Q3

Interim report January–September 2023

AlzeCure® is a Swedish pharmaceutical company that develops new innovative small molecule drug therapies for the treatment of severe diseases and conditions that affect the central nervous system, such as Alzheimer's disease and pain – indications for which currently available treatment is very limited. The company is listed on Nasdaq First North Premier Growth Market and is developing several parallel drug candidates based on three research platforms: NeuroRestore®, Alzstatin® and Painless.

NeuroRestore consists of two symptom-relieving drug candidates where the unique mechanism of action allows multiple indications – Alzheimer's disease, as well as cognitive disorders associated with traumatic brain injury, sleep apnea and Parkinson's disease, as well as treatment for depression.

The **Alzstatin** platform focuses on developing disease-modifying and preventive drug candidates for early treatment of Alzheimer's disease and comprises two candidates.

Painless is the company's research platform in the field of pain and contains two projects: ACD440, which is a drug candidate in the clinical development phase for the treatment of neuropathic pain, and TrkA-NAM, which targets severe pain in conditions such as osteoarthritis. AlzeCure® aims to pursue its own projects through preclinical research and development to an early clinical phase and is continually working on business development to find suitable outlicensing solutions or partnerships with other pharmaceutical companies.

FNCA Sweden AB is the company's Certified Adviser.
For more information, please visit www.alzecurepharma.com.

AlzeCure

150,000

It is estimated that around 150,000 people in Sweden live with dementia diseases, a figure that is expected to triple by 2050. Every year, around 25,000 people are affected, resulting in major care and healthcare costs for society. The direct costs are estimated to be higher than those caused by cancer and cardiovascular diseases.

50 million

Alzheimer's is the most common form of dementia, and worldwide around 50 million people are estimated to be living with dementiarelated diseases, a figure that is expected to rise to 82 and 152 million sufferers by the years 2030 and 2050 respectively.

Financial information

July – September 2023

Figures in parentheses refer to the corresponding period of the previous year.

- Net sales during the period totaled SEK 0 thousand (0).
- Earnings for the period totaled SEK –7,655 thousand (–11,097).
- Earnings per share, basic, totaled SEK -0.12 (-0.22).
- Cash flow from operating activities totaled SEK -7,771 thousand (-14,504).
- Total assets at the end of the period amounted to SEK 40,396 thousand (40,486).
- Cash and cash equivalents at the end of the period totaled SEK 37,461 thousand (37,169).

January – September 2023

Figures in parentheses refer to the corresponding period of the previous year.

- Net sales during the period totaled SEK 0 thousand (0).
- Earnings for the period totaled SEK –27,411 thousand (–45,291).
- Earnings per share, basic, totaled SEK -0.44 (-0.97).
- Cash flow from operating activities totaled SEK 11,418 thousand (-48,717).
- Total assets at the end of the period amounted to SEK 40,396 thousand (40,486).
- Cash and cash equivalents at the end of the period totaled SEK 37,461 thousand (37,169).

Significant events

July – September 2023

- On July 3, the company publishes a new scientific article presenting preclinical results demonstrating antidepressant effects of NeuroRestore ACD856.
- On July 11, the company publishes new disease-modifying data regarding NeuroRestore ACD856 for the treatment of Alzheimer's and cognitive disorders.
- On August 9, the company publishes positive clinical results from the Phase I clinical trial with NeuroRestore ACD856 for the treatment of Alzheimer's.
- On September 20, the company presents positive Phase II clinical data on ACD440 for neuropathic pain at the 2023 European Pain Federation (EFIC) conference.

January–June 2023

- In January, the company selects a Candidate Drug (CD) and initiates the preclinical development phase with the company's preventive and disease-modifying compound Alzstatin ACD680.
- In January, the last patient is included in the Phase II clinical trial with the leading non-opioid drug candidate in the Painless platform, ACD440, which is being developed to treat peripheral neuropathic pain.
- The company announces on March 13 that the last patient has completed treatment in the above clinical trial with ACD440.
- In April, the company has an abstract on non-opioid ACD440 for neuropathic pain accepted at the EFIC 2023 Conference.
- On May 17, the company holds its Annual General Meeting and Dr Janet Hoogstraate is elected to serve as a new member of the Board of Directors.
- The company announces on May 22 that a European patent has been granted for the NeuroRestore ACD856 Alzheimer's project.
- On May 24 the company announces positive proof-of-mechanism (POM) data from the Phase IIa clinical trial in neuropathic pain with the non-opioid ACD440.

Significant events after the end of the period

- The company reports in early October that Japan has granted a patent for NeuroRestore ACD856.

See page 61 of the company's 2022 annual report for a list of definitions.

A word from the CEO

The third quarter of 2023 was positive and eventful for AlzeCure Pharma. During the period, we presented new, positive, detailed proof-of-mechanism (POM) results from our Phase II clinical study with ACD440 for the treatment of peripheral neuropathic pain. In addition, we published new preclinical data for our clinical drug candidate NeuroRestore ACD856 supporting potential neuroprotective and disease-modifying effects in Alzheimer's and other neurodegenerative diseases. We also published new preclinical results demonstrating the antidepressant effects of our NeuroRestore compounds. It is gratifying to see that we are keeping up the pace as we continue to deliver and generate new data that strengthen our position, while also paving the way for new opportunities.

Development in the Painless platform, with the ACD440 and TrkA-NAM projects, continues to make progress. During the third quarter, we published positive and detailed results from the Phase II study with ACD440 for the treatment of peripheral neuropathic pain. The study results, which were presented in late September at the EFIC pain conference, showed a clear and significant effect on pain caused by cold or heat in patients with peripheral neuropathic pain. This temperature hypersensitivity is common in patients with neuropathic pain and is a major problem for these individuals. Moreover, it was observed that ACD440, which is a gel that is applied to the skin, was well tolerated and both the compound and the administration method demonstrate good suitability for further clinical development.

The positive Phase II results in patients with chronic peripheral neuropathic pain were in line with previously reported Phase Ib data and are important for further clinical development with ACD440. Neuropathic pain is an area with great unmet medical need, especially with respect to finding alternatives to opioids, and we believe that ACD440 could significantly improve quality of life for patients suffering from this type of pain. Moreover, we also see potential for this compound with respect to nociceptive pain.

Our second pain project, TrkA-NAM, which focuses on arthritis of the knee, also continues to make good progress, and during the period we conducted additional preclinical studies.

During the quarter, we also published three new articles about NeuroRestore ACD856, our leading drug candidate in Alzheimer's and cognition. The new results are promising and support the potential neuroprotective, neuroplastic and diseasedelaying effects of NeuroRestore ACD856, thereby demonstrating "disease-modifying" properties. The results also show that NeuroRestore could potentially be used in combination with antibody therapies, such as the recently approved LeqembiTM (lecanemab). NeuroRestore's disease-modifying data are also validated in part by Eisai's Trka-PAM E2511, which is also in clinical development phase. Eisai has recently published data that they believe support the potential of the drug candidate to have a disease-modifying effect in neurodegenerative diseases.

In October, we had the opportunity to present our results at the world-leading Alzheimer's conference CTAD, which was held in Boston in the US this year, where we showed new data concerning the potential disease-modifying effects of NeuroRestore ACD856.

We also published results from the Phase I clinical trial with NeuroRestore ACD856.[1] The study results showed that ACD856 activated regions of the brain relevant to cognition and depression. The drug candidate also demonstrated good safety and tolerability in humans. The potential of NeuroRestore for treatment of depression was also strengthened by data published in the scientific journal Nature[2], which demonstrated that the antidepressant effect of psychedelic drugs is mediated via the BDNF receptor (TrkB)[3].

Martin Jönsson, CEO

This BDNF-driven antidepressant effect has also been observed with other classes of antidepressants such as SSRIs, which was discussed in the journal Cell[4]. In July, we published new preclinical data indicating antidepressant effects of NeuroRestore compounds, including our clinical candidate ACD856[5]. The effects also appear to be primarily BDNF-driven. The publications have increased interest in NeuroRestore from both academia and other pharmaceutical companies. With more than 300 million people suffering from depression, there is a great need for safer and more effective drugs with a faster response time.

In October, the Japanese Patent Office approved our patent application for NeuroRestore, including ACD856. This is another important step for NeuroRestore, including ACD856, which was previously granted patent protection in the US and Europe until 2039.

Alzstatin, which aims to serve as a disease-modifying and preventive treatment in tablet form for Alzheimer's disease, continues to be developed according to plan. Alzstatin ACD680, our new follow-on candidate drug that offers patent advantages, is in the preclinical development phase and is undergoing safety testing. Alzstatin is a "gamma-secretase modulator" (GSM) that reduces production of the harmful amyloid-beta-42 protein, which generates plaques in the brain. This new class of drugs for Alzheimer's is now garnering increasing attention, and interest is steadily growing. The target mechanism is being validated by the Swiss pharmaceutical company Roche, which is also developing GSM drugs. At the CTAD Alzheimer's conference, Roche presented positive clinical data for its GSM RG6289 and announced that they are now preparing a Phase II clinical trial. This development is beneficial for our Alzstatin project, generating interest from both pharmaceutical companies and investors.

The FDA's full approval of the antibody drug Leqembi is highly significant for the entire Alzheimer's field, providing a clear path for the regulatory authority's approval process for this class of drugs. The approval also validates the hypothesis that amyloid-beta drives disease progression in Alzheimer's patients and that reducing the amount of this protein slows disease progression and cognitive decline. This is important for our Alzstatin project, which is based on this specific hypothesis. However, Alzstatin differs from the antibody drugs in several important respects. Alzstatin is being developed to prevent Alzheimer's; moreover, it is based on small molecules, which are expected to cause fewer side effects and will allow for simple oral administration with tablets or capsules. Small-molecule drugs also generally have lower manufacturing costs, which means they can reach a wider patient population.

We continue to focus on marketing communications and actively participate in various meetings and congresses to present our research to investors and potential partners. In November, we participated in BioEurope, the world's largest business development and partnership conference, which was held in Munich this year. We continue to encounter growing interest from institutional investors, pharmaceutical companies and other stakeholders that may be interested in investing in or in-licensing our development projects, or alternatively in entering into a partnership.

With three strong quarters in 2023, during which we delivered positive Phase II results, published data to support our projects and saw continued growing interest in both our research and the Alzheimer's field as a whole, I look forward to continuing to develop AlzeCure together with our ambitious, talented and productive employees and partners.

Stockholm, November 2023

Martin Jönsson

1) Önnestam K et al, J Prev Alz Disease, July, 2023: http://dx.doi.org/10.14283/jpad.2023.89
2) Moliner, R et al, Nature Neuroscience, (2023) 26, 1032–1041: https://www.nature.com/articles/s41593-023-01316-5
3) O'Grady C, Science, (2023) https://www.science.org/content/article/psychedelic-inspired-drugs-could-relieve-depression-without-causing-hallucinations
4) Casarotto PC et al, Cell, (2021) Mar 4;184(5):1299-1313; https://pubmed.ncbi.nlm.nih.gov/33606976/
5) Madjid et al, Psychopharmacology, (2023) https://doi.org/10.1007/s00213-023-06410-x

"The third quarter of 2023 was positive and eventful for AlzeCure Pharma. During the period, we presented new positive detailed proof-of-mechanism (POM) results from our Phase II clinical study with ACD440 for the treatment of peripheral neuropathic pain.

Martin Jönsson, CEO

Project portfolio

AlzeCure works with several research platforms:
NeuroRestore® and Alzstatin® – with a focus on Alzheimer's disease, where the leading candidate ACD856 is in clinical development phase.
Painless – focuses on pain treatment and contains two projects: ACD440 in clinical development phase and TrkA-NAM in research phase.

There are several small-molecule drug candidates in the various platforms: two in NeuroRestore and two in Alzstatin. There are also two projects in the Painless platform. A diversified drug portfolio paves the way for other indications, such as cognitive disorders associated with Alzheimer's, traumatic brain injury, sleep disturbances, Parkinson's disease and depression, as well as for severe pain in conditions such as neuropathy and osteoarthritis.

- The NeuroRestore platform is developing a new generation of symptom-relieving drugs for the treatment of illnesses with cognitive disorders, such as Alzheimer's disease. The target mechanism also has other potential indications, including depression and cognitive disorders in Parkinson's disease, traumatic brain injury and sleep disorders. The leading drug candidate in the project, ACD856, is in clinical development phase.
- Innovative disease-modifying and preventive oral drugs for Alzheimer's disease are under development within the Alzstatin platform. They are intended to enable simple administration of the drug and be more cost-effective. The two Alzstatin projects are in the preclinical development phase.
- The Painless platform includes two projects: TrkA-NAM and ACD440, which both focus on severe pain conditions.
  - The drug candidate ACD440 was in-licensed in January 2020 and affects a specific biological mechanism; the 2021 Nobel Prize in Physiology or Medicine was awarded for the discovery of this mechanism.
    The compound is being developed for the treatment of neuropathic pain, a field with great unmet medical need. The project is currently in the clinical development phase.
  - The TrkA-NAM project is aimed at treating other severe pain caused by disorders such as osteoarthritis, which today lacks sufficiently effective treatment. The project is currently in the research phase.

AlzeCure's project portfolio[1]

Platform	Candidate	Target	Indication	Research phase	Preclinical phase	Phase I	Phase II	Phase III
NeuroRestore	**ACD856**	Positive allosteric modulator (PAM) of Trk-receptors	Alzheimer's Disease, Sleep disorders, Traumatic brain injury, Parkinson's disease, Depression					
NeuroRestore	**ACD857**	Positive allosteric modulator (PAM) of Trk-receptors	Alzheimer's Disease					
Alzstatin	**ACD679**	Gamma secretase modulator (GSM)	Alzheimer's Disease					
Alzstatin	**ACD680**	Gamma secretase modulator (GSM)	Alzheimer's Disease					
Painless	**ACD440**	TrpV1 antagonist	Neuropathic Pain					
Painless	**TrkA-NAM**	Negative allosteric modulator (NAM) of TrkA-receptors	Osteoarthritic Pain & other severe pain conditions					

In progress Completed

1) For definitions of the phases, please see the AlzeCure Pharma website, www.alzecurepharma.com

Project development

AlzeCure works with research and development of innovative and effective new small molecule drugs for treatment of diseases that affect the nervous system and the brain, with a focus on Alzheimer's disease and pain. The need for new treatments for these severe illnesses is great; for example, disease-modifying therapy for Alzheimer's is expected to be able to generate more than USD 15 billion* in annual sales.

The company is simultaneously developing four drug candidates based on the two research platforms NeuroRestore and Alzstatin, along with two projects within the Painless platform – TrkA-NAM and ACD440.

A diversified portfolio of drug candidates paves the way for other indications, such as cognitive disorders associated with traumatic brain injury, Parkinson's disease and sleep disorders. With its broad portfolio of assets and values, the company maximizes shareholder value by working in multiple indicationareas where there is scientific support for the biological target mechanisms.

Neurology

Within NeuroRestore, a new generation of symptomatic drugs is being developed for the treatment of cognitive dysfunction (memory disorders) in Alzheimer's disease. The NeuroRestore substances are known as Trk-PAMs, which stimulate specific signaling of the neurotrophins NGF (Nerve Growth Factor) and BDNF (Brain Derived Neurotrophic Factor), which play an important role in normal neuronal function. The company initiated the first clinical trial with the primary drug candidate in NeuroRestore, ACD856, in late 2019. The study was completed on schedule in the second quarter of 2020. The results showed that ACD856 was well-suited for further clinical development, which led to the initiation of subsequent clinical trials, the SAD-study, according to plans in the end of 2020. In the third quarter of 2021 the MAD study was also initiated and both of these studies, which are part of the phase I program for the drug candidate, have had the primary purpose of assessing safety and tolerability in humans. The MAD study, which was concluded according to plan in June 2022, showed that ACD856 has a good safety and tolerability profile in humans.

Moreover, the results showed that the compound demonstrated good pharmacokinetic properties with rapid uptake in the body. In addition, ACD856 easily crosses the blood-brain barrier and can be measured in the spinal fluid; these important data support further clinical development work. Moreover, in September 2022 the company reported new EEG results from a planned exploratory analysis in the MAD study, which showed that ACD856 not only reaches the CNS, but also activates neuronal pathways in the brain, of relevance to both cognition and depression. ACD857 is in the research phase and also has the primary indication of cognitive dysfunction/Alzheimer's disease.

New preclinical data within the NeuroRestore platform show potential disease-modifying properties in this class of compounds. In fact, both neurotrophins, NGF and BDNF, play important roles in retaining normal function and development in nerve cells, as well as in protecting them from damage, known as neuroprotective effects. Nerve cell death clearly correlates with functional impairment in Alzheimer's patients and no drugs with these protective effects are currently available on the market. The preclinical studies show that treatment with ACD856 results in increased survival for the nerve cells. In 2022 and 2023, the studies were complemented by additional data concerning the neuroprotective, regenerative and long-term effects of ACD856. Moreover, data show that ACD856 increases the quantity of a specific protein that plays a key role in communication between nerve cells, which is severely affected in the disease. These important data, which highlight the potential of NeuroRestore as both a memory-improving and disease-modifying treatment, have been presented at a number of scientific conferences over the past two years.

There is also strong scientific support for this target mechanism in depression. NeuroRestore compounds, such as ACD856, have

1 **NeuroRestore® – the platform is developing a new generation of symptomatic drugs for the treatment of illnesses with cognitive disorders, such as Alzheimer's disease.**

2 **Alzstatin® – the platform develops innovative disease-modifying and preventive drugs for Alzheimer's disease.**

3 **Painless – two projects: TrkA-NAM and ACD440, which both focus on severe pain.**

> "Diagnostics and biomarkers within the field of Alzheimer's are active fields of research, where key advances made in recent years have been of great importance for diagnostics, as well as for evaluating new drug candidates."
>
> Henrik Zetterberg, professor at Sahlgrenska University and partner in AlzeCure's Alzstatin GSM project.

* Source: Asher Mullard, Nature, June 8, 2021; Landmark Alzheimer's drug Approval.
1) Madjid N. et al., Psychopharmacol. 2023 Aug;240(8):1789-1804.
2) Casarotto PC. et al., Cell. 2021 Mar 4;184(5):1299-1313.
3) Moliner R. et al., Nat Neurosci. 2023 Jun;26(6):1032-1041.
4) https://www.science.org/content/article/psychedelic-inspired-drugs-could-relieve-depression-without-causing-hallucinations

demonstrated effects in preclinical models for depression, with data published in August 2023[1] and that were further supported by data in recently released articles in the prestigious journals Cell[2], Nature[3] and Science[4]. These studies show that several different classes of antidepressants appear to mediate their effects via BDNF/TrkB, further strengthening the link between BDNF and depression. AlzeCure has demonstrated in preclinical models that NeuroRestore compounds possess antidepressant effects and they also induce the release of neurotransmitters in the brain that are associated with depression.

In May 2023, AlzeCure reported that the European Patent Office had granted a patent for NeuroRestore, including ACD856. This patent has been validated in 33 territories across Europe, including Germany, France, the UK, Spain, Italy and Sweden. This achievement is yet another important step for ACD856, in light of the previously granted US patent for this substance.

AlzeCure's disease-modifying research platform for Alzheimer's disease, Alzstatin, focuses specifically on reducing the production of toxic amyloid beta (Aβ42) in the brain. The substances in Alzstatin are known as gamma-secretase modulators (GSMs). Aβ plays a key pathological role in Alzheimer's disease and begins to accumulate in the brain years before clear symptoms develop.

The target mechanism in Alzstatin is confirmed by previously reported study results, which we believe validate the amyloid hypothesis and thus Alzstatin's focus. The small-molecule compounds in the Alzstatin platform simultaneously demonstrate several key properties that distinguish them from antibody treatments; for example, they can be taken as tablets, they easily cross the blood-brain barrier and they can be produced more cost-effectively.

The leading drug candidate within Alzstatin, ACD679, is in preclinical phase and alongside this work, the development of an additional drug candidate is in progress to ensure that the company has the best compound for clinical studies. This substance, ACD680, also entered the preclinical development phase in early January 2023. The drug candidate comes from a newly developed series of molecules that are expected to be advantageous from a patent perspective. New positive preclinical data on ACD680 were presented at the ADPD Alzheimer's and Parkinson's congress in late March 2023, in which the compound showed reductions of toxic Aβ42 by over 50% and good pharmacokinetic properties in vivo.

Pain

The Painless platform contains two projects aimed at developing new treatments for pain. Both projects involve non-opiates, which is important to emphasize, because of the inherent risk associated with opiates for abuse, overdose and secondary injuries – which has led to avoidance of opiates as first-line treatment for pain. Despite this treatment problem they are still frequently used, for which reason the need for new non-opiate treatments is great.

In January 2020, a drug candidate in the clinical development phase aimed at treating neuropathic pain, ACD440 (TRPV1 antagonist), was in-licensed. This project is an important strategic in-licensing that strengthens the company's current clinical portfolio. The ACD440 project has its origins in Big Pharma and is based on strong scientific grounds. The 2021 Nobel Prize in Physiology or Medicine was awarded for the discovery of and insights into TRPV1, the biological system that serves as the basis for ACD440 and is central to temperature regulation and pain. The compound that is being devel-

News in Q3

NeuroRestore/ACD856

- The company publishes several scientific articles on the latest results from the project during the quarter:
  -New preclinical disease-modifying data showing both neuroprotective and regenerative effects with ACD856
  -Antidepressant effects in preclinical models with NeuroRestore compounds, including ACD856
  -Positive clinical data showing both good tolerability and a CNS-mediated effect from the Phase I MAD (Multiple Ascending Dose) study with ACD856
- In September, the company also has an abstract on ACD856 accepted at the international Alzheimer's conference CTAD 2023.

ACD440

- In September the company presents detailed results from the Phase IIa clinical trial with ACD440 at the international pain conference EFIC 2023. The Phase IIa clinical trial was a double-blind, placebo-controlled, randomized, cross-over study aimed at evaluating the efficacy, safety and pharmacokinetics of ACD440. The main results from the study showed an effect on the intended target mechanism (POM) with a clear and significant analgesic effect on pain induced by cold and heat.
- The company receives Nasdaq's sustainability certification signaling its commitment to market transparency and high environmental standards.

Nobel Prize

The 2021 Nobel Prize in Physiology or Medicine was awarded for Professor David Julius' discovery of TRPV1, the biological system that serves as the basis for ACD440 and is central to temperature regulation and pain.

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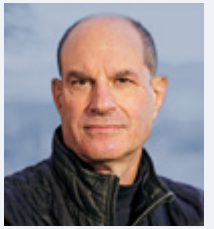


oped as a gel for topical treatment has previously undergone clinical trials, but at that time as oral treatment. As planned, AlzeCure initiated a Phase Ib clinical trial of the drug candidate in late 2020, which was completed in April 2021 and showed positive proof-of-mechanism (POM) results, i.e. an analgesic effect in humans. The efficacy of ACD440 was clearly significant compared with placebo. The compound was also well tolerated as a topical gel on the skin, indicating good suitability for further clinical development as topical treatment for neuropathic pain conditions. During the first quarter of 2022, the FDA provided feedback regarding the material and documentation submitted for a pre-IND meeting. The response was informative and, in June 2022, the company initiated a Phase II trial with ACD440 in patients with peripheral neuropathic pain. This exploratory double-blind, placebo-controlled, randomized, cross-over study aimed to evaluate the efficacy, safety and pharmacokinetics of the company's leading drug candidate in pain. AlzeCure reported positive top-line results from the study in May 2023, while the more detailed results from the study were presented at the international pain conference, EFIC, in September 2023. The patients, who were treated for 7+7 days in a cross-over design, ranged in age from 50-85 years and suffered from chronic neuropathic pain. Most of them were concurrently receiving alternative pain management therapies. Data from the study showed that ACD440 could demonstrate positive POM results in patients with chronic peripheral neuropathic pain; in other words, the drug candidate had an effect on the intended target mechanism. A clear and significant analgesic effect was observed in pain induced by cold and heat. This pain was reduced by about 50%, a significant and clinically relevant reduction. Temperature hypersensitivity is very common in the area of the skin where patients experience their neuropathic pain and is a major problem in daily life for these individuals. The positive POM results from this Phase II clinical trial were in line with previously reported Phase I results. Moreover, it was observed that ACD440, which is a topical gel that is applied to the skin in the painful area was well tolerated, and both the compound and the administration method demonstrated good suitability for further clinical development.

TrkA-NAM builds on the knowledge amassed and assets developed in the NeuroRestore platform, but with the purpose of developing new compounds that focus on providing pain relief in several conditions associated with severe pain. The goal of the project is to develop a small molecule "TrkA-negative allosteric modulator" that can reduce movement-induced and spontaneous pain in patients with painful osteoarthritis. The compounds in the platform block NGF-mediated signaling via TrkA receptors, a biological mechanism with strong genetic, preclinical and clinical validation with respect to its role in pain. The company received the first positive preclinical efficacy data during the latter part of 2020 and is actively working on the development of a drug candidate for preclinical safety studies. In September 2022, AlzeCure presented results for a new compound, AC-0027838, which has been identified as a potent and selective negative modulator of NGF/TrkA signaling in cell-based analyses, at the IASP international pain conference. The results showed a potent analgesic effect in a nociceptive pain model. The data also show that the compound has a powerful anti-inflammatory effect, which can potentiate the analgesic effects in clinical contexts. Analysis of the inflamed tissue also demonstrated significant effects on CGRP, a relevant biomarker for inflammation and pain.

Every 5 seconds someone in the world is diagnosed with Alzheimer's.

"About 70–80 percent of patients with neuropathic pain do not adequately respond to current first-line treatment, and AlzeCure is developing its new intended treatment specifically for individuals in this group.

Market trends affecting AlzeCure®

Increased social costs for Alzheimer's and other neurodegenerative diseases.
Costs associated with Alzheimer's and other neurodegenerative diseases are sharply rising and account for a substantial burden on the public healthcare system. The global cost to society for dementia is estimated at more than USD 1.3 trillion and is expected to almost triple over the next 30 years. These burgeoning costs increase the need for disease-modifying and/or preventive treatments appreciably.

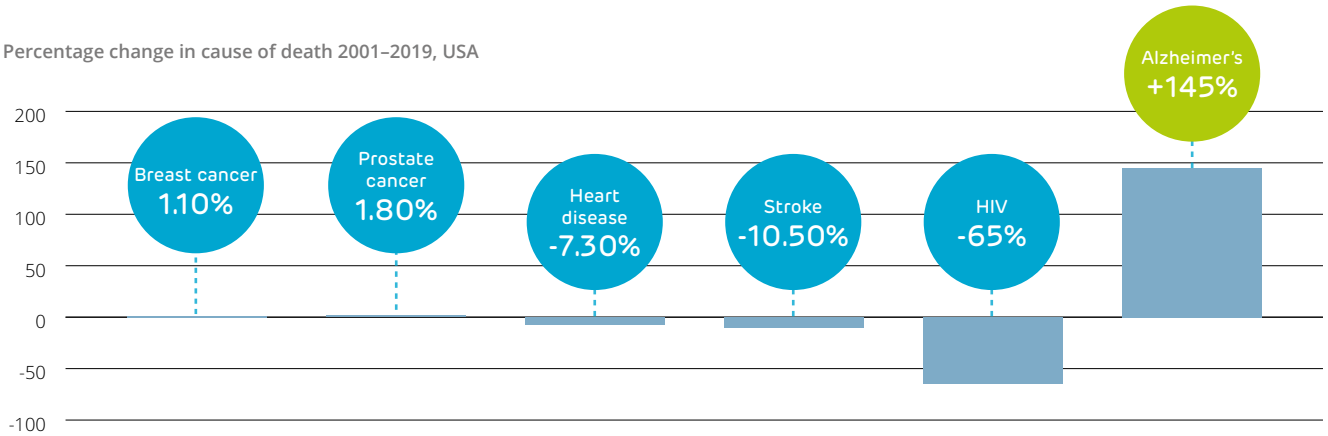
Increased need for treatment due to an aging population.
Old age is the greatest risk factor in dementia-related illnesses such as Alzheimer's, but also for pain problems. Life expectancy is anticipated to rise globally as a result of improving living standards and improved health care.

New treatment for Alzheimer's disease targeting amyloid plaques receives FDA approval
An antibody therapy (Aduhelm™) targeting amyloid pathology received approval in the US in June 2021 as the first disease-modifying treatment for Alzheimer's disease through the FDA's Accelerated Approval process. The approval is based on a "surrogate endpoint," in this case the reduction of beta-amyloid in the brain.

Two other antibody therapies targeting amyloid pathology were also granted "Breakthrough Therapy Designation" status, giving them access to the FDA's other fast track processes, which could lead to a significantly faster pathway to market for drugs in this important area.

Amyloid-based therapeutics show positive effects on cognitive function in Alzheimer's patients and receive full market approval
Leqembi (lecanemab), one of the above-mentioned antibody therapies targeting amyloid pathology, was reported in September 2022 in a pivotal Phase III study to have achieved its efficacy milestones, with significant positive effects on functional and cognitive decline, as well as a reduction in the quantity of amyloid plaque in the brain. These Phase III results, which support the amyloid hypothesis, have served as the basis for the full market approval received from the FDA on July 6, 2023. As a result, there is growing interest in research into other new drugs for the treatment of Alzheimer's disease, such as drugs that attack symptoms in other ways (NeuroRestore), as well as those (such as Alzstatin) that attack amyloid formation early in the course of disease, and that can be administered as tablets – unlike antibody treatment, which is administered intravenously. Drugs such as NeuroRestore and Alzstatin can also potentially be given in combination with existing therapy.

Percentage change in cause of death 2001–2019, USA



The mortality rate for Alzheimer's disease has risen sharply, while several other causes of death have fallen.

Major pharmaceutical companies are allocating investments in CNS-related illnesses to specialized research projects.
An increasing number of major pharmaceutical companies are starting investment funds aimed at smaller research companies and drug companies, as this is where a great deal of innovation takes place. The trend favors smaller R&D companies as opportunities for licensing agreements concerning the research, development and commercialization of drug candidates are increasing.

Development related to diagnostics & biomarkers for Alzheimer's disease
Significant progress has been made in this field through intensive work, including recent findings that a combination of blood-based biomarkers and simple cognitive tests have very high sensitivity for detection of Alzheimer's disease at an earlier stage. Currently, Alzheimer's disease is mainly diagnosed through clinical examination, including a lumbar puncture combined with tests of cognitive ability and brain imaging (PET). A spinal fluid test is an invasive procedure in which spinal fluid is drawn for analysis. PET diagnostics is a nuclear medicine imaging method used to identify differences between healthy brains and brains in patients with Alzheimer's. There is a great need to be able to correctly diagnose Alzheimer's in order to include a relevant population in clinical trials to develop drugs for the disease and the development that is taking place in the field, including in blood-based biomarkers, entails significant progress for the area.

Great need for new pain treatments
In the US alone, an estimated 50 million adults live with chronic or severe pain, and more people suffer from pain than diabetes, cardiovascular diseases and cancer combined. Data from Europe show similar results and the health and socioeconomic costs are estimated at 3-10 percent of gross domestic product in Europe. Regarding the efficacy of currently available drugs in the field, for example, approximately 80 percent of patients with neuropathic pain do not respond adequately to current treatment. Because of the risk of abuse, overdose and secondary injuries, there is also an effort to avoid opiates for treatment of pain. Consequently, there is currently a high unmet medical need for new, non-opiate treatments in this field.

Alzheimer's disease

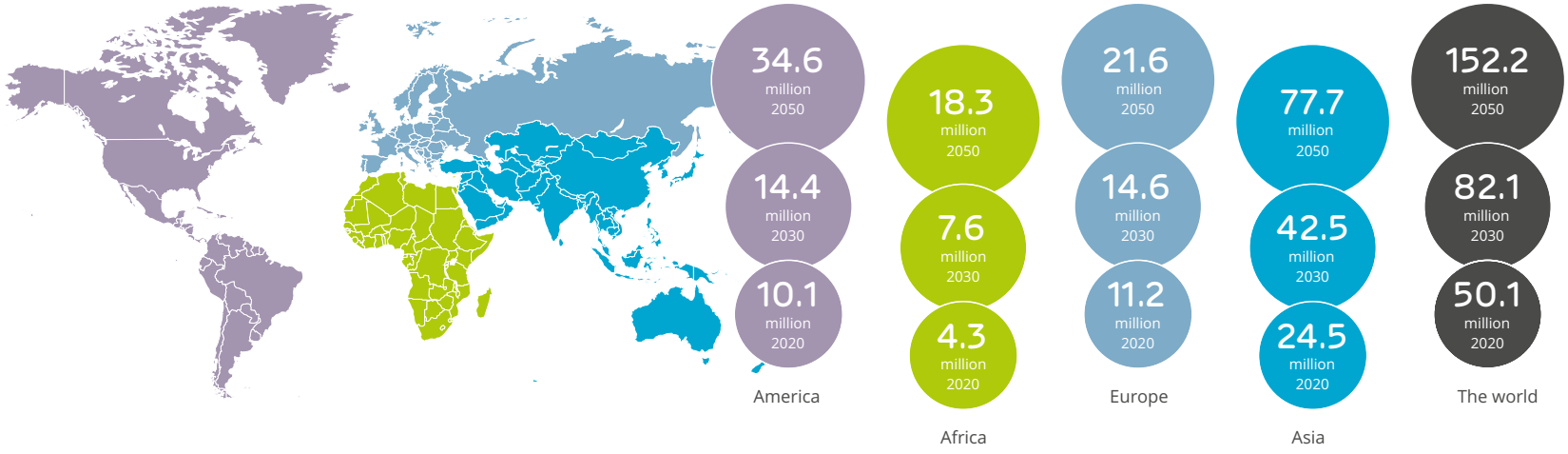
Alzheimer's is the most common form of dementia, with around 60–70 percent of all dementia cases stemming from this illness. It is a deadly disease that has a huge impact on sufferers and their relatives alike. Yet despite this, there is currently a lack of preventive and disease-modifying treatments in the global market.

Alzheimer's disease is a neurodegenerative disease, which is a collective term for various conditions in which the nerve cells of the brain gradually deteriorate and eventually die. Nerve cells have very limited regeneration and damage to them therefore becomes clear and crucial for the functionality of the nervous system. Nerve cell death in the brain in connection with Alzheimer's manifests through a variety of symptoms, such as impaired memory, as well as difficulties finding words, expressing oneself and understanding. Difficulties with the concept of time are also common. Eventually, sufferers experience orientation problems in their surroundings, and difficulties reading, writing and counting or managing practical tasks. Some have problems with perception and difficulty in recognizing what they see, and reasoning and planning become more difficult. With the passage of time, sufferers become more and more dependent on help from relatives and/or care services. Because a characteristic of the disease is its gradual onset, it can be difficult to identify when the problems actually began. Symptoms may also vary from person to person.

Alzheimer's is the most common form of dementia, with around 60–80 percent of all dementia cases stemming from this illness. Even though it is a deadly disease that has a huge impact on both sufferers and their relatives, currently no preventive or disease-modifying treatments are available. The disease starts with amyloid beta (Aβ) protein beginning to clump in the brain, which ultimately form the amyloid plaques so characteristic of the illness. These have a negative impact on nerve cell function and lead, inter alia, to reduced levels of important neurotransmitters in the brain. These neurotransmitters, such as acetylcholine and glutamate, are necessary for nerve cells to communicate with each other and for the normal operation of the brain. With time, the ability of nerve cells to survive also deteriorates and they die.

The reasons that some individuals develop the disease while others do not are as yet unknown, but it is clear that accumulations of Aβ amyloid in the brain play a central part in Alzheimer's. The most common risk factors for developing Alzheimer's are old age and genetic proclivity. The disease may appear early, between the ages of 40 and 65 for the hereditary form, but is most common after 65. The course of disease begins many years before the brain suffers from widespread nerve cell death and the patient shows clinical symptoms. A person diagnosed with Alzheimer's disease lives for an average of four to eight years after being diagnosed.

Geographic distribution and expected growth of prevalence of dementia.



Today, growing sums are being invested in medical research in Alzheimer's due to the extensive human suffering, and the costs to healthcare and society are considerable. Total global costs for dementia-related illnesses are estimated to exceed USD 1.3 trillion, which is expected to almost triple by 2050. The lack of effective symptom-relieving treatments and efficacious treatments that slow or prevent the course (disease-modifying) of the disease represent an urgent medical need. The few approved drugs sold in today's global market have only a limited symptom-relieving effect and entail problematic side effects. Thus there is a very urgent medical need for new symptomatic and disease-modifying treatments. A disease-modifying therapy for Alzheimer's is considered capable of generating more than USD 15 billion in annual sales.

In June 2021, the FDA approved a new Alzheimer's drug in the US, Aduhelm™ (aducanumab), for which one year of treatment costs about USD 28,000. Subsequently, three additional antibody drugs for the treatment of Alzheimer's disease received "Breakthrough Therapy Designation" from the FDA. This status provides access to FDA's other "fast track" processes. Applications for approval of two of these drugs were also submitted to the FDA. One of these, the antibody drug Leqembi (lecanemab), received full approval from the US Food and Drug Administration (FDA) in July 2023, after receiving conditional approval in January 2023. One year of treatment costs about USD 26,500. This approval demonstrates an accessible regulatory pathway for drugs within the field and has led to growing interest in research into new drugs for Alzheimer's disease. The results of the studies with these new Alzheimer's drugs have also validated the amyloid hypothesis – that Aβ plays a central role in the development of the disease in Alzheimer's patients.

Symptoms

Usually, the first signs of Alzheimer's are impaired memory, difficulties in finding words, expressing oneself and understanding. Difficulties with the concept of time are also common. Eventually, sufferers experience orientation problems in their surroundings, and difficulties reading, writing and counting or managing practical tasks. Some have problems with perception and difficulty in recognizing what they see, and reasoning and planning become more difficult. With the passage of time, sufferers become more and more dependent on help from relatives and/or care services. Because a characteristic of the disease is its gradual onset, it can be difficult to identify when the problems actually began. Symptoms may also vary from person to person.

Prevalence

As previously mentioned, Alzheimer's is the most common form of dementia, and worldwide over 50 million people were estimated to be living with dementia-related diseases in 2020, a figure that is expected to rise to 82 and 152 million sufferers by the years 2030 and 2050 respectively. Geographical distribution and the anticipated increase in dementia is shown in the figure above.

It is estimated that around 150,000 people in Sweden are living with dementia diseases, a figure that is expected to double by 2050. Every year, around 25,000 people are affected, resulting in major care and healthcare costs for society. The direct costs in Sweden are greater than those caused by cancer and cardiovascular diseases.

Treatment

On the global market there are currently two different classes of approved symptomatic drugs for the treatment of Alzheimer's disease to improve cognition and memory function.

- Cholinesterase inhibitors: The drug allows the neurotransmitter acetylcholine to work longer in the brain and thus boost nerve cell communications. The drug primarily provides symptom relief, rather than slowing the course of disease.
- NMDA inhibitors: The drug affects glutamate signaling, which plays an important part in nerve cell communications.

However, the effect of the above treatment methods is usually limited and associated with side effects. The most common side effects are gastrointestinal symptoms, including nausea, diarrhea and stomach pain. Other common side effects are problems associated with the heart, high blood pressure, dizziness and headache. The need for new drugs with better symptom-relieving effect and fewer side effects is thus urgent.

AlzeCure's NeuroRestore® and Alzstatin® platforms act in a completely different manner in their treatment of the disease than the drug classes described above. NeuroRestore seeks to improve communication between nerve cells by strengthening the signaling of neurotrophins such as BDNF and NGF, so that memory function is improved in the patient while also avoiding difficult side effects. Alzstatin is aimed at preventing or delaying the very occurrence of the illness by reducing production of toxic amyloid in the brain and thereby preventing the formation of amyloid aggregates such as oligomers and plaque in the brain.

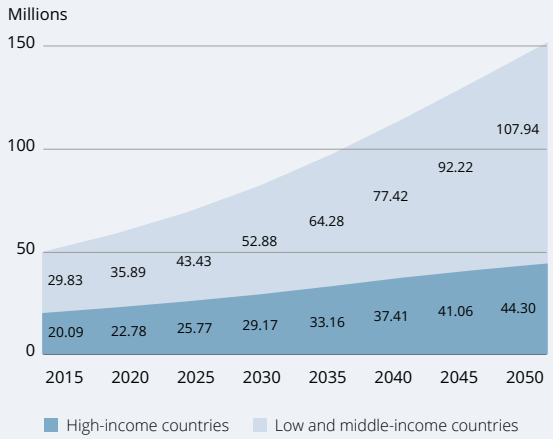
"I am so grateful that AlzeCure is running a project on gamma-secretase modulators (GSMs). There is so much genetic and biochemical data to support this approach, which could be a true primary prevention drug for Alzheimer's."

Henrik Zetterberg, professor at Sahlgrenska University and partner in AlzeCure's Alzstatin GSM project.

> The socioeconomic costs of Alzheimer's disease are currently very high. At the individual level, the problems the disease causes for patients and their families are of course the most important. Currently there is no effective medication for the disease, and subsequently there is a high unmet medical need for both new symptomatic and disease-modifying drugs within this important area.
>
> Professor Bengt Winblad, Karolinska Institutet

The figure below shows the expected growth in the number of cases of dementia between 2015 and 2050. The largest increase in number of cases of dementia and Alzheimer's is expected to occur in low and medium income countries (LMIC), since these countries are expected to demonstrate a higher relative improvement in quality of life than high-income countries (HIC), which leads to an increased life expectancy. The need for novel therapies continues to be very high since there are currently no satisfactory treatment options for such patients.

The number of individuals with dementia in low and middle-income countries compared with high-income countries



Other diseases with cognitive dysfunction

There are several other diseases in which cognitive functions such as memory function and learning are affected; in addition to the classic neurodegenerative diseases such as Alzheimer's and Parkinson's disease, other indications include sleep disorders and traumatic brain injury. The cognitive dysfunction in these indications could be addressed by drug candidates from the NeuroRestore platform.

Sleep apnea

More than 900 million people worldwide suffer from sleep apnea, the majority of whom are undiagnosed. A Swedish population study shows that 50 percent of women between the ages of 20 and 70 have mild sleep apnea and that 6 percent suffer from sleep apnea that is severe enough to require treatment. The condition occurs in particular with overweight and high blood pressure. As the population gradually becomes more overweight, the incidence of sleep apnea is also expected to increase. There is also a hereditary component associated with the condition. One consequence of suffering from sleep apnea is that the patient suffers from extreme fatigue, since the body reflexively wakes up when breathing stops. The body also suffers oxygen insufficiency since breathing is absent for long periods and the body does not get a chance to recover. This fatigue also leads to impaired cognitive ability. The patients' symptoms are somewhat similar to Alzheimer's, since memory function, learning and other cognitive abilities are negatively impacted by sleep apnea.

Traumatic brain injury (TBI)

Traumatic brain injury (TBI) is caused by external trauma where the nerve cells in the brain are immediately damaged. TBI is a major global health and socioeconomic problem and is a common cause of death, especially among young adults, and can cause lifelong injuries among those who survive. Every year about 10 million people suffer from TBI worldwide. In North America, TBI affects about 1.7 million individuals annually, with total medical costs of more than SEK 600 billion. The global market for treatment of TBI is expected to grow from SEK 970 billion in 2017 to SEK 1,350 billion in 2024. The two most common causes of TBI are traffic accidents and falls. The majority of other causes of cases of TBI are violence or work or sports-related. The increase in TBI is due in part to the increased use of vehicles in low and middle-income countries.

TBI has been shown to increase the risk of developing dementia-related diseases, such as Alzheimer's disease and other neurodegenerative diseases, such as Parkinson's disease. Studies show that a person who sustains a TBI is at an approximately 24 percent increased risk of suffering from dementia.

The symptoms of TBI may be both physical and mental, and vary depending on the severity of the injury. Common symptoms include memory loss, headache, fatigue, sleep difficulties, concentration difficulties and mood swings. Depression during or after TBI is common. Within one year, half of all people with TBI suffer from depression, and within seven years, two thirds are affected.

Parkinson's disease

Parkinson's disease is a chronic and progressive neurodegenerative disease. The diagnosis is based on the patient having a combination of motor symptoms, such as tremors, mobility impairment, muscle stiffness, and balance and walking difficulties. The symptoms occur mainly as a result of a gradual loss of dopamine-containing nerve cells in the brain. In addition to the motor problems, impairment of cognitive functions such as memory and attention are also common.

Common cognitive problems include difficulties with:

- Attention and concentration.
- Planning such as organizing an eventful day.
- Following complicated conversations and the ability to solve complex problems.
- Being able to quickly formulate thoughts.
- Remembering events or special details, but where clues often guide the memory back.

Dementia associated with Parkinson's disease is not an uncommon type of dementia, accounting for about 1.5–3 percent of all dementia cases.

Pain

Pain, both acute and chronic, afflicts millions of people around the world. Pain can be categorized in different ways, but one of the most common is nociceptive versus neuropathic pain.

Nociceptive pain is the result of activity in signaling pathways caused by tissue damage. Nociceptive pain is usually acute and develops in response to a specific situation, such as postsurgical pain and pain associated with sports injuries. It tends to disappear when the affected body part heals. An example of chronic nociceptive pain that lasts for more than 3–6 months is pain from osteoarthritis.

The body contains specialized nerve cells, which in turn have sensors known as nociceptors. They react to stimuli that can injure the body, such as extreme heat or cold, pressure, crushing and chemicals. These warning signals are then transmitted along the nervous system to the brain. This happens very quickly in real time, such as quickly pulling away hands after touching a hot oven, or not putting weight on an injured ankle.

Neuropathic pain is pain resulting from dysfunction in or direct damage to the nervous system. Neuropathic pain is almost always chronic. Chronic pain is a disabling disease that affects every aspect of the patient's life, which includes the ability of the individual to work and engage in social and leisure activities. Neuropathic pain affects a total of approximately 7–8 percent of the adult population, which means about 600 million people worldwide. People with certain diseases, such as diabetes and HIV, suffer from neuropathic pain to a greater extent; about 25 and 35 percent of patients with these conditions, respectively, experience neuropathic pain.

Peripheral neuropathic pain results from various types of damage to the nerve fibers, such as toxic, traumatic, metabolic, infection-related, or compressional injuries. Common symptoms are painful tingling or itching that can be described as a stabbing or burning pain, including a sensation of getting an electric shock. Patients may also experience allodynia (pain caused by a stimulus that usually does not cause pain) or hyperalgesia (increased pain from a stimulus that normally provokes pain). Examples of conditions associated with neuropathic pain are painful peripheral neuropathy caused by conditions such as diabetes, painful postherpetic neuralgia (shingles), neuropathic pain induced by chemotherapy and/or direct injury to the nerve.

Osteoarthritis ("wear and tear arthritis") can affect all joints of the body, but most common are the knees, hips, back and shoulders. It was previously believed that this pain was due entirely to local inflammation. It is now known that other mechanisms are involved, and that the pain is primarily nociceptive in nature. Osteoarthritis pain also affects most aspects of the patient's life; in addition to the severe pain itself, it limits mobility and the ability to work, while also making it difficult to engage in leisure activities and a social life. Physical exercise can only help to a limited extent, while existing drug treatments have only a small effect on the pain and should not be given to patients with conditions such as cardiovascular or lung disease. Therefore there is a great need for new effective drugs for the treatment of osteoarthritis pain.

Prevalence

An estimated 50 million adults in the US suffer from chronic pain that requires treatment. More Americans currently suffer from pain than diabetes, heart disease and cancer combined. The data from Europe show similar results and health and socioeconomic costs are estimated at 3–10 percent of gross domestic product in Europe.

The neuropathic pain market is characterized by high unmet medical need in all indications and in all major markets, where only 20–30 percent of patients respond to existing treatments. The patient population is expected to continue to grow, due to factors such as an aging population, an increased incidence of type 2 diabetes, and a growing number of cancer survivors who were previously treated with chemotherapy. The global market for neuropathic pain was valued at about USD 11 billion in 2020 and is expected to grow to USD 25 billion by 2027.

Woman suffering from postherpetic neuralgia after developing shingles:

"When I was diagnosed, and if someone had told me then, that — this is what you'll have to live with — then I'd have done something really crazy. This has really destroyed a large part of my life. I can tolerate a lot of pain, I've had breast cancer surgery, received chemotherapy and never complained, but this is horrendous. I've just received a new treatment, but I don't think it helps at all. " *Britt.*

600 million

Neuropathic pain affects a total of approximately 7–8 percent of the adult population, which means about 600 million people worldwide.

USD 25 billion

The global market for neuropathic pain was valued at about USD 11 billion in 2020 and is expected to grow to USD 25 billion by 2027.

Treatment

There is currently a major medical need for several different severe pain conditions. For example, about 70–80 percent of patients with neuropathic pain do not experience adequate pain relief with existing treatments. Because of the risk of abuse, overdose and secondary injuries, nowadays doctors avoid prescribing opiates as first-line treatment for pain. Despite this treatment problem they are still frequently used, for which reason the need for new non-opiate treatments is great.

Comments on the report

Financial overview

SEK thousand	July–Sept. 2023	July–Sept. 2022	Jan.–Sept. 2023	Jan.–Sept. 2022	Jan.–Dec. 2022
Net sales	0	0	0	0	0
Operating profit/loss	-7,969	-11,172	-28,228	-45,412	-56,442
Earnings for the period and comprehensive income	-7,655	-11,097	-27,411	-45,291	-56,239
Earnings per share, basic (SEK)	-0.12	-0.22	-0.44	-0.97	-1.18
Research expenses as a percentage of operating expenses (%)	70.5	79.9	72.9	83.4	81.6
Cash flow from operating activities	-7,771	-14,504	11,418	-48,717	-99,911
Total assets	40,396	40,486	40,396	40,486	70,836
Cash and cash equivalents	37,461	37,169	37,461	37,169	25,577
Debt/equity ratio (%)	83.0	78.6	83.0	78.6	85.4
Average number of shares, basic	62,087,012	50,733,365	62,087,012	46,683,667	47,696,091
Average number of employees	11	13	11	13	13

See the definitions below.

Revenue and profit/loss

The company had no net sales during the period, which is in line with its plan and with earlier periods.

The operating loss for the third quarter of 2023 totaled SEK -7,969 thousand (-11,172). The operating loss for the period January to September was SEK -28,228 thousand (-45,412). During the corresponding period in 2022 the company still had more capital-intensive research projects. The company continued to conduct research in the third quarter of 2023, with steady progress according to plan. Research expenses accounted for 70.5 percent (79.9) of operating expenses in the third quarter and a total of 72.9 percent (83.4) for the period January to September 2023. More information about research at AlzeCure can be found in the "Project Portfolio" and "Project Development" sections of this report.

Administrative expenses this quarter were on a par with such expenses during the same period the previous year. The same applies for the period January to September. The company plans to continue to focus on communication and business development, including internationally. Operating profit/loss is in line with the company's plan for 2023.

The company had 11 (13) employees on the closing date.

Earnings per share (basic) amounted to SEK -0.12 (-0.22) for the third quarter of 2023, and SEK -0.44 (-0.97) for the period January to September 2023.

Financial position

At the end of the period, equity was SEK 33,530 thousand (31,828) and the debt/equity ratio was 83.0 percent (78.6). Cash and cash equivalents at the end of the period totaled SEK 37,461 thousand (37,169).

During the fourth quarter of 2022 a rights issue raised SEK 31.7 million with a possible overallotment of SEK 15 million. The issue was 134.3% subscribed and raised a total of SEK 42.6 million before issue expenses; a total of 11,353,647 shares were issued. Issue expenses totaled SEK 3.0 million. The issue proceeds were received in January 2023. A late credit against issue expenses resulted in a slight increase in liquidity in the first half of 2023.

At the Annual General Meeting on May 17, 2023, the company launched another incentive program with 500,000 warrants aimed at the company's Chief Executive Officer. For more details, please see "Share-related compensation programs" in the report.

As of the closing date of September 30, 2023, a total of 500,000 warrants were issued. However, this results in a dilution effect of 0 percent on the closing date.

Cash flow and investments

Cash flow from operating activities including changes in working capital for the third quarter of 2023 totaled SEK -7,771 thousand (-14,504). For the period January to September 2023, the corresponding cash flow totaled SEK 11,418 thousand (-48,717).

Cash flow from investing activities totaled SEK 0 thousand (-0) in the third quarter and the corresponding figures for the period January to September 2023 are SEK 7 thousand (0). Historically, the company has mainly invested in laboratory equipment.

Cash flow from financing activities totaled SEK 0 thousand (0) for the third quarter of 2023. For the period January to September, cash flow from financing activities totaled SEK 459 thousand (44,145). Cash flow consists of a credited issue expense, attributable to the issuance in the fourth quarter of 2022 and a new incentive program aimed at the CEO.

Accounting policies and valuation principles

General information and compliance with IAS 34

The company's interim report has been prepared in accordance with IAS 34 Interim Financial Reporting, with consideration for the exceptions and additions to IFRS stated in RFR 2. AlzeCure Pharma AB (publ) is domiciled in Stockholm.

No expenses during the period have been deemed to meet the requirement for capitalization according to IAS38. The company's research has not yet advanced far enough for capitalization.

Significant accounting policies and valuation principles

This interim report has been prepared in compliance with the accounting policies and valuation principles applied in the company's most recent annual report.

Significant estimates and assumptions

When preparing interim reports, the Board and the CEO must, in accordance with the applicable accounting policies and valuation policies, make certain estimates, assessments and assumptions that affect the recognition and valuation of assets, provisions, liabilities, income and expenses. The outcome may deviate from these estimates and assessments and will very rarely amount to the same sum as the estimated outcome.

The estimates and assessments made in the interim report, including the assessment of the main causes of uncertainty, are the same as those applied in the most recent Annual Report.

Key ratios and definitions

Earnings per share: net sales for the period divided by the average number of shares during the period.

Debt/equity ratio: equity, and where applicable untaxed reserves (less deferred tax), in relation to total assets.

Research expenses as a percentage of total operating expenses: Research expenses divided by operating expenses, which include research expenses, administrative expenses and other operating expenses. Research expenses include the company's direct expenses relating to research activities such as expenditures for personnel, material and external services.

Significant risks and uncertainties

The company develops drug candidates and activities will always involve regulatory, market and financial risks. Financing risk is deemed to have increased as a result of the current financial climate and geopolitical turmoil. Financing risk refers to the ability to finance projects to the point of commercialization. The company manages this by the timely preparation of capital infusions. See also the "Going concern" section below.

Otherwise, no significant changes regarding those risks and uncertainty factors took place during the period compared with those presented in the most recent annual report.

The geopolitical situation in the world is extremely uncertain, and it is difficult to say how it may affect the company's development. The company currently has no transactions or activities associated with Russia.

The general economy, both domestically and internationally, will continue to be a challenge for all companies going forward. It is extremely likely that high inflation and higher interest rates will lead to increased costs. The company is very cost conscious and continues to focus on prioritizing activities.

Related party transactions

During the second quarter of 2022, a consulting agreement was signed, on arm's-length terms, with the company R Linder Consulting, which is owned by Board member Ragnar Linder. The agreement covers consulting services related to business development. During the third quarter of 2023 the fee for consulting services totaled SEK 23,000 and the total for the period January to September was SEK 72 thousand.

Going concern

The company's available funds and equity as of September 30, 2023, do not cover the liquidity needed to conduct the identified possible activities for the next 12 months. Financing risk has increased during the year as a result of the current financial climate and geopolitical turmoil. In light of these circumstances, the board is working diligently to prepare for a capital infusion in a timely manner. Otherwise, the company has the option of re-prioritizing its operations and adjusting its costs and expenses, based on the capital available in the company. The most recent issue was 134% oversubscribed and the support from our current shareholders feels reassuring.

Reconciliation of alternative performance measures

SEK thousand	July–Sept. 2023	July–Sept. 2022	Jan.–Sept. 2023	Jan.–Sept. 2022	Jan.–Dec. 2022
Research expenses as a percentage of total operating expenses:					
Research expenses	-5,628	-8,934	-20,651	-37,984	-46,183
Administrative expenses	-2,334	-2,191	-7,615	-7,334	-10,168
Other operating expenses	-17	-51	-64	-212	-230
Total operating expenses	**-7,979**	**-11,176**	**-28,330**	**-45,530**	**-56,581**
Research expenses as a percentage of total operating expenses:	**70.5%**	**79.9%**	**72.9%**	**83.4%**	**81.6%**
Debt/equity ratio (%) September 30, 2023:					
Total equity at end of period	33,530	31,828	33,530	31,828	60,482
Total assets at end of period	40,396	40,486	40,396	40,486	70,836
Debt/equity ratio (%):	**83.0%**	**78.6%**	**83.0%**	**78.6%**	**85.4%**

The share, share capital & ownership structure

The share

The share has traded on Nasdaq First North Premier Growth Market under the name ALZCUR since November 28, 2018.

Share-related compensation programs

In 2020 the company provided an incentive program with warrants aimed at the Chief Executive Officer. A total of 300,000 warrants were issued. The warrants, which were issued at the market price based on an external valuation as of May 20, 2020, entitled the holder to subscribe for shares during the period June 15, 2023 – July 5, 2023. Subscription did not occur.

The company offered an additional incentive program in 2023 with warrants, once again aimed at the Chief Executive Officer. A total of 500,000 warrants were issued. The warrants, which were issued at the market price based on an external valuation as of May 17, 2023, entitle the holder to subscribe for shares during the period July 1, 2026 – August 1, 2026. The issue price for newly subscribed shares totaled 150 percent of the volume-weighted average closing price for the company's shares on the Nasdaq First North Premier Growth Market during the 10 trading days preceding the Annual General Meeting on Wednesday, May 17, 2023. For more information, see the minutes from the annual meeting.

The total dilutive effect of the incentive programs is 0 percent on the closing date.

Financial calendar

Interim report Q4, October–December 2023	February 27, 2024
Annual Report 2023	April 4, 2024
Interim report Q1, January–March 2024	May 2, 2024
Annual General Meeting	May 14, 2024
Interim report Q2, April–June 2024	August 26, 2024
Interim report Q3, July–September 2024	November 11, 2024

Nomination Committee

AlzeCure Pharma's nomination committee for the 2024 Annual General Meeting was appointed in accordance with the principles adopted by the Annual General Meeting on May 22, 2019 and consists of: William Gunnarsson, appointed by BWG Invest Sàrl, Rolf Karlsson, appointed by FV Group AB, Peter Thelin, appointed by Sjuenda Holding AB and Thomas Pollare (Chairman of the Board).

Owners as of September 30, 2023

The 10 largest owners as of September 30, 2023	Number of shares	Share capital and votes
BWG Invest Sàrl	8,747,295	14.1%
FV Group AB	4,400,000	7.1%
Sjuenda Holding AB	4,400,000	7.1%
Avanza Pension	2,407,309	3.9%
SEB-Stiftelsen	2,286,666	3.7%
Futur Pension	1,856,230	3.0%
Nordnet Pensionsförsäkring AB	1,829,462	2.9%
AlzeCure Discovery AB	1,710,000	2.8%
Thomas Pollare	1,501,293	2.4%
Acturum Life	985,915	1.6%
10 largest owners	**30,124,170**	**48.5%**
Other	31,962,842	51.5%
TOTAL	**62,087,012**	**100%**

The Board's assurance

The Board of Directors and the CEO hereby certify that this interim report provides a true and fair view of the company's operations, position and results and describes significant risks and uncertainties facing the company.

Huddinge, November 9, 2023

Thomas Pollare
Chairman of the Board

Eva Lilienberg
Board member

Ragnar Linder
Board member

Ellen Donnelly
Board member

Janet Hoogstraate
Board member

Martin Jönsson
Chief Executive Officer

This report has been reviewed by the company's auditors.

For more information, please see www.alzecurepharma.com or contact:
Martin Jönsson, CEO, info@alzecurepharma.com

FNCA is the company's Certified Adviser.
FNCA Sweden AB, info@fnca.se

Review report of condensed interim financial information (Interim report) prepared in accordance with IAS 34 and Chapter 9 of the Swedish Annual Accounts Act (1995:1554)

To the Board of Directors of AlzeCure Pharma AB (publ), corporate ID number 559094–8302.

Introduction

We have reviewed the interim financial information in summary (interim report) of Alzecure Pharma AB (publ.) as of 30 September 2023 and the nine-month period then ended. The Board of Directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity." A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review has a different focus and is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards.

The procedures performed in a review do not enable us to obtain assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not, in all material respects, prepared in accordance with IAS 34 and the Swedish Annual Accounts Act.

Stockholm, November 9, 2023
Grant Thornton Sweden AB

Camilla Nilsson
Authorized Public Accountant

Income statement and other comprehensive income

SEK thousand	July–Sept. 2023	July–Sept. 2022	Jan.–Sept. 2023	Jan.–Sept. 2022	Jan.–Dec. 2022
Net sales	0	0	0	0	0
Operating expenses					
Research expenses	-5,628	-8,934	-20,651	-37,984	-46,183
Administrative expenses	-2,334	-2,191	-7,615	-7,334	-10,168
Other operating income	10	4	102	118	139
Other operating expenses	-17	-51	-64	-212	-230
Operating profit/loss	**-7,969**	**-11,172**	**-28,228**	**-45,412**	**-56,442**
Profit/loss from financial items					
Interest income and similar profit/loss items	315	75	824	125	207
Interest expenses and similar profit/loss items	-1	0	-7	-4	-4
Loss after financial items	**-7,655**	**-11,097**	**-27,411**	**-45,291**	**-56,239**
Earnings for the period and comprehensive income	**-7,655**	**-11,097**	**-27,411**	**-45,291**	**-56,239**
Earnings for the period per share, basic, SEK	-0.12	-0.22	-0.44	-0.97	-1.18
Earnings for the period per share, diluted, SEK	-0.12	-0.22	-0.44	-0.97	-1.18
Average number of shares, basic	62,087,012	50,733,365	62,087,012	46,683,667	47,696,091
Average number of shares, diluted	62,087,012	51,033,365	62,087,012	47,057,000	48,051,091

Balance sheet

SEK thousand	Sept. 30, 2023	Sept. 30, 2022	Dec. 31, 2022
ASSETS			
Non-current assets			
Capital subscribed but not yet paid in	0	0	42,455
Intangible fixed assets			
Project rights	17	17	17
Total intangible fixed assets	**17**	**17**	**17**
Tangible fixed assets			
Equipment, tools and installations	486	988	852
Total tangible fixed assets	**486**	**988**	**852**
Financial fixed assets	0	7	7
Total non-current assets	**503**	**1,012**	**876**
Current assets			
Current receivables			
Other current receivables	1,118	1,333	1,377
Prepaid expenses and accrued income	1,314	972	551
Total current receivables	**2,432**	**2,305**	**1,928**
Cash and bank balances	**37,461**	**37,169**	**25,577**
Total current assets	**39,893**	**39,474**	**27,505**
TOTAL ASSETS	**40,396**	**40,486**	**70,836**

SEK thousand	Sept. 30, 2023	Sept. 30, 2022	Dec. 31, 2022
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	1,552	1,268	1,268
Share capital not registered	0	0	284
Total restricted equity	**1,552**	**1,268**	**1,552**
Unrestricted equity			
Share premium reserve	362,440	322,663	361,981
Accumulated profit/loss	-303,051	-246,812	-246,812
Profit/loss for the period	-27,411	-45,291	-56,239
Total unrestricted equity	**31,978**	**30,560**	**58,930**
Total equity	**33,530**	**31,828**	**60,482**
Current liabilities			
Trade payables	1,915	3,117	4,845
Other current liabilities	323	339	333
Accrued expenses and deferred income	4,628	5,202	5,176
Total current liabilities	**6,866**	**8,658**	**10,354**
Total liabilities	**6,866**	**8,658**	**10,354**
TOTAL EQUITY AND LIABILITIES	**40,396**	**40,486**	**70,836**

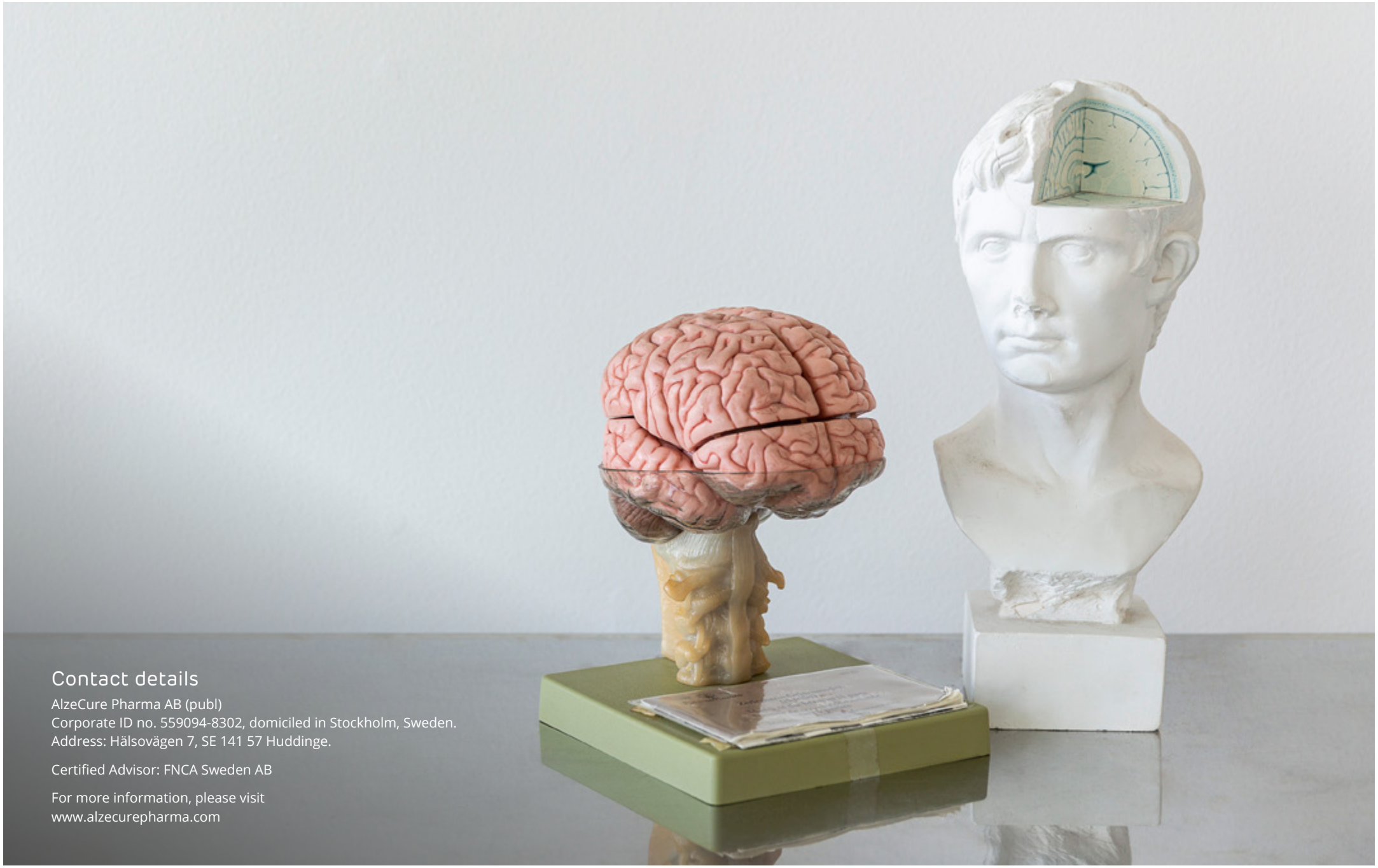
Statement of change in equity

SEK thousand	Share capital	Share premium reserve	Accumulated profit/loss	Profit/loss for the year	Total equity
Opening balance January 1, 2022	**944**	**278,842**	**-169,031**	**-77,781**	**32,974**
Appropriation of earnings			-77,781	77,781	0
Rights issue	303	48,187			48,490
Issue expenses		-7,231			-7,231
Set-off issue	21	2,978			2,999
Issue expenses		-113			-113
New share issue	284	42,292			42,576
Issue expenses		-2,974			-2,974
Earnings for the year and comprehensive income				-56,239	-56,239
Closing balance December 31, 2022	**1,552**	**361,981**	**-246,812**	**-56,239**	**60,482**

Opening balance January 1, 2023	**1,552**	**361,981**	**-246,812**	**-56,239**	**60,482**
Appropriation of earnings			-56,239	56,239	0
Rights issue					0
Issue expenses		39			39
Warrants		420			420
Earnings for the period and comprehensive income				-27,411	-27,411
Closing balance September 30, 2023	**1,552**	**362,440**	**-303,051**	**-27,411**	**33,530**

Cash flow statement

SEK thousand	July–Sept. 2023	July–Sept. 2022	Jan.–Sept. 2023	Jan.–Sept. 2022	Jan.–Dec. 2022
Operating activities					
Operating loss before financial items	-7,969	-11,172	-28,228	-45,412	-56,442
Adjustment for items not included in cash flow, etc.					
Depreciation and amortization	109	145	366	434	570
Interest received	315	75	824	125	207
Interest paid	-1	0	-7	-4	-4
Cash flow from operating activities before changes in working capital	-7,546	-10,952	-27,045	-44,857	-55,669
Statement of change in working capital					
Change in current receivables	-157	168	41,951	155	-41,923
Change in trade payables	-57	-1,346	-2,930	-2,854	-1,126
Change in current operating liabilities	-11	-2,374	-558	-1,161	-1,193
Net cash flow from operating activities	**-7,771**	**-14,504**	**11,418**	**-48,717**	**-99,911**
Investing activities					
Repayment of financial fixed assets	0	0	7	0	0
Cash flow from investing activities	**0**	**0**	**7**	**0**	**0**
Financing activities					
Issues	0	0	420	51,489	94,065
Issue expenses	0	0	39	-7,344	-10,318
Cash flow from financing activities	**0**	**0**	**459**	**44,145**	**83,747**
Cash flow for the year	**-7,771**	**-14,504**	**11,877**	**-4,572**	**-16,164**
Cash and cash equivalents at beginning of period	45,232	51,673	25,577	41,741	41,741
Cash and cash equivalents at end of period	**37,461**	**37,169**	**37,454**	**37,169**	**25,577**



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