Interim report January–September 2021

AlzeCure® is a Swedish pharmaceutical company that develops new innovative 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 symptomatic drug candidates where the unique mechanism of action allows for multiple indications, including Alzheimer's disease, as well as cognitive disorders associated with traumatic brain injury, sleep apnea and Parkinson's disease. The Alzstatin platform focuses on developing disease-modifying and preventive drug candidates for early treatment of Alzheimer's disease and comprises two drug 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 through an early clinical phase and is continually working on business development to find suitable outlicensing solutions with other pharmaceutical companies.

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is the company's Certified Adviser.

For more information, please visit www.alzecurepharma.com.

AlzeCure

Financial information

July–September 2021

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

- Net sales during the period totaled SEK 0 thousand (0).
- Loss for the period totaled SEK -16,507 thousand (-21,455).
- Earnings per share, basic, totaled SEK -0.44 (-0.57).
- Total assets at the end of the period amounted to SEK 68,299 thousand (138,334).
- Cash and cash equivalents at the end of the period totaled SEK 62,672 thousand (132,976).

January–September 2021

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

- Net sales during the period amounted to SEK 0 thousand (0).
- The earnings for the period amounted to SEK –55,162 thousand (–53,646).
- Earnings per share before dilution amounted to SEK –1.46 (–1.42).
- Total assets amounted to SEK 68,299 thousand (138,334) at the end of the period.
- Cash and cash equivalents amounted to SEK 62,672 thousand (132,976) at the end of the period.

Significant events

January–September 2021

- The company appointed Associate Professor Märta Segerdahl Storck, MD/PhD, to serve as Chief Medical Officer (CMO). Dr. Segerdahl took up the position on April 1 and is responsible for our clinical development activities. She is also part of AlzeCure's management group.
- In April the company received, slightly ahead of plan, positive and significant efficacy data from the phase Ib clinical trial with the drug candidate ACD440 for neuropathic pain. It was also well tolerated as a topical treatment.
- Eva Lilienberg was elected to serve on AlzeCure's Board of Directors at the Annual General Meeting on May 17. Eva further strengthens the company with her broad international regulatory and commercial experience.
- In July, a new publication on ACD856 was published in the journal Cells, describing the preclinical development of the substances within the NeuroRestore platform and results were presented. (Identification of Novel Positive Allosteric Modulators of Neurotrophin Receptors for the Treatment of Cognitive Dysfunction, Cells 2021 Jul23; 10 (8): 1871.)
- New data supporting targeting Trk receptors with ACD856 for treatment of Alzheimer's disease presented at Alzheimer's Association International Conference (AAIC) 2021 on July 26-30 in Denver USA.
- In August the company received approval from the Medical Products Agency to be able to give additional doses of ACD856 in the clinical phase I study (single ascending dose, SAD) with ACD856, as its good tolerability enables higher doses to be tested.
- In August the company received approval from the regulatory authorities in Sweden to begin the next clinical phase I study (multiple ascending dose, MAD) with the candidate drug ACD856 focused on Alzheimer's disease.

Significant events after the end of the period

- In October the first participant in the clinical phase I study (MAD) with the drug candidate ACD856 was dosed.
- The company presented the potential of the NeuroRestore project in depression at the European College of Neuropsychophamacology (ECNP 2021 on October 2-5 in Lisbon.

A word from the CEO

During the third quarter, we received positive data from our Phase I SAD clinical trial with the drug candidate ACD856, which is part of the NeuroRestore platform and which we are developing with a focus on Alzheimer's disease. We also received approval to test higher doses of the compound in the study, which is now underway, and after the end of the quarter we also started our Phase I MAD clinical trial with this compound. Regarding our ACD440 pain project, that belongs to the Painless platform and targets neuropathic pain, we have now submitted a request for a pre-IND meeting to the FDA for a planned Phase II study. We also focused on further developing new compounds in our preclinical pain project, TrkA-NAM, with the aim of choosing a drug candidate for the project in the second half of 2021. Thus we have once again closed the books on yet another positive and very active quarter at AlzeCure.


Martin Jönsson, CEO

AlzeCure continues to make good progress, according to plan, in areas that are increasingly relevant and drawing greater attention. Interest in Alzheimer's disease is growing, which was particularly evidenced by the US Food and Drug Administration's (FDA) approval over the summer of a new drug for the disease, Aduhelm™ (aducanumab), the first new drug for Alzheimer's disease in 18 years. Subsequently, the FDA granted "Breakthrough Therapy Designation" to three additional antibody drugs for Alzheimer's disease.

Through its actions and announcements, the FDA has demonstrated its understanding of the great medical need in this area and its support for the amyloid hypothesis: that the build-up of harmful amyloid beta in the brain plays a fundamental role in the development of Alzheimer's disease.

The FDA decisions and the increased activity in the field of Alzheimer's are highly encouraging, both for patients and for AlzeCure with respect to interest from Big Pharma in our Alzheimer's projects. We see great benefits from our projects, which are based on small molecules that do not require invasive administration in the inpatient setting, but can be taken as a tablet at home. Small molecules can also be more easily designed to better penetrate the blood-brain barrier and they are often more cost-effective than biologics, which is important for chronic treatment. With the dementia and Alzheimer's patient population – currently 50 million patients worldwide – expected to triple within the next 30 years, there will be high demand for preventive therapies that avert damage to brain structures and that are not resource-intensive.

Our Alzstatin project platform aims to develop preventive disease-modifying treatments for Alzheimer's by reducing production of harmful amyloid-beta and thereby preventing accumulation of pathological amyloid in the brain. In the Alzstatin program we have preclinical studies that have shown that we can reduce the quantity of harmful amyloid-beta by 50 percent. ACD679 is currently in the preclinical development phase, while research continues in the ACD680 follow-up project to ensure that we can choose the best possible compound for future clinical trials.

ACD856 is part of the innovative NeuroRestore platform with a primary focus on symptomatic treatment of Alzheimer's – in other words, improving the memory and other cognitive problems that are so typical of the disease. The ongoing SAD clinical trial with ACD856 is evaluating tolerability and safety. During the third quarter, we received positive data in the study and applied for the testing of even higher doses, which was granted by the Swedish Medical Products Agency. These studies have now been initiated, as has the MAD clinical trial (Phase I), in line with our communicated objectives. Our other drug candidate in the NeuroRestore platform, ACD857, is in the preclinical development phase. We plan to use this compound for an indication within the field of cognitive dysfunction, which includes Alzheimer's.

We also see continued promising progress in our pain platform Painless, which consists of two projects, ACD440 and TrkA-NAM. ACD440 is a TRPV1 antagonist for topical use aimed at treating neuropathic pain. The project is based on discoveries for which the 2021 Nobel Prize in Physiology or Medicine was awarded this year. We have used the groundbreaking discovery of TRPV1 and its link to pain perception in our ACD440 clinical program. Based on the positive results from the Phase Ib clinical trial of ACD440, which were obtained earlier than expected last spring, we were able to report positive and significant safety and tolerability results, as well as early signals of efficacy on pain. The neuropathic pain indication currently generates global pharmaceutical sales of USD 10.8 billion each year and is expected to grow significantly to over USD 25 billion by 2027 (GlobalData, 2021). Data suggests that more than half of patients with neuropathic pain today do not achieve adequate pain relief. This indicates the great unmet medical need, as well as the potential in this field and for our ACD440 project. We hope to be able to apply to initiate a Phase II clinical trial by the end of this year. The patients we intend to treat suffer from chronic pain, a patient population that is expected to continue to grow, in part due to the aging population.

TrkA-NAM, our second pain project within the Painless platform, is aimed at treating severe pain conditions. One such example is osteoarthritis, which is estimated to affect over 300 million people. After having received positive efficacy data from our preclinical pain studies, we are now actively working to select a final drug candidate for the project, with the goal of doing so in the fourth quarter of 2021.

During the quarter we continued to have a strong focus on marketing communication and participated in several meetings and conferences. Together with Professor Maria Eriksdotter from Karolinska Institutet and others, we arranged a symposium in September focusing on NeuroRestore. The symposium was very well received and is recorded and available on our website. During the quarter, we also published several abstracts and posters at scientific congresses (AAIC and ECNP), as well as a scientific article in the journal Cells on our NeuroRestore project ACD856*, among other topics. These publications demonstrate the interest in and the scientific quality of the data we generate. We continue to work on reaching out to both private and institutional investors, as well as other pharmaceutical and research companies that may be interested in investing in or in-licensing our development projects, or alternatively in entering into a partnership.

I am very pleased to report that AlzeCure continues to make good progress together with our dedicated and motivated employees. We have several promising projects under development within fields with great unmet medical need, which is incredibly motivating. The rising interest and activity in the field of Alzheimer's is beneficial to us, for which reason we look to the future with continued growing confidence.

Stockholm, November 2021
Martin Jönsson

*) Dahlström et al, Identification of Novel Positive Allosteric Modulators of Neurotrophin Receptors for the Treatment of Cognitive Dysfunction, Cells 2021, 10(8), 1871; https://www.mdpi.com/2073-4409/10/8/1871/htm

Five important milestones for 2021

1. **Results from the SAD, phase Ia clinical study for NeuroRestore® ACD856 – summer 2021**
2. **Results from the phase Ib clinical trial for Painless ACD440 – summer 2021**
3. **Start the MAD, phase Ia clinical study for NeuroRestore® ACD856 – H2 2021**
4. **Choose the first drug candidate for the TrkA-NAM pain project – H2 2021**
5. **Apply for phase IIa clinical trial for Painless ACD440 in neuropathic pain – H2 2021**

> "During another active quarter, AlzeCure received positive data as planned from the Phase I SAD clinical trial with ACD856, which is being developed with a focus on Alzheimer's disease, and has now also initiated the Phase I MAD clinical trial with this compound.
>
> 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 drug candidates in the various platforms: two in NeuroRestore and two in Alzstatin. There are also two projects in the Painless platform. A diversified portfolio of drug candidates paves the way for other indications, such as cognitive disorders associated with Alzheimer's, traumatic brain injury, sleep apnea and Parkinson's disease, as well as for severe pain in conditions such as neuropathy and osteoarthritis.

- The NeuroRestore platform is developing a new generation of symptomatic drugs for the treatment of cognitive disorders, such as Alzheimer's disease. The biological mechanism also enables targetting other potential indications, including depression and cognitive dysfunction in Parkinson's disease, traumatic brain injury and sleep disorders.
- Innovative disease-modifying and preventive drugs for Alzheimer's disease are under development within the Alzstatin platform.
- The Painless platform includes two non-opioid 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; for which the discovery of this mechanism was awarded the 2021 Nobel Prize in Physiology or Medicine. 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 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	Indication	Research phase	Preclinical phase	Phase I	Phase II	Phase III
NeuroRestore	ACD856	Alzheimer's disease Sleep disorders/ Traumatic brain injury Parkinsons Disease					
	ACD857	Alzheimer's disease					
Alzstatin	ACD679	Alzheimer's disease					
	ACD680	Alzheimer's disease					
Painless	ACD440	Neuropathic pain					
	TrkA-NAM	Osteoarthritis pain					

In progress Completed

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

Project development

AlzeCure is focused on research and development of innovative and effective new small molecule drugs for 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, a disease-modifying therapy for Alzheimer's is expected to be able to generate more than USD 10 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 dysfunction associated with traumatic brain injury, Parkinson's disease and sleep disorders. With its broad portfolio of assets, the company maximizes shareholder value by working in multiple indication areas 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 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, with results supporting the continued clinical development of ACD856. Continued clinical trials were initiated in late 2020, also according to plan. 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 the primary purpose of assessing safety and tolerability in humans. ACD857 is in the research phase and also has the primary indication of cognitive dysfunction/Alzheimer's disease. At the end of last year the drug candidate entered into the next phase of development, which aims to assess the preclinical safety profile before clinical trials can begin.

AlzeCure's disease-modifying research platform for Alzheimer's disease, Alzstatin, focuses on reducing the production of toxic amyloid beta (Aβ) in the brain. 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 leading drug candidate in the Alzstatin platform, ACD679, is currently undergoing the important safety pharmacological and toxicological studies necessary before clinical trials may begin. Alongside this work, the development of an additional drug candidate is in progress (ACD680) to ensure that the company has the best compound for clinical studies.

> "Diagnostics and biomarkers within the field of Alzheimer's is an active field of research, where key advances made in recent years have been of great importance for diagnostics, as well as for evaluating new drug candidates.
>
> Professor Henrik Zetterberg, University of Gothenburg; University College of London

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

2 **Alzstatin® – is developing innovative disease-modifying and preventive drugs for Alzheimer's disease.**

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

Pain

AlzeCure's Painless platform contains two projects aimed at 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.

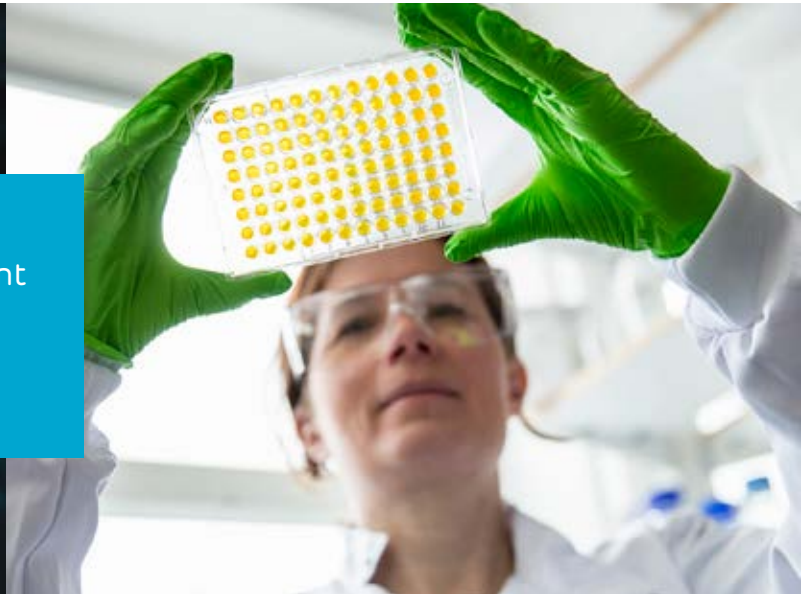
TrkA-NAM builds on the knowledge amassed and assets developed in the NeuroRestore platform. The project, which is aimed at severe pain in conditions such as osteoarthritis, is currently in the research phase and the company received the first preclinical efficacy data in 2020, according to plan. The aim is for the project to select a drug candidate in the second half of 2021.

In January 2020, a drug candidate in the clinical development phase aimed at treating neuropathic pain, ACD440, 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 developed 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 this year and showed positive proof-of-mechanism data, i.e. an analgesic effect in humans. The efficacy of ACD440 was clearly significant compared with placebo. It 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. The company is now planning subsequent phase II trials.

50 million

In the US alone, an estimated 50 million adults live with chronic or severe pain, and more people suffer from pain than diabetes, heart disease and cancer combined.

"About 50 percent of neuropathic pain patients do not respond to current first-line treatment and AlzeCure is developing its new treatment specifically for this group of individuals.



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 trillion and is expected to 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.

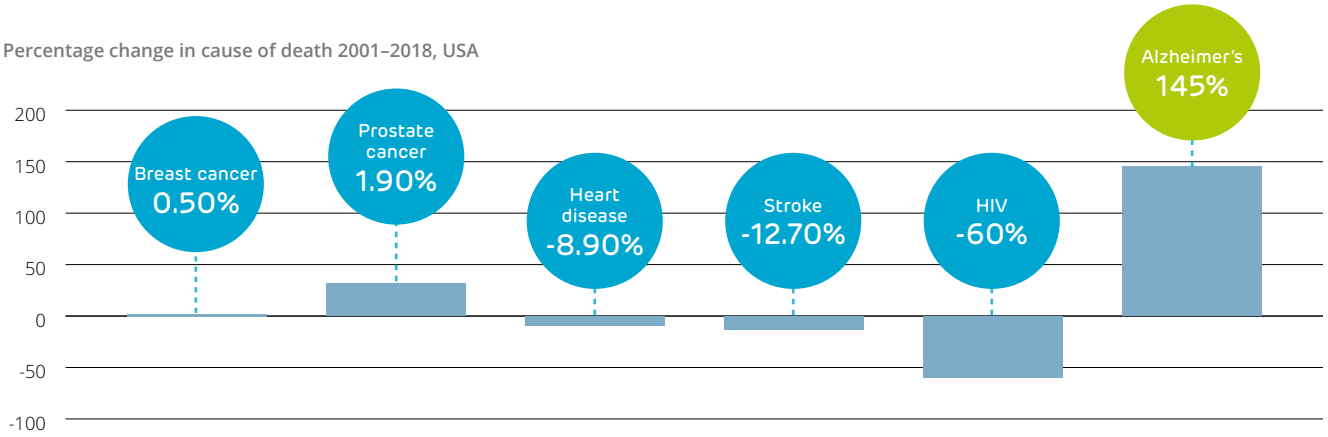
New treatment for Alzheimer's disease targeting amyloid plaques receives FDA approval
An antibody therapy (Aduhelm) targeting amyloid pathology received approval in June as the first disease-modifying treatment for Alzheimer's disease through the FDA's Accelerated Approval process. The approval is based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

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
Alzheimer's disease is currently diagnosed mainly 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 people with Alzheimer's. There is a great need to be able to correctly diagnose Alzheimer's in order to include a correct population in clinical trials to develop drugs for the disease. Significant progress has been made through intensive work in the field, 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.

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, heart disease 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, only half of patients with neuropathic pain respond satisfactorily 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.

Percentage change in cause of death 2001–2018, USA



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

x3

The number of people worldwide with dementia is expected to triple from the current 50 million to 150 million in 2050.

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.

Alzheimer's disease causes nerve cells in the brain to die. The parts of the brain usually affected are the hippocampus (the brain's memory center), the temporal and parietal lobes. The disease starts with amyloid beta (Aβ) protein beginning to aggregate 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 changes in the levels of 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.

The reasons why 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 heredity. The disease may appear early, between the ages of 40 and 65 for the hereditary form, but is most common after 65.

Today, substantial sums are invested in medical research into 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 at around USD 1 trillion, which is expected to triple by 2050. The lack of effective symptomatic treatments and efficacious treatments for the course of the disease represent an urgent medical need. The few approved drugs sold in today's global market only have 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 10 billion in annual sales. In June 2021, the FDA approved a new Alzheimer's drug in the US, Aduhelm™ (aducanumab). Subsequently, three additional Alzheimer's drugs – donanemab, lecanemab and gantenerumab – received "Breakthrough Therapy Designation" from the FDA. This status provides access to FDA's other "fast track" processes. The application for approval of lecanemab was submitted to the FDA in September. Taken together, there is growing interest in research into new drugs in the field of Alzheimer's disease.

Symptoms

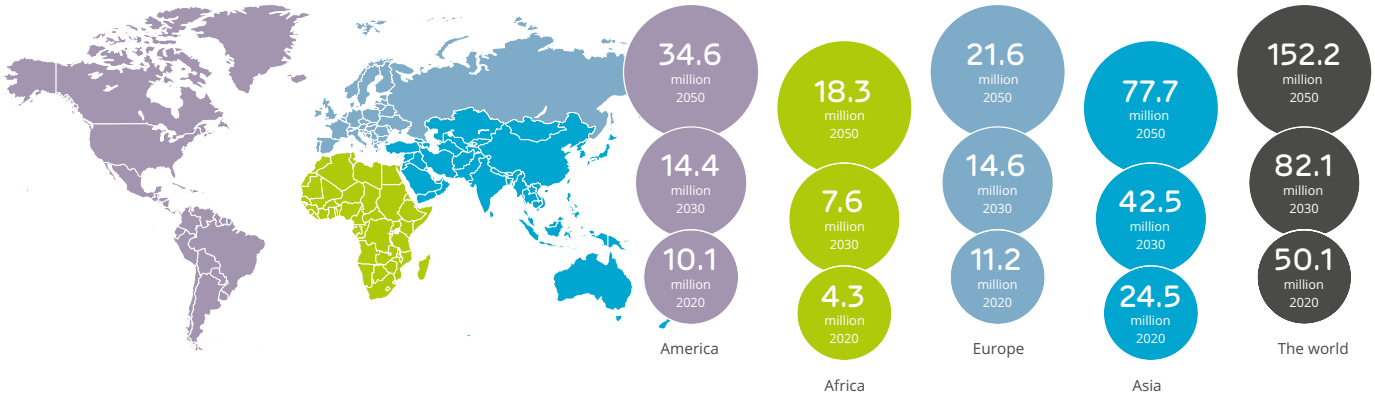
Usually, the first signs of Alzheimer's are impaired memory, difficulties in finding words, expressing oneself and understanding. Difficulties with the concept of time are also common. Eventually, sufferers experience orientation problems in their surroundings, and difficulties reading, writing and counting 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 below.

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 together.

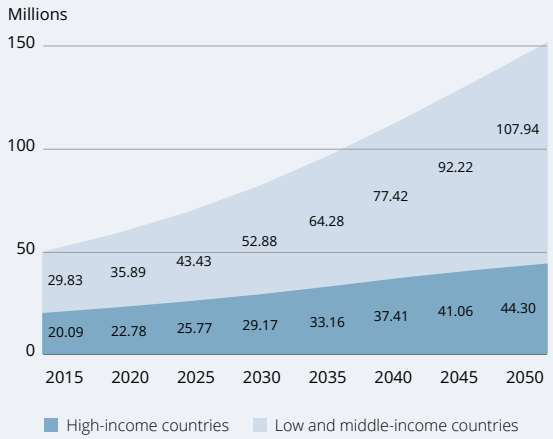
Geographic distribution and expected growth of prevalence of dementia.



> 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



Treatment

Today there are two classes of symptomatic drugs for the treatment of Alzheimer's disease.

Cholinesterase inhibitors: The drug allows the neurotransmitter acetylcholine to be active longer in the brain and thus boost nerve cell communications. The drug does not slow down progression of the illness, it only relieves the symptoms.

NMDA inhibitors: The drug affects glutamate signaling, which plays an important part in nerve cell communications.

However, the effect of cholinesterase and NMDA inhibitors is usually limited and associated with side effects. 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 drugs described above. NeuroRestore aims to improve communication between nerve cells by means of a unique mechanism so that memory function is improved in the patient while also avoiding difficult side effects. Alzstatin is aimed at preventing 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.

Other diseases with cognitive dysfunction

There are several other diseases in which cognitive functions such as memory and learning are affected; in addition to the classic neurodegenerative diseases such as Alzheimer's and Parkinson's disease, other indications include sleep disorders (e.g. sleep apnea) and traumatic brain injury.

Sleep apnea

An estimated 100 million people worldwide suffer from sleep apnea, the majority of whom are undiagnosed. In Sweden, about 300,000–400,000 people (10 percent of all women and 20 percent of all men) between the ages of 30 and 60 suffer from the condition, which is strongly associated with overweight. 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's symptoms are somewhat similar to Alzheimer's, where memory, 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, work or sports-related. The increase in TBI is due in part to the increased use of motor vehicles in low and middle-income countries.

According to the Glasgow Coma Scale, TBI is divided into three categories as follows:

- Mild TBI – loss of memory, confusion or disorientation for a maximum of 30 minutes
- Moderate TBI – loss of memory for 20 minutes – 6 hours
- Severe TBI – loss of memory for more than 6 hours

AlzeCure aims to improve cognitive ability in people with mild TBI. TBI has been shown to increase the risk of developing dementia-related diseases, such as Alzheimer's disease and other neurodegenerative diseases, e.g. Parkinson's disease. Studies show that a person who sustains a TBI has 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. Symptoms include loss of memory, headache, fatigue and mood swings, as well as sleep and concentration difficulties. About 30–70 percent of those who suffer from TBI also suffer from depression.

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 and neuropathic pain.

Nociceptive pain is the result of activity in signaling pathways caused by actual tissue damage or potentially tissue-damaging stimuli. Examples of nociceptive pain include postoperative pain, arthritic pain and pain associated with sports injuries. Nociceptive pain is usually acute and develops in response to a specific situation. It tends to disappear when the affected body part heals.

The body contains specialized nerve cells called nociceptors that detect harmful stimuli or things that can injure the body, such as extreme heat or cold, pressure and chemicals. These warning signals are then transmitted along the nervous system to the brain, resulting in nociceptive pain. This happens very quickly in real time, as when people quickly remove their hands if they touch a hot oven or stop bearing weight on an injured ankle. Other examples of nociceptive pain are post-operative pain and visceral pain.

Neuropathic pain is often chronic and is initiated by dysfunction or damage to the nervous system. Chronic pain is a disability 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. People with some conditions, such as diabetes and HIV, are affected to a greater extent where approximately 25 percent and 35 percent respectively experience neuropathic pain.

Peripheral neuropathic pain results from various types of damage to the nerve fibers, such as toxic, traumatic, metabolic, infectious 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). Three common conditions of neuropathic pain are painful peripheral neuropathy caused by conditions such as diabetes, painful postherpetic neuralgia (shingles), and neuropathic pain induced by chemotherapy.

Prevalence

An estimated 50 million adults in the US experience chronic or severe pain, and more Americans 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 half 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 cancer that requires 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.

Treatment

There is currently a major medical need for several different severe pain conditions. For example, only about 50 percent of patients with neuropathic pain respond to existing treatments. Because of the risk of abuse, overdose and secondary injuries, doctors nowadays avoid prescribing opiates as first-line treatment for pain. Despite this treatment problem they are still frequently used, and therefore the need for new non-opiate treatments is great.

7-8%

Neuropathic pain affects a total of approximately 7–8 percent of the adult population.

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.

> One in five people in the population suffers from chronic pain that requires treatment. Living with pain is incredibly stressful for the patient, both physically and mentally. One of three patients seek medical care because of pain. The available treatments are not sufficiently effective and are often associated with addiction problems. There is great potential for a new drug here, especially with a favorable side effect profile and without risk of addiction.
>
> Dr. Märta Segerdahl, CMO

Comments on the report

Financial Overview

SEK thousand	July–September 2021	July–September 2020	January–September 2021	January-September 2020	January-December 2020
Net sales	0	0	0	0	0
Operating profit/loss	-16,542	-21,503	-55,277	-53,812	-71,579
Earnings for the period and comprehensive income	-16,507	-21,455	-55,162	-53,646	-71,366
Earnings per share. basic (SEK)	-0.44	-0.57	-1.46	-1.42	-1.89
Research expenses as a percentage of operating expenses (%)	85.3	90.6	84.4	86.5	86.3
Total assets	68,299	138,334	68,299	138,334	117,827
Cash and cash equivalents	62,672	132,976	62,672	132,976	112,434
Dept/equity ratio (%)	81.4	92.9	81.4	92.9	94.0
Average number of shares. basic	37,765,715	37,765,715	37,765,715	37,765,715	37,765,715
Average number of employees	11	8	11	8	8

See the definitions below.

Revenue and profit/loss

The company had no net sales during the period. Other operating income largely relates to currency gains this quarter as well. No government aid for increased sick pay was received during the quarter.

Earnings for the third quarter of 2021 totaled SEK -16,542 thousand (-21,503). The operating loss for the period January to September was SEK -55,277 thousand (-53,812). The company continued to conduct its research activities at an intensive pace during the third quarter, with steady development. Research expenses accounted for 85.3 percent of operating expenses in the third quarter. During January to September 2021 research expenses accounted to 84.4 percent of the operating expenses. More information about research at AlzeCure can be found in the Project Portfolio and Project Development sections of this report.

Administrative costs were somewhat higher this quarter, and also for the total period, compared with the same period the previous year. The company continues to focus on communication and business development and has also expanded internationally in 2021.

The company had 12 employees on the closing date. The COVID-19 pandemic is still underway, even though the restrictions have been taken away, and the company continues to take necessary measures to protect its employees and limit any negative impact on the company's operations. The company's business has not been affected so far to any great extent by the pandemic.

Earnings per share, basic, totaled SEK -0.44 (-0.57) for the third quarter, and SEK -1.46 (-1.42) for the period January to September 2021.

Financial position

At the end of the period, equity was SEK 55,593 thousand (128,475) and the debt/equity ratio was 81.4 percent (92.9).

Cash and cash equivalents at the end of the period totaled SEK 62,672 thousand (132,976).

In 2019 the company launched an incentive program with warrants aimed at the Board of Directors. A total of 110,000 warrants were issued.

During the second quarter of 2020 the company launched an incentive program, this time with warrants aimed at the company's Chief Executive Officer. A total of 300,000 warrants were issued. For more details regarding the warrant programs, please see "Share-related compensation programs" in the report.

As of the closing date, September 30, a total of 410,000 warrants were issued, resulting in a dilution effect of 1 percent.

Cash flow and investments

Cash flow from operating activities including changes in working capital for the third quarter of 2021 totaled SEK -15,243 thousand (-20,154). For the period January to September 2021, the corresponding cash flow totaled SEK -49,708 thousand (-49,133).

Cash flow from investing activities totaled SEK -0 thousand (-195) during the third quarter. For the period January to September, the corresponding cash flow totaled SEK -54 thousand (-504). The company mainly invests in laboratory equipment.

Cash flow from financing activities totaled SEK 0 thousand (0) for the third quarter of 2021. For the period January to September, cash flow from financing activities totaled SEK 0 thousand (114).

Accounting policies and valuation principles

General information and compliance with IAS 34
This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting. AlzeCure Pharma AB (publ) is domiciled in Stockholm. Because the company is not a group, it applies IFRS with the adjustments required under RFR2 Accounting for legal entities.

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.

Reconciliation of alternate performance measures

SEK thousand	July–September 2021	July–September 2020	January–September 2021	January-September 2020	January-December 2020
Research expenses as a percentage of total operating expenses:					
Research expenses	-14,174	-19,653	-47,041	-47,041	-62,356
Administrative expenses	-2,370	-1,880	-8,372	-6,877	-9,375
Other operating expenses	-78	-151	-355	-443	-508
Total operating expenses	**-16,622**	**-21,684**	**-55,768**	**-54,361**	**-72,239**
Research expenses as a percentage of total operating expenses:	**85.3%**	**90.6%**	**84.4%**	**86.5%**	**86.3%**
Debt/equity ratio (%) September 30, 2021:					
Total equity at end of period	55,593	128,475	55,593	128,475	110,755
Total assets at end of period	68,299	138,334	68,299	138,334	117,827
Debt/equity ratio (%):	**81.4%**	**92.9%**	**81.4%**	**92.9%**	**94.0%**

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. No significant changes regarding those risks and uncertainty factors took place during the period compared with those presented in the most recent annual report. Financing risk constitutes the ability to finance projects to commercialization. The company manages this by the timely preparation of new share issues.

The COVID-19 pandemic is still underway, even though the restrictions have been taken away, and the company continues to take necessary measures to protect its employees and limit any negative impact on the company's operations. The company is carefully monitoring the situation and complying with the recommendations and restrictions of the Public Health Agency of Sweden.

Continued operation
The company's available funds and equity as of September 30, 2021 is not sufficient to cover the identified possible operations for the next 12 months. In light of this, work is under way to secure possible financing alternatives. The Board considers that the prospects are good to finance the company's operations, so that continued operations will be ensured for the next 12 months. The company otherwise has the opportunity to re-prioritize operations and to adjust costs and expenses based on the capital available in the company.

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. On September 30, 2021, the number of shares in the company totaled 37,765,715.

Owners as of September 30, 2021

The ten largest owners as of September 30, 2021	Number of shares	Share capital and votes
BFCM P/C BFCM Sweden Retail LT	4,403,265	11.7%
FV Group AB	2,000,000	5.3%
AlzeCure Discovery	1,710,000	4.5%
Sjuenda Holding AB	1,578,600	4.2%
Nordnet Pensionsförsäkring AB	1,578,124	4.2%
SEB-Stiftelsen	1,400,000	3.7%
Futur Pension	1,051,700	2.8%
Thomas Pollare	881,877	2.3%
Pontus Forsell	873,643	2.3%
Gunnar Nordvall	852,000	2.3%
10 largest owners	**16,329,209**	**43.2%**
Other	21,436,506	56.8%
TOTAL	**37,765,715**	**100%**

Share-related compensation programs

In 2019 the company launched an incentive program with warrants aimed at some members of the Board of Directors. A total of 110,000 warrants were issued: 35,000 warrants went to Thomas Pollare and 25,000 warrants each went to An van Es Johansson, Ragnar Linder and Pirkko Sulila Tamsen.

The warrants, which were issued at the market price as of May 22, 2019, entitle the holder to subscribe for shares during the period June 15–30, 2022. 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 May 22, 2019.

In 2020 the company also launched an incentive program, this time 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, entitle the holder to subscribe for shares during the period June 15, 2023 – July 5, 2023. 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 20, 2020.

The total dilutive effect of the two incentive programs is 1%.

Financial calendar

Interim report Q4, October–December 2021	February 24, 2022
2021 Annual Report	6 April 2022
Interim report Q1, Januar-March 2022	5 May 2022
Annual General Meeting	17 May 2022
Interim report Q2, April-June 2022	25 August 2022
Interim report Q3, July-September 2022	10 November 2022

Nomination Committee

AlzeCure Pharma's nomination committee for the 2022 Annual General Meeting was appointed in accordance with the principles adopted by the Annual General Meeting on May 17, 2021 and consists of: William Gunnarsson, appointed by BFCM P/C BFCM Sweden Retail LT, Bo Rydlinger, appointed by FV Group AB, Liselotte Jansson, appointed by AlzeCure Discovery AB and Thomas Pollare (Chairman of the Board)

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 10, 2021

Thomas Pollare
Chairman of the Board

Eva Lilienberg
Board member

Ragnar Linder
Board member

Ellen Donnelly
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, +46 (0)8 528 00 399, info@fnca.se.

Auditor's report

Auditor's report on review of interim financial information in summary (interim report) prepared in accordance with IAS 34 and Chapter 9 of the Swedish Annual Accounts Act (1995:1554).

To the board of AlzeCure Pharma AB (publ), corporation number 559094–8302

Introduction

We have reviewed the interim financial information in summary (interim report) of Alzecure Pharma AB (publ.) as of 30 September 2021 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 10 November 2021
Grant Thornton Sweden AB

Camilla Nilsson
Authorized Public Accountant

Income statement and other comprehensive income

SEK thousand	July–September 2021	July–September 2020	January–September 2021	January-September 2020	January-December 2020
Net sales	0	0	0	0	0
Operating expenses					
Research expenses	-14,174	-19,653	-47,041	-47,041	-62,356
Administrative expenses	-2,370	-1,880	-8,372	-6,877	-9,375
Other operating income	80	181	491	549	660
Other operating expenses	-78	-151	-355	-443	-508
Operating profit/loss	**-16,542**	**-21,503**	**-55,277**	**-53,812**	**-71,579**
Profit/loss from financial items					
Interest income and similar profit/loss items	35	48	116	167	214
Interest expenses and similar profit/loss items	0	0	-1	-1	-1
Loss after financial items	**-16,507**	**-21,455**	**-55,162**	**-53,646**	**-71,366**
Earnings for the period and comprehensive income	**-16,507**	**-21,455**	**-55,162**	**-53,646**	**-71,366**
Earnings for the period per share, basic (SEK)	-0.44	-0.57	-1.46	-1.42	-1.89
Earnings for the period per share, diluted (SEK)	-0.44	-0.57	-1.46	-1.42	-1.89
Average number of shares, basic	37,765,715	37,765,715	37,765,715	37,765,715	37,765,715
Average number of shares, diluted	38,175,715	38,175,715	38,175,715	38,009,049	38,050,715

Balance sheet

SEK thousand	September 30, 2021	September 30, 2020	December 31, 2020
ASSETS			
Non-current assets			
Intangible fixed assets			
Project rights	17	17	17
Total intangible fixed assets	**17**	**17**	**17**
Tangible fixed assets			
Equipment, tools and installations	1,567	1,913	1,944
Total tangible fixed assets	**1,567**	**1,913**	**1,944**
Financial fixed assets	7	7	7
Total non-current assets	**1,591**	**1,937**	**1,968**
Current assets			
Current receivables			
Advance to supplier	0	0	703
Trade receivables	0	80	8
Other current receivables	1,708	2,673	2,349
Prepaid expenses and accrued income	2,328	668	365
Total current receivables	**4,036**	**3,421**	**3,425**
Cash and bank balances	**62,672**	**132,976**	**112,434**
Total current assets	**66,708**	**136,397**	**115,859**
TOTAL ASSETS	**68,299**	**138,334**	**117,827**

SEK thousand	September 30, 2021	September 30, 2020	December 31, 2020
EQUITY AND LIABILITIES			
Fixed equity			
Share capital	944	944	944
Total fixed equity	**944**	**944**	**944**
Free equity			
Share premium reserve	278,842	278,842	278,842
Accumulated profit/loss	-169,031	-97,665	-97,665
Profit/loss for the period	-55,162	-53,646	-71,366
Total free equity	**54,649**	**127,531**	**109,811**
Total equity	**55,593**	**128,475**	**110,755**
Current liabilities			
Trade payables	7,722	7,812	3,966
Other current liabilities	322	187	199
Accrued expenses and deferred income	4,662	1,860	2,907
Total current liabilities	**12,706**	**9,859**	**7,072**
Total liabilities	**12,706**	**9,859**	**7,072**
TOTAL EQUITY AND LIABILITIES	**68,299**	**138,334**	**117,827**

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, 2020	**944**	**278,728**	**-46,807**	**-50,858**	**182,007**
Appropriation of earnings	0	0	-50,858	50,858	0
Warrant program	0	114	0	0	114
Earnings for the year and comprehensive income	0	0	0	-71,366	-71,366
Closing balance December 31, 2020	**944**	**278,842**	**-97,665**	**-71,366**	**110,755**

Opening balance January 1, 2021	**944**	**278,842**	**-97,665**	**-71,366**	**110,755**
Appropriation of earnings	0	0	-71,366	71,366	0
Earnings for the period and comprehensive income	0	0	0	-55,162	-55,162
Closing balance September 30, 2021	**944**	**278,842**	**-169,031**	**-55,162**	**55,593**

Cash flow statement

SEK thousand	July–September 2021	July–September 2020	January–September 2021	January-September 2020	January-December 2020
Operating activities					
Operating loss before financial items	-16,542	-21,503	-55,277	-53,812	-71,579
Adjustment for items not included in cash flow, etc.					
Depreciation and amortization	146	130	431	359	495
Interest received	35	48	116	167	214
Interest paid	0	0	-1	-1	-1
Cash flow from operating activities before changes in working capital	-16,361	-21,325	-54,731	-53,287	-70,871
Statement of change in working capital					
Change in trade receivables	80	42	8	-64	8
Change in other current receivables	-1,738	1,397	-619	-893	-969
Change in trade payables	1,857	176	3,756	4,815	969
Change in other current operating liabilities	919	-444	1,878	296	1,355
Net cash flow from operating activities	**-15,243**	**-20,154**	**-49,708**	**-49,133**	**-69,508**
Investing activities					
Acquisition of tangible fixed assets	0	-195	-54	-504	-671
Cash flow from investing activities	**0**	**-195**	**-54**	**-504**	**-671**
Financing activities					
Warrant program	0	0	0	114	114
Cash flow from financing activities	**0**	**0**	**0**	**114**	**114**
Cash flow for the year	**-15,243**	**-20,349**	**-49,762**	**-49,523**	**-70,065**
Cash and cash equivalents at beginning of period	77,915	153,325	112,434	182,499	182,499
Cash and cash equivalents at end of period	**62,672**	**132,976**	**62,672**	**132,976**	**112,434**

Contact details

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AlzeCure