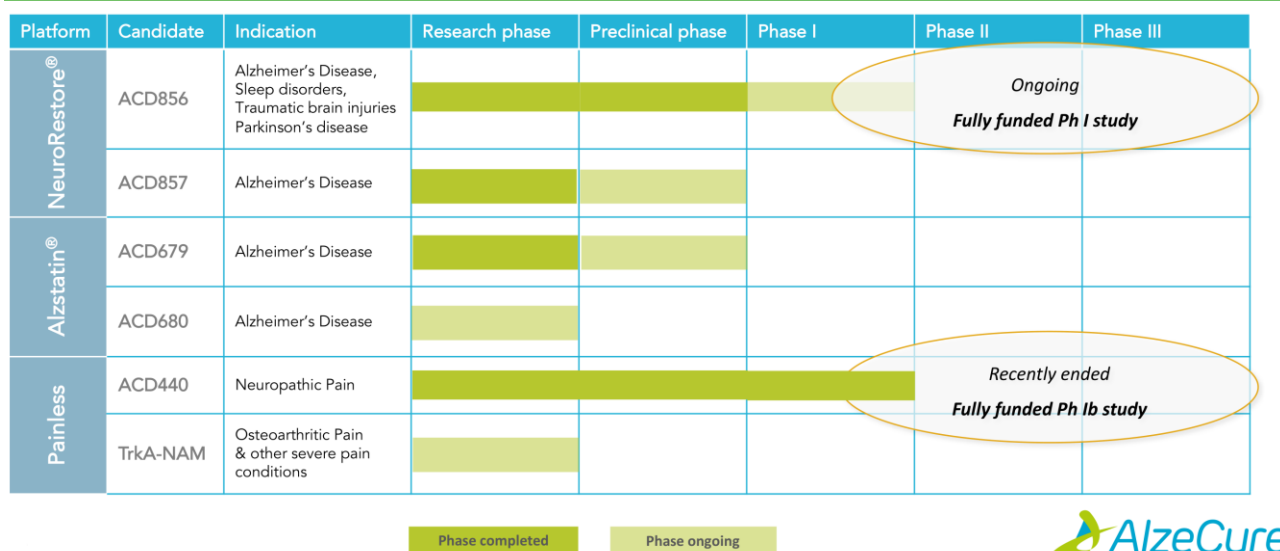
Our risk-adjusted NPV for AlzeCure is now SEK826m or SEK21.9 per share (from SEK729m or SEK19.3 per share) as we have increased our probability of success for ACD440 to 20% from 10%, given management's guidance it will progress to the next trial (Phase II). AlzeCure had cash of SEK94.2m at the end of Q121, which should provide funding into 2022. The next catalysts are the data from the Phase I study with ACD856 and aducanumab's PDUFA date.

## Painless platform R&D event: Key takeaways

AlzeCure's Painless platform currently consists of in-licensed asset ACD440, which is being developed as a topical treatment for neuropathic pain (Phase Ib), and TrkA-NAM for osteoarthritic pain (early preclinical). Non-opioid based analgesics complement and diversify AlzeCure's R&D pipeline well, in our view, which also includes two other platforms focused on AD (for detailed analysis, please see our recent [initiation report](#)).

On 11 May 2021, the company held [an R&D event](#), where it presented ACD440 and TrkA-NAM in detail. Areas of specific interest for us included an update on the upcoming Phase IIa study of ACD440; and a detailed introduction to the novel mechanism of action of TrkA-NAM by AlzeCure's Head of Discovery and Research Pontus Forsell. In the past, AlzeCure had organised [similar events](#) with key opinion leaders for its AD assets.

**Exhibit 1: AlzeCure's R&D pipeline**



Source: AlzeCure

### ACD440: Phase IIa trial for neuropathic pain in planning

ACD440 is being developed for peripheral neuropathic pain, which is a symptom of a broad group of different, underlying conditions such as diabetic nephropathy, chemotherapy induced pain or herpetic neuralgia. Given the potentially large patient heterogeneity across this indication, we believe that management will likely investigate ACD440 in specific sub-populations of patients. No specific guidance was provided at the R&D event on Phase IIa trial design, but we expect this will likely be communicated during H221 and should better define the commercial scope for ACD440. We note that an [upcoming revision](#) to the International Classification of Diseases and Related Health Problems (ICD) of the World Health Organization (WHO), effective 1 January 2022, should provide clearer diagnostic criteria for neuropathic pain and should help aid patient selection in future studies.

### TrkA-NAM: Distinctly different mechanism to anti-NGFs

A deep-dive into the TrkA-NAM programme highlighted why this approach is differentiated from the nerve growth factor (NGF) targeting antibodies that, although effective, have disappointed due to safety issues (more background details are in our initiation report). Of particular note is Pfizer/Lilly's tanezumab which remains under FDA review for osteoarthritic pain despite concerns surrounding

its risk/benefit profile and the cases of rapidly progressing osteoarthritis observed across various trials. AlzeCure believes that TrkA-NAM could offer a safety improvement over anti-NGF antibodies through selectively attenuating NGF/TrkA signalling while sparing NGF/p75NTR signalling (more detailed explanation of mechanism of action is in our initiation report). So, TrkA-NAM is a more selective mechanism than Trk-inhibitors or anti-NGF antibodies. In addition, AlzeCure's TrkA-NAM compounds are small molecules, which have several advantages over antibodies including more convenient administration and lower COGS. AlzeCure should present preclinical efficacy data at IASP in June 2021. The nomination of a clinical candidate is expected during H221.

In terms of a directly comparable programme, we note that Asahi Kasei is currently investigating its TrkA inhibitor, AK1830 (formerly ARRY-954), in two Phase II trials for [osteoarthritic pain](#) and [lower back pain](#). What is particularly notable is that this was in-licensed as a preclinical asset from Array BioPharma in [March 2016](#), in a deal worth c \$75m (\$12m upfront, \$64m milestone plus royalties) for commercial rights in Asia, highlighting the near-term value which could be crystallised from the TrkA-NAM programme.

## Valuation and financials

Our risk-adjusted NPV of AlzeCure is now SEK826m or SEK21.9 per share (from SEK729m or SEK19.3 per share), as we have increased our probability of success for ACD440 to 20% from 10%, updated for the last reported net cash position and rolling forward our model. A full breakdown of our valuation and underlying assumptions can be found in our initiation report.

**Exhibit 2: AlzeCure sum-of-the-parts valuation**

Product	Indication	Launch	Peak sales* (\$m)	NPV (SEKm)	Probability of success	rNPV (SEKm)	NPV/share (SEK)
NeuroRestore – ACD856	AD	2030	4,600	6,160.1	5.0%	495.6	13.1
Painless – ACD440	Neuropathic pain	2028	500	1,023.5	20.0%	236.6	6.3
Net cash, last reported				94.2	100.0%	94.2	2.5
<b>Valuation</b>				<b>7,277.7</b>		<b>826.4</b>	<b>21.9</b>

Source: Edison Investment Research. Note: WACC = 12.5%. \*Peak sales are rounded to the nearest \$100m.

In May, AlzeCure reported Q121 results that were broadly in-line with our expectations. The reported net cash of SEK94.2m at the end-Q121 should provide funding into 2022. We assume an illustrative long-term liability of SEK57m in 2022 (as per our research principles, in lieu of equity funding). Notably, its existing budget is sufficient to reach the final readouts from both clinical trials, as well as other potential catalysts from the preclinical R&D pipeline.

**Exhibit 3: Financial summary**

Year end 31 December	SEK'000s	2018	2019	2020	2021e	2022e
		IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>						
Total revenues		0	0	0	0	0
Cost of sales		0	0	0	0	0
Gross profit		0	0	0	0	0
SG&A (expenses)		(2,558)	(6,035)	(9,375)	(9,609)	(9,850)
R&D costs		(36,828)	(44,499)	(61,861)	(71,861)	(75,454)
Other income/(expense)		3,597	(84)	152	0	(254)
Exceptionals and adjustments		0	0	0	0	0
Reported EBITDA		(35,789)	(50,618)	(71,084)	(81,470)	(85,558)
Depreciation and amortisation		(104)	(290)	(495)	(544)	(580)
Reported Operating Profit/(loss)		(35,893)	(50,908)	(71,579)	(82,015)	(86,137)
Finance income/(expense)		(92)	50	213	68	0
Other income/(expense)		0	0	0	0	0
Exceptionals and adjustments		0	0	0	0	0
Reported PBT		(35,985)	(50,858)	(71,366)	(81,947)	(86,137)
Income tax expense		0	0	0	0	0
Reported net income		(35,985)	(50,858)	(71,366)	(81,947)	(86,137)
Basic average number of shares, m		22.8	37.8	37.8	37.8	37.8
Basic EPS (SEK)		(1.58)	(1.35)	(1.89)	(2.17)	(2.28)
Diluted EPS (SEK)		(1.58)	(1.35)	(1.89)	(2.17)	(2.28)
<b>BALANCE SHEET</b>						
Property, plant and equipment		597	1,768	1,944	2,071	2,162
Intangible assets		17	17	17	17	17
Other non-current assets		7	7	7	7	7
Total non-current assets		621	1,792	1,968	2,095	2,186
Cash and equivalents		234,549	182,499	112,434	30,356	1,000
Trade and other receivables		8	16	8	12	10
Other current assets		2,604	2,448	3,417	3,417	3,417
Total current assets		237,161	184,963	115,859	33,785	4,427
Non-current loans and borrowings*		0	0	0	0	56,870
Total non-current liabilities		0	0	0	0	56,870
Trade and other payables		3,646	2,997	3,966	3,966	3,966
Other current liabilities		967	1,751	3,106	3,106	3,106
Total current liabilities		4,613	4,748	7,072	7,072	7,072
Equity attributable to company		233,169	182,007	110,755	28,808	(57,329)
<b>CASH FLOW</b>						
Operating Profit/(loss)		(35,893)	(50,908)	(71,579)	(82,015)	(86,137)
Depreciation and amortisation		104	290	495	544	580
Other adjustments		0	0	0	0	0
Movements in working capital		(392)	283	1,363	(4)	2
Interest paid / received		(93)	50	213	68	0
Income taxes paid		0	0	0	0	0
Cash from operations (CFO)		(36,274)	(50,285)	(69,508)	(81,407)	(85,556)
Capex		(459)	(1,461)	(671)	(671)	(671)
Acquisitions & disposals net		0	0	0	0	0
Other investing activities		0	0	0	0	0
Cash used in investing activities (CFIA)		(459)	(1,461)	(671)	(671)	(671)
Net proceeds from issue of shares		217,330	(381)	0	0	0
Movements in debt		0	0	0	0	56,870
Other financing activities		0	77	114	0	0
Cash from financing activities (CFF)		217,330	(304)	114	0	56,870
Increase/(decrease) in cash and equivalents		180,597	(52,050)	(70,065)	(82,078)	(29,356)
Cash and equivalents at beginning of period		53,952	234,549	182,499	112,434	30,356
Cash and equivalents at end of period		234,549	182,499	112,434	30,356	1,000
Net (debt) cash		234,549	182,499	112,434	30,356	(55,870)

Source: AlzeCure Pharma accounts, Edison Investment Research. Note: \*Long-term debt used instead of equity issue.

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