



COMPANY UPDATE

Healthcare

Fair value: SEK32.0–47.0

Share price: SEK21.9

Guard Therapeutics

POINTER data preview: high risk, high potential reward

Research analysts:
Maria Karlsson Osipova
DNB Carnegie Investment Bank AB

We expect Guard Therapeutics to report top-line Phase IIb POINTER data on RMC-035 in Q4 2025. Promising data from the AKITA trial suggests good potential for success, in our view, though risks remain high. We reiterate our fair value range of SEK32.0–47.0 per share.

Critical data readout coming up. In Q4, Guard Therapeutics is set to deliver its most important readout to date with the release of top-line results from the Phase IIb POINTER trial of its lead drug candidate, RMC-035. The study is evaluating RMC-035 versus placebo for its ability to improve eGFR (estimated glomerular filtration rate, a measure of kidney function) at 90 days in patients undergoing open-heart surgery. We expect the announcement in Q4 and anticipate it will be a major share price driver.

Good prerequisites for a positive outcome – although risk remains high. In the Phase IIa trial AKITA, RMC-035 demonstrated a notable ability to preserve renal function, as measured by eGFR at 90 days, compared with placebo. While this was only a secondary endpoint in AKITA, it is the primary endpoint in POINTER. The company aims to achieve a 30% relative risk reduction in MAKE at 90 days (major adverse kidney events: death, dialysis, or ≥25% loss of kidney function), which it expects to correspond to an eGFR improvement of c3.5 mL/min versus placebo. Based on this, our assessment is that an eGFR delta of c3.5 mL/min or more would likely be considered a study success. For context, in AKITA, the overall population showed a 4.3 mL/min delta at 90 days, and the relevant lower-dose subgroup achieved 7.9 mL/min. If POINTER delivers similar or better results, we believe the trial may likely produce a statistically significant improvement in the primary endpoint. Given the competitive landscape and the ongoing trials in the field, we believe Guard Therapeutics is well positioned to generate efficacy data ahead of peers.

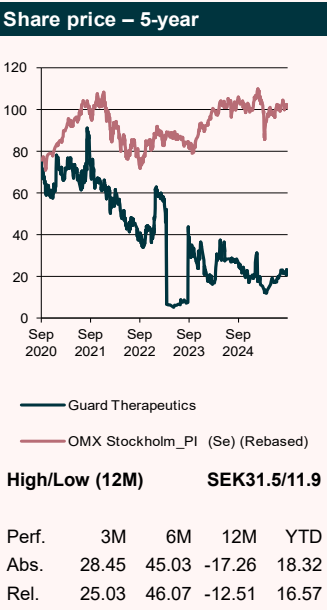
We reiterate our fair value range of SEK32.0-47.0 per share.

Correction: The sensitivity table on p8 has been replaced. There are no changes to estimates or fair value range. The original report was published 29 September 2025 at 06:55 CET

Changes in this report			
	From	To	Chg
EPS adj. 2025e	-7.96	-7.96	0%
EPS adj. 2026e	10.7	10.7	0%
EPS adj. 2027e	0.29	0.29	0%

Key facts	
No. shares (m)	20.2
Market cap. (USDm)	47
Market cap. (SEKm)	442
Net IB Debt. (SEKm)	-16
Adjustments (SEKm)	0
EV (2025e) (SEKm)	426
Free float	64.7%
Avg. daily vol. ('000)	34
BBG	GUARD SS
Fiscal year end	December
Share price as of (CET)	26 Sep 2025 14:11

Key figures (SEK)	2024	2025e	2026e	2027e
Sales (m)	0	0	263	15
EBITDA (m)	-100	-130	215	5
EBIT (m)	-100	-130	215	5
EPS	-8.59	-7.96	10.7	0.29
EPS adj.	-8.59	-7.96	10.7	0.29
DPS	0.00	0.00	0.00	0.00
Sales growth Y/Y	n.a.	n.a.	+chg	-94%
EPS adj. growth Y/Y	-chg	+chg	+chg	-97%
EBIT margin	n.m.	n.m.	81.8%	36.3%
P/E adj.	n.m.	n.m.	2.0	75.3
EV/EBIT	neg.	neg.	0.9	33.3
EV/EBITA	neg.	neg.	0.9	33.3
EV/EBITDA	neg.	neg.	0.9	33.3
P/BV	7.1	27.7	1.9	1.9
Dividend yield	0.0%	0.0%	0.0%	0.0%
FCF yield	-21.5%	-32.9%	51.8%	3.3%
Equity/Total Assets	68.1%	99.3%	92.6%	89.4%
ROCE	-181.1%	n.m.	174.2%	2.5%
ROE adj.	-183.5%	-479.5%	174.2%	2.5%
Net IB debt/EBITDA	0.5	0.1	-1.1	-47.5



Source: DNB Carnegie (estimates), FactSet, Infront & company data

This report has been commissioned and sponsored by Guard Therapeutics. Commissioned research is considered to be marketing communication (i.e. not investment research under MiFID II). This material may be subject to restrictions on distribution in certain areas.

Please see the last two pages for important disclosures. This report was completed and disseminated at 30 September 2025, 11:46 CET
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Equity story

Near term: within 12M

We expect Guard Therapeutics to report top-line results from its Phase IIb POINTER study in late 2025/early 2026. The study focuses on RMC-035, the company's lead candidate, in patients undergoing open-heart surgery. We expect this milestone to serve as a significant catalyst for the share price.

Long-term outlook: 5Y+

The long-term equity story for Guard Therapeutics centres on RMC-035 demonstrating encouraging clinical data and eventually achieving market approval. There are currently no approved treatments for acute kidney injury, and we believe this represents a significant opportunity.

Key risks:

- Clinical development risk.
- Regulatory risk.
- Funding risk.

Company description

Guard Therapeutics is a Swedish clinical-stage biotechnology company engaged in the research and development of new pharmaceuticals targeting areas with significant medical needs. The company focuses on the field of kidney diseases.

Key industry drivers

- Ageing population.
- Increasing prevalence of kidney diseases.
- Advancements in biomarkers and diagnostics.

Industry outlook

- We expect the market for kidney diseases to grow significantly over the coming years, primarily driven by rising patient needs and advancements in science, with new novel therapies getting approved.

Largest shareholders, capital

Jan Ståhlberg	20.7%
Stiftelsen Industrifonden	14.3%
Swedbank Robur Fonder	9.9%

Cyclicality

Cyclicality: No
Not cyclical

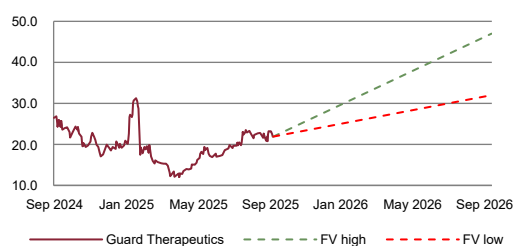
Key peers

Synact Pharma, Vicore Pharma, IRLAB Therapeutics.

Valuation and methodology

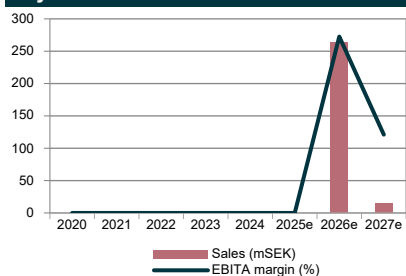
We use a DCF-based sum-of-the-parts approach in our valuation of Guard Therapeutics.

Fair value range 12M



The lower end of our fair value range is based on our DCF-based SOTP model using a WACC of 20%.
The upper end of our fair value range is based on our DCF-based SOTP model using a WACC of 14%.

Key metrics



P/E 12-months forward



Long-term valuation trend



Source: DNB Carnegie (estimates) & company data

The POINTER trial – Phase IIb

Study design

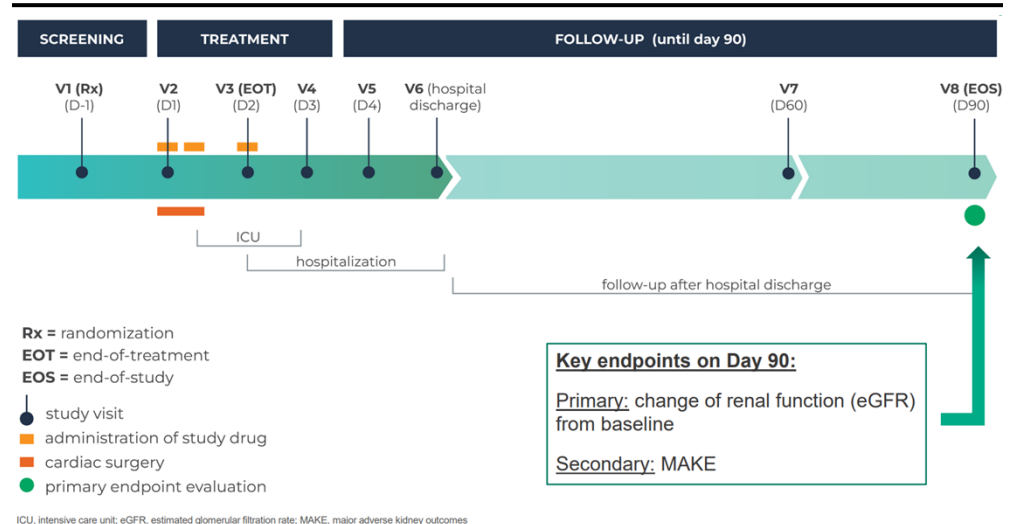
POINTER is a randomised, double-blind, placebo-controlled trial. Patients are assigned to one of three arms: RMC-035 at 60mg, RMC-035 at 30mg, or placebo, in a 2:2:3 allocation ratio. The study aimed to enrol a minimum of 30% of patients with CKD (chronic kidney disease), defined as eGFR less than 60ml/min/1.73m².

The primary endpoint of the study is the change in eGFR from baseline to 90 days post-surgery. This measure formed the basis for the power calculations and determined the number of patients included. A secondary endpoint is the occurrence of major adverse kidney events (MAKE) at 90 days, defined as death, initiation of dialysis, or a $\geq 25\%$ reduction in eGFR compared to pre-surgery levels. For the primary efficacy analysis, data from the two RMC-035 dose groups will be pooled and compared against the placebo group.

The study included two independent safety reviews by the Data Safety Monitoring Committee (DSMC), both of which concluded positively.

The last patient was enrolled in early June 2025, and in September the company announced that the final patient had successfully completed the last scheduled 90-day follow-up visit (last patient last visit). We believe these milestones position the company to present top-line data from the study in Q4 2025.

Study design – POINTER



Source: Company

Competitive landscape

Acute kidney injury (AKI) is an important field, especially in cardiac surgery, since AKI is a frequent and serious complication, affecting up to 40% of patients and markedly increasing the risk of death, prolonged ICU stay, and long-term progression to chronic kidney disease. While supportive care, such as dialysis and fluid management, remains essential, there is a critical need for treatments that can directly target AKI and prevent long-term kidney damage. Addressing AKI in high-risk patients, such as those undergoing major surgeries or suffering from sepsis, is a key area where we believe improvements are necessary to reduce mortality and enhance recovery.

As there are no approved drugs for the treatment of AKI, several companies are working in this field. The treatment landscape is constantly evolving; however, we only see five relevant projects (and a sixth which has been terminated recently). Below, we have summarised our selection of most relevant trials in the space.

Alexion

Ravulizumab, a long-acting complement C5 inhibitor, is in Phase III development for the prevention of cardiac surgery-associated acute kidney injury (CSA-AKI) in patients with chronic kidney disease (CKD) undergoing procedures with cardiopulmonary bypass. Ultomiris (the brand name under which Alexion/AstraZeneca markets ravulizumab) is already approved for major indications such as paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), among others. There are, however, no prior clinical data for ravulizumab in acute kidney injury, making the ongoing ARTEMIS trial in cardiac surgery the first to explore this setting.

The ARTEMIS study (NCT05746559), a global randomised, double-blind, placebo-controlled trial, is evaluating a single pre-operative dose of ravulizumab to reduce major adverse kidney events (MAKE) and the severity of CSA-AKI. Enrolment began in 2023, with primary completion expected in 2026 and full study readout in 2027. Eligibility criteria for the trial included patients with known or apparent chronic kidney disease (CKD), with an estimated glomerular filtration rate (eGFR) between 20 and <60 mL/min/1.73 m². In addition, participants had to be at risk for postsurgical kidney events, defined as a Society of Thoracic Surgeons (STS) Calculator Renal Failure Risk Score of ≥2.8% at screening.

Since the trial start on 6 April 2023, the primary completion date has been changed four times, resulting in a cumulative extension of 15 months (*Source: Bloomberg, Alexion*), which in our view signals recruitment challenges due to the nature of the patient population – high-risk CKD patients. In September, it was announced that Alexion's ARTEMIS trial had completed recruitment, with the last patient enrolled, and that it is possible efficacy data may come sooner than previously anticipated.

Compared with Guard Therapeutics' POINTER trial of RMC-035, ARTEMIS focuses on a narrower, high-risk CKD subset and would deliver its first efficacy readout in the cardiac surgery setting at a later timepoint, while POINTER targets broader kidney protection across a wider surgical population with data expected as early as in 2025. We believe that this positions Guard Therapeutics ahead of peers' timelines and with a potentially broader initial label.

Genentech

Genentech is developing GDC-8264, a RIP1 kinase inhibitor, for the prevention of AKI in patients undergoing cardiac surgery with cardiopulmonary bypass. The Phase II trial (NCT06602453) is a randomised, double-blind, placebo-controlled study that will be conducted in two parts. The primary endpoints are the incidence of MAKE at day 90 and the overall rate of adverse events within 90 days post-surgery. Key secondary outcomes include the incidence of AKI within the first seven days after surgery, changes in estimated glomerular filtration rate (eGFR) up to 90 days, the number of patients who develop new or worsened state CKD by day 90, and the proportion of participants who experience MAKE30 and MAKE60 at days 30 and 60 post-surgery. The ambition is to recruit approximately 400 patients (*source: ClinicalTrials.gov*). Eligible patients must have at least one or two predefined AKI risk factors depending on surgery type, such as age >70, CKD with eGFR <60 mL/min/1.73 m², diabetes, COPD, reduced LVEF <40%, or preoperative anaemia (Hb <10 g/dL). In addition, participants must have stable kidney function without any AKI episodes within two weeks prior to screening.

In our view, compared with Guard Therapeutics, this represents a relevant endpoint and a large-scale study – almost as if combining both AKITA and POINTER. However, the timeline is long, with expected completion at the end of 2027.

AM Pharma

Ilofotase alfa, developed by AM-Pharma, is a recombinant alkaline phosphatase designed to protect the kidneys, especially in patients with sepsis-associated acute kidney injury (SA-AKI). By detoxifying harmful molecular patterns that contribute to kidney damage, Ilofotase alfa showed some signals of efficacy in Phase II. Further, after a pre-planned interim futility analysis, the Phase III trial was terminated. There are currently no data on its effects in AKI related to cardiac surgery from earlier trials.

This study focuses on acute endpoints: after surgery, kidney function is monitored by measuring serum creatinine levels on days 1–5, with the aim of assessing changes in kidney function compared to baseline. It is worth noting that Novartis, which terminated its trial earlier in 2025, used a similar short-term creatinine-based endpoint. We view Guard Therapeutics as being in a stronger position as its trials we believe align better with published recommendations on endpoints. Nonetheless, we will be closely following AM Pharma's trial results, with trial completion expected later in Q3 2025.

Why we believe creatinine falls short as a Phase II endpoint

A consensus report published in *Intensive Care Medicine* in 2024 highlights that although serum creatinine and urine output remain the basis for defining AKI, they are crude and non-specific markers that combine a variety of different pathophysiological processes into a single outcome. Because of this limitation, creatinine is not considered an ideal endpoint for early-phase studies. Based on this, we believe it may be challenging to translate a potential effect from this Phase II trial into further trial planning. Moreover, given the variability and lack of sensitivity of creatinine as a biomarker, a large sample size would likely be required to adequately power the study and detect a true treatment effect, which in turn increases trial complexity, cost and timelines.

Source: *Intensive Care Medicine*, 2024

Endpoints as suggested by consensus based on clinical trial phase

Endpoint	Clinical trial phase
Rate of change in GFR	Phase II
Sustained change in GFR	Phase II
Change in biomarker values specific for kidney damage	Phase II
Change in genomic or metabolomic variables	Phase II
Change in levels of inflammatory mediators	Phase II
Presence or progression of proteinuria	Phase II
Major Adverse Kidney Events (MAKE)	Phase III or IV
Days free of organ support therapies (renal replacement therapy, invasive mechanical ventilation, ICU/hospital free and alive days)	Phase III or IV
Death	Phase III or IV
AKI trajectories	Phase III or IV
Dialysis	Phase III or IV
Hospital readmission	Phase III or IV
eGFR reduction or CKD progression	Phase III or IV

Source: *Intensive Care Medicine*, 2024 (<https://doi.org/10.1007/s00134-024-07560-y>)

AKI in cardiac surgery – pipeline overview

Company (Drug)	Phase			Mechanism	Efficacy in heart surgery	Status	Comment
	I	II	III				
Guard Therapeutics (RMC-035)		●		A1M (alpha-1-microglobulin) analogue	Yes	Ongoing, fully recruited	Expecting readout Q4 2025e
Alexion (ravulizumab)			●	C5 inhibitor	-	Ongoing trial, fully recruited	Topline data Q2 2026e
Genentech (GDC-8264)		●		RIP1 inhibitor	-	Ongoing trial, recruiting	Completion Q4 2027e
AM Pharma (ilofotase alpha)		●		Human alkaline phosphatase	-	Ongoing trial, recruiting	Completion Q3 2025e
Renibus Therapeutics (RBT-1)			●	Iron sucrose + stannous protoporphyrin	-	Ongoing	Focus on acute outcomes, no efficacy on kidney endpoints in Ph II
Arch Biopartners (TLP-02)		●		Cilastatin	-	Ongoing, recruiting	Completion Q4 2026e
Novartis (TIN-816)		●		Recombinant human CD39	-	Terminated	Terminated

Relevance for Guard Therapeutics

Source: GlobalData, company, DNB Carnegie (graph structuring and conclusions)

Defining good data, in our view

We see a clear risk-reducing aspect in the fact that the company has already conducted a similar study (AKITA) in a similar patient population. Before AKITA, no meaningful patient efficacy data was available to guide the study design. We believe the trial delivered valuable real-world insights into the effect size of RMC-035, allowing the company to design POINTER with a higher probability of achieving a statistically significant result. The company anticipates that both dose levels in the POINTER study (30 and 60 mg) are above the maximum effective dose, enabling pooling of dose groups in the primary efficacy analysis.

In the AKITA study, the incidence of AKI was used as a surrogate endpoint in place of 90-day eGFR. This approach allowed for a smaller sample size while still providing an early indication of efficacy, as detecting an effect on AKI generally requires fewer patients than evaluating 90-day eGFR.

However, regulatory authorities have confirmed that 90-day eGFR is the appropriate endpoint for approval, since short-term creatinine fluctuations are not clinically meaningful unless dialysis is required. Importantly, the highest dose in the POINTER study corresponds to the lower dose used in AKITA, and the company therefore does not expect to observe the transient creatinine increases reported in AKITA.

In POINTER, eGFR will be measured both continuously, using the exact value to analyse variation across the full range, and dichotomously, categorising patients based on whether they experience a 25% or greater loss of kidney function. The primary endpoint will be based on the continuous eGFR measurement at 90 days. The study is powered to detect a statistically significant difference for this endpoint but not for MAKE90, which is a binary composite endpoint. Detecting significance for a binary endpoint generally requires more patients, so if statistical significance is nonetheless achieved for MAKE90, it would likely indicate a larger-than-expected effect size, which would be an encouraging outcome.

In terms of effect size, the company aims to achieve a 30% relative risk reduction, while the FDA has indicated that a 20% reduction of the individual MAKE component would be sufficient for approval in a pivotal Phase III trial. This means the RMC-035 group would have a 30% lower risk of reaching any of the MAKE90 criteria compared to the placebo group. So, what

magnitude of delta in eGFR between the two groups would be needed to achieve a 30% relative risk reduction between the two groups?

The company expects an eGFR improvement of c3mL/min to reduce MAKE by 30%. Based on this, our assessment is that an eGFR delta of c3.5mL/min or more would likely be considered a study success.

For context, in AKITA (where eGFR was a secondary endpoint), the overall study population showed an improvement (delta) of 4.3mL/min at 90 days. In the subgroup that received the lower dose (equivalent to the highest dose in POINTER, n=65), the improvement was 7.9mL/min. If POINTER delivers similar results, it will likely produce a statistically significant improvement in the primary endpoint.

DNB Carnegie's interpretation of potential POINTER outcomes

	Low likelihood for statistical significance	High likelihood for statistical significance	Differentiated
Δ eGFR	<3 mL/min	c3.5 mL/min	>3.5 mL/min
Chances of attracting industry partner	Low	➡	High

Source: DNB Carnegie

What would not be good to see

In POINTER, examples of what would not be good to see include failure to meet the primary endpoint, lack of a clear efficacy signal on MAKE, or difficult-to-interpret asymmetry in treatment effects between eGFR and MAKE.

Opportunities beyond open-heart surgery

Guard Therapeutics has actively chosen not to initiate a clinical programme in sepsis at this stage. The main reason is that the development risk is considered significantly higher than in cardiac surgery, primarily due to the greater heterogeneity of injury mechanisms and the difficulty of controlling these factors within the framework of clinical trials. However, we believe sepsis remains an extremely important potential follow-up indication once RMC-035 has potentially shown efficacy in CS-AKI.

An additional advantage of this development path according to the company is that the dosing is expected to be similar to that used in cardiac surgery. Furthermore, the regulatory pathway to market approval is well defined, which provides an opportunity to initiate a registrational Phase III study of RMC-035 relatively quickly following a positive decision. With successful development in cardiac surgery, there would thus be the possibility to rapidly advance a registrational programme in sepsis.

Valuation

We continue to use a sum-of-the-parts approach in our valuation of Guard Therapeutics. In our model, we project peak sales of USD635m for RMC-035 in CS-AKI and USD205m in KTX-AKI. Due to the absence of completed clinical trials, we have excluded other potential AKI indications from our valuation. Further, our assumptions include a partnership deal for RMC-035 in 2026 with a total value of USD600m, comprising an upfront payment of USD35m, contingent on positive top-line results from the Phase IIb POINTER trial. Additionally, we estimate Guard Therapeutics will receive 14% of net sales for RMC-035.

Our fair value is SEK32–47/share. The lower end of our fair value range is based on our DCF-based SOTP model using a WACC of 20% and the upper end is based on a model using a WACC of 14%.

SOTP valuation – lower end (20% WACC) and higher end (14% WACC)

Project	Launch	Probability	Peak sales (USDm)	Valuation approach	rNPV (SEKm)	rNPV/share (SEK)
RMC-035, CS-AKI	2028	30%	635	DCF, WACC 20%	644	32
RMC-035, Kidney Tx	2030	13%	205	DCF, WACC 20%	26	1
Unallocated costs, incl. tax					-143	-7
Enterprise value (EV), SEKm					527	26
Net cash Q1 2025 + est. net proceeds					123	6
Total rNPV					650	32

Project	Launch	Probability	Peak sales (USDm)	Valuation approach	rNPV (SEKm)	rNPV/share (SEK)
RMC-035, CS-AKI	2028	30%	635	DCF, WACC 14%	1,008	50
RMC-035, Kidney Tx	2030	13%	205	DCF, WACC 14%	47	2
Unallocated costs, incl. tax					-222	-11
Enterprise value (EV), SEKm					833	41
Net cash Q1 2025 + est. net proceeds					123	6
Total rNPV					956	47

Source: DNB Carnegie (estimates) & company

Sensitivity table – WACC (%) and LoA (%)

		LOA (%)				
		10%	20%	30%	40%	50%
WACC (%)	12%	26	41	54	69	84
	14%	24	36	47	60	73
	17%	20	30	39	49	59
	20%	17	25	32	40	48
	23%	15	21	27	33	40

Source: DNB Carnegie (estimates)

Risks

Clinical development risk: Clinical trials for RMC-035 may fail to demonstrate safety and efficacy, leading to delays or termination of development.

Regulatory risk: Regulatory approval processes are complex and stringent, with no guarantee of approval even after successful trials.

Financial risks: Biotechnology companies often rely heavily on external funding. Guard Therapeutics may need to raise additional capital, diluting shareholder value. As a development-stage company, Guard Therapeutics may not generate consistent revenue streams until RMC-035 reaches commercial stage.

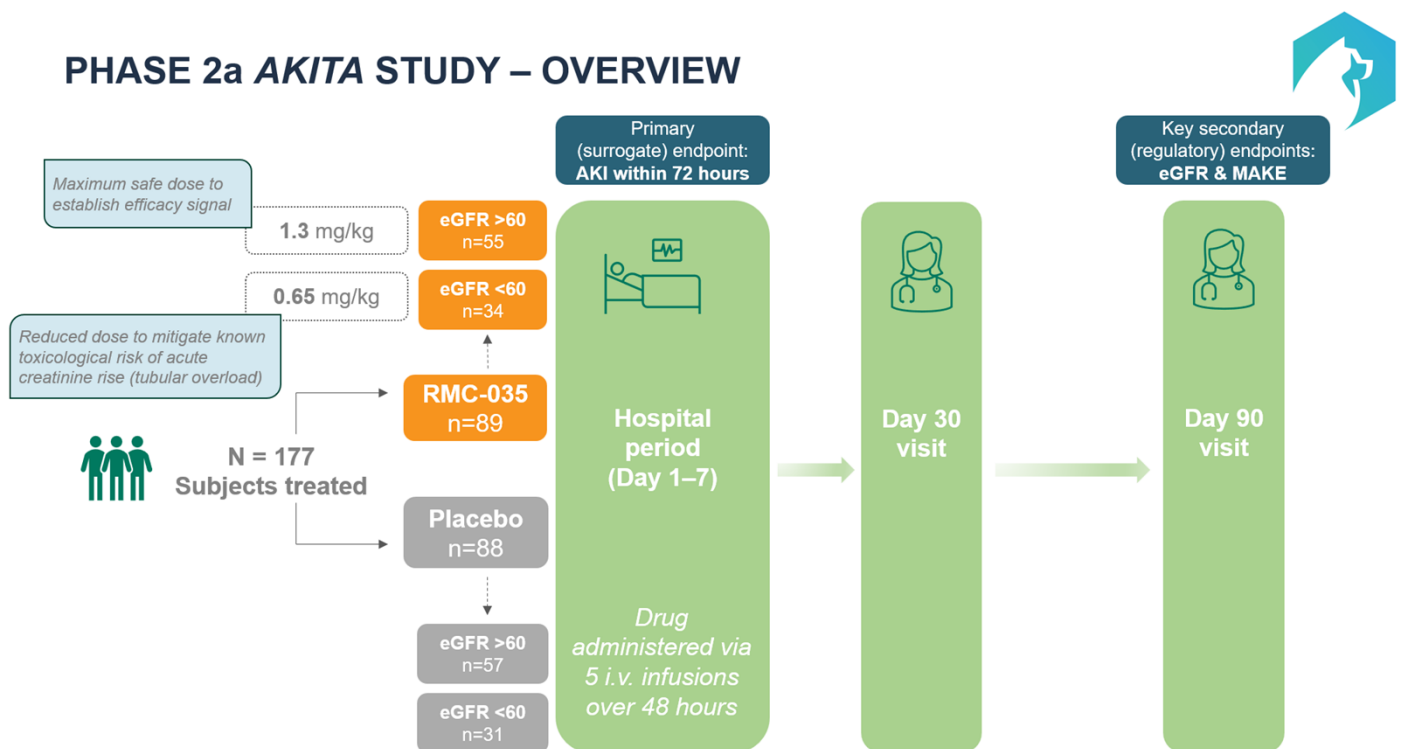
Appendix

The AKITA trial (Phase IIa)

Background and study design

The purpose of the Phase II AKITA study has been to investigate RMC-035's efficacy in preventing AKI during open-heart surgery. The study was randomised, double-blind and placebo-controlled, with a total of 177 patients randomised and dosed in the trial. It only recruited patients at high risk of developing AKI based on established clinical risk factors. The primary endpoint was evaluated after three days, although patients were monitored over 90 days to check safety and secondary endpoints. The primary endpoint in the study was a binary variable: "the number of patients who developed AKI within 72 hours of surgery". The secondary endpoints focused on long-term kidney outcomes and included the change in eGFR from baseline to Day 90 and the composite MAKE endpoint at Day 90, defined as death, post-surgery dialysis, or a $\geq 25\%$ reduction in eGFR from baseline.

AKITA overview



Source: Company

Study results

The primary (short-term) endpoint, incidence of AKI within 72 hours after surgery, was not reached. Importantly though, pre-defined secondary endpoints demonstrated the intended long-term benefit of RMC-035 with improved kidney function compared with placebo. The results supported advancement in the clinical development programme and highlight the potential of RMC-035 as a novel short-term treatment for kidney protection.

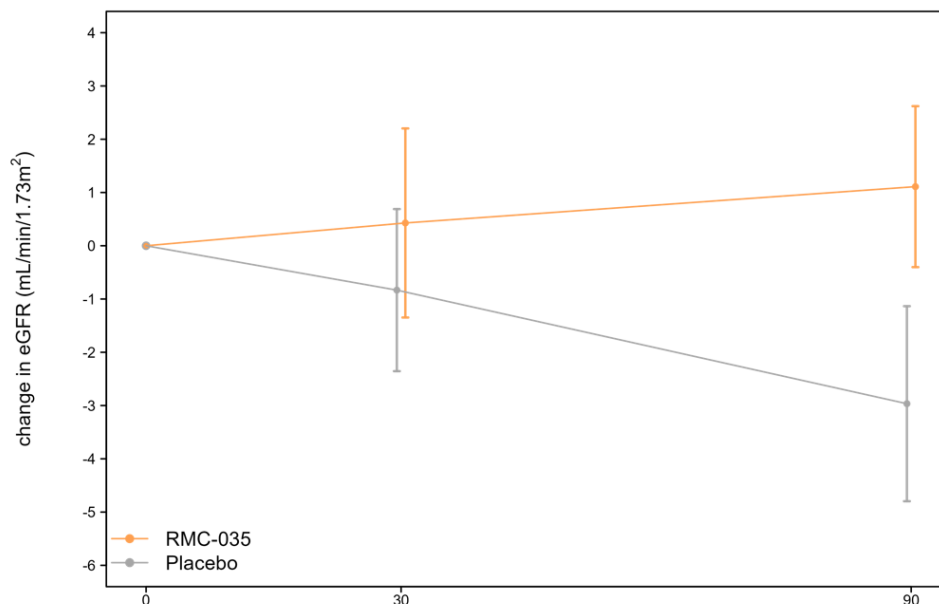
The overall AKI incidence was 50.6% with RMC-035 versus 39.8% with placebo ($p = 0.12$). In patients with baseline eGFR ≥ 60 mL/min/1.73m² at the higher dose, an acute, reversible creatinine rise drove a higher AKI rate; this exposure-related effect met AKI criteria, but confounded true AKI assessment and is not expected at future therapeutic dosing. No excess AKI risk was observed in patients with baseline eGFR < 60 mL/min/1.73m² receiving the lower dose.

For the secondary endpoints, the study demonstrated clinically meaningful benefits on long-term kidney outcomes. At Day 90, treatment with RMC-035 was associated with a favourable difference in eGFR change versus placebo (+4.3 mL/min/1.73m²; $p = 0.06$). The effect was more pronounced in patients with baseline eGFR <60 mL/min/1.73m² (+7.9; $p = 0.05$) compared with those with baseline eGFR ≥60 mL/min/1.73m² (+2.3; $p = 0.41$). In addition, the MAKE90 composite endpoint (death, dialysis, or ≥25% eGFR decline) was significantly reduced with RMC-035 compared with placebo (6.7% versus 15.9%; $p = 0.047$), with consistent effects observed across subgroups.

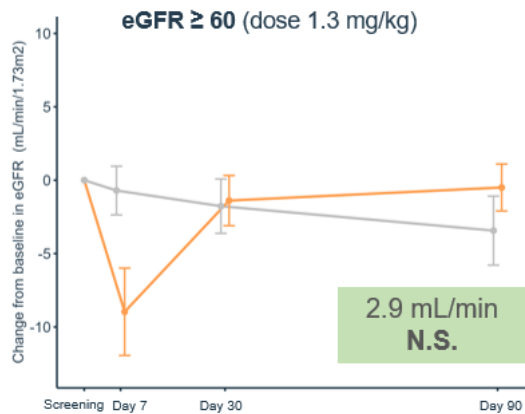
Safety was overall consistent with prior studies. Adverse events reflected the background risk of open-heart surgery patients. Infusion-related reactions occurred more frequently in the RMC-035 arm, were generally mild to moderate, and tended to appear after the fourth or fifth dose.

To put these results into context, a 2018 workshop sponsored by the National Kidney Foundation in association with the FDA and EMA indicated that a treatment effect on eGFR (improvement compared with placebo) of 0.5–1.0 mL/min per year over a three-year period would, with a high probability, lead to a clinically relevant improvement in patients' long-term kidney function and fewer incidences of terminal renal failure.

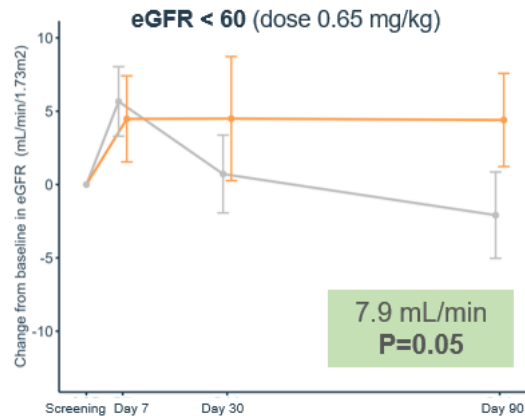
AKITA: Effect on eGFR (kidney function) at 90 days, full population



Source: Company (Study 21-ROS-05 CSR; Error bars indicate mean \pm standard error; eGFR change assessed by a Mixed Model of Repeated Measures)

AKITA: Effect on eGFR (kidney function) at 90 days, split by baseline kidney function (pre-specified)

Efficacy reduced with high dose exceeding exposure threshold for acute creatinine increase (eGFR decline)



Robust efficacy observed with lower dose not exceeding exposure threshold for acute creatinine increase

eGFR
endpoint
met in
subgroup
eGFR < 60

Source: Company (Study 21-ROS-05 CSR; Error bars indicate mean \pm standard error; eGFR change assessed by a Mixed Model of Repeated Measures; N.S., not significant)

AKITA: Secondary endpoint MAKE90 (death, dialysis, $\geq 25\%$ eGFR loss)

eGFR cutoff	RMC-035 (n=89) Rate (90% CI)	Placebo (n=88) Rate (90% CI)		Risk ratio (90% CI)	p-value
10 %	20.2 (13.2-27.2)	28.4 (20.5-36.3)		0.71 (0.46-1.10)	0.200
15 %	15.7 (9.4-22.1)	25.0 (17.4-32.6)		0.64 (0.39-1.05)	0.138
20 %	12.4 (6.6-18.1)	20.5 (13.4-27.5)		0.61 (0.35-1.08)	0.150
25 %	6.7 (2.4-11.1)	15.9 (9.5-22.3)		0.41 (0.19-0.88)	0.047
30 %	4.5 (0.9-8.1)	15.9 (9.5-22.3)		0.30 (0.13-0.70)	0.010

0.25 0.5 1 1.5

Favours RMC-035 Favours placebo

Source: DNB Carnegie (estimates) & company

Financial statements

Profit & loss (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Sales	0	0	0	0	0	0	0	0	263	15
COGS	0	0	0	0	0	0	0	0	0	0
Gross profit	0	0	0	0	0	0	0	0	263	15
Other income & costs	0	0	-40	-82	-115	-115	-100	-130	-48	-10
Share in ass. operations and JV	0	0	0	0	0	0	0	0	0	0
EBITDA	0	0	-40	-82	-115	-115	-100	-130	215	5
Depreciation PPE	0	0	0	0	0	0	0	0	0	0
Depreciation lease assets	0	0	0	0	0	0	0	0	0	0
Amortisation development costs	0	0	0	0	0	0	0	0	0	0
Amortisation other intangibles	0	0	0	0	0	0	0	0	0	0
Impairments / writedowns	0	0	0	0	0	0	0	0	0	0
EBITA	0	0	-40	-82	-115	-115	-100	-130	215	5
Amortization acquisition related	0	0	0	0	0	0	0	0	0	0
Impairment acquisition related	0	0	0	0	0	0	0	0	0	0
EBIT	0	0	-40	-82	-115	-115	-100	-130	215	5
Share in ass. operations and JV	0	0	0	0	0	0	0	0	0	0
Net financial items	0	0	0	0	2	2	4	0	0	0
of which interest income/expenses	0	0	0	0	2	2	4	0	0	0
of which interest on lease liabilities	0	0	0	0	0	0	0	0	0	0
of which other items	0	0	0	0	0	0	0	0	0	0
Pre-tax profit	0	0	-40	-82	-113	-113	-96	-129	216	6
Taxes	0	0	0	0	0	0	0	0	0	0
Post-tax minorities interest	0	0	0	0	0	0	0	0	0	0
Discontinued operations	0	0	0	0	0	0	0	0	0	0
Net profit	0	0	-40	-82	-113	-113	-96	-129	216	6
Adjusted EBITDA	0	0	-40	-82	-115	-115	-100	-130	215	5
Adjusted EBITA	0	0	-40	-82	-115	-115	-100	-130	215	5
Adjusted EBIT	0	0	-40	-82	-115	-115	-100	-130	215	5
Adjusted net profit	0	0	-40	-82	-113	-113	-96	-129	216	6
Sales growth Y/Y	na	na	na	na	na	na	na	na	+chg	-94.3%
EBITDA growth Y/Y	na	na	-chg	-chg	-chg	-chg	+chg	-chg	+chg	-97.5%
EBITA growth Y/Y	na	na	-chg	-chg	-chg	-chg	+chg	-chg	+chg	-97.5%
EBIT growth Y/Y	na	na	-chg	-chg	-chg	-chg	+chg	-chg	+chg	-97.5%
EBITDA margin	nm	nm	nm	nm	nm	nm	nm	nm	81.8%	36.3%
EBITA margin	nm	nm	nm	nm	nm	nm	nm	nm	81.8%	36.3%
EBIT margin	nm	nm	nm	nm	nm	nm	nm	nm	81.8%	36.3%
Tax rate	na	na	na	na	na	na	na	na	na	na
Cash flow (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
EBITDA	0	0	-40	-82	-115	-115	-100	-130	215	5
Paid taxes	0	0	0	0	0	0	0	0	0	0
Change in NWC	0	0	2	4	12	-6	1	-16	13	9
Interests paid	0	0	0	0	0	0	0	0	0	0
Actual lease payments	0	0	0	0	0	0	0	0	0	0
Non cash adjustments	0	0	0	1	1	3	3	0	0	0
Discontinued operations	0	0	0	0	0	0	0	0	0	0
Total operating activities	0	0	-38	-78	-102	-116	-95	-145	229	15
Capex tangible assets	0	0	0	0	0	0	0	0	0	0
Capitalised development costs	0	0	0	0	0	0	0	0	0	0
Capex - other intangible assets	0	0	0	0	0	0	0	0	0	0
Acquisitions/divestments	0	0	0	0	0	0	0	0	0	0
Other non-cash adjustments	0	0	0	0	0	0	0	0	0	0
Total investing activities	0	0	0	0	0	0	0	0	0	0
Dividend paid and received	0	0	0	0	0	0	0	0	0	0
Share issues & buybacks	0	0	75	178	114	0	65	107	0	0
Change in bank debt	0	0	0	0	0	0	0	0	0	0
Other cash flow items	0	0	-1	-1	-1	-1	-2	0	0	0
Total financing activities	0	0	74	176	113	-1	63	107	0	0
Operating cash flow	0	0	-38	-78	-102	-116	-95	-145	229	15
Free cash flow	0	0	-38	-78	-102	-116	-95	-145	229	15
Net cash flow	0	0	36	99	10	-117	-32	-38	229	15
Change in net IB debt	0	0	36	99	12	-117	-30	-38	229	15
Capex / Sales	nm	nm	nm	nm	nm	nm	nm	nm	0.0%	0.0%
NWC / Sales	nm	nm	nm	nm	nm	nm	nm	nm	-2.5%	-116.8%

Source: DNB Carnegie (estimates) & company data

Financial statements, cont.

Balance sheet (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Acquired intangible assets	0	0	0	0	0	0	0	0	0	0
Other fixed intangible assets	0	0	0	0	0	0	0	0	0	0
Capitalised development	0	0	0	0	0	0	0	0	0	0
Tangible assets	0	0	0	0	0	0	0	0	0	0
Lease assets	0	0	0	0	0	0	0	0	0	0
Other IB assets (1)	0	0	0	0	0	0	0	0	0	0
Other non-IB assets	0	0	0	0	0	0	0	0	0	0
Fixed assets	0	0	0	0	0	0	0	0	0	0
Inventories (2)	0	0	0	0	0	0	0	0	0	0
Receivables (2)	0	0	1	1	1	1	0	0	0	0
Prepaid exp. & other NWC items (2)	0	0	0	1	1	1	1	0	5	6
IB current assets (1)	0	0	0	0	0	0	0	0	0	0
Other current assets	0	0	0	0	0	0	0	0	0	0
Cash & cash equivalents (1)	0	0	90	189	201	84	54	16	245	260
Current assets	0	0	91	190	203	85	56	16	250	266
Total assets	0	0	91	190	203	85	56	16	250	266
Shareholders' equity	0	0	80	176	177	67	38	16	232	238
Minorities	0	0	0	0	0	0	0	0	0	0
Other equity	0	0	0	0	0	0	0	0	0	0
Total equity	0	0	80	176	177	67	38	16	232	238
Deferred tax	0	0	0	0	0	0	0	0	0	0
LT IB debt (1)	0	0	0	0	0	0	0	0	0	0
Other IB provisions (1)	0	0	0	0	0	0	0	0	0	0
Lease liabilities	0	0	0	0	0	0	0	0	0	0
Other non-IB liabilities	0	0	5	4	3	2	0	0	0	0
LT liabilities	0	0	5	4	3	2	0	0	0	0
ST IB debt (1)	0	0	0	0	0	0	0	0	0	0
Payables (2)	0	0	3	6	11	5	9	0	8	11
Accrued exp. & other NWC items (2)	0	0	3	4	11	11	8	0	11	17
Other ST non-IB liabilities	0	0	0	0	0	0	0	0	0	0
Liabilities - assets held for sale	0	0	0	0	0	0	0	0	0	0
Current liabilities	0	0	7	11	23	17	18	0	19	28
Total equity and liabilities	0	0	91	190	203	85	56	16	250	266
Net IB debt (=1)	0	0	-90	-189	-201	-84	-54	-16	-245	-260
Net working capital (NWC) (=2)	0	0	-6	-9	-21	-15	-16	0	-13	-22
Capital employed (CE)	0	0	84	179	180	68	38	16	232	238
Capital invested (CI)	0	0	-6	-9	-21	-15	-16	0	-13	-22
Equity / Total assets	nm	nm	87%	92%	88%	78%	68%	99%	93%	89%
Net IB debt / EBITDA	nm	nm	2.2	2.3	1.7	0.7	0.5	0.1	-1.1	-47.5
Per share data (SEK)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Adj. no. of shares in issue YE (m)	0.00	0.00	213.0	343.1	503.1	10.06	12.29	20.17	20.17	20.17
Diluted no. of Shares YE (m)	0.00	0.00	213.0	343.1	503.1	10.06	12.29	20.17	20.17	20.17
EPS	na	na	-0.38	-0.30	-0.27	-0.44	-8.59	-7.96	10.7	0.29
EPS adj.	na	na	-0.38	-0.30	-0.27	-0.44	-8.59	-7.96	10.7	0.29
CEPS	na	na	-0.38	-0.30	-0.27	-0.44	-8.59	-7.96	10.7	0.29
DPS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BVPS	na	na	0.37	0.51	0.35	6.63	3.09	0.79	11.5	11.8
Performance measures	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
ROE	nm	nm	-101.2%	-64.2%	-63.9%	-92.9%	-183.5%	-479.5%	174.2%	2.5%
Adj. ROCE pre-tax	na	na	na	-62.2%	-62.8%	-91.4%	-181.1%	-479.5%	174.2%	2.5%
Adj. ROIC after-tax	na	na	na	1140.0%	777.9%	647.1%	645.4%	na	na	-31.1%
Valuation	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
FCF yield	0.0%	0.0%	-8.6%	-17.6%	-23.1%	-26.3%	-21.5%	-32.9%	51.8%	3.3%
Dividend yield YE	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend payout ratio	na	na	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend + buy backs yield YE	nm	nm	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EV/Sales YE	nm	nm	nm	nm	nm	nm	nm	nm	0.75	12.09
EV/EBITDA YE	nm	nm	neg.	neg.	neg.	neg.	neg.	neg.	0.9	33.3
EV/EBITA YE	nm	nm	neg.	neg.	neg.	neg.	neg.	neg.	0.9	33.3
EV/EBITA adj. YE	nm	nm	neg.	neg.	neg.	neg.	neg.	neg.	0.9	33.3
EV/EBIT YE	nm	nm	neg.	neg.	neg.	neg.	neg.	neg.	0.9	33.3
P/E YE	na	na	nm	nm	nm	nm	nm	nm	2.0	>50
P/E adj. YE	na	na	nm	nm	nm	nm	nm	nm	2.0	>50
P/BV YE	na	na	>50	>50	>50	5.18	5.99	27.69	1.91	1.86
Share price YE (SEK)	28.6	49.2	62.3	63.2	38.2	34.3	18.5	21.9		

Source: DNB Carnegie (estimates) & company data

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**DNB Bank ASA
DNB Carnegie**

Dronning Eufemias gate 30
0191 Oslo | Norway
Telephone: +47 915 04800

www.dnb.no

DNB Carnegie Investment Bank AB

Regeringsgatan 56
103 38 Stockholm | Sweden
Telephone: +46 8 676 88 00

www.dnbcarnegie.se

**DNB Carnegie Investment Bank,
Denmark Branch**

Overgaden neden Vandet 9B PO Box 1935
1414 Copenhagen K | Denmark
Telephone: +45 32 88 02 00

**DNB Bank ASA, Singapore Branch
DNB Carnegie**

1 Wallich Street Downtown Core 06
#30-01, Guoco Tower, Singapore 078881
Telephone: +65 6260 0111

**DNB Carnegie Investment Bank AB,
Finland Branch**

Eteläesplanadi 2 PO Box 36
FI-00131 Helsinki | Finland
Telephone: +358 9 618 71 230

**DNB Bank ASA, London Branch
DNB Carnegie**

The Walbrook Building, 25 Walbrook
London EC4N 8AF | England
Telephone: +44 20 7216 4000

**DNB Carnegie Investment Bank AB,
UK Branch**

Finwell House, 26 Finsbury Square
London EC2A 1DS | England
Telephone: +44 20 7216 4000

DNB Markets, Inc.

30 Hudson Yards
New York, NY 10001 USA
Telephone: +1 212 551 9800

Carnegie, Inc.

20 West 55th St.
New York N.Y. 10019
Telephone: +1 212 262 5800