# INTERIM REPORT JANUARY - JUNE 2024



# Second quarter 2024 in short

The first regulatory approval to start the phase 2b study POINTER is obtained in Canada. A directed share issue of approximately SEK 60 million is carried out to the company's major shareholders.

### SUMMARY OF INTERIM REPORT

Second quarter, April-June 2024

Net sales: KSEK 0 (0)

Loss for the period: KSEK -23,874 (-32,965) Earnings per share\*: SEK -2.33 (-3.28)

Equity/asset ratio\*\*: 81% (81)

Cash and cash equivalent: KSEK 91.587 (128.253)

### January-June 2024

Net sales: KSEK 0 (0)

Loss for the period: KSEK -38,381 (-72,885) Earnings per share\*: SEK -3.78 (-7.24)

### **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.

### **AUDITORS REVIEW**

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

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

<sup>\*\*</sup>Equity/asset ratio: Equity divided by total assets per June 30th, 2024.

# Significant events

# SIGNIFICANT EVENTS IN THE SECOND QUARTER

- At the annual general meeting in May, in accordance with the nomination committee's proposal, two new members were elected to the Board of Directors: Khatereh Ahmadi, head of Search and Evaluation Business Development Europe & Middle East at MSD and Hege Hellström, Chief Commercial Officer at Advicenne and board member at Camurus, Vivesto and InflaRx.
- In early April, Health Canada approved the company's application to include patients in the planned clinical phase 2b study, POINTER.
- The scientific journal American Journal of Physiology Renal Physiology published an article at the end of May summarizing important preclinical results of the company's investigational drug RMC-035.
- In June, the Board of Directors decided, with the support of the authorization received at the annual general meeting on May 8, to carry out a directed share issue of approximately SEK 60 million to the existing shareholders Jan Ståhlberg, Stiftelsen Industrifonden, Swedbank Robur Fonder and Strand Kapitalförvaltning. The board also proposed to carry out a non-guaranteed rights issue (repair issue) during the third quarter of 2024 to give all shareholders the opportunity to defend their holdings on the same terms as in the directed issue.

### **COMMENTS ON SIGNIFICANT EVENTS**

During the second quarter, preparations continued for the planned phase 2b study, POINTER. The first regulatory approval from Health Canada to include patients in the study was an important milestone, and after the end of the quarter, all approvals were obtained to also start the study in Europe. Patient recruitment is expected to begin shortly.

We are welcoming two new members to the company's Board of Directors, Khatereh Ahmadi and Hege Hellström. Both members bring new and valuable expertise in business development and commercialization of pharmaceuticals, which further strengthens us as the company now enters a later phase of development of RMC-035 as a novel kidney-protective drug.

We are also pleased that during the period we were able to secure additional capital of approximately SEK 60 million via a directed issue to the company's major shareholders, which testifies to their continued faith in and support for the company on our continued journey.

# SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- On July 3, an extraordinary general meeting was held which, among other things, authorized the Board of Directors to carry out the repair issue. The company also communicated preliminary timelines regarding the execution of the issue.
- At the beginning of July, the remainder of Industrifonden's allocation, SEK 13 million, in the directed issue could be completed after the investment was approved by the Inspectorate for Strategic Products ("ISP").
- Through the central European application process, the company obtained approvals from regulatory authorities and ethics committees in Spain, Germany and the Czech Republic to include patients in the clinical phase 2b POINTER study.



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### Chief executive's review

Following favorable feedback from the U.S. Food and Drug Administration (FDA) on the continued development plan and design of the phase 2b POINTER study for the drug candidate RMC-035 at the beginning of the year, the positive momentum continued into the second quarter. We obtained the first regulatory approval of the phase 2b study POINTER already in April, followed by further gratifying news in August, when the study was approved by the relevant authorities in the EU. During the period, we also secured financing via a directed share issue of SEK 60 million to initiate further development work with RMC-035.

In April, the Canadian drug agency Health Canada was the first authority to approve our application to include patients in the POINTER trial of RMC-035 as a kidney-protective treatment in open-heart surgery. This is an important milestone in our continued

clinical development program. After the end of the period, the study was also approved by the relevant regulatory authorities and ethics committees in the EU, which means that all approvals required to start the study are now in place in the countries where the

study is planned to be carried out, i.e. Canada, Spain, Germany and the Czech Republic

The POINTER study is a randomised, double-blind and placebo-controlled phase 2b study, with the main purpose of establishing an optimal dosing regimen and precise target group for treatment in a subsequent pivotal phase 3 study. The study is expected to include approximately 160 patients divided into two different dose arms of RMC-035 (60 mg and 30 mg) and a control arm (placebo). The study's primary endpoint is change in renal function (eGFR) from the start of the study to 90 days after surgery. Patient recruitment is expected to last approximately one year, and overall study results are expected to be available around six months later.

To facilitate the planned start of the POINTER study, the board approved a directed share issue of approximately SEK 60 million on June 17, supported by the authorization granted at the annual general meeting on May 8. We and our main shareholders are grateful to carry out this cost-effective capital acquisition, which increases the company's financial flexibility and enables the start of the POINTER study according to plan. The increased ownership by several of our main shareholders signals strong support as the company enters the next phase of development

As compensation for the shareholders who did not participate in the directed share issue, an extraordinary general meeting on July 3 decided on a nonguaranteed rights issue (repair issue) during the third quarter of 2024, where all existing shareholders will have the opportunity to defend their shares on the same terms as in the directed issue.

Our research and development continues to garner great scientific interest. In May the well-respected American Journal of Physiology – Renal Physiology published an article summarizing important preclinical results showing consistently positive effects of RMC-035 in a large number of kidney injury models. The results provide the basis for the clinical development of RMC-035 as a kidney-protective treatment in open heart surgery. The article has also been selected for APSselect, a collection of the American Physiological Society, which showcases some of the best recently published articles in physiological research.

We also continue to strengthen our organization and Board of Directors as the company now enters a later stage of development. At the annual general meeting, Khatereh Ahmadi and Hege Hellström were elected as non-executive directors of the board. Dr. Ahmadi has over 20 years of experience in the pharmaceutical industry and is currently Head of Search and Evaluation Business Development Europe & Middle East at MSD. She has held CEO and BD roles in biotechnology companies, including ReViral, which was acquired by Pfizer in 2022. Hege Hellström, currently Chief Commercial Officer at Advicenne, has over 30 years of experience in sales, marketing, strategic development and business management within several major pharmaceutical companies such as Genzyme and Sanofi, with particular experience in kidney medicine.

Overall, I am optimistic about the future for Guard Therapeutics, with clear progress in our research and development projects, positive and constructive dialogue with regulatory authorities, and continued strong support from our larger owners. The clinical program with RMC-035 remains our primary focus, and we expect inclusion of the first patient in the phase 2b POINTER study shortly. Recent important milestones strengthen our belief in RMC-035 as a new unique treatment for kidney damage in cardiac surgery.

Chief Executive Officer



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 with focus on acute kidney injury - a medically prioritized area with the potential to save lives and prevent the onset and progression of chronic kidney disease to end-stage renal disease (renal failure), which requires life-sustaining dialysis treatment and/or kidney transplantation.

The company's clinical drug candidate RMC-035 represents a completely new class of drugs (first-inclass), being a recombinant and modified variant of the endogenous protein alpha-1-microglobulin. It has the ability to protect 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 being developed as a kidney-protective treatment for patients at high risk of developing acute kidney injury. It is intended as a short-term treatment and delivered by intravenous infusion in the hospital-setting (specialty care).

Guard Therapeutics initially targets two separate indications for RMC-035 development: open-heart surgery and kidney transplantation. Both indications

represent a large unmet need without any approved therapies to reduce kidney injuries that occur because of these surgical procedures. In heart surgery, many patients are at risk of losing a significant part of their kidney function, and in patients undergoing kidney transplantation the transplanted kidney (graft) may not reach the expected and optimal function.

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 openheart surgery and who are at increased risk of acute kidney injury.

RMC-035 has been evaluated in an extensive phase 1 program and a larger global phase 2 study (AKITA), with the principal results communicated in the autumn of 2023. These showed a clinically relevant and statistically significant improvement in key endpoints linked to renal function at 90 days after open-heart surgery with RMC-035 treatment compared to placebo. Based on these results, the project recently entered late phase development with a phase 2b dose-optimization study (POINTER), and in case of positive results, a subsequent pivotal phase 3 study will follow. In kidney transplantation, a phase 1b study was completed to evaluate the safety and pharmacokinetics of RMC-035 specifically in conjunction with kid-

ney transplantation. Once the optimal dose has been determined in heart surgery the company will assess the next steps for development in other indications, including kidney transplantation.

Guard Therapeutics also has a preclinical development platform (the GTX platform) of novel proprietary peptides (i.e., shorter protein fragments) based on RMC-035, and the endogenous protein alpha-1-microglobulin, with the goal of expanding the company's pipeline and broadening the therapeutic use of alpha-1-microglobulin to additional disease areas requiring chronic treatment.

### **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 preclinical programs, with the goal of maximizing value for both patients and shareholders.

### **MEDICAL NEED**

Currently, no approved therapies exist to prevent or treat kidney injuries related to heart surgery and kidney transplantation, or to address the serious consequences of these injuries.

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 chronic kidney disease, which can increase the likelihood of requiring dialysis or a kidney transplant in the future. Moreover, it is estimated that approximately 30,000

patients in the United States undergo open-heart surgery each year with pre-existing chronic kidney disease. These patients are at particularly high risk of further kidney injury during surgery, which can lead to the acceleration and progression of chronic kidney disease.

In addition to the risk of requiring dialysis or a kidney transplant in the future, chronic kidney disease also contributes to other negative health outcomes, such as cardiovascular disease, reduced quality of life, and increased mortality.

In cases of end-stage renal disease (i.e. renal failure), life-sustaining chronic dialysis and/or kidney transplantation becomes necessary. Unfortunately, the prognosis for patients undergoing dialysis is poor, with an annual mortality rate of 15-20% - worse than many forms of metastatic cancer. The healthcare costs associated with this condition are also significant, often accounting for 2-3% of the total national healthcare budget, despite the patient group representing only 0.02-0.03% of the population. Therefore, protecting the kidneys from injury is essential to prevent the progression of chronic kidney disease and the development of end-stage renal disease.

Kidney transplantation is often the preferred treatment modality for end-stage renal disease. However, since most transplants use kidneys from deceased donors, the organ typically suffers acute injury during the time between procurement and transplantation, and in the recipient immediately after the procedure. This injury results in poorer kidney function, both short-term and long-term, and increases the risk of needing another transplant in the future.



### **MARKET OVERVIEW**

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

### **Open-heart Surgery**

Based on an external analysis of future pricing for RMC-035 in the U.S. and reliable data on the number of patients undergoing open-heart surgery each year in major markets such as the U.S., EU, and Japan, the global market potential can be estimated with reasonable accuracy.

Approximately half a million patients undergo openheart 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.

The external analysis suggests an expected price per patient of \$5,000–\$7,500 for open-heart surgery in the U.S., assuming broad usage without restrictions. This translates to an annual market potential of \$500–750 million in the U.S. alone. Assuming a price point of half that in the EU, the market potential there is estimated at \$250–400 million. Consequently, the global market potential exceeds \$1 billion annually, especially when factoring in other major markets such as Japan and China.

The analysis also supports a higher price point in the U.S. (up to \$20,000–30,000 per patient) for more restricted use of RMC-035 in specific high-need patient groups, such as those with chronic kidney disease. 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 expected pricing of RMC-035 for 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 shortand 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 \$350 million in the U.S. and Europe.

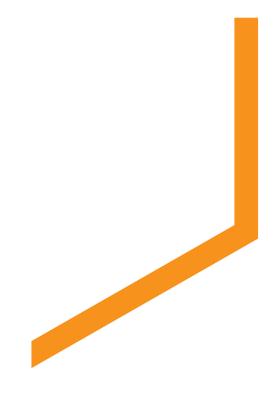
### Referenses:

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

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

Valerie A. Luycks et al Reducing the burden of kidney disease. Bull World Health Organ 2018;96.

USRDS Annual Data Report 2022, chpt 9.



### 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 openheart surgery.

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 openheart surgery.

The results from the AKITA study demonstrated a clinically relevant and statistically significant beneficial effect of RMC-035 on renal function at 90 days post-surgery compared to placebo. This was 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), which include death, dialysis treatment, and/or at least a 25% loss of kidney function.

The study results provide strong support for advancing the clinical development program, with the next step being a phase 2b study aimed at identifying the optimal dosage of RMC-035 and the preferred target patient population. This phase 2b study, named POINTER, is expected to inform the most efficient design of a pivotal phase 3 study. Key design elements

and the study protocol have been reviewed and approved by the U.S. FDA.

The primary endpoint of the study is the change in eGFR from study start to 90 days post-surgery, aligning with the planned follow-up period. The study is expected to enroll approximately 160 patients, divided into two different dose arms of RMC-035 and a placebo group. Patient recruitment is expected to begin shortly.



#### **Fast Track**

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 openheart 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 US and is given to pharmaceutical projects to ensure that new treatments can be made available more quickly to patients with serious diseases where there is a high medical need.

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	Initiation phase

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

### CLINICAL STUDIES IN KIDNEY TRANSPLANTATION

Based on promising preclinical and clinical study results, the company has decided to extend the clinical development program for RMC-035 to include kidney transplantation. In this context, RMC-035 will be administered to recipients of kidneys from deceased donors to mitigate transplant-related kidney (graft) injury and ultimately enhance both kidney graft function and survival.

A phase 1b clinical study has been conducted for this indication, with the primary objective of evaluating the pharmacokinetic properties of RMC-035 in conjunction with kidney transplantation. Once the optimal dosage for heart surgery patients has been established, there is potential to effectively advance RMC-035 development also for kidney transplantation.

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





### **REVENUE AND EARNINGS**

#### Revenue

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

### **Operating loss**

The operating result for the second quarter amounted to KSEK -23,689 (-34,678) and for the entire period January-June 2024 to KSEK -41,036 (-75,296).

Research and development expenditure accounted for the majority of the company's expenses, which totaled at KSEK -21,383 (-31,954) for the quarter and -36,283 (-70,141) KSEK for the first 6 months of the year. The higher costs last year compared to the same period this year are due to an, at that time, intense recruitment phase in the AKITA study. The costs this year are mainly linked to preparations for the start of the phase 2b POINTER study.

The marketing and sales costs for the company in the second quarter amounted to KSEK -908 (-978) and for the period January-June to KSEK -1,812 (-1,827). The administrative costs amounted to KSEK -1,444 (-1,353) for the second quarter and to KSEK -2,914 (-2,855) for the entire period.

Other operating income and operating expenses mainly comprised exchange differences on trade payables and amounted to KSEK -27 (-475) by June this year.

### **Net financial items**

Net financial items, which until March this year amounted to KSEK 2,655 (2,412), mainly consists of unrealized exchange rate differences on the company's currency accounts, KSEK 1,882, as well as interest income from fixed interest accounts and currency accounts, KSEK 780.

### **FINANCIAL POSITION**

On June 30, 2024, the company had an equity ratio of 81 percent, which is in line with what we had in 2023. Equity amounted to KSEK 74,943 at the end of June, compared to KSEK 105,665 at the same time last year.

The company's cash and cash equivalents comprising cash and bank balances, including liquid investments amounted to KSEK 91,587 (128,253). Liquidity has increased since the previous quarter following the completion of a directed share issue in June this year. The issue, which provided the company with a total of KSEK 58,107 after issue costs, is planned to be used for the implementation of the POINTER study. As the remainder of Industrifonden's allocation in the directed issue can only be completed after the investment has been approved by the Inspectorate for Strategic Products ("ISP"), which took place in July, KSEK 13,040 of the proceeds is accounted for after the end of the period.

At the end of the period, the balance-sheet total amounted to KSEK 93,038 (130,228).

### **CASH FLOW AND INVESTMENTS**

Due to the share issue, the company had a positive cash flow for the second quarter of 2024, amounting to KSEK 27,042 (-38,304). For the half year the posted cash flow was KSEK 5,963 (-74,002). Cash flow from operating activities during the second quarter amounted to -18,326 (-38,217) KSEK and -37,704 (-72,865) for the first 6 months of the year.

The cash flow from financing activities during the same period amounted to KSEK 45,368 (-87) and KSEK 43,667 (-1,137), 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 Kapitalmarknads-granskning AB, ca@skmg.se.

On June 30, 2024, after the registration of the new issue, the number of shares in the company amounted to 11,618,095. 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 11,618,095.00 on June 30th, 2024.

Symbol: GUARD

ISIN: SE0021181559

No of shares: 11,618,095

Quota value: SEK 1.00

Trading unit: 1 share

Share capital: SEK 11,618,095.00

### **OWNERSHIP STRUCTURE ON JUNE 30, 2024**

Shareholder			
June 30th 2024	Number of shares	Share of votes	Share of capital
STÅHLBERG, JAN	2,314,090	19.92%	19.92%
M2 ASSET MANAGEMENT AB	1,160,334	9.99%	9.99%
STIFTELSEN INDUSTRIFONDEN	1,158,688	9.97%	9.97%
SWEDBANK ROBUR HEALTHCARE	1,110,818	9.56%	9.56%
FÖRSÄKRINGSAKTIEBOLAGET, AVANZA PENSION	653,443	5.62%	5.62%
STRAND SMÅBOLAGSFOND	422,690	3.64%	3.64%
KARLSSON, AXEL	276,552	2.38%	2.38%
NORDNET PENSIONSFÖRSÄKRING AB	256,286	2.21%	2.21%
ALLA MÖLLER AB	117,488	1.01%	1.01%
DAHLQVIST, JAN	88,301	0.76%	0.76%
ÖVRIGA	4,059,405	34.94%	34.94%
TOTAL	11,618,095	100%	100%

# Income statement

(KSEK)	QUA	RTER	HALF-YEAR		FULL-YEAR
	Apr 1, 2024 Jun 30, 2024	Apr 1, 2023 Jun 30, 2023	Jan 1, 2024 Jun 30, 2024	Jan 1, 2023 Jun 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	-21,383	-31,954	-36,283	-70,141	-105,773
Marketing and sales costs	-908	-978	-1,812	-1,827	-3,766
Administrative expenses	-1,444	-1,353	-2,914	-2,855	-5,383
Other operating income	0	0	0	0	0
Other operating expenses	46	-393	-27	-475	-151
Operating loss	-23,689	-34,678	-41,036	-75,296	-115,073
Financial income	-177	1,716	2,663	2,416	2,197
Financial expense	-8	-3	-8	-5	-447
Net financial items	-185	1,713	2,655	2,412	1,750
Pre-tax loss	-23,874	-32,965	-38,381	-72,885	-113,323
Tax on profit for the period	-	-	-	-	-
LOSS FOR THE PERIOD	-23,874	-32,965	-38,381	-72,885	-113,323

# Balance sheet

(KSEK)	Jun 30, 2024	Jun 30, 2023	Dec 31, 2023
ASSETS			
Non-current assets			
Property, plant and equipment	0	7	0
Total non-current assets	0	7	0
Current assets			
Other receivables	494	765	667
Prepaid expenses and accrued income	956	1,202	819
Current receivables	1451	19 67	1,486
Cash and cash equivalents (Note 6)	91,586	128,253	83,741
Cash and bank balances	91,586	128,253	83,741
Total current assets	93,038	130,220	85,227
TOTAL ASSETS	93,038	130,228	85,227
EQUITY AND LIABILITIES			
Equity			
Share capital	11,618	10,062	10,062
Non-restricted share premium reserve	777,746	731,204	732,711
Retained earnings	-676,040	-562,716	-562,716
Loss for the period	-38,381	-72,885	-113,323
Total equity	74,943	105,665	66,733
Non-current liabilities			
Provision for social security contributions – incentive	482	1	469
scheme ( <i>Note 7</i> ) Non-current trade payables	0	1,413	1,413
Total non-current liabilities	482	1,413	1,882
		,,,,,	.,
Current liabilities			
Trade payables	5,301	9,698	5,494
Tax liabilities	154	332	268
Other payables	275	288	293
Accrued expenses and deferred income	11,883	12,831	10,557
Total current liabilities	17,613	23,149	16,613
Total liabilities (Note 8)	18,095	24,562	18,494
TOTAL EQUITY AND LIABILITIES	93,038	130,228	85,227

# Statement of cash flows

(KSEK)	QUA	RTER	HALF	-YEAR	FULL-YEAR
	Apr 1, 2024	Apr 1, 2023	Jan 1, 2024	Jan 1, 2023	Jan 1, 2023
	Jun 30, 2024	Jun 30, 2023	Jun 30, 2024	Jun 30, 2023	Dec 31, 2023
Operating activities					
Operating loss	-23,689	-34,678	-41,036	-75,296	-115,073
Adjustments for non-cash items	640	813	1,573	1,197	2,835
Interest received	372	546	566	1,170	2,005
Interest paid	-8	-5	-8	-5	-5
Cash flows from operating activities before changes in working capital	-22,686	-33,323	-38,904	-72,934	-110,237
Change in working capital					
Increase/decrease in receivables	79	127	249	-385	288
Increase/decrease in current liabilities	4,281	-5,021	951	453	-6,096
Change in working capital	4,360	-4,894	1,201	68	-5,808
Cash flows from operating activities	-18,326	-38,217	-37,704	-72,865	-116,046
Investing activities					
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
Financing activities  New share issue incl overhead costs*	45,067	0	45.067	0	-111
Increase/decrease in non-current liabilities	301	-87	45,067 -1,400	-1,137	-668
Cash flows from financing activities	45,368	-87	43,667	-1,137	- <b>779</b>
- Cush Hows from Infancing activities	45,500	-07	45,007	-1,137	-113
Change in cash and cash equivalents	27,042	-38,304	5,963	-74,002	-116,825
Cash and cash equivalents at beginning of	,		-,	-,	-,
period	65,085	165,387	83,741	201,008	201,008
Effects of exchange rate changes on cash and cash equivalents	-541	1,171	1,883	1,247	-443
CASH AND CASH EQUIVALENTS AT END OF PERIOD	91,587	128,253	91,587	128,253	83,741

<sup>\*</sup>The amount in 2023 mainly includes overheads in connection with the reverse split.

# Changes in equity

(KSEK)	Share capital	Non- restricted share premium reserve*	Retained earnings	Profit/loss for the year	TOTAL
Opening balance (OB) January 1, 2023	10,062	730,015	-449,887	-112,839	177,360
Transfer OB	-	-	-112,839	112,839	0
Employee stock options (not 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	732,711	-562,716	-113,323	66,733
Opening balance (OB) January 1, 2024	10,062	732,711	-562,716	-113,323	66,733
Transfer OB	-	-	-113,323	113,323	0
Employee stock options (not 7)	-	1,524	-	-	1,524
Share issue	1,556	45,262	-	-	46,819
Share issue costs	-	-1,752	-	-	-1,752
Loss for the period	-	-	-	-38,381	-38,381
<b>EQUITY JUNE 30, 2024</b>	11,618	777,746	-676,040	-38,381	74,943

<sup>\*</sup>As of June 30th, 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' interim report for the period January–June 2024 has been approved for publication by decision of the Board of Directors on August 21, 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 June 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, after the consolidation of shares (e.g. reverse split) the company had 10,061,615 (503,080,745) shares registered. In June 2024, a new issue was carried out and on June 30, 2024, the company had 11,618,095 (503,080,745) registered shares.

Weighted average number of shares for the period January-June 2024 amounted to 10,155,688 (10,061,615) before and after dilution. Weighted average number of shares for the second quarter 2024 amounted to 10,249,761 (10,061,615) before and af-

ter 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 June amounted to SEK -3.78 (-7.24), based on the earnings for January-June divided by the average number of shares before full dilution. The corresponding result for the second quarter amounted to SEK -2.33 (-3.28).

### **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 31st, there are 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 -1,537 (-1,183).

Full exercise of granted options minus the options that have been revoked as of June 30th, 2024, i.e. a total of 29,700,001 options, would result in a dilution of shareholders by 4.9 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, June 30, 2024	9,750,001	19,950,000

<sup>\*</sup>Each option entitles to 0.02 shares.

### NOTE 8

### **Contingent liabilities**

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

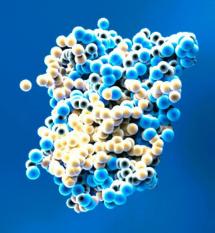
# Submission of interim report

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 August 22, 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





### 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

Interim report Q3 2024: November 13, 2024 Year-end report 2024: February 20, 2025

