GUARD THERAPEUTICS

ANNUAL REPORT 2020

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Company Information

COMPANY NAME: Guard Therapeutics International AB (publ)
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UPCOMING FINANCIAL REPORTS

Interim report January-March 2021:	12 MAY 2021
Interim report January-June 2021:	19 AUGUST 2021
Interim report January-September 2021:	18 NOVEMBER 2021
Year-end report 2021:	22 FEBRUARY 2022

DEFINITIONS

By ”Guard Therapeutics” or ”Company” is meant Guard Therapeutics International AB (publ) with organization number 556755–3226.

All amounts are reported in thousands of SEK (KSEK) unless otherwise stated.

The auditor has reviewed the Swedish version of this Annual Report.

”The first study of ROSgard in patients undergoing open heart surgery is proceeding well and we are anticipating taking our unique drug project further in a global phase 2 program in the autumn.”

Tobias Agervald, CEO

Chief Executive's Review

During 2020 we have been able to report positive results from three phase 1 studies of ROSgard, an investigational drug with the potential to reduce the risk of acute kidney injury in a number of different patient groups

During the past financial year, we have been able to report positive results from three phase 1 studies of ROSgard, an investigational drug with the potential to reduce the risk of acute kidney injury in a number of different patient groups, and a further clinical trial commenced at a cardiac surgery center in Germany in March 2021. It is a considerable success that, despite the ongoing corona pandemic, we have been able to continue development of the drug project without any major delays, even though in various respects we have naturally been compelled to adapt our activities and our plans to the new conditions that the outbreak of the virus has entailed.

The primary aim of the recently initiated study is to evaluate ROSgard's safety profile in connection with repeated doses in patients undergoing open heart surgery while using a heart-lung machine, a population where up to 40% have been reported to develop an acute kidney injury. The top line results are expected to be available as early as during the summer and we are anticipating being able to initiate a global phase 2 program in the same patient group in the autumn. The United States Food and Drug Administration (FDA), has provided constructive feedback on the design of the forthcoming trial program and we are now preparing an application to be able to eventually include U.S. clinical sites in the study. At the same time, patent protection for ROSgard in both the U.S. and Europe has been further strengthened, and we have now secured market exclusivity right through to 2037 in both of these regions, which together correspond to almost 70 per cent of the global pharmaceuticals market.

Conducting drug development is a meticulous task which requires in-depth knowledge within numerous different areas. For the world at large, the most obvious advances are often linked to presentation of new results from completed clinical studies, however, the value inherent in a drug project also increases simultaneously behind the scenes. This takes place, for example, through making progress within production development, submitting new patent applications, clearing up regulatory question marks, optimizing the design of forthcoming clinical studies and building relationships with potential commercial partners. Enabling such progress requires strong leadership, an effective structural capacity and an understanding of the high quality requirements that are placed on each element in the development work. Since the start of 2020, we have consciously strengthened Guard Therapeutics' internal expertise and resources through the recruitment of five new colleagues with extensive experience from senior positions within both large and small pharmaceutical companies, and we will shortly be presenting a scientific board which will give us access to world-leading expertise within nephrology, intensive care and thoracic surgery, with the aim of ensuring the final design of the forthcoming phase 2 program.

A treatment which prevents acute kidney injury in connection with heart surgery can reduce the need for life-supporting dialysis treatment or kidney transplant in this vulnerable patient group, but the potential for ROSgard is much greater than that. The investigational drug may also play an important role in protecting the kidneys in connection with organ transplants, cancer treatments and severe infections such as COVID-19. The total market for treatments of acute kidney injury is calculated at between SEK 250 and 300 billion, and it is estimated to grow further in the future. Our strategy is now to document the efficacy of ROSgard in patients undergoing open heart surgery in order to incrementally expand the development program into further patient segments. All of this with the aim of maximum value creation for large patient groups as well as for our shareholders in a resource-efficient and balanced approach to risk.

Tobias Agervald

Chief Executive Officer

Financial Summary[1]

(KSEK) INCOME STATEMENT	2020-01-01 2020-12-31	2019-01-01 2019-12-31	2018-01-01 2018-12-31	2017-01-01 2017-12-31	2016-01-01 2016-12-31
Net sales	-	-	-	-	-
Capitalized development costs	-	-	-	-	-
Other operating income	143	-	-	-	200
Operating expenses	-40,420	-40,432	-78,518	-66,428	-53,750
Depreciation/Impairment	-	-	-	-	-
Operating profit	**-40,277**	**-40,432**	**-78,518**	**-66,428**	**-53,550**
Net financial items	-7	-25,978	-655	-163	-17
Profit/loss before taxes	**-40,284**	**-66,410**	**-79,173**	**-66,591**	**-53,567**
Profit/loss for the year	**-40,284**	**-66,410**	**-79,173**	**-66,591**	**-53,567**

BALANCE SHEET	2020-12-31	2019-12-31	2018-12-31	2017-12-31	2016-12-31
Intangible assets	-	-	-	14,983	13,056
Tangible assets	44	205	421	756	1,155
Financial assets	-	-	24,937	18,280	18,280
Other current assets	1,136	1,902	1,664	8,072	8,149
Cash and cash equivalents	90,042	53,839	13,832	7,473	6,812
Total Assets	**91,222**	**55,946**	**40,854**	**49,564**	**47,452**
Equity	79,686	44,950	10,641	38,009	35,329
Long-term liabilities	5,032	5,778	-	-	-
Short-term liabilities	6,503	5,218	30,213	11,555	12,123
Total Equity and Liabilities	**91,222**	**55,946**	**40,854**	**49,564**	**47,452**

CASH FLOW ANALYSIS	2020-01-01 2020-12-31	2019-01-10 2019-12-31	2018-01-10 2018-12-31	2017-01-01 2017-12-31	2016-01-01 2016-12-31
Cash flow from operating activities before changes in working capital	-40,125	-40,998	-63,856	-65,208	-52,176
Changes in working capital	2,163	-19,642	12,067	-489	5,578
Cash flow from investing activities	118	-73	-6,657	-2,913	-4,903
Cash flow from financing activities	74,047	100,719	64,805	69,271	39,729
Change in cash and cash equivalents	36,203	40,007	6,359	661	-11,772
Cash and cash equivalents at the beginning of the period	53,839	13,832	7,473	6,812	18,584
Cash and cash equivalent at the end of the period	**90,042**	**53,839**	**13,832**	**7,473**	**6,812**

KEY FIGURES	2020-12-31	2019-12-31	2018-12-31	2017-12-31	2016-12-31
Cash liquidity (%) [2]	1,402	1,068	51	135	123
Equity ratio (%) [3]	87	80	26	77	74
Dividend (SEK)	-	-	-	-	-

[1]Numbers represent the legal entity Guard Therapeutics AB (in previous reports referred to as parent company).
[2]Cash liquidity: Current assets (excl. inventories) divided by short-term liabilities
[3]Equity ratio: Equity as a percentage of total assets

Guard Therapeutics AB

Guard Therapeutics AB (publ) was founded in 2008 by researchers at Lund University, Sweden. The company develops new pharmaceutical therapies with a focus on treatments for acute kidney injuries (AKI). Guard Therapeutics' lead investigational drug ROSgard (RMC-035) is based on an endogenous protein – alpha-1-microglobulin – which is considered one of the body's most powerful and universal defense systems against oxidative stress.

VISION

Guard Therapeutics' vision is to offer new classes of drugs which improve the possibility of preventing and treating acute kidney injuries (AKI). The ultimate objective is to save lives, but also to avoid chronic and severe consequences of AKI such as life supporting dialysis treatment.

BUSINESS MODEL AND STRATEGY

Guard Therapeutics' business model and overall strategy is to conduct professional drug development of high scientific quality. In the current phase of development, the company is working with carefully selected external partners for e.g. drug manufacturing and the conduct of clinical trials. The goal is to document, in a time- and cost-effective way, clinically relevant effects in well-defined patient groups where there is currently no available treatments. Partnership and licensing agreements to support the drug development activities will be evaluated on a continuous basis with the aim of maximizing the underlying potential of ROSgard. The company sees excellent opportunities for broadening the clinical development program within acute kidney injury in the future and also for expanding its pipeline to other therapeutic areas.

PROJECT BACKGROUND

All cells and tissues are continuously exposed to harmful substances which, simply put, cause tissue damage, impaired cell function and accelerated ageing. Many of these substances are generated spontaneously within various biochemical processes linked to e.g. cellular energy production. During cellular respiration, a process in which the intra-cellular energy producing units (mitochondria) utilize oxygen to generate energy, so called free radicals, referred to as Reactive Oxygen Species (ROS), are produced.

During evolution, the body has developed a number of defense mechanisms which neutralizes the harmful effects of ROS and other toxic substances. Without this defense system, the body would be more susceptible to cell-and organ damage and at increased risk of developing various types of diseases. The endogenous protein alpha-1-microglobulin (A1M) is an integral part of this defense system.

The A1M protein is primarily synthesized in the liver, secreted into the bloodstream and subsequently distributed to the body's different organs and cells. The protein's principal function is to bind to and neutralize harmful substances before transporting them to the kidneys for excretion via the urine. It thereby acts as a circulating "waste basket" for cleaning up waste products which form spontaneously in the body. Another important function is to bind and protect the cells' mitochondria when they are subject to stress and potential damage. This preserves the cells' energy production and makes them more resistant to harmful substances. An important secondary effect of the protein's "cleaning function" is also to reinforce the body's own capacity for tissue regeneration. All in all, it can be said that the protein protects, cleans and repairs the body's cells and tissues.

The company's lead investigational drug, ROSgard (RMC-035), is based on the scientific concept of augmenting the protective effects of native A1M when the body's own defense capacity is insufficient to combat acute cell and organ damage.

ROSgard protects: It protects proteins, DNA, mitochondria, cells and tissues against oxidative stress. The protection of mitochondria, the cells' built-in power plant, is considered to be an important mechanism for combatting kidney injury.

ROSgard cleans: It captures and neutralizes harmful and reactive oxygen radicals that are formed during oxidative stress (Reactive Oxygen Species or ROS). It also neutralizes another detrimental substance, heme, which is released when red blood cells rupture (hemolysis).

ROSgard repairs: It supports the body's regenerative processes by eliminating harmful tissue molecules.

OUR INNOVATION – ROSGARD

ROSgard is a so-called "first-in-class" drug candidate for the treatment of acute kidney injury. ROSgard is a synthetic and modified variant of the endogenous protein A1M, and accordingly has a number of important functions that are judged to be important in preventing acute kidney injury. ROSgard has demonstrated robust and reproducible treatment effects in many different preclinical animal models, which supports its potential as a therapeutic in human disease. In general terms, drugs that are based on endogenous proteins also have a lower risk of unforeseen side effects that can arise as a result of the proteins' natural function.

ROSgard is manufactured with recombinant DNA technology, and is specifically targeted at combining the desirable pharmacological properties of endogenous A1M with improved stability and solubility, which are important properties for the drug manufacturing.

Notably, with regard to the antioxidative properties of ROSgard, it presents significant benefits as compared to "traditional antioxidants":

- acts in several ways – its molecular mechanisms comprise both an enzymatic effect (reductase activity), direct binding to ROS and heme and mitochondrial binding and protection. These mechanisms contribute both individually and synergistically to its favorable treatment effects observed in preclinical studies.
- binds effectively to ROS – its capacity to bind and neutralize radicals is estimated to be approximately ten times higher compared with, for example, vitamins C and E
- permanent effect – unlike many other antioxidants, ROSgard is not transformed into a harmful substance after binding to ROS
- has a natural distribution to the kidneys – as its natural route of elimination, ROSgard is filtered in the kidneys and taken up by proximal tubular kidney cells i.e., the inital site of injury before AKI develops.
- has a natural elimination route – broken down and discharged via the kidneys without the formation of harmful residual products

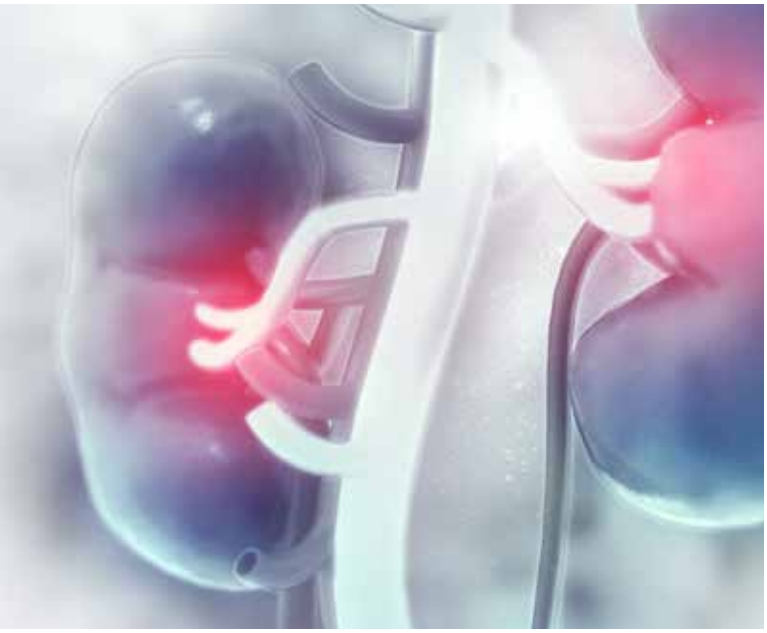
ACUTE KIDNEY INJURY– A MAJOR MEDICAL NEED

The kidneys are complex organs with a number of important functions such as regulating blood pressure, fluid balance, the blood's salt balance and acidity, as well as secreting water-soluble waste products. They also stimulate the production of red blood cells and

ROSgard combines the desirable pharmacological properties of the endogenous proteins A1M with improved stability and solubility.

contribute to the production of active vitamin D. The kidneys work round the clock without interruption and thus require a lot of energy. If the kidneys lose approximately 90% of their function, life-supporting treatment is generally required in the form of dialysis or a kidney transplant1.

Acute kidney injury is characterized by rapid deterioration of kidney function, which can arise within hours or a few days, and can lead to a transient or permanent loss of the remaining kidney function. Mild kidney damage rarely leads to any specific symptoms, but more pronounced damage can lead to reduced urine production, swollen legs or feet, impaired appetite, nausea, vomiting, confusion, cramps, anxiety, restlessness or drowsiness. Acute kidney injury has a mortality rate of about 20%. Mortality is higher among intensive care patients, closer to 50%, leading to around 2 million deaths every year[2,3]. Almost 25% of all survivors of acute kidney damage end up with chronically impaired kidney function, and 5–6 % of intensive care patients need either life-long dialysis treatment or a kidney transplant.[34] Acute kidney damage is also linked to further serious consequences such as increased risk of infection, high blood pressure, muscle weakness, chronic kidney disease and a shortened lifespan. The incidence of acute kidney injury is almost 20 times higher today compared with 25 years ago[2] and globally more than 13 million people suffer from some form of acute kidney damage every year.



Acute kidney injury also has extensive adverse economic consequences within healthcare. High income countries spend more than 2–3% of their annual healthcare budget on the treatment of terminal kidney disease, even though this patient group comprises less than 0.03% of the general population.[5] For example, the UK spends between £430 and £620 million per annum on dealing with acute kidney injury, which is more than the total costs for breast, lung and skin cancer combined.[5] The costs in the USA for acute kidney injury are estimated at more than $30 billion per annum.[6] These figures are probably lower than the actual costs, as numerous complications that were previously put down to diabetes and high blood pressure are in many cases now ascribed to impaired kidney function.

There are major medical needs in relation to acute kidney injury, and they are continuously increasing. There are currently no effective treatment methods and no approved drugs to prevent kidney injury. Clinical treatment is principally aimed at maintaining a normal fluid balance and good circulation in the kidneys, eliminating potentially harmful drugs and other risk factors and also minimizing other complications that can arise in connection with the damage. In more serious cases, acute life-supporting dialysis treatment is given.

1 Think Kidneys - UK Renal Registry's NHS program website.

2 Yang (2017) A new scoring model for the prediction of mortality in patients with acute kidney injury. Scientific Reports 7, Article no. 7862

3 Li (2013) Acute kidney injury: global health alert. Kidney Int 83, 372–376

4 Selby (2012) Use of Electronic Results Reporting to Diagnose and Monitor AKI in Hospitalized Patients. CJASN 7 (4) 533-540

5 Luyckx (2018) The global burden of kidney disease and the sustainable development goals. WHO website.

6 Monocl (2017) Indication analysis Acute Kidney Injury.

ACUTE KIDNEY INJURY IN CONNECTION WITH CARDIAC SURGERY

The kidneys are considered to be the most important target organ for treatment with ROSgard, mainly because of its rapid biodistribution to the kidneys, and because the kidneys are very sensitive to hypoxia. Acute kidney injury can arise in connection with a large range of clinical conditions, including surgical interventions, drug toxicity (e.g. chemotherapy), organ transplantation and severe infections (figure 1).

Figure 1. Common causes of AKI

Guard Therapeutics is focusing initially on the treatment of acute kidney injury in patients undergoing open heart surgery using a heart lung machine. The main patient population is subjects undergoing coronary artery by-pass graft (CABG) surgery with or without heart valve replacement. Acute kidney injury often occurs in connection with open heart surgery due to impaired blood perfusion and oxygenation (ischemia reperfusion injuries), as well as increased levels of heme in the bloodstream, which is harmful to the kidneys and is released when red blood cells are mechanically destroyed in the heart lung machine.[1,2] This in turn activates a local inflammation, which also acts as a catalyst for the development of acute kidney injury. As ROSgard effectively targets both ischemia reperfusion injuries and heme toxicity, cardiac surgery patients is assessed as the most important initial target patient population.

ROSgard is administered to patients via intravenous infusion. Its protective effects are achieved conceptually in a two-step process: the first step neutralizes ROS and heme directly in the bloodstream. In the second step, ROSgard is rapidly absorbed by the kidneys, thus preventing a local injury when kidney cells are exposed to ROS and heme, which form continuously in high levels during the surgical procedure (figure 2). As the acute kidney damage occurs and manifests within the first 1-2 days after the operation, ROSgard is administered in repeated doses over 2-3 days, with the aim of optimizing the effects of the treatment.

1 Schaer (2013) Hemolysis and free hemoglobin revisited: exploring hemoglobin and hemin scavengers as a novel class of therapeutic proteins. Blood 121(8), 1276-1284

2 O´Neal (2016) Acute kidney injury following cardiac surgery: current understanding and future directions. Crit Care 20(1), 187

Figure 2. Model of renal protection with ROSgard

MARKET POTENTIAL

The total market potential for the area of acute kidney injury is estimated at SEK 250–300 billion. There are significant variations in these estimates based on exactly which patient segments and risk groups are covered. A report from DelvenInsights estimates the total value of acute kidney injuries in seven major markets (USA, EU5, Japan) at nearly SEK 40 billion based on approximately 1.5 million new cases per year[1].

Regarding the primary indication for the Company's investigational drug ROSgard – prevention of acute kidney injury in connection with open heart surgery – some 400,000 coronary artery bypass grafts are currently performed each year in the US and EU5 (Germany, Spain, Italy, France and the UK)[2]. Globally, the figure exceeds 800,000[2]. Since Guard Therapeutics focuses on the group at highest risk of developing acute kidney injury, the total patient base for treatment with ROSgard is estimated to be in the range of 30–50 per cent of all patients.

An earlier trend of a declining number of open procedures, mainly due to alternative and less invasive surgical techniques, appears to have ceased. The number of open procedures is now expected to increase at a compound annual growth rate (CAGR) of 5.8 per cent until 2025, according to a report from Grand View Research[3]. This is in line with estimates from Transparency Market Research[4] and Technavio[5], which respectively predict a CAGR of 5.3 per cent and 6 per cent.

It is currently difficult to predict the exact price per patient for an approved drug that prevents acute kidney injury in connection with heart surgery. A reasonable assumption is that it will be in the range of USD 5,000-10,000[6] per patient but this will depend on a number of factors, such as the effect of the drug and the outcome measures used in a registrational study, estimated cost savings for hospital and intensive care, and the estimated value of any positive effects on patient-reported outcome measures. In this context there are several objective measures of direct cost savings (in addition to the purely medical treatment benefit) from the prevention of acute kidney injury:

- **Dialysis treatment**: a reduced need for postoperative dialysis treatment will save health services large sums of money. In the United States the cost of emergency dialysis treatment is approximately USD 1,000 per day. A small number of patients need lifelong dialysis treatment costing around USD 90,000 a year[7], or else a kidney transplant which entails even higher costs during the first year after the transplantation.
- **Hospital care:** acute kidney injury is usually linked to prolonged stay in the intensive care unit following surgery, and overall hospitalization time. In the EU and the U.S. the cost per day for intensive care is between USD 3,000 and USD 10,000. Given that an acute kidney injury prolongs the need for intensive care by an average of 3.5 days, the direct cost saving is in the region of USD 30,000[8]. Moreover, the total length of hospital stay is normally increased, resulting in costs of USD 1,000–4,000 per day of care[8].
- **Increased costs for patients with chronic kidney disease**: Some 20–30 per cent of patients who develop acute kidney injury are also at risk of suffering from chronic renal impairment, or chronic kidney disease. This condition is linked to both increased morbidity and mortality as well as high care costs over a longer period of time. The cost of treating and caring for a patient with chronic kidney disease is estimated at USD 1,700–12,700 annually[9], depending on the severity of the underlying disease.

There is thus great commercial potential in the area of acute kidney injury. Based on current assumptions, maximum annual sales of ROSgard are estimated at SEK 5–10 billion for the primary indication alone.

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1 DelvenInsights. Acute Kidney Injury (AKI) - Market Insights, Epidemiology and Market Forecast-2028

2 Market Research Report. Coronary Artery Bypass Graft Market Size, CABG Industry Report, 2025

3 Grand View Research. Coronary Artery Bypass Graft Market Size Worth $127.6 Million By 2025

4 Transparency Market Research. Coronary Artery Bypass Graft Market (abstract).

5 Technavio. Global Coronary Artery Bypass Grafts (CABG) Market 2017-2021 (abstract).

6 Monocl Strategy & Communication AB, November 2018

7 United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018

8 Henry Kaiser Family Foundation. State Health Facts Hospital Adjusted Expenses per Inpatient Day for 2017.

9 Honeycutt (2013) Medical Costs of CKD in the Medicare Population. JASN 24(9): 1478-83

CLINICAL STUDIES WITH ROSGARD

Study	Target Group	Dosing	Endpoint*	Country	Status
ROS-01	Healthy subjects	Single dose (0.08-2.6 mg/kg)	Safety, tolerability	Sweden	Completed
ROS-02	Healthy subjects	Multiple dosing (0.43-1.3 mg/kg)	Safety, tolerability	Sweden	Completed
ROS-03	Renal impairment	Single dose (0.22 or 0.43 mg/kg)	Pharmacokinetics	Sweden	Completed
ROS-04	Heart Surgery	Multiple dosing (0.65 or 1.3 mg/kg)	Safety, tolerability	Germany	Ongoing

Figure 3. Clinical phase 1 studies with ROSgard.
**Primary endpoint in the studies. Additional endpoints also analyzed.*

- **ROS-01** is a double-blind, placebo-controlled, first-in-human study. ROSgard is administered as an intravenous infusion over a period of 30 minutes in single ascending doses to healthy subjects. A total of 34 subjects were included in the study (24 received ROSgard and 10 received a placebo).
- **ROS-02** is a double-blind, placebo-controlled study in which ROSgard was administered to healthy trial subjects in multiple ascending doses. A total of 18 subjects were included in the study (12 received ROSgard and 6 received a placebo).
- **ROS-03** is an open-label study with the primary aim of evaluating ROSgard's pharmacokinetic properties in subjects with varying degrees of impaired kidney function not yet on dialysis treatment. A total of 8 subjects with a broad spectrum of kidney function (eGFR >15 and <90 ml/min/1.73 m2) were included sequentially in the study (all received ROSgard).
- **ROS-04** is an ongoing, double-blind, placebo-controlled study in patients undergoing open heart surgery with additional risk factors for acute kidney injury. A total of 12 subjects will be recruited for the study (8 will receive ROSgard and 4 a placebo). The patients will receive a total of 5 doses of ROSgard during the first 48 hours after cardiac surgery. The first doses will be given during surgery, with start of the first dose administration before onset of cardio-pulmonary bypass (connection to the heart lung machine).

The results of the completed phase 1 studies indicate that ROSgard is safe and generally well tolerated, both in healthy subjects and in patients with renal impairment. Pharmacokinetic results indicate linear (dose-proportional) pharmacokinetics and rapid initial elimination time of ROSgard from the blood stream due to its uptake in the kidneys. Based on these results, the first study in the primary target patient population for treatment has been initiated – patients undergoing open heart surgery who have additional risk factors for acute kidney injury. Based on the results of the ongoing study, the final design of the planned phase 2 program will be completed, including the choice of dose and dosing regimen.

UNDERLYING RESEARCH AND PATENTS

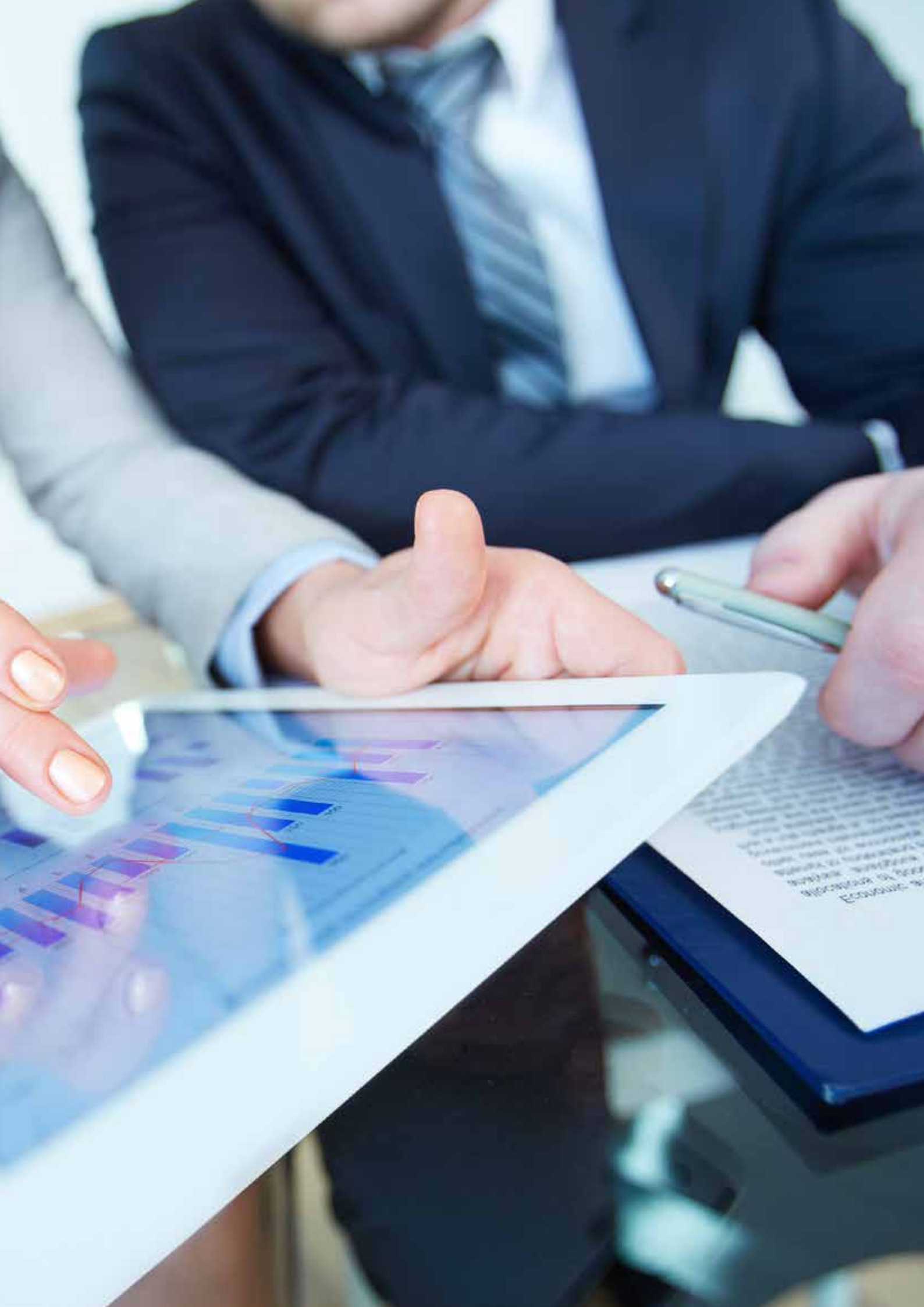
Guard Therapeutics has obtained several important patent approvals during the year and also continued to actively revise the overall patent portfolio in order to obtain relevant intellectual property rights that are consistent with the company's commercial and development objectives. The company has received an approval for ROSgard as a product (substance patent) in the U.S. and Australia, and the European Patent Office (EPO) has issued a preliminary decision (Intention to Grant) in relation to forthcoming approval of the corresponding patent application in Europe. These patents are valid until 2037. The company also has ongoing patent applications for the corresponding patent in other major countries such as Japan, China, Canada and Brazil.

In addition to this, the company holds a number of approved patents covering medicinal use of ROSgard and structurally adjacent molecules in the treatment of kidney injury and other medical conditions and diseases linked to oxidative stress in the U.S. and major EU countries. The company also has an approved patent in the U.S. and major EU countries for protection of mitochondria, as well as an ongoing global patent application concerning protection of bone marrow cells.

Patent family	Approved countries	Ongoing applications	Period of validity
Substance patent (ROSgard and various A1M variants)	USA, Australia, Europe (Intention to Grant)	Canada, Japan, China, Korea, Eurasia, India, Singapore, Brazil, Mexico, South Africa, New Zealand	2037
Medical use of A1M	USA, EP3**	---	2029
Protection against kidney damage during radiation therapy (PRRT *)	USA	---	2036
Treatment of mitochondrial diseases	USA, EP5***	---	2033
Protection of bone marrow cells	---	USA, Europe, Japan, China, Canada, Australia	2038

**Peptide-receptor radionuclide therapy*

***EP3: Germany, United KIngdom, France*
****EP5: Germany, United Kingdom, France, Spain, Italy*



Shareholder information

SHARE INFORMATION

The Guard Therapeutics AB (publ) share was listed on AktieTorget on April 3, 2013. In June 2017, the company changed its listing to Nasdaq First North, with first trading day on June 20, 2017. The Company's Certified Adviser is Svensk Kapitalmarknadsgranskning AB, +46 11 32 30 732, ca@skmg.se.

On December 31st, 2020 the number of shares was 212,998,874. There is one share class. Each share gives entitlement to one (1) vote at the annual general meeting and equal rights to share in the Company's assets and earnings. The share's quota value is SEK 0.02, and the share capital amounted to SEK 4,259,977.48 SEK as of December 31st, 2020.

- Tickername: GUARD
- ISIN code: SE0009973357
- Number of shares outstanding: 212,998,874
- Quota value: 0.02 SEK
- Trading unit: 1 share
- Share capital: 4,259,977.48 SEK

SHARE CAPITAL HISTORY

Event	Change in no. of shares	Total no. of shares	Change in Share Capital	Total Share Capital	Quotient value
2008 Incorporation	1,000	1,000	100,000.00	100,000.00	100.00
2008 Issue of new shares	124	1,124	12,400.00	112,400.00	100.00
2008 Issue of new shares	101	1,225	10,100.00	122,500.00	100,00
2009 Issue of new shares	370	1,370	37,000.00	137,000.00	100.00
2010 1000:1 Share split	1,368,630	1,370,000	-	137,000.00	0.10
2010 Issue of new shares	630,000	2,000,000	63,000.00	200,000.00	0.10
2012 Issue of new shares[1]	1,074,375	3,074,375	107,437.50	307,437.50	0.10
2013 Bonus issue	-	3,074,375	307,347.50	614,785.00	0.20
2014 5:1 Share split	12,297,500	15,371,875	-	614,785.00	0.04
2014 Issue of new shares [2]	13,609,230	28,981,105	544,369.20	1,159,244.20	0.04
2015 Issue of new shares [3]	6,119,290	35,100,395	244,771.60	1,404,015.80	0.04
2015 Issue of new shares TO1 [4]	2,710,301	37,810,696	108,412.04	1 512 427,84	0.04
2016 Issue of new shares	16,804,752	54,615,448	672,190.08	2,184,617.92	0.04
2017 Issue of new shares	106,666,668	161,282,116	4,266,666.72	6,451,284.64	0.04
2017 1:20 Reversed Share split	-153,218,011	8,064,105	-	6,451,284.64	0.80
2017 Issue of new shares TO	233,335	8,297,440	186,668.00	6,637,952.64	0.80
2018 Issue of new shares	12,449,400	20,746,840	9,959,520.00	16,597,472.64	0.80
2019 Reduction in share capital		20,746,840	-8,298,736.64	8,298,736.00	0.40
2019 Issue of new shares	82,987,356	103,734,196	33,194,942.40	41,493,678.40	0.40
2019 Issue of new shares	25,933,549	129,667,745	10,373,419.60	51,867,098.00	0.40
2019 Issue of new shares TO [5]	24,456,411	154,124,156	489,128.22	52,356,226.22	0.34
2020 Reduction in share capital [6]		154,124,156	-49,273,743.10	3,082,483.12	0.02
2020 Issue of new shares[7]	58,874,718	212,998,874	1,177,494.36	4,259,977.48	0.02

1 The issue of new shares consisted of three consecutive issues:

1.1 Cash and offset issue of SEK 3,423,750 and 4,388,750 respectively with a total of 312,500 newly issued shares.

1.2 Non-cash issue of SEK 15,625,000 kronor and 625,000 newly issued shares through 1,250,000 shares obtained in Preelumina Diagnostics AB, which thereby becomes a wholly-owned subsidiary of Guard Therapeutics AB.

1.3 Cash issue of SEK 3,421,875 and 136,875 newly issued shares.

2 The issue consisted of a cash issue of SEK 18,000,620 and an offset of SEK 15,000,000.

3 The issue in May consisted of a cash issue of SEK 29,223,836 and an offset of SEK 2,500,000.

4 The issue in May 2015 included subscription warrants which accrued SEK 15,278,054 in November 2015.

5 The issue in February 2019 included subscription warrants which accrued for SEK 24,456,411 before issue expenses in October 2019. The amount which increases the share capital is calculated on the quote value of 0.020 in accordance with a resolution at the extraordinary general meeting on October 23, 2019.

5 Decision to reduce the company's share capital to be transferred to non-restricted equity was taken at the annual general meeting in October 2019. The reduction in share capital was registered with the Swedish Companies Registration Office on January 7, 2020.

6 The issue was a combined rights issue and overallotments issue.

OWNERSHIP DISTRIBUTION

GUARD THERAPEUTICAL'S TEN LARGEST SHAREHOLDERS AS OF 31 DECEMBER 2020[1]

Owner	Number of Shares	Share of Capital/ Votes (%)
FÖRSÄKRINGSAKTIEBOLAGET, AVANZA PENSION	22,104,976	10.38 %
ARNHULT, RUTGER (M2 ASSET MANAGEMENT AB)	17,463,701	8.20 %
STÅHLBERG, JAN	15,585,526	7.32 %
UNIONEN	6,666,666	3.13 %
NORDNET PENSIONSFÖRSÄKRING AB	6,111,176	2.87 %
GALBA HOLDING AB	4,333,333	2.03 %
KARLSSON, AXEL	4,099,349	1.92 %
LGT BANK LTD, W8IMY	2,666,666	1,25 %
NILSSON, HÅKAN	2,572,786	1.21 %
FLODBERG, MÅNS OLA	1,800,000	0.85 %
ÖVRIGA	129,594,695	60.84 %
TOTAL	**212,998,874**	**100.00%**

[1] *Including related persons and companies*

Board of directors & Chief executive officer

Cristina Glad | Chairman of the board

Born in 1952, Cristina Glad has been a member of Guard Therapeutics AB's board since November 2012. Cristina Glad holds a PhD in Biochemistry and an E*MBA, and is an entrepreneur with more than 25 years' experience of research and business development within biotechnology and pharmaceutical development. In her role as both CEO and deputy CEO, Glad has been involved in developing BioInvent International AB from a technology platform company into a company with several investigational drugs in its product portfolio. She has been a consultant in her own company since December 2013. Glad is a member of the Royal Swedish Academy of Engineering Sciences (IVA).

- Number of shares: 77,190

Göran Forsberg | Member of the board

Born in 1963, Göran Forsberg has been a board member of Guard Therapeutics AB since May 2019. Göran Forsberg holds a PhD in Biochemistry and is an Associate Professor. He has more than 30 years' experience of pharmaceutical development, in both the Biotech industry and within large pharmaceutical companies. Göran Forsberg has extensive experience of many different aspects of pharmaceutical development, as well as business development and investor relations. Göran Forsberg has been CEO of Cantargia AB since 2014. Prior to that, he worked as business development manager at Active Biotech. His previous experience derives from positions at Pharmacia, KabiGen and the University of Adelaide in Australia.

- Number of shares: 40,912

Johannes Hulthe | Member of the board

Born in 1970, Johannes Hulthe has been a board member of Guard Therapeutics AB since May 2019. Johannes Hulthe holds a PhD (medicine) and MSc (economics) and has more than 17 years' experience from the pharmaceutical industry. Lecturer in cardiovascular prevention at Sahlgrenska University Hospital, Gothenburg. Johannes Hulthe was employed for 13 years at AstraZeneca, occupying the role of vice president within clinical drug development for cardiovascular, metabolism and kidney disease when he left the company in 2014.

- Number of shares: 0

Lars Höckenström| Member of the board

Born in 1956, Lars Höckenström has been a board member of Guard Therapeutics AB since October 2019. Lars holds an MSc in business and economics and has 35 years' experience within the finance sector, including as an analyst and advisor in public and private transactions as well as fund management. He was co-founder and partner of Aragon Fondkommission AB, analyst at Öhman FK AB, head of research at Matteus FK AB, analyst and portfolio manager at Catella Kapitalförvaltning AB and also co-founder and Senior Advisor at Naventus Corporate Finance AB.

- Number of shares: 20,000

Tobias L. Agervald | Chief Executive Officer

Tobias L. Agervald holds a PhD in medical sciences and is a an MD and board-certified specialist physician within internal medicine and nephrology, with extensive experience within global research and pharmaceutical development in both early and late phases. He is an internationally recognized researcher within experimental medicine focusing on kidney diseases, and has conducted research at institutions including Harvard Medical School in Boston and Indiana University School of Medicine in Indianapolis. His most recent position was as Senior Medical Director at Astellas Pharma Global Clinical Development in Leiden, the Netherlands.

Tobias is a global key opinion leader within cardiorenal diseases and previously acted as an expert for the evaluation of drug pipelines and development strategies, as well as design and execution of clinical studies via advisory committees.

Other assignments: Previously expert consultant, lecturer and/or member of steering committees for large pharmaceutical companies including AbbVie, Sanofi Aventis, Genzyme, Shire, Amgen, SOBI and Astellas. Board member of TE Medical Consulting AB. Affiliated researcher at the Karolinska Institutet.

- Number of shares: 1,042,693[1]

The shareholding indicated is valid as of March 31, 2021

1 Reported shareholding in Guard Therapeutics AB also includes holding for spouse and children, as well as shares owned via companies.

Scientific advisory committee

SCIENTIFIC ADVISORY COMMITTEE

Guard Therapeutics has a well-established network of global experts and key opinion leaders (KOLs) with the aim of ensuring top quality input by world-leading experts regarding the design and execution of the clinical development program for ROSgard. The company has recently established a Scientific Advisory Committee with the specific aim of optimizing the design of the forthcoming phase 2 program within cardiac surgery. The composition of this committee will be communicated in the near future.

Directors' Report

OPERATIONS

Guard Therapeutics AB (publ) was founded in 2008 by researchers working at Lund University. The company is a development company that is aiming to develop and commercialise pharmaceutical drugs with a focus on acute kidney injury, a medically prioritised area with the potential to save lives and prevent severe chronic consequences of renal impairment, such as life-sustaining dialysis treatment. The company is currently prioritising acute kidney injury in connection with heart surgery in its clinical development programme.

MERGER WITH THE SUBSIDIARY PREELUMINA DIAGNOSTICS

In June 2020, Guard Therapeutics decided to initiate a merger process to merge the wholly owned subsidiary Preelumina Diagnostics AB into the parent company. The merger was registered by the Swedish Companies Registration Office with effect from 30 September 2020

Following the merger of Preelumina, Guard Therapeutics is no longer a parent company. This means that consolidated financial statements are no longer prepared from 30 September 2020. All comparative figures in the report refer to the legal entity Guard Therapeutics AB (which in older reports was the parent company and was presented as such).

Guard Therapeutics has no further shareholdings in other companies.

SIGNIFICANT EVENTS IN THE FIRST QUARTER OF 2020

- On 17 January, Guard Therapeutics initiated a new clinical study to document ROSgard's pharmacokinetics and safety in renal impairment
- On 4 February, the company announced that it had recruited Lars Olsson as Head of CMC with the task of leading the company's strategically important development activities in production processes, formulation work, bioanalytical methods as well as other activities. The recruitment was the starting shot for an overall strategy of strengthening the company's internal expertise in key functions required for the continued clinical development of ROSgard.
- On 17 March, positive top-line results were reported from the last and highest dose group in a clinical phase 1a single ascending dose (SAD) study of the investigational drug ROSgard in healthy individuals. The study showed that ROSgard has a favourable safety profile and appropriate pharmacokinetic properties, even at a higher dose than that intended to be administered in future patient studies in cardiac surgery.

SECOND QUARTER

- On 4 June, the company announced that Karin Botha had been appointed Chief Financial Officer. The recruitment of a new CFO with specific experience from the pharmaceutical industry is aimed at strengthening the company's financial and administrative processes and to meet future requirements linked to the company's development and commercialisation strategy.

THIRD QUARTER

- On 6 July, the company announced that Peter Gilmour had been appointed Head of Preclinical Science. Peter Gilmour will contribute to the design and implementation of preclinical studies as well as the ongoing clinical development programme for Guard Therapeutics' investigational drug ROSgard.
- On 8 July, a positive follow-up analysis from the phase 1 study of ROSgard was presented.
- On 20 August, the company announced that it was carrying out a fully underwritten rights issue to raise approximately SEK 66.8 million and proposed that authorisation be given for an over-allotment option to raise a further SEK 9.8 million.
- On 28 September, positive top-line results were reported from a phase 1 study of ROSgard in individuals with renal impairment.

FOURTH QUARTER

- On 5 October, the company announced that the rights issue had been 214 per cent subscribed and that the over-allotment option had been fully exercised. In total, the company raised around SEK 76.5 million before issue costs.

- Guard Therapeutics received a Notice of Allowance for ROSgard from the United States Patent and Trademark Office (US-PTO) for its patent application no. 16/085,500, which protects the company's biological investigational drug ROSgard as a product.
- On 28 December, the company announced that Ann-Kristin Myde had been appointed new Head of Global Project Management. With extensive knowledge from some of the world's largest companies in the pharmaceutical industry, Ann-Kristin will bring valuable expertise, especially in the form of experience from development of treatments for kidney failure. Ann-Kristin will take up her position on 1 April 2021.
- At the end of the year, a pre-IND meeting was held with the US Food and Drug Administration (FDA).

SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

- The German medical regulatory body BfArM approved the company's application to conduct a phase 1b study of the investigational drug ROSgard. The study will be conducted in the primary target group for treatment – patients undergoing open heart surgery who have additional risk factors for acute kidney injury.
- Sara Thuresson was recruited to a newly created position as Head of Clinical Operations. Sara will take up her post on 1 May 2021.
- On 19 March, the company announced that the first patient had been dosed in a phase 1b study of the investigational drug ROSgard. The phase 1b study is being carried out at the University Hospital in Münster, Germany
- The company received approval for a patent from the United States Patent and Trademark Office (USPTO). The patent approval follows the previous provisional approval (Notice of Allowance) that was granted and communicated in December 2020
- The company announced that its Nomination Committee intends to propose that Johan Bygge be elected as new Chairman of the Board and Pia Gideon as a Director at the forthcoming ordinary general shareholders' meeting on 12 May 2021.
- On 9 April, it was announced that the European Patent Office (EPO) had issued a notice of Intention to Grant for a patent application that protects the company's biological investigational drug ROSgard as a product and its medical use. The next step in the process is formal approval, after which the patent will be valid until 2037.
- On 12 April, the company's shareholders were given notice of the Annual General Meeting to be held on Wednesday 12 May 2021.

RISKS AND UNCERTAINTIES

Limited resources

Guard Therapeutics is a small company with limited resources in terms of management, administration and capital. For the implementation of the strategy, it is essential that the resources be used in an optimal way for the company. There is a risk that the company's resources will be insufficient, resulting in financial and operational problems.

Dependence on key personnel and employees

Guard Therapeutics bases its success on the knowledge, experience and creativity of a small number of individuals. The company is dependent on being able to find qualified personnel in the future. The company is working hard to reduce its dependence through good documentation of all operations, including procedures and work methods.

Earnings capacity and capital requirements

Drug development is a time- and cost-intensive activity. It cannot be ruled out that it will take longer than expected before the company achieves a positive cash flow. To cover these costs, Guard Therapeutics will need to raise new capital. There are no guarantees that it will be possible to raise capital on terms favourable to shareholders. A failure to generate sufficient profits could affect the company's market value.

Sales risk

It is not possible to establish with certainty that the products developed by the company will receive the positive reception in the market that is reflected in this memorandum. The quantity of products sold may be lower and the time it takes to establish the company in the market may be longer than the company currently has reason to believe.

Tax losses

In view of the fact that Guard Therapeutics' business has generated significant deficits, the company has substantial accumulated tax losses. There is currently no expiration date limiting use of the company's tax losses. However, it is uncertain at what point in time it will be possible to use these tax losses to offset taxable profits, as the company has not yet generated any profits. Changes in ownership and historical and any future capital raisings could result in restrictions on the amount of tax losses that can be used in the future. The company's ability to use its tax losses in the future could also be adversely affected by chan-

ges in the applicable legislation. Such restrictions on the right to use the company's accumulated tax losses could have a negative impact on Guard Therapeutics' financial position and results.

Risk from the ongoing coronavirus outbreak (Covid-19)
The business activities of Guard Therapeutics have not yet been significantly affected by the ongoing corona-virus outbreak. However, the company cannot rule out certain delays in the ongoing clinical studies due to slower recruitment of trial subjects or other impacts on the contract research companies engaged by the company. As the company has no revenue and has a small and cost-effective organisation, it is estimated that its financial results would not be significantly affected in the event of minor delays in the clinical programme.

ONGOING EFFORTS TO ENSURE THE COMPANY'S FINANCING

The Board works continuously to secure financing for the company's operations based on different scenarios.

THE BOARD OF DIRECTORS' PROPOSED APPROPRIATION OF RETAINED EARNINGS

KSEK	
Non-restricted reserves	115,711
Loss for the year	-40,284
Total	**7,426**

The Board of Directors proposes that the available funds, kSEK 75,426, be carried forward. No dividend is thus proposed.

Income Statement

(KSEK)	NOTE	2020-01-01 2020-12-31	2019-01-01 2019-12-31
Operating income			
Net sales		-	-
Cost of goods sold		-	-
Gross profit		**-**	**-**
Operating expenses	*6 – 10*		
Research and development costs		-35,415	-33,667
Marketing and sales costs		-1,923	-3,315
Administrative costs		-3,081	-3,450
Other operating income		143	-
Other operating expenses		-	-
Operating profit		**-40,277**	**-40,432**
Financial income and expense			
Financial income		-	-
Financial expense	*11*	-7	-856
Write-down subsidiaries	*14*	-	-25,122
Profit before tax		**-40,284**	**-66,410**
Tax for the period	*12*	-	-
Loss for the period		**-40,284**	**-66,410**

Balance Sheet

(KSEK)	NOTE	2020-12-31	2019-12-31
ASSETS			
Fixed assets			
Tangible fixed assets	*13*	44	205
Shares in subsidiaries	*14*	-	-
Fixed assets total		**44**	**205**
Current assets			
Tax asset		-	22
Other assets		709	1,354
Prepaid expenses and accrued income		427	526
Cash and bank		90,042	53,839
Current assets total		**91,178**	**55,741**
TOTAL ASSETS		**91,222**	**55,946**
EQUITY AND LIABILITIES			
Equity			
Share capital		4,260	52,356
Development funds		-	-
Share premim account		443,273	320,385
Retained earnings		-327,563	-261,381
Loss for the year		-40,284	-66,410
Total equity		**79,686**	**44,950**
Long term liabilities			
Synthetic option	*8*	230	410
Long term accounts payables		4,803	5,368
Long term liabilities total		**5,032**	**5,778**
Short term liabilities			
Trade payables		2,978	2,519
Group liabilities		0	136
Tax liabilities		222	-
Other liabilities		200	138
Accrued expenses and deferred income	*15*	3,102	2,425
Short term liabilites total		**6,503**	**5,218**
Total liabilities		**11,536**	**10,995**
TOTAL EQUITY AND LIABILITIES		**91,222**	**55,946**

Statement of changes in equity

(KSEK)	Share capital	Share premium account	Retained earnings	Profit/Loss for the year	TOTAL
Opening balance 1 January 2019	**16,597**	**255,424**	**-182,208**	**-79,173**	**10,641**
Conversion of previous year's result	-	-	-79,173	79,173	0
Issue of new shares[1]	33,195	37,344	-	-	70,539
Issue of new shares[2]	10,373	16,857	-	-	27,230
Reduction of share capital	-8,299	8,299	-	-	0
Warrants[3]	489	23,967	-	-	24,456
Issue costs	-	-21,507	-	-	-21,507
Profit/Loss for the period	-	-	-	-66,410	-66,410
Equity 31 December 2019	**52,356**	**320,384**	**-261,381**	**-66,410**	**44,950**
Opening balance 1 January 2020	**52,356**	**320,384**	**-261,381**	**-66,410**	**44,950**
Conversion of previous year's result	-	-	-66,410	66,410	0
Merger with subsidiary			228		228
Reduction of share capital	-49,274	49,274	-	-	0
Rights Issue	1,027	65,760			66,787
Over allotment	150	9,600			9,750
Issue costs		-1,744			-1,744
Profi/Loss for the period	-	-	-	-40,284	-40,284
Equity 31 December 2020	**4,260**	**443 273**	**-327,563**	**-40,284**	**79,686**

1 Issue costs was MSEK 17.5
2 Issue costs was MSEK 3.7
3 Issue costs was MSEK 0.3

Statement of cash flows

(KSEK)	2020-01-01 2020-12-31	2019-01-01 2019-12-31
Operating activitities		
Operating loss	-40,280	-40,432
Depreciations	161	290
Received interest	-	-
Paid interest	-6	-856
Cash flow from operating activities before working capital	**-40,125**	**-40,998**
Changes in working capital		
Increase/decrease in receivables	692	-238
Increase/decrease in trade payables	1,471	-19,404
Changes in working capital	**2,163**	**-19,642**
Cash flow from operating activities	*-37,962*	*-60,640*
Investing activities		
Aquisition of tangible assets	-	-73
Aquisition of intangible assets	-	-
Aquisition of financial assets	-	-
Cash from subsidiary at merger	118	
Cash flow from investing activities	**118**	**-73**
Financing activities		
Issues of new shares	74,793	100,719
Increase/decrease in long term payables	-746	-
Cash flow from financing activities	**74,047**	**100,719**
Cash flow for the period	36,203	40,007
Cash and cash equivalent at the beginning of the period	53,839	13,832
Cash and cash equivalent at the end of the period	**90,042**	**53,839**

Notes to the financial statements

NOTE 1

General information

Guard Therapeutics AB, corp. ID no. 556755–3226, has its registered office in Lund, Sweden.

Guard Therapeutics was previously the parent company of the Guard Therapeutics Group. Following the merger of the wholly owned subsidiary Preelumina as of 30 September 2020, the group ceased to exist and only Guard Therapeutics AB is therefore reported.

Guard Therapeutics' annual report for the period January–December 2020 has been approved for publication under a resolution of the Board of 20 April 2021.

Unless otherwise stated, all amounts are expressed in thousands of Swedish kronor (kSEK). Figures in parentheses refer to the previous period.

NOTE 2

Summary of significant accounting policies

Significant accounting policies applied in preparing these annual accounts are described in the following. Unless otherwise stated, these policies have been applied consistently for all the years presented.

Basis of preparation of financial statements

Following the merger of the subsidiary company Preelumina, the former parent company Guard Therapeutics AB no longer prepares consolidated financial statements. As consolidated financial state-ments are no longer prepared in accordance with IFRS, the former parent company has, in accordance with the applicable regulations, switched to accounting and financial reporting in accordance with BFNAR 2021:1 Annual Accounts and Consolidated Financial Statements (K3) as of the financial year beginning on 1 January 2020.

The transition to K3 has not had any impact on Guard Therapeutics AB's financial statements.

Preparing financial statements in accordance with K3 requires the use of critical accounting estimates. Management is also required to make certain judgements in applying the company's accounting policies.

Accounting policies, changes to accounting policies and disclosures

No changes to accounting policies affecting Guard Therapeutics AB's financial statements came into effect in 2020.

Translation of foreign currency

Transactions and balance sheet items

Transactions in foreign currency are translated to the functional currency at transaction date exchange rates. Foreign exchange gains and losses arising from such transactions and upon translation of monetary assets and liabilities in foreign currency at closing rates are recognised in the income statement.

Intangible assets

Capitalised product development costs

The company is engaged in research and development on new products. Research expenditure is expensed as incurred. Development costs directly attributable to the development of identifiable and unique products are recognised as intangible assets when the following criteria are met:

- it is technically feasible to complete the product so that it will be available for use,
- the company intends to complete the product for use or sale,
- there is reason to expect that the company will be able to use or sell the product,
- it can be shown that the product will generate probable future economic benefits,
- adequate technical, economic, and other resources are available to complete the development of and use or sell the product, and
- the costs attributable to the product during its development can be reliably measured.

Directly attributable expenditure that is capitalised includes expenditure for employees plus a reasonable portion of indirect costs.

Other development expenditure which does not meet these criteria are expensed as incurred.

Expenditure for the company's ongoing drug

development work is capitalised as internally generated intangible assets after approved phase 3.

Previously expensed development expenditure is not capitalised in later periods.

Property, plant and equipment

Property, plant and equipment are recognised at cost less depreciation. Cost includes expenditure directly attributable to the acquisition of the asset.

Any additional expenditure is added to the carrying amount of the asset or recognised as a separate asset, as appropriate, only when it is probable that the future economic benefits associated with the asset will accrue to the company and the cost can be reliably measured.

Assets are depreciated on a straight-line basis as follows:

Machinery and equipment: 5 years

Residual values and useful lives of assets are tested at the end of each reporting period and adjusted where necessary. An asset's carrying amount is written down to the recoverable amount immediately if the carrying amount exceeds the estimated recoverable amount.

Gains and losses on the sale of an item of property, plant and equipment are determined by comparing the sale proceeds and the carrying amount, whereby the difference is recognised in other operating income or other operating expenses in the income statement.

Impairment of non-financial non-current assets

When there is an indication of impairment of an asset, an impairment test is performed. If the recoverable amount of the asset is less than the carrying amount, the asset is written down to the recoverable amount. In testing for impairment, assets are grouped to the lowest levels at which there are separate identifiable cash flows (cash-generating units). For other assets than goodwill, which were previously written down, an impairment test is made at each balance sheet date to determine if a reversal is required.
In the income statement, impairment losses and reversals of impairment losses are recognised in the function where the asset is used.

Financial instruments – general information

Financial instruments are accounted for in accordance with the rules in K3, Chapter 11, which provide for cost-based measurement.

Financial instruments accounted for in the balance sheet include securities, trade and other receivables, short-term investments, trade payables, loans and derivatives. The instruments are recognised in the balance sheet when Guard Therapeutics AB becomes party to the contractual provisions of the instrument.

Financial assets are derecognised when the right to receive cash flows from the instrument has expired or been transferred, and the company has transferred substantially all risks and rewards of ownership.

Financial liabilities are derecognised when the obligations have been settled or otherwise been extinguished.

The fair value of current receivables and liabilities is equal to the carrying amount, as the discount effect is insignificant.

Trade receivables

Trade receivables are financial instruments which consist of amounts due from customers for goods or services sold in the ordinary course of business. If payment is expected within one year or earlier, trade receivables are classified as current assets. If not, they are recognised as non-current assets.

Trade receivables are initially recognised at fair value and subsequently measured at amortised cost using the effective interest method, less any provisions for impairment.

Cash and cash equivalents

Cash and cash equivalents are financial instruments. In the balance sheet, the item comprises cash and bank deposits. In cash flow, the item comprises cash, bank deposits and the company's cash pool.

Equity

Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new ordinary shares or options are recognised in equity as a deduction from the proceeds of the issue.

Reserve for development costs
To the extent that the parent company has internally generated intangible assets, the capitalised amount is, as of 2016, transferred from non-restricted equity to reserve for development costs less depreciation.

Trade payables

Trade payables are financial instruments and refer to obligations to pay for goods and services purchased from suppliers in the ordinary course of business. Trade payables are classified as current liabilities if they fall due within one year. If not, they are recognised as non-current liabilities.

Trade payables are initially recognised at fair value and subsequently measured at amortised cost using the effective interest method.

Current and deferred tax

Deferred tax is recognised, by applying the balance sheet liability method, for all temporary differences between the carrying amounts and tax bases of assets and liabilities in the financial statements. Deferred income tax is calculated by applying tax rates that have been enacted or announced at the balance sheet date and that are expected to apply when the deferred tax asset is realised, or the deferred tax liability is settled.

The Board will address the issue of recognising deferred tax assets arising from tax losses only when the company has started to generate profits.

Employee benefits

Retirement benefit obligations
The company only has defined contribution pension plans.

Defined contribution pension plans are post-employment benefit plans under which the company pays fixed contributions to a separate legal entity. The company has no legal or constructive obligations to pay further contributions if this legal entity does not hold sufficient assets to pay all employee benefits related to employee service in the current and prior periods.

In a defined contribution pension plan, the company pays contributions to publicly or privately managed pension schemes on a mandatory, contractual or voluntary basis. Once the contributions have been paid, the company has no further payment obligations. The contributions are recognised as staff costs when they fall due. Prepaid contributions are recognised as an asset to the extent that cash repayments or reductions of future payments may accrue to the company.

Synthetic options
The company's synthetic options, for which a market premium has been paid, are measured and recognised at fair value using an option valuation model.

The liability is continuously remeasured at fair value using an option valuation model based on the applicable terms. Changes in value during the term of the options are recognised as staff costs. If the synthetic options are exercised by the holder, the financial liability, which was previously remeasured at fair value, is settled. Any realised gain or loss is recognised in profit or loss as staff costs. If synthetic options expire out of the money, the reported liability is recognised as income.

Leases

The company only has operating leases for commercial premises and computers. Leases in which a significant share of the risks and benefits of ownership are retained by the lessor are classified as operating leases. Payments made during the lease term are charged to the income statement on a straight-line basis over the lease term.

Statement of cash flows

The statement of cash flows is prepared using the indirect method. This means that the net profit or loss is adjusted for transactions which have not resulted in incoming or outgoing payments during the period, and for any income or expenses attributable to cash flows from investing or financing activities.

NOTE 3

Significant estimates and judgements

Estimates and judgements are reviewed on an ongoing basis, and are based on historical experiences and other factors, including expectations of future events that are considered reasonable under existing circumstances.

Critical accounting estimates and judgements
The company makes estimates and assumptions about the future. By definition, the resulting accounting estimates will not always equal the related actual results. Estimates and assumptions which involve a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities in the next financial year are addressed below.

Intangible assets
Expenditure for the company's ongoing drug development work is capitalised as internally generated intangible assets from approved phase 3.

NOTE 4

Financial risk management

A research company such as Guard Therapeutics has a high operational and financial risk, as projects run by the company are in different phases of development where a number of parameters affect the probability of commercial success. The business is thus subject to risks related to drug development, competition, technology development, patents, regulatory requirements, capital requirements, currencies, interest rates as well as other factors. No significant changes regarding risks or uncertainties occurred during the period.

From an accounting perspective, there are four main types of risk: market risk, credit risk, currency risk and liquidity risk. Guard Therapeutics AB is not yet exposed to market risk or credit risk, but liquidity can be a risk for the company. The company carefully monitors forecasts for its liquidity reserve to ensure that it has sufficient cash and cash equivalents to meet its operational requirements. Currency

risk arises from the company's exposure to the euro and the company continuously assesses the need for currency hedging. Other risks and uncertainties are described in the Directors' Report.

NOTE 5

Earnings per share

The company had 212,998,874 shares registered at 31 December 2020. Earnings as at 31 December 2019 have been divided by 154,124,156 shares. The weighted average number of shares for 2020 was 165,819,991 on an undiluted and diluted basis. For 2019, the weighted average number of shares was 101,507,981 on an undiluted basis and 118,711,752 on a fully diluted basis.

Earnings per share at 31 December 2020 were SEK -0.19 (-0.43) based on earnings for the period divided by the average number of shares on an undiluted basis.

NOTE 6

Operating expenses by nature of expense

Operating expenses in the income statement are presented classified by the functions "Research and development costs", "Selling expenses" and "Administrative expenses". Total expenses by function are distributed across the following expenses by nature:

(KSEK)	2020	2019
Project costs[1]	28,857	22,855
Other external expenses	4,970	6,206
Staff costs	6,432	11,081
Depreciation, amortisation and impairment (note 13)	161	290
Total research and development costs, selling expenses and administrative expenses	**40,420**	**40,432**

[1]In the 2019 annual accounts, project costs were accounted for as Premises and operating costs including laboratory costs and other external expenses

NOTE 7
Employees

AVERAGE NUMBER OF EMPLOYEES	2020 NUMBER OF EMPLOYEES	2020 OF WHICH MEN	2019 NUMBER OF EMPLOYEES	2019 OF WHICH MEN
TOTAL COMPANY	**3**	**2**	**5**	**2**

GENDER DISTRIBUTION FOR DIRECTORS AND OTHER SENIOR EXECUTIVES	2020 NUMBER AT YEAR-END	2020 OF WHICH MEN	2019 NUMBER AT YEAR-END	2019 OF WHICH MEN
Directors	4	3	4	3
CEO and other executives	3	2	1	1
TOTAL	**7**	**5**	**5**	**4**

NOTE 8
Salaries and Remunerations

FINANCIAL YEAR 2020 (KSEK)	FEE	BASIC SALARY	VARIABLE REMUNERA-TION	RETIREMENT BENEFIT COST	SOCIAL SEC CONTRIBU-TION	TOTAL
Cristina Glad, Chariman of the Board[1]	240	-	-	-	25	**265**
Göran Forsberg, Director[1]	120	-	-	-	38	**158**
Johannes Hulthe, Director[1]	120	-	-	-	38	**158**
Lars Höckenström, Director[1]	120	-	-	-	38	**158**
Tobias Agervald, CEO	-	1,234	439	1,007	754	**3,434**
TOTAL BOARD AND CEO	**600**	**1,234**	**439**	**1,007**	**892**	**4,171**
Other employees	-	1,639	-	213	533	**2,385**
TOTAL COMPANY	**600**	**2,873**	**439**	**1,220**	**1,424**	**6,556**

[1] *Fee approved at Annual General Meeting 2020.*

Severence Pay

A mutual notice period of six months applies between the company and the CEO. There is no contractual severance pay to the CEO.

Synthetic option

On February 12, 2019, the Company transferred to the CEO a synthetic option corresponding to the value of what is now 2,202,234 shares in the Company. In the event that the CEO exercises the synthetic option, this entitles the CEO to a cash remuneration, the amount of which is determined on the basis of how much the market value of the underlying 2,202,234 shares exceeds the established exercise price. On December 31, 2020, the synthetic option was worth a total of SEK 229,535, which corresponds to SEK 0.10 per underlying share. The synthetic option runs until 12 February 2022. If the CEO's employment in the Company ceases for any reason, the CEO shall offer the synthetic option to the Company. This also applies if the CEO wishes to transfer the synthetic option. Detailed terms are outlined in the transfer agreement. The synthetic option has affected earnings with an income of KSEK 181 during the year.

FINANCIAL YEAR 2019 (KSEK)	FEE	BASIC SALARY	VARIABLE REMUNERATION	RETIREMENT BENEFIT COST	SOCIAL SEC CONTRIBUTION	TOTAL
Cristina Glad, Chairman[1]	240	-	-	-	75	**315**
Göran Forsberg, Director[1]	120	-	-	-	38	**158**
Johannes Hulthe, Director[1]	120	-	-	-	38	**158**
Lars Höckenström, Director[2]	70	-	-	-	22	**92**
Tobias Agervald, CEO[3]	-	1,342	952	818	919	**4,031**
Tomas Eriksson, outgoing CEO [4]	-	680	-	137	247	**1,065**
TOTAL BOARD AND CEO	**550**	**2,022**	**952**	**955**	**1,339**	**5,818**
Other employees	-	3,469	-	440	1,195	**5,105**
TOTAL	**550**	**5,491**	**952**	**1,395**	**2,535**	**10,924**

1 Elected at Annual General Meeting May 29, 2019. Fee approved at AGM.
2 Elected at Extraordinary General Meeting 23 oktober 2019. Fee approved at Extraordinary General Meeting.
3 Ingoing CEO per January 15, 2019
4 Outgoing CEO per Januari 15, 2019

NOTE 9

Related party disclosures

Related party transactions comprise of consulting services concluded at fair market value

2020 (KSEK)	
Antaros Medical (co-owned by Director Johannes Hulthe)[1]	35
TOTAL BOARD AND CEO	**35**
Other employees	0
TOTAL COMPANY	**35**

2019 (KSEK)	
Ermén Produktion & Redovisning AB (owned by Anders Ermén, outgoing Chairman of the Board)	49
Antaros Medical (co-owned by Director Johannes Hulthe)[1]	729
TOTAL BOARD AND CEO	**778**
Other employees	0
TOTAL COMPANY	**778**

[1] *The agreement with Antaros Medical was entered into before Johannes Hulthe was elected member of the board.*

NOTE 10

Auditors' fees and expenses

Öhrlings PricewaterhouseCoopers (KSEK)	2020	2019
Audit Engagement	192	156
Audit services in addition to the audit engagement	43	77
Tax advisory services	-	-
Other services	164	70
TOTAL	**399**	**303**

NOTE 11
Financial expenses

KSEK	2020	2019
Interest expense	7	856
TOTAL	**7**	**856**

NOTE 12
Taxes

The company's total tax deficit as of December 31, 2020 amounts provisionally, including deductible temporary differences, to KSEK 398,225 (356,870). The accumulated deficit in the subsidiary Preelumina was KSEK 19,630 before the merger, the entire amount has been transferred to Guard Therapeutics AB as a result of the merger.

In 2020, a reconsideration was submitted to the Swedish Tax Agency for adjustment of accumulated deficits that was not included at the time of transition to IFRS in 2015. The reconsideration has been approved and the higher comparative figure for 2019 compared with amounts reported in 2019 is in accordance with the new decision from the Swedish Tax Agency.

Deferred tax assets on the accumulated deficit have been valued at zero as it is currently not possible to assess when the tax loss carryforward may be utilized.

Reconciliation of reported tax (KSEK)	AMOUNT	TAX RATE	TAX EFFECT
Tax effect on profit/loss of the year	-40,284	21,4 %	8,621
Sum of Tax effect of non-deductible expenses and Tax effect of deductible expenses recognised directly in equity	-1,070	21,4 %	229
Tax losses for which no deferred tax asset has been recognised			8,850
Reported tax of the year			0

NOTE 13
Tangible assets

(KSEK)	2020-12-31	2019-12-31
Ingoing accumulated acquisition value	2,023	1,950
Investment	0	73
Outgoing accumulated acquisition value	**2,023**	**2,023**
Ingoing accumulated depreciation	-1,819	-1,529
Depreciation	-161	-290
Outgoing accumulated depreciation	**-1,979**	**-1,819**
CLOSING BALANCE	**44**	**205**

NOTE 14
Financial assets

(KSEK)	2020-12-31	2019-12-31
Ingoing accumulated acquisition value	0	24,937
Shareholder contribution	0	185
Write-down	0	-25,122
CLOSING BALANCE	**0**	**0**

In 2019, patents in the subsidiary were ended or transferred to the parent company Guard Therapeutics. This resulted in a write-down of the value of the shares in the subsidiary as Preelumina no longer had any remaining patents. The write-down had no effect on cash flow. In 2020, Preelumina merged with the parent company Guard Therapeutics.

NOTE 15
Accrued expenses and deferred income

(KSEK)	2020-12-31	2019-12-31
Accrued salary incl social security contributions	1,065	853
Accrued holiday pay debt incl social sec contributions	499	252
Other accrued expenses	1,538	1,320
TOTAL	**3,102**	**2,425**

NOTE 16
Appropriation of retained earnings

The Boards proposal of appropriation of retained earnings

(KSEK)	2020-12-31
Non-restricted reserves	115,711
Loss for the year	- 40,284
SUM	**75,426**

The Board of Directors proposes that available funds of KSEK 75,426 to be carried forward. Thus, no dividend is proposed.

NOTE 17
Contingent Liability

The company has no pledged collateral or other contingent liabilities as of 2020-12-31, nor as of 2019-12-31.

NOTE 18
Significant events after the end of the financial year

- The German medical regulatory body BfArM approved the company's application to conduct a phase 1b study of the investigational drug ROSgard. The study will be conducted in the primary target group for treatment – patients undergoing open heart surgery who have additional risk factors for acute kidney injury.

- Sara Thuresson was recruited to a newly created position as Head of Clinical Operations. Sara will take up her post on 1 May 2021.
- On 19 March, the company announced that the first patient had been dosed in a phase 1b study of the investigational drug ROSgard. The phase 1b study is being carried out at the University Hospital in Münster, Germany.
- The company received approval for a patent from the United States Patent and Trademark Office (USPTO). The patent approval follows the previous provisional approval (Notice of Allowance) that was granted and communicated in December 2020.
- The company announced that its Nomination Committee intends to propose that Johan Bygge be elected as new Chairman of the Board and Pia Gideon as a Director at the forthcoming ordinary general shareholders' meeting on 12 May 2021.
- On 9 April, it was announced that the European Patent Office (EPO) had issued a notice of Intention to Grant for a patent application that protects the company's biological investigational drug ROSgard as a product and its medical use. The next step in the process is formal approval, after which the patent will be valid until 2037.
- On 12 April, the company's shareholders were given notice of the Annual General Meeting to be held on Wednesday 12 May 2021.

Signatures

The annual accounts have been prepared in accordance with generally accepted accounting standards and provide a true and fair view of the company's financial position and results. The Directors' Report for the company gives a true and fair overview of the performance, financial position and earnings of the company, and describes significant risks and uncertainties faced by the company. The income statement and balance sheet will be presented for adoption at the Annual General Meeting on May 12, 2021.

Lund, April 21. 2021

Cristina Glad
Chariman of the Board

Göran Forsberg
Member of the Board

Johannes Hulthe
Member of the Board

Lars Höckenström
Member of the Board

Tobias Agervald
Chief Executive Officer

We presented our auditor's report on 21 april 2021
Öhrlings PricewaterhouseCoopers AB

Ola Bjärehäll
Authorised Public Accountant

GUARD
THERAPEUTICS

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