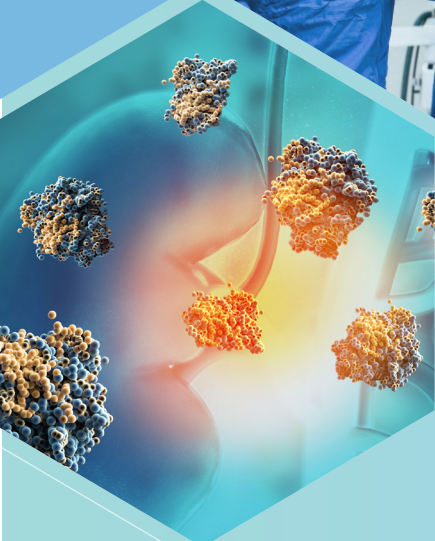


# YEAR-END REPORT

## JANUARY - DECEMBER 2024



**GUARD**  
THERAPEUTICS

# Fourth quarter 2024 in short

*During the fourth quarter, patient recruitment for the Phase 2b POINTER study gained momentum, in line with our high expectations, as all participating clinics have now been activated.*

## **SUMMARY OF YEAR-END REPORT**

### **Fourth quarter, October-December 2024**

**Net sales: KSEK 0 (0)**

**Loss for the period: KSEK -25,958 (-17,096)**

**Earnings per share\*: SEK -2.11 (-1.70)**

**Equity/asset ratio\*\*: 68% (78)**

**Cash and cash equivalent: KSEK 54,186 (83,741)**

### **January-December 2024**

**Net sales: KSEK 0 (0)**

**Loss for the period: KSEK -96,066 (-113,323)**

**Earnings per share\*: SEK -8.62 (-11.26)**

\* Earnings per share before and after dilution: Loss of the period divided by the average number of shares during the period.

\*\*Equity/asset ratio: Equity divided by total assets per December 31st, 2024.

---

## **DEFINITIONS**

By "Guard Therapeutics" or "Company" is meant Guard Therapeutics International AB (publ) with corporate ID no. 556755-3226.

All amounts are presented in thousands of Swedish Kronor (KSEK) unless otherwise stated. Figures in parentheses refer to the corresponding period last year.

## **AUDITORS REVIEW**

This report has not been reviewed by the company's auditor.

**INTERIM REPORTS AND ANNUAL REPORTS ARE AVAILABLE AT  
[WWW.GUARDTHERAPEUTICS.COM](http://WWW.GUARDTHERAPEUTICS.COM)**

# Significant events

## SIGNIFICANT EVENTS IN THE FOURTH QUARTER

- On 2 October, the previous rights issue (compensation issue) was registered with the Swedish Companies Registration Office and the company was infused with approximately SEK 7.2 million.
- In mid-October, the first patient in Europe was dosed in the clinical Phase 2b POINTER study, which evaluates the drug candidate RMC-035 as a kidney protective treatment in patients undergoing open-heart surgery.
- In December, the nomination committee for 2024 was presented, consisting of Jan Ståhlberg (own holdings), Peter Wolpert (Stiftelsen Industrifonden), Marianne Nilsson (Swedbank Robur Fonder) and Johan Bygge (Chairman of the Board).

## SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- In early January, an important milestone was reached in the POINTER study, with 25% of the planned number of patients enrolled and all participating clinics open for patient recruitment.
- The company announced that the outcome of the first of two planned safety analyses during the conduct of the study is expected to be available in the first quarter of 2025. In line with standard practice, the analyses are blinded to the company and are performed by an independent Data Safety Monitoring Committee (DSMC).
- The company announced the establishment of a new Scientific Advisory Committee comprised of seven globally recognized experts in nephrology and drug development. The committee will play a key advisory role in the company's late-stage development strategy, including the design of the upcoming Phase 3 study of RMC-035 in open-heart surgery.
- The Board of Directors proposed a rights issue which, if fully subscribed, will generate approximately SEK 150 million in gross proceeds. The rights issue is conditional upon a positive outcome in the first safety review in the POINTER-study and approval by an extraordinary general meeting on 6 March, 2025.

## COMMENTS ON SIGNIFICANT EVENTS

Our primary focus in the near future is the conduct of the POINTER study. It is therefore very encouraging that the initiation phase has progressed well and that patient recruitment is meeting our high expectations.

At the same time, we are pleased with the continued strong commitment from our main shareholders, who are represented on the company's nomination committee.

We now look forward to reaching further important milestones in recruitment to the study and communicating the outcome of the first safety analysis in the near future.



## Chief executive's review

*The fourth quarter marked the end of an eventful and highly rewarding year for Guard Therapeutics. In mid-October, we enrolled the first patient in Europe in our Phase 2b clinical trial, POINTER, evaluating the drug candidate RMC-035 as a kidney protective treatment in open-heart surgery. This followed the study's initiation in Canada earlier in the autumn. Shortly after the start of the new year, we reached a significant milestone having enrolled 25% of the planned number of patients.*

The development of the POINTER study is central to the company's immediate future, making it especially gratifying to have successfully initiated the study with strong momentum. All participating clinics are now open for patient recruitment, which is an encouraging milestone for our continued efforts. It is also

inspiring to closely follow the study's progress, which is the result of extensive and intensive preparatory work carried out since autumn 2023, following the positive results from the previous Phase 2a AKITA study involving 177 patients.

The primary objective of the POINTER study is to establish a dosing regimen optimized for both safety and efficacy. This approach aligns with standard principles of drug development and serves as preparation for a subsequent pivotal Phase 3 study. The study design builds on the promising results from AKITA, which, for the first time, demonstrated the intended kidney protective treatment effect of RMC-035 in patients. Importantly, efficacy was demonstrated using the same endpoint anticipated for a pivotal study (MAKE90), which is highly encouraging and significantly reduces the remaining development risk.

The POINTER study involves 19 high-quality clinical sites across Canada, Germany, the Czech Republic, and Spain, collectively aiming to enroll approximately 160 patients. Patient recruitment is expected to continue for about one year from the study's initiation in August, with overall study results anticipated about six months later.

In line with standard practice, an independent Data Safety Monitoring Committee (DSMC) will review safety data during the course of the study. These reviews will occur after dosing one-third and two-thirds of the planned number of patients, respectively. The outcome of the first interim safety review is expected at the beginning of March. Unlike the AKITA study, the interim analysis will not assess treatment efficacy; the study will only be discontinued if a significant safety risk associated with the treatment is identified.

To support the continuation of our ambitious and important clinical program with RMC-035, we successfully secured additional capital during the year. In late June, we completed a directed share issue of approximately SEK 60 million to several of our major shareholders, enabling the planned initiation of the POINTER study. This was followed by a so-called compensation issue, providing all existing shareholders the opportunity to participate on the same terms as the directed issue.

After the end of the reporting period, we further announced our intention to carry out a rights issue of approximately SEK 150 million, of which approximately SEK 120 million is guaranteed through letters of intent and guarantee commitments. This capital raise enables a number of value-creating and critical activities, including the completion of the POINTER study,

necessary preparations for phase 3, and the opportunity to intensify ongoing and future business development activities.

We are also pleased to note the significant support from our main shareholders for these transactions, which is highly favorable for our continued development.

It is gratifying to note that several of our important research findings were published during the year in internationally renowned, peer-reviewed journals, including eClinicalMedicine (part of Lancet Discovery Science) and the American Journal of Physiology – Renal Physiology. These publications align with our commitment to maintaining a high scientific standard and ensuring transparency in the company's research and development progress.

Finally, I would like to extend a heartfelt thank you to our entire team for their hard work and dedication throughout the year, especially in connection with the launch of the POINTER study. Following the strong start of the study in 2024, we look forward to achieving several key milestones in 2025. These include the outcomes of planned safety analyses during the conduct of the study, as well as operational milestones such as the completion of patient recruitment and the collection of data that will form the basis for the analysis and communication of overall study results.

In summary, we successfully executed our operational plan this year, fully in line with our expectations. This progress brings us closer to our goal of offering a new and unique kidney protective treatment with significant patient benefits in an area currently lacking effective therapeutic options. In the long term, such a treatment also has the potential to reduce the substantial healthcare costs associated with both acute and chronic kidney disease.



**Tobias Agervald**  
Chief Executive Officer



# About Guard Therapeutics AB

*Guard Therapeutics International AB (publ) is a Swedish clinical-stage biotechnology company that identifies and develops new therapies for diseases with a high unmet medical need for more effective treatments. The company focuses on kidney diseases.*

## **FOCUS ON ACUTE KIDNEY INJURY**

Guard Therapeutics AB (publ) identifies and develops new therapies for kidney diseases, focusing on acute kidney injury. This is a medically prioritized area with the potential to save lives and prevent the onset and progression of chronic kidney disease (CKD) to end-stage renal disease (ESRD, or renal failure), which necessitates life-sustaining dialysis treatment and/or kidney transplantation.

The company's clinical-stage lead candidate RMC-035 represents a completely new first-in-class drug, being a modified variant of the endogenous protein alpha-1-microglobulin. It protects cells and their mitochondria from damage caused by oxygen deprivation and elevated levels of the oxygen-binding and toxic protein heme. Favorable treatment effects of RMC-035 have been observed in a large number of preclinical disease models, including models of kidney diseases.

RMC-035 has a natural affinity for the kidneys and is intended as a short-term treatment delivered by intravenous infusion in the hospital-setting (specialty care) to patients who are at high risk of developing acute kidney injury.

### **RMC-035 in open-heart surgery**

Many patients undergoing open-heart surgery are at

high risk of kidney injury. RMC-035 effectively blocks the injury mechanisms triggered during the procedure, making kidney protection in the context of heart surgery the primary target for its clinical development.

RMC-035 has been evaluated in an extensive Phase 1 program and a larger global Phase 2 study (AKITA) including a total of 177 patients. The results, communicated in autumn 2023, demonstrated a clinically relevant and statistically significant improvement in key endpoints related to renal function 90 days after surgery with RMC-035 treatment compared to placebo. Based on these results, the company has chosen to initiate a Phase 2b study, POINTER, with the aim of identifying the optimal dosage regimen and target patient population prior to a subsequent pivotal Phase 3 study. The POINTER study is expected to include approximately 160 patients and the first patient in the study was enrolled at the end of August 2024.

### **Fast Track Designation**

RMC-035 has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA), for reducing the risk of death, dialysis or an irreversible loss of kidney function in patient undergoing open-heart surgery and who are at increased risk of acute kidney injury.

Fast Track Designation is a government program designed to speed up the registration process in the U.S. and is given to pharmaceutical projects to ensure that new treatments can be made available faster to patients with serious diseases where there is a high medical need.

## **ADDITIONAL OPPORTUNITIES FOR RMC-035**

### **RMC-035 in kidney transplantation**

The therapeutic goal of RMC-035 in kidney transplantation is to enhance the long-term function of the transplanted kidney, thereby reducing the risk of future dialysis or the need for another kidney transplant. The first clinical study of RMC-035 for this indication has been completed, focusing on evaluating its pharmacokinetic properties in kidney transplant recipients. This paves the way for an efficacy study as the next step.

### **RMC-035 in sepsis**

Patients with sepsis are at very high risk of developing acute kidney injury, which can lead to permanent loss of kidney function. Based on favorable preclinical results for RMC-035, and with additional clinical data from heart surgery, there are thus good opportunities to expand its use to sepsis. The clinical data gathered from the heart surgery program further support the accelerated progression of RMC-035 to a pivotal study in sepsis.

## **CHRONIC KIDNEY DISEASE**

### **GTX peptides**

Guard Therapeutics has developed a preclinical platform of novel peptides (short protein fragments) termed GTX peptides. These peptides share the core function of RMC-035 (alpha-1-microglobulin) and are specifically designed to enable chronic treatment in new disease areas. GTX peptides have demonstrated robust efficacy in various kidney disease models and can, unlike RMC-035, be administered via subcutaneous injection. Several development opportunities have been identified for GTX peptides, including late-stage CKD, where the goal is to eliminate or delay the need for dialysis or kidney transplantation. Additionally, GTX peptides aim to slow the progressive loss of kidney function in various rare kidney diseases, such as Alport's syndrome.

## **BUSINESS MODEL AND STRATEGY**

Guard Therapeutics' business model and overarching strategy are founded on professional drug development of the highest scientific quality. The company continuously evaluates partnerships, licensing opportunities, and project acquisitions to support the clinical development of RMC-035 and our preclinical programs, with the goal of maximizing value for both patients and shareholders.

## **MEDICAL NEED**

There are currently no approved treatments for preventing or treating all forms of acute kidney injury, including in the patient groups for which RMC-035 is intended.

Many patients undergoing open-heart surgery already have impaired kidney function due to pre-existing conditions such as diabetes or heart failure. If these patients sustain additional kidney injury during surgery, they are at risk of developing CKD, which may eventually necessitate dialysis or a kidney transplant. Moreover, it is estimated that approximately 30,000 patients in the U.S. undergo open-heart surgery each year with pre-existing CKD. These patients face a particularly high risk of further kidney injury during surgery, accelerating CKD progression.

Beyond increasing the likelihood of requiring dialysis or transplantation, CKD contributes to other severe health outcomes, including cardiovascular disease, reduced quality of life, and increased mortality.

In cases of ESRD (renal failure), life-sustaining chronic dialysis or kidney transplantation becomes necessary. Unfortunately, the prognosis for patients on dialysis is poor, with an annual mortality rate of 15–20% in hemodialysis patients, exceeding that of many metastatic cancers. Moreover, the healthcare costs of ESRD are substantial, consuming 2–3% of total national healthcare budgets, even though affected patients represent only 0.02–0.03% of the population. Protecting the kidneys from injury is therefore crucial for preventing CKD progression and the development of ESRD.

Kidney transplantation is the preferred treatment for ESRD. However, most transplanted kidneys are from deceased donors and suffer acute injury during procurement, transplantation, and the immediate post-operative period. This injury impairs both short- and

long-term kidney function, increasing the risk of requiring dialysis or repeat transplantation in the future.

Sepsis is another condition frequently associated with kidney injury, often leading to CKD. Kidney injury is the most common complication of sepsis and a significant driver of its high morbidity and mortality rates.

## MARKET OVERVIEW

Guard Therapeutics recognizes the significant potential to create value for patients, society, and shareholders by developing innovative therapies to prevent and treat kidney injury associated with open-heart surgery, kidney transplantation and sepsis.

### Open-heart surgery

Based on multiple analyses of expected future drug price, reimbursement and market access pathways in the U.S., combined with reliable data on the number of patients undergoing open-heart surgery each year in major markets such as the U.S., the EU, and Japan, the global market potential can be estimated with reasonable accuracy.

Approximately half a million patients undergo open-heart surgery annually in the EU and the U.S., with an estimated 30–50% likely to benefit from treatment with RMC-035. This corresponds to about 100,000 patients in the U.S. (40% of all cardiac surgery patients in the U.S.) and a similar number in the EU.

With a conservative estimate of price for RMC-035, supporting its formulary inclusion, the annual market potential in the U.S. alone is USD 0.5-1 billion. The global market potential thus exceeds USD 1 billion annually, considering other major markets such as the EU, Japan, and China.

Even a more limited use in specific patient groups, such as those with CKD, results in a favorable market potential based on a justified higher price. The target patient population and the design of a future pivotal study, which will consider both benefit/risk and market potential, will be informed by clinical study results, dialogue with regulatory authorities, and more detailed market assessments.

### Kidney Transplantation

Guard Therapeutics has not conducted an independent analysis of market potential for RMC-035 in kidney transplantation; however, current evidence from heart surgery provides a solid reference point. The market should be estimated based solely on kidney transplants from deceased donors, as these carry the highest risk of impaired kidney function both short- and long-term. Each year, approximately 20,000 deceased-donor kidney transplants are performed in the U.S. and 16,000 in Europe.

Similar to open-heart surgery, the treatment is expected to target patients at relatively higher risk of acute kidney injury. A reasonable assumption is that half of all deceased-donor kidney transplants could initially be treated with RMC-035, representing a total market potential of approximately USD 350 million in the U.S. and Europe. The global market potential is estimated to exceed USD 600 million.

### Other indications

In the U.S. alone, each year approximately 1.7 million individuals develop sepsis, around half of whom suffer from acute kidney injury. The medical need for a kidney protective treatment in this patient population is remarkable, and the addressable market for RMC-035 is estimated to exceed USD 5 billion.

The total market for GTX peptides in CKD is estimated to exceed USD 8 billion.

#### References:

External market research, *RMC-035 Pricing and Reimbursement assessment*. October 2022.

Internal data on file.

<https://www.cdc.gov/sepsis>

USRDS Annual Data Report 2023: <https://usrds-adr.niddk.nih.gov/2023>



## CLINICAL STUDIES OF RMC-035 IN OPEN-HEART SURGERY

RMC-035 has undergone extensive safety and pharmacokinetic evaluation in four separate Phase 1 studies involving healthy subjects, patients with impaired renal function, and patients undergoing open-heart surgery.

### AKITA (Phase 2a)

The global Phase 2 AKITA study was successfully completed in 2023. This randomized, double-blind, placebo-controlled trial was designed to assess the kidney protective effect of RMC-035 in patients at high risk of developing acute kidney injury during open-heart surgery.



The results demonstrated a clinically relevant and statistically significant beneficial effect of RMC-035 on renal function 90 days after surgery, as measured by both the change in eGFR compared to pre-surgery levels and a reduced risk of serious renal events according to the MAKE criteria (Major Adverse Kidney Events). MAKE is a composite endpoint consisting of either death, dialysis treatment, and/or at least a 25% loss of kidney function.

Overall, the results demonstrate a favorable treatment effect of RMC-035 based on the endpoints that are expected to be used in a registrational Phase 3 study. If our results are confirmed in such a study, they could form the basis for market approval.

### POINTER (Phase 2b)

Based on the promising efficacy results in the AKITA study, the subsequent Phase 2b POINTER study has been initiated, aimed at identifying the optimal dosage and preferred target patient population for treatment with RMC-035. The design of the study has been reviewed by the U.S. FDA, as well as regulatory authorities in Europe and Canada where the study is being conducted.



## POINTER

POINTER is a randomized, double-blind and placebo-controlled study and is expected to include a total of approximately 160 patients, of which at least 30% have chronic kidney disease defined as eGFR less than 60 ml/min/1.73m<sup>2</sup>. The study has two different dose arms of RMC-035 (60 mg and 30 mg) and a control arm (placebo). The patients are allocated across the treatment arms in a 2:2:3 ratio. Renal function before surgery is a stratification factor, which means that patients with and without chronic kidney disease will be evenly distributed between all treatment arms.

The primary endpoint of the study is the change in eGFR from study start to 90 days post-surgery, in line with the planned follow-up period. MAKE at 90 days post-surgery is a secondary endpoint consisting of either death, dialysis or  $\geq 25\%$  loss of eGFR compared to pre-surgery. Data from the two RMC-035 dose arms will be pooled and compared against placebo in the primary efficacy analyses.

An independent Data Safety Monitoring Committee (DSMC) will review study data for safety two times during the study, after one and two-thirds of the planned patient population, respectively. The results of these analyses will be blinded to the company.

Patient recruitment began at the end of August 2024 and is expected to last approximately one year. The overall study results are expected to be available about six months after completion of patient recruitment.

Study	Phase	Population	Dosing	Key endpoints	Locations	Status
ROS-01	Phase 1	Healthy subjects	Single dose (0.08-2.6 mg/kg)	Safety, tolerability	Sweden	Completed
ROS-02	Phase 1	Healthy subjects	Multiple dosing (0.43-1.3 mg/kg)	Safety, tolerability	Sweden	Completed
ROS-03	Phase 1	Renal impairment	Single dose (0.22 or 0.43 mg/kg)	Pharmacokinetics	Sweden	Completed
ROS-04	Phase 1b	Cardiac surgery	Multiple dosing (0.65 or 1.3 mg/kg)	Safety, tolerability	Germany	Completed
AKITA	Phase 2	Cardiac surgery	Multiple dosing (0.65 or 1.3 mg/kg)	Efficacy, safety	Europe, North America	Completed
POINTER	Phase 2b	Cardiac surgery	Multiple dosing (30 mg or 60 mg)	Efficacy, safety	Europe, North America	Ongoing

Figure 1. Clinical studies with RMC-035 in cardiac surgery, including early Phase 1 studies.

### CLINICAL STUDIES OF RMC-035 IN KIDNEY TRANSPLANTATION

A first clinical study of RMC-035 has been conducted in patients undergoing kidney transplantation. The primary objective of the study was to assess its safety profile and pharmacokinetic properties following multiple dosing in connection with the transplantation. The results pave the way for the next phase of development—the design of an efficacy study.

Study	Phase	Population	Dosing	Key endpoint	Location	Status
ROS-06	Phase 1b	Kidney transplantation	Multiple dosing, variable dose (start dose 0.3 mg/kg)	Pharmacokinetics	Sweden	Completed

Figure 2. Clinical studies with RMC-035 in kidney transplantation





# Financial information

## REVENUE AND EARNINGS

### Revenue

In 2024 the company had net sales of KSEK 0 (0).

### Operating loss

The operating result for the fourth quarter amounted to KSEK -27,089 (-15,330) and for the entire period January-December 2024 to KSEK -99,905 (-115,073).

Research and development expenditure accounted for the majority of the company's expenses, which totaled at KSEK -24,325 (-13,029) for the quarter and -90,326 (-105,773) KSEK for the the year. The increased costs in the fourth quarter vs previous year is mainly related to the phase 2b POINTER study.

The marketing costs for the company in the fourth quarter amounted to KSEK -976 (-1,113) and for the period January-December to KSEK -3,795 (-3,766). The administrative costs amounted to KSEK -1,608 (-1,421) for the fourth quarter and to KSEK -6,123 (-5,383) for the entire period. The increase vs last year is mainly linked to an increased activity supporting moving into late phase activities.

Other operating income and operating expenses mainly comprised exchange differences on trade payables and amounted to KSEK 339 (-151) by end of December this year.

### Net financial items

Net financial items, which for the year amounted to KSEK 3,840 (1,750), mainly consisted of unrealized exchange rate differences on the company's foreign currency accounts, KSEK 2,538, as well as interest income from fixed interest accounts and foreign currency accounts, KSEK 1,310. Net financial items increased in the fourth quarter with KSEK 1,131 (-1,767), as a result of the weakening of the Swedish Krona vs main currencies EUR/GBP/USD during the period.

## FINANCIAL POSITION

On December 31, 2024, the company had an equity ratio of 68 percent, vs 78 percent last year. Equity amounted to KSEK 37,967 at the end of December, compared to KSEK 66,733 at the same time last year.

The company's cash and cash equivalents comprising cash and bank balances, including liquid investments amounted to KSEK 54,186 (83,741). During the quarter, the company was supplied with liquid funds of approximately MSEK 7.2, the proceeds from the rights issue that was carried out in September, and settled in October.

After the close of the period, on February 17, the board of directors proposed a rights issue, which, subject to a positive outcome of the first safety review in the POINTER study and approval by the extraordinary general meeting on March 6, will generate approximately MSEK 150 in gross proceeds if fully subscribed.

The issue is guaranteed to 80% or approximately MSEK 120. The net proceeds, if fully subscribed, are estimated to about MSEK 136.

At the end of the period, the balance-sheet total amounted to KSEK 55,741 (85,227).

### CASH FLOW AND INVESTMENTS

Guard Therapeutics had a cash flow of KSEK -13,503 (-17,326) in the fourth quarter of 2024. For the period January-December, the cash flow was KSEK -32,093

(-116,825). Cash flow from operating activities during the fourth quarter amounted to KSEK -20,517 (-17,328) and -94,751 (-116,046) for the year.

The cash flow from financing activities during the same periods amounted to KSEK 7,014 (3) and KSEK 62,658 (-779), respectively.

### DIVIDEND

The board of directors proposes that no dividend shall be distributed related to the fiscal year 2024.

## Shareholder information

### THE SHARE

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 Growth Market, with the first trading day on June 20, 2017.

The Company's Certified Adviser is Svensk Kapitalmarknadsgranskning AB, ca@skmg.se.

On December 31, 2024, the number of shares in the company amounted to 12,294,878. There is one share class, with each share entitling the holder to equal rights to share in the company's assets and earnings and to one vote at the company's general meetings. The share's quota value is SEK 1.00, and the share capital amounted to SEK 12,294,878 on December 31st, 2024.

- **Symbol: GUARD**
- **ISIN: SE0021181559**
- **No of shares: 12,294,878**
- **Quota value: SEK 1.00**
- **Trading unit: 1 share**
- **Share capital: SEK 12,294,878.00**

### OWNERSHIP STRUCTURE ON DECEMBER 31, 2024

Shareholder December 31th 2024	Number of shares	Share of votes	Share of capital
STÅHLBERG, JAN	2,314,090	18.82%	18.82%
STIFTELSEN INDUSTRIFONDEN	1,598,227	13.00%	13.00%
SWEDBANK ROBUR HEALTHCARE	1,158,688	9.42%	9.42%
M2 ASSET MANAGEMENT AB	1,110,818	9.03%	9.03%
AVANZA PENSION	704,303	5.73%	5.73%
STRAND SMÅBOLAGSFOND	422,690	3.44%	3.44%
NORDNET PENSIONSFORSÄKRING AB	353,872	2.88%	2.88%
RÄFSAB AB	276,552	2.25%	2.25%
ALLA MOLLER AB	117,488	0.96%	0.96%
DAHLQVIST, JAN	88,301	0.72%	0.72%
OTHER	4,149,849	33.75%	33.75%
<b>TOTAL</b>	<b>12,294,878</b>	<b>100%</b>	<b>100%</b>

# Income statement

(KSEK)	OCTOBER-DECEMBER		JANUARY-DECEMBER	
	Oct 1, 2024	Oct 1, 2023	Jan 1, 2024	Jan 1, 2023
	Dec 31, 2024	Dec 31, 2023	Dec 31, 2024	Dec 31, 2023
Net sales	-	-	-	-
Cost of goods sold	-	-	-	-
<b>Gross profit</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Research and development expenditure	-24,325	-13,029	-90,326	-105,773
Marketing and sales costs	-976	-1,113	-3,795	-3,766
Administrative expenses	-1,608	-1,421	-6,123	-5,383
Other operating income	-180	0	339	0
Other operating expenses	0	233	0	-151
<b>Operating loss</b>	<b>-27,089</b>	<b>-15,330</b>	<b>-99,905</b>	<b>-115,073</b>
Financial income	1,131	-1,324	3,848	2,197
Financial expense	0	-443	-8	-447
<b>Net financial items</b>	<b>1,131</b>	<b>-1,767</b>	<b>3,840</b>	<b>1,750</b>
<b>Pre-tax loss</b>	<b>-25,958</b>	<b>-17,096</b>	<b>-96,066</b>	<b>-113,323</b>
Tax on profit for the period	-	-	-	-
<b>LOSS FOR THE PERIOD</b>	<b>-25,958</b>	<b>-17,096</b>	<b>-96,066</b>	<b>-113,323</b>

# Balance sheet

(KSEK)	Dec 31, 2024	Dec 31, 2023
<b>ASSETS</b>		
<i>Non-current assets</i>		
Property, plant and equipment	0	0
<b>Total non-current assets</b>	<b>0</b>	<b>0</b>
<i>Current assets</i>		
Other receivables	422	667
Receivables subscribed unpaid capital (Note 6)	0	0
Prepaid expenses and accrued income	1,134	819
<b>Current receivables</b>	<b>1,555</b>	<b>1,486</b>
Cash and cash equivalents (Note 6)	54,186	83,741
<b>Cash and bank balances</b>	<b>54,186</b>	<b>83,741</b>
<b>Total current assets</b>	<b>55,741</b>	<b>85,227</b>
<b>TOTAL ASSETS</b>	<b>55,741</b>	<b>85,227</b>
<b>EQUITY AND LIABILITIES</b>		
<i>Equity</i>		
Share capital	12,295	10,062
Share capital, not registered	0	0
Non-restricted share premium reserve	797,777	732,711
Retained earnings	-676,040	-562,716
Loss for the period	-96,066	-113,323
<b>Total equity</b>	<b>37,967</b>	<b>66,733</b>
<i>Non-current liabilities</i>		
Provision for social security contributions – incentive scheme (Note 7)	39	469
Non-current trade payables	0	1,413
<b>Total non-current liabilities</b>	<b>39</b>	<b>1,882</b>
<i>Current liabilities</i>		
Trade payables	9,428	5,494
Tax liabilities	78	268
Other payables	304	293
Accrued expenses and deferred income	7,924	10,557
<b>Total current liabilities</b>	<b>17,735</b>	<b>16,613</b>
<b>Total liabilities (Note 8)</b>	<b>17,775</b>	<b>18,494</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>55,741</b>	<b>85,227</b>

# Statement of cash flows

(KSEK)	OCTOBER-DECEMBER		JANUARY-DECEMBER	
	Oct 1, 2024	Oct 1, 2023	Jan 1, 2024	Jan 1, 2023
	Dec 31, 2024	Dec 31, 2023	Dec 31, 2024	Dec 31, 2023
<i>Operating activities</i>				
Operating loss	-27,089	-15,330	-99,905	-115,073
Adjustments for non-cash items*	618	907	2,824	2,835
Interest received	409	809	1,322	2,005
Interest paid	0	0	-8	-5
<b>Cash flows from operating activities before changes in working capital</b>	<b>-26,062</b>	<b>-13,613</b>	<b>-95,767</b>	<b>-110,237</b>
<i>Change in working capital</i>				
Increase/decrease in receivables	-146	-353	-81	288
Increase/decrease in current liabilities	5,691	-3,362	1,098	-6,096
<b>Change in working capital</b>	<b>5,545</b>	<b>-3,715</b>	<b>1,017</b>	<b>-5,808</b>
<b>Cash flows from operating activities</b>	<b>-20,517</b>	<b>-17,328</b>	<b>-94,751</b>	<b>-116,046</b>
<i>Investing activities</i>				
Acquisition of property, plant and equipment	-	-	-	-
Acquisition of intangible assets	-	-	-	-
Acquisition of non-current financial assets	-	-	-	-
<b>Cash flows from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Financing activities</i>				
New share issue incl overhead costs**	7,186	-111	64,500	-111
Increase/decrease in non-current liabilities	-172	114	-1,842	-668
<b>Cash flows from financing activities</b>	<b>7,014</b>	<b>3</b>	<b>62,658</b>	<b>-779</b>
<b>Change in cash and cash equivalents</b>	<b>-13,503</b>	<b>-17,326</b>	<b>-32,093</b>	<b>-116,825</b>
Cash and cash equivalents at beginning of period	66,775	103,195	83,741	201,008
<i>Effects of exchange rate changes on cash and cash equivalents</i>	914	-2,128	2,538	-443
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>54,186</b>	<b>83,741</b>	<b>54,186</b>	<b>83,741</b>

\*\*Non-cash items include stock options, depreciations and unrealized exchange rate differences on the accounts payables.

\*\*The amount in 2023 mainly includes overheads in connection with the reverse split

# Changes in equity

(KSEK)	Share capital	Ongoing share issue	Non-restricted share premium reserve*	Retained earnings	Profit/loss for the year	TOTAL
<b>Opening balance January 1, 2023</b>	<b>10,062</b>	<b>0</b>	<b>730,015</b>	<b>-449,887</b>	<b>-112,839</b>	<b>177,360</b>
Transfer OB	-	-	-	-112,839	112,839	0
Employee stock options (not 7)	-	-	2,808	-	-	2,808
Reverse split equation issue	-	-	-	-	-	0
Reverse split costs	-	-	-111	-	-	-111
Loss for the period	-	-	-	-	-113,323	-113,323
<b>EQUITY DECEMBER 31, 2023</b>	<b>10,062</b>	<b>0</b>	<b>732,711</b>	<b>-562,716</b>	<b>-113,323</b>	<b>66,733</b>
<b>Opening balance January 1, 2024</b>	<b>10,062</b>	<b>0</b>	<b>732,711</b>	<b>-562,716</b>	<b>-113,323</b>	<b>66,733</b>
Transfer OB	-	-	-	-113,323	113,323	0
Employee stock options (not 7)	-	-	2,799	-	-	2,799
Directed issue	1,994	-	57,996	-	-	59,991
Rights issue	239	-	6,947	-	-	7,186
Share issue costs	-	-	-2,677	-	-	-2,677
Loss for the period	-	-	-	-	-96,066	-96,066
<b>EQUITY DECEMBER 31, 2024</b>	<b>12,295</b>	<b>0</b>	<b>797,777</b>	<b>-676,040</b>	<b>-96,066</b>	<b>37,967</b>

\*As of December 31st, 2024, the company had no restricted share premium reserve.



# Notes to the financial statements

## NOTE 1

### General information

Guard Therapeutics AB, Corp. Reg. No. 556755-3226, has its registered office in Stockholm, Sweden.

Guard Therapeutics' year-end report for the period January–December 2024 has been approved for publication by decision of the Board of Directors on February 19, 2025.

All amounts are presented in thousand Swedish kronor (KSEK) unless otherwise stated. Figures in parentheses refer to the corresponding period last year.

## NOTE 2

### Summary of significant accounting policies

The significant accounting policies adopted in the preparation of this year-end report are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

#### *Basis of preparation*

The financial statements of Guard Therapeutics have been prepared in accordance with the applicable regulations under BFNAR 2012:1 Annual Accounts and Consolidated Financial Statements (K3).

The preparation of financial statements in conformity with K3 requires the use of certain 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*

The accounting policies applied when preparing this year-end report are consistent with those used in the preparation of the 2023 Annual Report unless otherwise stated below. The Annual Report is available on the company's website.

In 2024, no amendments to accounting policies that entered force had any impact on Guard Therapeutics' financial statements.

## NOTE 3

### Significant estimates and judgements

Estimates and judgements are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

#### *Critical accounting estimates and judgements*

The company makes estimates and assumptions about the future. The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Estimates and assumptions which involve a significant risk of material adjustments to the carrying amounts of assets and liabilities in the coming financial year are described below.

#### *Intangible assets*

As of December 31, 2024, no development expenses have been reported as intangible assets in the balance sheet, as the criteria for capitalization have not been deemed to be met in the development projects being conducted. For more information about the criteria for reporting intangible assets, refer to note 2 in the annual report.

Research expenses are expensed when incurred.

## NOTE 4

### Risks and uncertainties

A research company like Guard Therapeutics is characterized by a high operational and financial risk, as projects that the company runs are in different phases of development, where a number of parameters affect the probability of commercial success. In summary, the business is associated with risks related to, among other things, drug development, competition, technology development, patents, authority requirements, capital requirements, currencies and interest rates. For further information, see also comment in the Directors' report in the Annual Report.

During the current period, no significant changes regarding external risk or uncertainty factors are deemed to have occurred.

## NOTE 5

### Earnings per share

The company had, after a consolidation of shares (so-called reverse split) 10,061,615 shares registered in December 2023, and as of December 31, 2024, the company had 12,294,878 shares registered after final registration of the rights issue which took place in September.

Weighted average number of shares for the full year 2024 amounted to 11,150,087 (10,061,615) before and after dilution. Weighted average number of shares for the fourth quarter 2024 amounted to 12,292,281 (10,061,615) before and after dilution.

Earnings per share at the end of December amounted to SEK -8.62 (-11.26), based on the earnings for January-December divided by the average number of shares before full dilution. The corresponding result for the fourth quarter amounted to SEK -2.11 (-1.70).

## NOTE 6

### Cash and cash equivalents

Cash and cash equivalents comprise financial instruments. In the balance sheet, the item comprises cash and bank balances, including liquid investments. In the cash flow, the item comprises cash, bank balances and liquid investments.

## NOTE 7

### Employee stock options

The objective of the employee option plans is to secure long-term commitment among the company's senior executives, key employees and consultants through a remuneration system linked to the company's future value growth.

#### Employee stock option program 2021

At the Annual General Meeting on May 12, 2021, the shareholders passed a resolution to introduce the Employee option plan 2021.

The Employee option plan 2021 encompassed a total of 11,200,000 options. Additional options may no longer be granted. As of December 31, 2024 there were a total of 9,750,001 outstanding options. During 2024, no options have been granted, exercised or revoked.

#### Employee stock option program 2023

At the Extraordinary General Meeting on February 24, 2023, the shareholders passed a resolution to introduce the Employee option plan 2023. The Employee option plan 2023 encompassed a total of 21,000,000 options. Additional options may no longer be granted. In February 2023, 19,950,000 options were granted at a fixed exercise price of SEK 1.45 per option. The options were issued to the CEO, other senior executives and key personnel in the company. During 2024, no options have been granted or revoked.

In 2024, the two employee option programs together had an impact on earnings of KSEK -2,369 (-3,270).

Full exercise of granted options minus the options that have been revoked as of December 31st, 2024, i.e. a total of 29,700,001 options, would result in a dilution of shareholders by 4.6 percent.

After the consolidation of the company's shares (reverse split) which was carried out at the end of December 2023, each option entitles to the equivalent of 0.02 shares.

Refer to Note 9 in the 2023 Annual Report for further information about the plan.

### Changes in existing employee stock option programs (number of stock options)

Number of options*	EMPLOYEE STOCK OPTION PROGRAM 2021	EMPLOYEE STOCK OPTION PROGRAM 2023
<b>Ingoing value, 1 januari 2024</b>	<b>9,750,001</b>	<b>19,950 000</b>
Granted options	-	-
Exercised options	-	-
Revoked options	-	-
<b>Total change</b>	<b>0</b>	<b>0</b>
<b>Outstanding options at the end of the period, Dec 31, 2024</b>	<b>9,750,001</b>	<b>19,950,000</b>

\*Each option entitles to 0.02 shares.

## NOTE 8

### Contingent liabilities

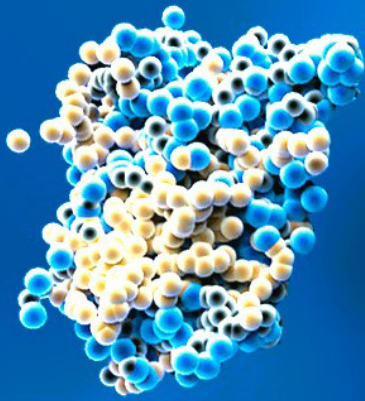
The Company had no pledged collateral or other contingent liabilities as of December 31, 2024, nor as of December 31, 2023.

# Submission of year-end report

This year-end report has been approved for publication by the Board of Directors and the Chief Executive Officer. The information was submitted for publication, through the agency of the CEO, at 08.30 a.m. on February 20, 2025.

Guard Therapeutics International AB  
Nybrogatan 34  
SE-114 39 Stockholm, Sweden  
Switchboard: +46 8 670 65 51  
[www.guardtherapeutics.com](http://www.guardtherapeutics.com)

**Tobias Agervald**  
Chief Executive Officer



# GUARD THERAPEUTICS



## COMPANY INFORMATION

COMPANY NAME: Guard Therapeutics International AB (publ)

CORP. REG. NO.: 556755-3226

LEGAL FORM: Public limited company

ADDRESS: Nybrogatan 34, SE-114 39 Stockholm, Sweden

TELEPHONE: +46 8 670 65 51

WEB SITE: [www.guardtherapeutics.com](http://www.guardtherapeutics.com)

## FINANCIAL CALENDAR

Annual Report 2024: April, 14 2025 (tentative date)

Interim report Q1 2025: May 5, 2025

Interim report Q2 2025: August 21, 2025

Interim Report Q3 2025: November 13, 2025

Bokslutskommuniké 2025: February 20. 2026

## GENERAL MEETING

Extraordinary General Meeting, March 6, 2025

Annual General Meeting, May 5, 2025

