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NEWS FLASH

Healthcare

Fair value: SEK2.80–4.60

Share price: SEK1.09

Alzinova

FDA clears ALZ-101 for Fast Track

Research analysts:
Maria Karlsson Osipova
DNB Carnegie Investment Bank AB

The FDA has granted Fast Track Designation for ALZ-101, following encouraging safety and early efficacy data from the completed Phase Ib trial. We view this as a clearly positive regulatory milestone that recognises the potential of ALZ-101, facilitates closer FDA interaction and faster review, and increases partnering attractiveness ahead of the planned Phase II study. Our fair value range remains SEK2.80–4.60 per share.

Fast track designation for ALZ-101 granted. During the weekend, Alzinova announced that the FDA has granted Fast Track Designation for the vaccine candidate ALZ-101 in Alzheimer's disease. The decision follows positive safety and early efficacy signals from the completed Phase Ib trial.

What does it mean? Fast Track designation provides a framework to accelerate the development and review of promising therapies for serious conditions. It allows for more frequent interactions and written communication with the FDA regarding clinical trial design, data collection, and biomarker use. Drugs granted this status may also become eligible for Accelerated Approval and Priority Review, provided certain criteria are met. In addition, Fast Track enables Rolling Review, allowing companies to submit parts of their regulatory application as they are completed, rather than waiting until the full dossier is ready, which potentially can shorten the overall review timeline.

Clearly positive news. In our view, the Fast Track Designation not only recognises the potential of ALZ-101 to address a major unmet medical need in Alzheimer's disease but also facilitates closer interaction with the FDA and the possibility of an expedited review process. We view this as a meaningful regulatory milestone that could facilitate future clinical development for ALZ-101 and we believe this will increase partnering attractiveness ahead of the planned Phase II study.

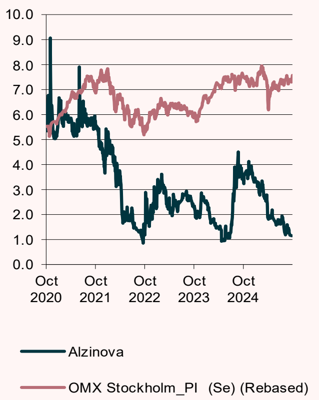
Upcoming events

Key facts

No. shares (m)	104.3
Market cap. (USDm)	12
Market cap. (SEKm)	114
Net IB Debt. (SEKm)	-107
Adjustments (SEKm)	0
EV (2025e) (SEKm)	7
Free float	81.8%
Avg. daily vol. ('000)	467
BBG	ALZ SS
Fiscal year end	December
Share price as of (CET)	03 Oct 2025 17:29

Key figures (SEK)	2024	2025e	2026e	2027e
Sales (m)	0	0	0	0
EBITDA (m)	-20	-41	-81	-91
EBIT (m)	-20	-41	-81	-91
EPS	-0.31	-0.34	-0.62	-0.69
EPS adj.	-0.31	-0.34	-0.62	-0.69
DPS	0.00	0.00	0.00	0.00
Sales growth Y/Y	-chg	n.a.	n.a.	n.a.
EPS adj. growth Y/Y	+chg	-chg	-chg	-chg
EBIT margin	n.m.	n.m.	n.m.	n.m.
P/E adj.	n.m.	n.m.	n.m.	n.m.
EV/EBIT	neg.	neg.	0.2	neg.
EV/EBITA	neg.	neg.	0.2	neg.
EV/EBITDA	neg.	neg.	0.2	neg.
P/BV	0.8	0.5	0.4	0.5
Dividend yield	0.0%	0.0%	0.0%	0.0%
FCF yield	-32.5%	-50.9%	-82.6%	-89.3%
Equity/Total Assets	92.9%	99.7%	99.7%	99.6%
ROCE	-17.2%	-22.3%	-30.0%	-34.6%
ROE adj.	-17.3%	-17.8%	-23.9%	-27.5%
Net IB debt/EBITDA	0.7	2.6	1.6	0.3

Share price – 5-year



High/Low (12M)				**SEK4.1/1.1**
Perf.	3M	6M	12M	YTD
Abs.	-34.02	-41.93	-69.27	-68.38
Rel.	-37.95	-52.23	-69.89	-73.89

Source: DNB Carnegie (estimates), FactSet, Infront & company data

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DNB Bank ASA
DNB Carnegie
Dronning Eufemias gate 30
0191 Oslo | Norway
Telephone: +47 915 04800

www.dnb.no

DNB Carnegie Investment Bank AB

Regeringsgatan 56
103 38 Stockholm | Sweden
Telephone: +46 8 676 88 00

www.dnbcarnegie.se

DNB Carnegie Investment Bank, Denmark Branch
Overgaden neden Vandet 9B PO Box 1935
1414 Copenhagen K | Denmark
Telephone: +45 32 88 02 00

DNB Bank ASA, Singapore Branch
DNB Carnegie
1 Wallich Street Downtown Core 06
#30-01, Guoco Tower,Singapore 078881
Telephone: +65 6260 0111

DNB Carnegie Investment Bank AB, Finland Branch
Eteläesplanadi 2 PO Box 36
FI-00131 Helsinki | Finland
Telephone: +358 9 618 71 230

DNB Bank ASA, London Branch
DNB Carnegie
The Walbrook Building, 25 Walbrook
London EC4N 8AF | England
Telephone: +44 20 7216 4000

DNB Carnegie Investment Bank AB, UK Branch
Finwell House, 26 Finsbury Square
London EC2A 1DS | England
Telephone: +44 20 7216 4000

DNB Carnegie, Inc.

30 Hudson Yards
New York, NY 10001 USA
Telephone: +1 212 551 9800