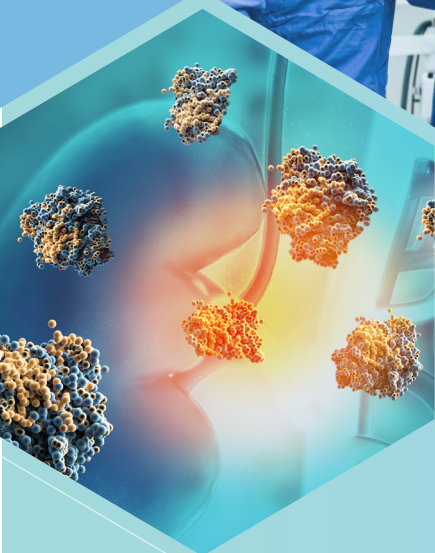


INTERIM REPORT

JANUARY - SEPTEMBER 2024



GUARD
THERAPEUTICS

Third quarter 2024 in short

The first patient in the phase 2b study POINTER is dosed and the results from the AKITA study are published in the respected journal eClinical Medicine (Lancet Discovery Science).

SUMMARY OF INTERIM REPORT

Third quarter, July-September 2024

Net sales: KSEK 0 (0)

Loss for the period: KSEK -31,727 (-23,342)

Earnings per share*: SEK -2.65 (-2.32)

Equity/asset ratio: 84% (79)**

Cash and cash equivalent: KSEK 66,775 (103,195)

January-September 2024

Net sales: KSEK 0 (0)

Loss for the period: KSEK -70,108 (-96,227)

Earnings per share*: SEK -6.51 (-9.56)

** 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 September 30th, 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**

Significant events

SIGNIFICANT EVENTS IN THE THIRD QUARTER

- At the beginning of July, the remainder of Industrifonden's allocation in the directed issue could be completed after the investment was approved by the Inspectorate for Strategic Products ("ISP"), whereby the company received approximately SEK 13 million in liquid funds.
- The company obtained approvals, through the European application process, from regulatory authorities and ethics committees in Spain, Germany and the Czech Republic, to include patients in the Phase 2b clinical study POINTER with the drug candidate RMC-035 as a kidney-protective treatment in open heart surgery.
- At the end of August, the first patient in the POINTER study was dosed. Dosing took place at the Heart and Lung Institute in Québec, Canada.
- The results of the completed Phase 2 study, AKITA, were published in the reputable scientific journal eClinicalMedicine (Lancet Discovery Science).
- During September, in accordance with the decision of an extraordinary general meeting on July 3, a rights issue was carried out to compensate the shareholders who did not participate in the directed issue. The so-called compensation issue was subscribed at approximately 8.9 percent and brings the company approximately 7.2 MSEK before issue costs.

SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- On 2 October, the rights issue (compensation issue) was registered with the Swedish Companies Registration Office and the company was infused with approximately SEK 7.2 million.
- Guard Therapeutics announced in mid-October that the first patient in Europe had been dosed in the POINTER study.

COMMENTS ON SIGNIFICANT EVENTS

The POINTER study was initiated as planned during the third quarter following previous approvals by relevant regulatory authorities and ethics committees in both North America and Europe. The start of the study is a great success for the company and the result of intensive preparatory work that began already after the positive outcome of the AKITA study.

We now look forward to activating the remaining participating clinics and expanding the patient recruitment base to achieve our ambitious goals regarding study execution.



Chief executive's review

During the third quarter, we reached the symbolically important milestone of enrolling the first patient in Canada in the phase 2b POINTER study, evaluating our clinical drug candidate RMC-035 as a kidney-protective treatment in open-heart surgery. Following the end of the reporting period, we were also able to announce the start of the study in Europe.

The dosing of the first patient in the POINTER study occurred in late August, in Canada, at the Heart and Lung Institute of Québec, one of many high-quality clinical sites participating in the POINTER study. The study has since also started at a number of hospitals in Europe.

A total of 19 clinical sites across Canada, Germany, the Czech Republic, and Spain will participate in the study. Patient recruitment is expected to take approximately one year, with overall study results anticipated around six months thereafter.

The POINTER study is a randomized, double-blind, placebo-controlled phase 2b study of RMC-035, with the primary purpose to establish an optimal dosing regimen and precise target population prior to a subsequent pivotal phase 3 study. The study is expected to include approximately 160 patients divided into two different dose arms of RMC-035 as well as a control arm (placebo). The primary endpoint is change in kidney function (estimated glomerular filtration rate, eGFR) from the start of the study to the end of the follow-up period at 90 days after surgery.

During the study, an independent Data Safety Monitoring Committee (DSMC) will review safety data on two occasions, after one-third and two-thirds of the planned number of patients, respectively. Although this data review will remain blinded to the company, we plan to communicate the DSMC's overall conclusions and recommendations regarding the continuation of the study. The first data review outcome is expected to be available in the first quarter of 2025.

We discern a great interest in our research and development efforts, both from the scientific community and other stakeholders. In September, the prestigious scientific journal *eClinicalMedicine*, part of *Lancet Discovery Science*, published an article describing the main findings from our previously completed phase 2a clinical study, AKITA.

This publication underscores the importance of the AKITA trial, particularly the treatment effect observed in relation to the predefined and clinically relevant endpoints of renal function (eGFR) and major adverse kidney events (MAKE). The MAKE outcome is especially noteworthy, as it is the primary efficacy measure expected to support a future market approval for RMC-035.

As reported in June, after the end of the second quarter, we carried out a directed share issue of approximately 60 million SEK to several of our major shareholders to support the planned start of the POINTER study. The strong backing from our main shareholders underscores their confidence in the company as we progress to the next phase of development. To compensate shareholders who did not participate in the directed issue, we subsequently conducted a non-guaranteed rights issue (compensation issue), giving all existing shareholders the opportunity to maintain

their ownership on the same terms as in the directed issue. The outcome of the compensation issue was announced at the end of September.

In recent years, Guard Therapeutics has established itself as a key player in the development of drugs targeting acute kidney injury, with a unique depth of technical, scientific, and operational expertise. Our drug candidate, RMC-035, is the only treatment with evidence for clinically relevant protection against kidney injury associated with open-heart cardiac surgery, as measured by endpoints acceptable for regulatory approval.

Our primary focus is now on conducting the POINTER study according to plan and in alignment with our high standards. We are off to a strong start with recent significant milestones and are experiencing strong enthusiasm from study staff and participating clinics to drive the study to completion. Our ultimate goal is to offer a new and unique treatment with substantial patient benefits in an area where currently no treatment options exist. By extension, RMC-035 also has the potential to reduce healthcare costs given the extensive resources required to manage acute and chronic kidney disease.

We now look forward to the next milestone in the study, including the outcome of the first safety review conducted by the DSMC.



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 class of drugs (first-in-class), 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 several preclinical disease models.

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 coun-

teracts the injury mechanisms triggered during the procedure, making kidney protection in conjunction with heart surgery a priority in 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, which were communicated in the autumn of 2023, demonstrated a clinically relevant and statistically significant improvement in key endpoints linked to renal function at 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

RMC-035 treatment for patients undergoing kidney transplantation aims to improve the long-term function of the transplanted kidney (graft), thereby reducing the risk of future dialysis or repeat transplantation. 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 and clinical efficacy of RMC-035 in open-heart surgery, there is significant opportunity to expand its use to sepsis. Emerging clinical data from the heart surgery program further support the rapid advancement 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) known as GTX peptides. These peptides share the core function of RMC-035 (alpha-1-microglobulin) but are specifically designed to enable chronic treatment in new disease areas. Unlike RMC-035, GTX peptides can be administered via subcutaneous injection. GTX peptides have shown robust efficacy in many different models of kidney disease. Several development opportunities have been identified for GTX peptides, both in late-stage CKD, with the aim of eliminating the need for or delaying the time to dialysis or kidney transplantation, as well as slowing the progressive loss of kidney function in a number of rare kidney diseases, for example 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 ongoing pre-clinical programs, with the goal of maximizing value for both patients and shareholders.

MEDICAL NEED

Currently, no approved therapies exist to prevent or treat acute kidney injuries associated with, for example, open-heart surgery, kidney transplantation or sepsis.

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%, 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 critical to 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 development. Kidney damage 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 and reimbursement 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, supporting unrestricted use of RMC-035, 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 comprehensive clinical study results, dialogue with regulatory authorities, and more detailed market analyses.

Kidney Transplantation

Guard Therapeutics has not conducted an independent analysis of market potential for RMC-035 in kidney transplantation, but current evidence from heart surgery provides a solid reference point. The market potential 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, approximately 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)

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

The results of the AKITA study demonstrated a clinically relevant and statistically significant beneficial effect of RMC-035 on renal function at 90 days after surgery, measured by both the change in renal function (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 repeated in such a study, this can thus form the basis for market approval.



POINTER

POINTER (Phase 2b)

Based on the promising efficacy results in the AKITA study, a subsequent Phase 2b study, POINTER, 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 is a randomized, double-blind and placebo-controlled Phase 2b 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/1.73m². 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 so-called 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. Major adverse kidney events (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 approximately 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 (30mg or 60mg)	Efficacy, safety	Europe, North America	Ongoing

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

CLINICAL STUDIES 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 evaluate the safety and pharmacokinetic properties of RMC-035 at repeated dosing in conjunction with kidney transplantation. The results enable the next step in 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

The company had net sales of KSEK 0 (0) in the second quarter and in the first 6 months of the year.

Operating loss

The operating result for the third quarter amounted to KSEK -31,781 (-24,447) and for the entire period January-September 2024 to KSEK -72,817 (-99,743).

Research and development expenditure accounted for the majority of the company's expenses, which totaled at KSEK -29,718 (-22,603) for the quarter and -66,001 (-92,744) KSEK for the first 9 months of the year. The increased costs in the third quarter are mainly related to the start of the phase 2b POINTER study.

The marketing costs for the company in the third quarter amounted to KSEK -1,007 (-827) and for the period January-September to KSEK -2,819 (-2,653). The administrative costs amounted to KSEK -1,601 (-1,108) for the third quarter and to KSEK -4,515 (-3,962) 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 519 (-383) by September this year.

Net financial items

Net financial items, which until September this year amounted to KSEK 2,709 (3,516), mainly consists of unrealized exchange rate differences on the company's foreign currency accounts, KSEK 1,624, as well as interest income from fixed interest accounts and foreign currency accounts, KSEK 1,093.

FINANCIAL POSITION

On September 30, 2024, the company had an equity ratio of 84 percent, vs 79 percent last year. Equity amounted to KSEK 63,287 at the end of September, compared to KSEK 83,132 at the same time last year.

The company's cash and cash equivalents comprising cash and bank balances, including liquid investments amounted to KSEK 66,775 (103,195). During the quarter, the company was supplied with liquid funds of approximately SEK 13 million after the Inspectorate for Strategic Products ("ISP") approved the last part of Industrifonden's investment in the directed share issue in June. However, the proceeds from the rights issue that was carried out in September, SEK 7.2 million, was not settled until October 2, 2024 and remains a receivable in the third quarter

At the end of the period, the balance-sheet total amounted to KSEK 75,561 (104,781).

CASH FLOW AND INVESTMENTS

Guard Therapeutics had a cash flow of KSEK -24,553 (-25,496) in the third quarter of 2024. For the period January-September, the cash flow was KSEK -18,590 (-99,498).

Cash flow from operating activities during the third

quarter amounted to KSEK -36,530 (-25,851) and -74,234 (-98,716) for the first 9 months of the year.

The cash flow from financing activities during the same periods amounted to KSEK 11,977 (355) and KSEK 55,644 (-782), respectively.

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 September 30, 2024, after the registration of the directed issue, but before the rights issue the number of shares in the company amounted to 12,055,988. 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 12,055,988.00 on September 30th, 2024.

- **Symbol: GUARD**
- **ISIN: SE0021181559**
- **No of shares: 12,055,988**
- **Quota value: SEK 1.00**
- **Trading unit: 1 share**
- **Share capital: SEK 12,055,988.00**

OWNERSHIP STRUCTURE ON SEPTEMBER 30, 2024*

Shareholder September 30th 2024	Number of shares	Share of votes	Share of capital
STÅHLBERG, JAN	2,314,090	19.19%	19.19%
STIFTELSEN INDUSTRIFONDEN	1,598,227	13.26%	13.26%
SWEDBANK ROBUR HEALTHCARE	1,158,688	9.61%	9.61%
M2 ASSET MANAGEMENT AB	1,110,818	9.21%	9.21%
AVANZA PENSION	664,766	5.51%	5.51%
STRAND SMÅBOLAGSFOND	422,690	3.51%	3.51%
NORDNET PENSIONSFORSÄKRING AB	297,426	2.47%	2.47%
RÄFSAB AB	276,552	2.29%	2.29%
ALLA MOLLER AB	117,488	0.97%	0.97%
DAHLQVIST, JAN	88,301	0.73%	0.73%
OTHER	4,006,942	33.24%	33.24%
TOTAL	12,055,988	100%	100%

*the rights issue, the outcome of which was reported on September 24, was registered with the Swedish Companies Registration Office on October 2 and is therefore not included in the total number of shares or the number of shares per shareholder in the table above

Income statement

(KSEK)	JULY-SEPTEMBER		JANUARY-SEPTEMBER		FULL-YEAR
	Jul 1, 2024 Sep 30, 2024	Jul 1, 2023 Sep 30, 2023	Jan 1, 2024 Sep 30, 2024	Jan 1, 2023 Sep 30, 2023	Jan 1, 2023 Dec 31, 2023
Net sales	-	-	-	-	-
Cost of goods sold	-	-	-	-	-
Gross profit	0	0	0	0	0
Research and development expenditure	-29,718	-22,603	-66,001	-92,744	-105,773
Marketing and sales costs	-1,007	-827	-2,819	-2,653	-3,766
Administrative expenses	-1,601	-1,108	-4,515	-3,962	-5,383
Other operating income	546	0	519	0	0
Other operating expenses	0	90	0	-383	-151
Operating loss	-31,781	-24,447	-72,817	-99,743	-115,073
Financial income	54	1,105	2,717	3,521	2,197
Financial expense	0	0	-8	-5	-447
Net financial items	54	1,105	2,709	3,516	1,750
Pre-tax loss	-31,727	-23,342	-70,108	-96,227	-113,323
Tax on profit for the period	-	-	-	-	-
LOSS FOR THE PERIOD	-31,727	-23,342	-70,108	-96,227	-113,323

Balance sheet

(KSEK)	Sep 30, 2024	Sep 30, 2023	Dec 31, 2023
ASSETS			
<i>Non-current assets</i>			
Property, plant and equipment	0	4	0
Total non-current assets	0	4	0
<i>Current assets</i>			
Other receivables	574	536	667
Receivables subscribed unpaid capital (Note 6)	7,186	0	0
Prepaid expenses and accrued income	1,027	1,046	819
Current receivables	8,787	1,582	1,486
Cash and cash equivalents (Note 6)	66,775	103,195	83,741
Cash and bank balances	66,775	103,195	83,741
Total current assets	75,561	104,777	85,227
TOTAL ASSETS	75,561	104,781	85,227
EQUITY AND LIABILITIES			
<i>Equity</i>			
Share capital	12,056	10,062	10,062
Share capital, not registered	239	0	0
Non-restricted share premium reserve	797,140	732,014	732,711
Retained earnings	-676,040	-562,716	-562,716
Loss for the period	-70,108	-96,227	-113,323
Total equity	63,287	83,132	66,733
<i>Non-current liabilities</i>			
Provision for social security contributions – incentive scheme (Note 7)	211	355	469
Non-current trade payables	0	1,413	1,413
Total non-current liabilities	211	1,768	1,882
<i>Current liabilities</i>			
Trade payables	6,693	8,850	5,494
Tax liabilities	116	266	268
Other payables	283	306	293
Accrued expenses and deferred income	4,971	10,459	10,557
Total current liabilities	12,064	19,881	16,613
Total liabilities (Note 8)	12,274	21,649	18,494
TOTAL EQUITY AND LIABILITIES	75,561	104,781	85,227

Statement of cash flows

(KSEK)	JULY-SEPTEMBER		JANUARY-SEPTEMBER		FULL-YEAR
	Jul 1, 2024	Jul 1, 2023	Jan 1, 2024	Jan 1, 2023	Jan 1, 2023
	Sep 30, 2024	Sep 30, 2023	Sep 30, 2024	Sep 30, 2023	Dec 31, 2023
<i>Operating activities</i>					
Operating loss	-31,781	-24,447	-72,817	-99,743	-115,073
Adjustments for non-cash items	632	813	2,206	2,010	2,835
Interest received	347	667	913	1,837	2,005
Interest paid	0	0	-8	-5	-5
Cash flows from operating activities before changes in working capital	-30,801	-22,967	-69,706	-95,901	-110,237
<i>Change in working capital</i>					
Increase/decrease in receivables	-184	385	65	0	288
Increase/decrease in current liabilities	-5,544	-3,268	-4,593	-2,815	-6,096
Change in working capital	-5,729	-2,884	-4,528	-2,815	-5,808
Cash flows from operating activities	-36,530	-25,851	-74,234	-98,716	-116,046
<i>Investing activities</i>					
Acquisition of property, plant and equipment	-	-	-	-	-
Acquisition of intangible assets	-	-	-	-	-
Acquisition of non-current financial assets	-	-	-	-	-
Cash flows from investing activities	0	0	0	0	0
<i>Financing activities</i>					
New share issue incl overhead costs*	12,247	0	57,314	0	-111
Increase/decrease in non-current liabilities	-271	355	-1,671	-782	-668
Cash flows from financing activities	11,977	355	55,644	-782	-779
Change in cash and cash equivalents	-24,553	-25,496	-18,590	-99,498	-116,825
Cash and cash equivalents at beginning of period	91,587	128,253	83,741	201,008	201,008
<i>Effects of exchange rate changes on cash and cash equivalents</i>	-259	438	1,624	1,685	-443
CASH AND CASH EQUIVALENTS AT END OF PERIOD	66,775	103,195	66,775	103,195	83,741

*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
Opening balance (OB) January 1, 2023	10,062	0	730,015	-449,887	-112,839	177,360
Transfer OB	-	-	-	-112,839	112,839	0
Employee stock options (<i>not</i> 7)	-	-	2,808	-	-	2,808
Reverse split equation issue	0	-	-	-	-	0
Reverse split costs	-	-	-111	-	-	-111
Loss for the period	-	-	-	-	-113,323	-113,323
EQUITY DECEMBER 31, 2023	10,062	0	732,711	-562,716	-113,323	66,733
Opening balance (OB) January 1, 2024	10,062	0	732,711	-562,716	-113,323	66,733
Transfer OB	-	-	-	-113,323	113,323	0
Employee stock options (<i>not</i> 7)	-	-	2,162	-	-	2,162
Directed issue	1,994	-	57,996	-	-	59,991
Rights issue	0	239	6,947	-	-	7,186
Share issue costs	-	-	-2,677	-	-	-2,677
Loss for the period	-	-	-	-	-70,108	-70,108
EQUITY SEPTEMBER 30, 2024	12,056	239	797,140	-676,040	-70,108	63,287

*As of June 30th, 2024, the company had no restricted share premium reserve.

** The Rights issue carried out in September 2024 was registered with the Swedish Companies Registration Office after the end of the period, on 2 October 2024.

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' interim report for the period January–September 2024 has been approved for publication by decision of the Board of Directors on November 12, 2024.

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 interim 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 interim 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 September 30, 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

In December 2023, the company had 10,061,615 (503,080,745) shares registered after consolidation of shares (so-called reverse split). During June–July 2024, a new issue was carried out and as of September 30, 2024, the company had 12,055,988 (503,080,745) shares registered. The rights issue carried out during September was registered with the Swedish Companies Registration Office after the end of the period, on 2 October.

Weighted average number of shares for the period January–September 2024 amounted to 10,766,576 (10,061,615) before and after dilution. Weighted av-

average number of shares for the third quarter 2024 amounted to 11,975,073 (10,061,615) before and after dilution. For comparison purposes the average number of shares for previous periods are recalculated with the consolidation ratio of 1:50.

Earnings per share at the end of September amounted to SEK -6.51 (-9.56), based on the earnings for January-September divided by the average number of shares before full dilution. The corresponding result for the third quarter amounted to SEK -2.65 (-2.32).

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. The proceeds from the rights issue in September 2024 was settled in October in connection with registration with the Swedish Companies Registration Office and is therefore a receivable on the balance sheet date of September 30, 2024.

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 September 30, 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.

So far in 2024, the two employee option programs together had an impact on earnings of KSEK -1,903 (-2,347).

Full exercise of granted options minus the options that have been revoked as of September 30th, 2024, i.e. a total of 29,700,001 options, would result in a dilution of shareholders by 4.7 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
Ingoing value, 1 januari 2024	9,750,001	19,950 000
Granted options	-	-
Exercised options	-	-
Revoked options	-	-
Total change	0	0
Outstanding options at the end of the period, Sept 30, 2024	9,750,001	19,950,000

*Each option entitles to 0.02 shares.

NOTE 8

Contingent liabilities

The Company had no pledged collateral or other contingent liabilities as of September 30, 2024, nor as of September 30, 2023.

Submission of interim report

This interim 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 November 13, 2024.

Guard Therapeutics International AB
Nybrogatan 34
SE-114 39 Stockholm, Sweden
Switchboard: +46 8 670 65 51
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

FINANCIAL CALENDAR

Year-end report 2024: February 20, 2025