# INTERIM REPORT JANUARY - MARCH 2024



# First quarter 2024 in short

FDA provides positive feedback on our clinical development project with RMC-035. Preparations for the POINTER study are progressing well with the first regulatory approval to start the study in Canada.

#### SUMMARY OF INTERIM REPORT

First quarter, January-March 2024

Net sales: 0 KSEK (0)

Loss for the period: -14,507 KSEK (-39,920) Earnings per share\*: -1.44 SEK (-3.97)

Equity/asset ratio\*\*: 80% (82)

Cash and cash equivalent: 65,085 KSEK (165,387)

#### **DEFINITIONER**

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 March 31st, 2024.

# Significant events

# SIGNIFICANT EVENTS IN THE FIRST QUARTER

- In January 2024, it was announced that the US Food and Drug Administration (FDA) had given positive feedback regarding the continued development of the company's clinical drug candidate RMC-035 as a kidney-protective treatment in open-heart surgery. The next development step involves a phase 2b study (POINTER) with the aim of, among other things, identifying an optimal dosage of RMC-035.
- In January, the company organized an R&D Update focusing on the next development step for RMC-035 in cardiac surgery as well as progress within the preclinical development platform consisting of new peptides intended for chronic treatment.

# SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- The nomination committee presented its proposal with two new board members, 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 and Vivesto.
- In early April, the pharmaceuticals authority Health Canada approved the company's application to include patients in Canada in the planned phase 2b clinical study POINTER.

#### **COMMENTS ON SIGNIFICANT EVENTS**

In connection with our latest R&D Update, we presented the ongoing development work and our continued strategy for RMC-035. This strategy has been anchored through a consultative meeting with the US Food and Drug Administration, FDA, which is crucial to our endeavor to get RMC-035 approved as a drug in the future. We also had the opportunity to introduce for the first time our preclinical development platform, with promising treatment results for new potential drug candidates.

During the first quarter, we intensified our preparations for the planned phase 2b study of RMC-035, named POINTER. Shortly after the end of the quarter, we received the first approval to include patients in the study from Health Canada. We are now awaiting further assessments from regulatory authorities in Europe and relevant ethics committees. At the same time, contract negotiations are ongoing with hospital clinics that are expected to participate in the study, and we are working on completing other documentation and logistics required to be able to start the study according to plan during the third quarter of this year.



## Chief executive's review

The start of the new year brought positive developments as the U.S. Food and Drug Administration (FDA) provided favorable feedback on the continued development plan for our clinical drug candidate RMC-035 in mid-January. This positive outcome from the FDA meeting serves as a clear validation of our clinical phase 2 data and bolsters our confidence in RMC-035 as a novel treatment for kidney injury in open-heart surgery.

Following standard drug development principles, preparations are underway for a phase 2b study, POIN-TER, with the main objective of identifying an optimal dosing regimen and precise target population for treatment. This strategy is considered to enable the most effective design of a subsequent pivotal phase 3 study. The development strategy is further supported by the Fast Track Designation previously granted by the FDA.

The primary efficacy measure of the POINTER study is change in kidney function (eGFR) from study initiation to 90 days after surgery, corresponding to the study's total follow-up period. Patient recruitment is expected to commence in the third quarter of 2024 and last for approximately one year. Past experiences and established contacts with relevant hospitals worldwide provide us with good prospects for recruiting patients at the same high pace as in previous studies of RMC-035 in heart surgery.

Shortly after the end of the period, we announced that Health Canada, as the first regulatory authority, has approved our application to include patients in the POINTER study. This milestone is significant for our ongoing clinical development of RMC-035. Meanwhile, parallel application processes for study initiation are underway in several European countries.

At our R&D Update at the end of January, we also introduced our GTX platform, a preclinical development platform consisting of new potential drug candidates based on the endogenous protein alpha-1-microglobulin for the treatment of chronic diseases. Preclinical candidates show favorable treatment effects of several peptides in various models, including chronic kidney disease, an area with high medical need and of strategic interest to the company. Over the coming year, we plan to develop a comprehensive plan for how this platform can best create future value for patients and shareholders alike.

Meanwhile, we continue to strengthen our organization and board. The Nomination Committee has proposed the election of Khatereh Ahmadi and Hege Hellström as board members. Dr. Ahmadi has over 20 years of experience in the pharmaceutical industry and currently serves as Head of Search and Evaluation Business Development Europe & Middle East at MSD, where she has also been actively involved in business development and licensing in the oncology field in Europe. Hege Hellström has over 30 years of experience in sales, marketing, strategic development, and corporate management in several major pharmaceutical companies, with particular expertise in nephrology.

Overall, we see a bright future for the company with clear progress in our development projects. Our primary focus remains on our clinical project with RMC- 035. The convincing efficacy data from the phase 2 AKITA study, the positive response from the FDA regarding our development plan, and the encouraging and rapid approval from Health Canada to include patients in the phase 2b POINTER study strengthen our commitment to developing RMC-035 into an approved drug with the potential to prevent and treat kidney injuries in a large number of patients.

**Tobias Agervald**Chief Executive Officer

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

### **FOCUS ON ACUTE KIDNEY INJURIES**

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 both the onset and progression of chronic kidney disease as well as end-stage renal failure, which requires life-sustaining dialysis treatment or kidney transplantation.

The company's clinical drug candidate RMC-035 represents a completely new mechanims (first-in-class) and consists of a recombinant and modified variant of the endogenous protein, alpha-1-microglobulin. The drug candidate has the ability to protect cells and their mitochondria against damage caused by oxygen deprivation and elevated levels of the oxygen-binding and toxic protein hem. It has a natural targeting of the kidneys and has shown good treatment effect in a number of different preclinical models of, among other things, kidney diseases.

The drug candidate is intended as a short-term treatment (maximum up to 5 days) and is administered intravenously in specialist care, to patients who are at high risk of developing acute kidney injury.

Guard Therapeutics has chosen to prioritize two different indication areas (patient groups) for RMC-035 in clinical development: open-heart surgery and kid-

ney transplantation. In both of these areas, there is currently a lack of approved and effective treatments to reduce the kidney injury that occurs as a result of these surgical procedures. In cardiac surgery, many patients risk losing a significant part of their kidney function, and in kidney transplantation, that the transplanted kidney does not achieve the desired (optimal) function.

RMC-035 has been granted Fast Track Designation by the 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.

In cardiac surgery, RMC-035 has been evaluated in an extensive phase 1 program as well as in a larger global phase 2 study (AKITA) for which so-called top line results were communicated in September 2023. These showed a clinically relevant and statistically significant improvement in key endpoints linked to renal function at 90 days after surgery in patients treated with RMC-035 compared to placebo. Based on these results, the company plans to advance the clinical development to late phase.

In kidney transplantation, a phase 1b study was completed in 2023, the purpose of which was to evaluate the safety and pharmacokinetics of RMC-035 in this

patient group. After determining the optimal dose for open-heart surgery, the company also sees the possibility of taking RMC-035 to the next development phase in the kidney transplant indication.

Guard Therapeutics also has a preclinical development platform (the GTX platform) which aims at the development of new peptides (shorter protein fragments) based on the protein alpha-1-microglobulin, with the goal of expanding the company's pipeline and enabling a broadening of the clinical development to new indication areas.

#### **BUSINESS MODEL AND STRATEGY**

Guard Therapeutics' business model and overall strategy are based on professional drug development of high scientific quality. Partnerships, licensing, or acquisitions of projects are continuously evaluated to support both the clinical development of RMC-035 and existing preclinical development programs, as well as to create value for patients and shareholders in the best possible way.

#### **MEDICAL NEED**

There is currently no approved treatment to prevent kidney injury associated with cardiac surgery and kidney transplantation, as well as the serious consequences of these injuries.

Many patients undergoing open-heart surgery often have impaired kidney function before the operation due to other existing conditions such as diabetes or heart failure. When these patients suffer additional kidney damage during surgery, they risk developing chronic kidney disease, which in turn increases the risk of future need for dialysis or kidney transplantation. Furthermore, it is estimated that approximately 30,000 patients in the United States alone who

undergo open-heart surgery each year have pre-existing chronic kidney disease. These patients are at particularly high risk of kidney injury during surgery, leading to accelerated and progressive chronic kidney disease.

In addition to the risk of future need for dialysis or kidney transplantation, chronic kidney disease also contributes to other negative health consequences such as cardiovascular diseases, impaired quality of life, and increased mortality.

In cases of so-called end-stage renal failure, life-sustaining chronic dialysis treatment or kidney transplantation is required. Unfortunately, the prognosis for patients with end-stage renal failure undergoing dialysis treatment is very poor. The annual mortality rate in this patient group is between 15-20%, which is worse than for many forms of metastatic cancer. Healthcare costs are also very high and often amount to 2-3% of the total national healthcare budget, despite the fact that the patient group represents only 0.02-0.03% of the total population. Therefore, it is crucial to protect the kidneys from injury to avoid progressive chronic kidney disease and end-stage renal failure.

In many cases, kidney transplantation is the best treatment for end-stage renal failure. However, most kidney transplants are performed using a deceased donor, which inevitably results in acute damage to the transplanted kidney during the period between organ retrieval and transplantation, as well as in the recipient immediately after transplantation. This leads to poorer kidney function both in the short and long term, with an increased risk of needing a new kidney transplant.



#### **MARKET OVERVIEW**

Guard Therapeutics sees significant potential in creating value for patients, society, and shareholders by developing new and innovative drugs to counteract the kidney injury that occurs during open-heart surgery and kidney transplantation.

### **Cardiac Surgery**

The global market for acute kidney injuries (which includes a large number of patient groups) is estimated to be between 25 and 30 billion USD and is projected to further increase in the future due to an aging population with underlying conditions that increase the risk of acute kidney injuries.

Based on an external analysis regarding the future pricing of RMC-035 in the US, as well as reliable data on the number of patients undergoing open-heart surgery each year in major markets (such as the US, EU, Japan), the global market potential can be estimated with relatively good precision.

In total, close to half a million patients undergo openheart surgery each year in the EU and the US, of which approximately 30–50% are estimated to benefit from treatment with RMC-035. This corresponds to about 100,000 patients in the US (40% of the total number of cardiac surgical patients in US) and roughly the same number of patients in the EU

An external analysis of pricing for RMC-035 in the US indicated an expected price per patient between 5,000–7,500 USD for open-heart surgery based on broader usage without restrictions. The annual market potential solely in the US thus amounts to 500–750 million USD. Assuming half the price in the EU, the market potential lands somewhere between 250–400 million USD. The global market potential therefore exceeds 1 billion USD annually, especially considering other major markets such as Japan and China.

The analysis also supports a higher price in the US (20–30,000 USD per patient) based on a more restricted usage of RMC-035 in specific patient groups with high medical needs, such as chronic kidney disease. A comprehensive set of clinical study results, dialogue with regulatory authorities, and more detailed mar-

ket analyses will guide the design of a future registrational study that takes into account both benefit/risk and market potential.

#### **Kidney Transplantation**

Guard Therapeutics has not performed an independent analysis of expected pricing in kidney transplantation, but current evidence in cardiac surgery provides good guidance. The market potential should be estimated solely on the basis of kidney transplantation with a deceased donor, as this is fraught with the highest risk of impaired function of the transplanted kidney both in the short and long term. In the US and Europe, approximately 20,000 and 16,000 deceased donor kidney transplants are performed each year, respectively.

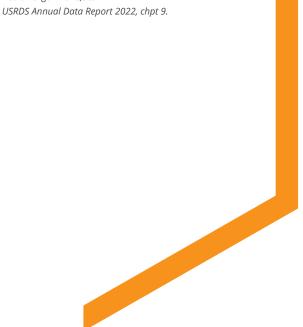
As with open-heart surgery, the treatment is expected to be aimed at those patients who run a relatively higher risk of acute kidney injury. A reasonable assumption is that half of all deceased-donor kidney transplants could initially be treated with RMC-035, which would mean a total market potential in the US and Europe of approximately \$350 million..

#### 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.



#### **CLINICAL STUDIES IN CARDIAC SURGERY**

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

In 2023, a large global phase 2 study (AKITA) was completed. AKITA is a global, randomised, double-blind and placebo-controlled phase 2 study aimed at evaluating the renal protective effect of RMC-035 in patients at increased risk of developing acute kidney injury during open-heart surgery.

The results from the AKITA study showed a clinically relevant and statistically significant positive effect on renal function of RMC-035 at 90 days after surgery. Measured both as change in renal function (eGFR) compared to before surgery and as a reduced risk of so-called serious renal events according to the MAKE criteria (Major Adverse Kidney Events) consisting of death, dialysis treatment or at least 25% loss of kidney function.

The study results thus provide clear support for the advancement of the clinical development program where the next step includes a phase 2b study, with the aim of, among other things, identifying an optimal dosage of RMC-035 and the exact target group for treatment. The phase 2b study, named POINTER, is also expected to enable the most efficient design of a registrational phase 3 study.

The study's primary endpoint is change in eGFR from study start to 90 days after surgery, which corresponds to the planned follow-up period. In total, the study is expected to include approximately 160 patients divided into two different dose arms of RMC-035 and placebo. Patient recruitment is planned to begin in the third quarter of 2024.



#### **Fast Track**

RMC-035 has been granted Fast Track Designation by the US 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 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

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

# CLINICAL STUDIES IN KIDNEY TRANSPLANTATION

Based on positive preclinical and clinical study results, the company has chosen to expand the clinical development program for RMC-035 to kidney transplantation. Within this indication, the recipient of a donated kidney from a deceased donor will be treated with RMC-035 in order to reduce the damage that occurs in connection with the transplant, and ultimately to improve both kidney function and survival of the donated kidney.

A first clinical phase 1b study has been conducted in this indication. The primary objective of the study was to evaluate the pharmacokinetic properties of RMC-035 in the context of kidney transplantation. After the optimal dose for cardiac surgery has been determined, there is also the possibility of taking RMC-035 within this indication further into the next development phase. With demonstrated concept validation and established dose cardiac surgery, there are potential opportunities to move directly towards a registrational phase 2b/3 study in 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

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

#### **Operating loss**

The operating loss for the first quarter amounted to KSEK -17,347 (-40,618).

Research and development expenditure accounted for the majority of the company's expenses, which totaled at KSEK -14,900 (-38,187) in the first quarter. The reduced costs compared to the same period last year are due to the fact that we were then in an intensive phase of patient recruitment for the phase 2a study AKITA, which ended later that year. The costs this year are mainly linked to preparations for the phase 2b study POINTER.

The company's marketing and sales costs amounted to KSEK -904 (-849) for the first quarter and the administrative expenses amounted to KSEK -1,471 (-1,502).

Other operating income and operating expenses mainly comprised exchange differences on trade payables and amounted to KSEK -72 (-80) KSEK by March this year.

#### **Net financial items**

Net financial items, which until March this year amounted to KSEK 2,840 (698), mainly consists of unrealized exchange rate differences on the company's currency accounts, KSEK 2,423, as well as interest income from fixed interest accounts and currency accounts, KSEK 416.

#### **FINANCIAL POSITION**

As of March 31, 2024, the company had an equity/assets ratio of 80%, compared with 82% last year. At the end of March, equity totaled KSEK 53,035, compared with KSEK 137,821 at the same date one year earlier.

The company's cash and cash equivalents comprising cash and bank balances, including liquid investments amounted to KSEK 65,085 (165,087).

At the end of the period, the balance-sheet total amounted to KSEK 66,623 (167,492).

#### **CASH FLOW AND INVESTMENTS**

Guard Therapeutics posted cash flow for the first quarter 2024 of KSEK -21,079 (-35,698) KSEK. For the same period, cash flows from operating activities amounted to KSEK -19,378 (-34,648).

Cash flow from financing activities amounted to KSEK -1,701 (-1,150) KSEK.

## 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 18, 2023, a consolidation of shares (a so-called reverse split) was carried out with a ratio of 1:50. After the consolidation, the number of shares in the company amounted to 10,061,615. 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 10,061,615.00 on March 31st, 2024.

Symbol: GUARD

ISIN: SE0021181559

No of shares: 10,061,615

Quota value: 1.00 SEK

Trading unit: 1 share

Share capital 10,061,615.00 SEK

### **OWNERSHIP STRUCTURE ON MARCH 31, 2024**

Shareholder			
March 31st 2024	Number of shares	Share of votes	Share of capital
STÅHLBERG, JAN	1,649,197	16.39%	16.39%
M2 ASSET MANAGEMENT AB	1,110,818	11.04%	11.04%
STIFTELSEN INDUSTRIFONDEN	933,334	9.28%	9.28%
SWEDBANK ROBUR HEALTHCARE	666,667	6.63%	6.63%
FÖRSÄKRINGSAKTIEBOLAGET, AVANZA PENSION	635,122	6.31%	6.31%
STRAND SMÅBOLAGSFOND	352,756	3.51%	3.51%
KARLSSON, AXEL	276,552	2.75%	2.75%
NORDNET PENSIONSFÖRSÄKRING AB	249,553	2.48%	2.48%
ALLA MÖLLER AB	98,050	0.97%	0.97%
DAHLQVIST, JAN	88,301	0.88%	0.88%
ÖVRIGA	4,001,265	39.77%	39.77%
TOTAL	10,061,615	100%	100%

# Income statement

(KSEK)	Q	Q1		
	Jan 1, 2024 Mar 31, 2024	Jan 1, 2023 Mar 31, 2023	Jan 1, 2023 Dec 31, 2023	
Net sales	-	-	-	
Cost of goods sold	-	-	-	
Gross profit	0	0	0	
Research and development expenditure	-14,900	-38,187	-105,773	
Marketing and sales costs	-904	-849	-3,766	
Administrative expenses	-1,471	-1,502	-5,383	
Other operating income	0	0	0	
Other operating expenses	-72	-80	-151	
Operating loss	-17,347	-40,618	-115,073	
Financial income	2,840	700	2,197	
Financial expense	0	-2	-447	
Net financial items	2,840	698	1,750	
Pre-tax loss	-14,507	-39,920	-113,323	
Tax on profit for the period	-	-	-	
LOSS FOR THE PERIOD	-14,507	-39,920	-113,323	

# Balance sheet

(KSEK)	Mar 31, 2024	Mar 31, 2023	Dec 31, 2023
ASSETS			
Non-current assets			
Property, plant and equipment	0	11	0
Total non-current assets	0	11	0
Current assets			
Other receivables	616	806	667
Prepaid expenses and accrued income	922	1,288	819
Current receivables	1,538	2,094	1,486
Cash and cash equivalents (Note 6)	65,085	165,387	83,741
Cash and bank balances	65,085	165,387	83,741
Total current assets	66,623	167,481	85,227
TOTAL ASSETS	66,623	167,492	85,227
EQUITY AND LIABILITIES			
Equity			
Share capital	10,062	10,062	10,062
Non-restricted share premium reserve	733,521	730,395	732,711
Retained earnings	-676,040	-562,716	-562,716
Loss for the period	-14,507	-39,920	-113,323
Total equity	53,035	137,821	66,733
Non-current liabilities			
Provision for social security contributions – incentive scheme ( <i>Note 7</i> )	180	88	469
Non-current trade payables	0	1,413	1,413
Total non-current liabilities	180	1,500	1,882
Current liabilities	7.000	40.764	F 40.4
Trade payables	7,866	10,761	5,494
Tax liabilities	184	362	268
Other payables	415	305	293
Accrued expenses and deferred income	4,942	16,743	10,557
Total current liabilities	13,407	28,171	16,613
Total liabilities (Note 8)	13,588	29,671	18,494
TOTAL EQUITY AND LIABILITIES	66,623	167,492	85,227

# Statement of cash flows

(KSEK)	Q	Q1		
	Jan 1, 2024	Jan 1, 2023	Jan 1, 2023	
	Mar 31, 2024	Mar 31, 2023	Dec 31, 2023	
Operating activities				
Operating loss	-17,347	-40,618	-115,073	
Adjustments for non-cash items	934	384	2,835	
Interest received	194	624	2,005	
Interest paid	0	0	-5	
Cash flows from operating activities before changes in working capital	-16,219	-39,610	-110,237	
Change in working capital				
Increase/decrease in receivables	170	-512	288	
Increase/decrease in current liabilities	-3,330	5,474	-6,096	
Change in working capital	-3,159	4,962	-5,808	
Cash flows from operating activities	-19,378	-34,648	-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	
Financing activities				
New share issue incl overhead costs*	_	_	-111	
Increase/decrease in non-current liabilities	-1,701	-1,150	-668	
Cash flows from financing activities	-1,701	-1,150	-779	
Change in cash and cash equivalents	-21,079	-35,698	-116,825	
Cash and cash equivalents at beginning of period	83,741	201,008	201,008	
Effects of exchange rate changes on cash and cash equivalents	2,423	76	-443	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	65,085	165,387	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)	-	809	-	-	809
Share issue	-	-	-	-	-
Share issue costs	-	-	-	-	-
Loss for the period	-	-	-	-14,507	-14,507
EQUITY MARCH 31, 2024	10,062	733,521	-676,040	-14,507	53,035

<sup>\*</sup>As of March 31, 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–March 2024 has been approved for publication by decision of the Board on May 7, 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 March 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.

Expenses for research 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 has, after the consolidation of shares (e.g. reverse split) in December 2023, 10,061,615 (503,080,745) shares registered.

Weighted average number of shares for the period January-March 2024 amounted to 10,061,615 (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 March amounted to SEK -1.44 (-3.97), based on the earnings for January-March divided by the average number of shares before full dilution.g.

#### **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 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 -520 (-461).

Full exercise of granted options minus the options that have been revoked as of March 31, 2024, i.e. a total of 29,700,001 options, would result in a dilution of shareholders by 5.6 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
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, March 31, 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 March 31, 2024, nor as of March 31, 2023.

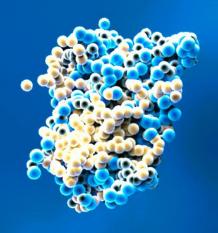
# Submission of interim report

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 May 8, 2023.

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### **Tobias Agervald**

Chief Executive Officer





### COMPANY INFORMATION

COMPANY NAME: Guard Therapeutics International AB (publ)

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LEGAL FORM: Public limited company

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### FINANCIAL CALENDAR

Interim report Q2 2024: August 22, 2024 Interim report Q3 2024: November 13, 2024 Year-end report 2024: February 20, 2025

### GENERAL MEETING

Annual General Meeting May 8, 2024

