Guard Therapeutics

Sector: Biotech

A binary case with asymmetric upside

Redeye initiates coverage of Guard Therapeutics, a clinical-stage biotech developing innovative therapies for diseases with high unmet needs, focusing on kidney protection at different events of stress. The company is nearing a decisive readout in its phase IIb POINTER study, evaluating RMC-035 as a renal protective agent during cardiac surgery, expected in Q4 2025e. While facing a binary event, we believe the modest valuation offers an asymmetric risk/reward opportunity.

Phase IIb readout to confirm kidney protection in cardiac surgery…

Guard is developing RMC-035, an endogenous biologic with first-in-class and first-to-market potential, as a renal protection agent for cases of kidney stress, preventing subsequent potential dialysis or need for kidney transplantation – leading to substantial healthcare savings. In the phase IIa AKITA study in cardiac surgery, RMC-035 demonstrated proof of concept (PoC) for renal protection and a favourable safety profile. Based on this and historical data, we estimate a 65% probability of success (PoS) for the POINTER study, which we consider a conservative assumption. Positive results would pave the way for a licensing agreement in 2026e, and we model a risk-adjusted USD650m deal. We project a US accelerated approval in 2028e in cardiac surgery based on interim eGFR data from a subsequent phase III study, broader approvals in 2029e, and peak sales of USD0.8bn in this indication.

…with read across to sepsis and kidney transplantation

RMC-035 also holds potential in sepsis and kidney transplantation, where similar mechanisms of kidney injury are involved. Sepsis represents a substantial potential market (we conservatively estimate peak sales of USD2.7bn, and approval in 2032e), while transplantation qualifies as an orphan indication (USD0.4bn peak sales estimate, approval in 2031e). The rationale for both indications relies on POINTER; failure would leave little to no basis for further development. If POINTER succeeds, RMC-035 can progress from preclinical to phase III in sepsis, offering considerable optionality.

We initiate coverage with a base case of SEK43 per share

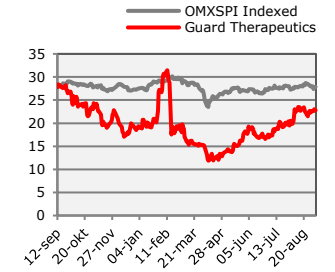
We view the current valuation as modest, with our model indicating the market implicitly assigns just above a 30% PoS to the ongoing trial, a stance we consider overly conservative given the positive AKITA results. Redeye initiates coverage with a base case of SEK43 per share, framing the setup as an asymmetric risk/reward with solid odds of materialising. Our SEK89 bull case assumes a 100% PoS for the phase IIb trial, reflecting the potential value of a positive readout, while our SEK2 bear case captures the downside in the event of an unsuccessful outcome in the trial.

Key Financials (SEKm)	2023	2024	2025e	2026e	2027e
Revenues	0	0	0	123	123
EBITDA	-115	-100	-128	75	83
Net Income	-113	-96	-128	51	58

FAIR VALUE RANGE

BEAR	BASE	BULL
2	43	89

$GUARD VERSUS OMXS30



REDEYE RATING

KEY STATS

Ticker	GUARD
Market	First North
Share Price (SEK)	21,6
Market Cap (SEKm)	435
Net Debt (SEKm)	-100
Free Float (%)	65%
Avg. daily volume ('000)	28,4

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Investment Case

Attractive risk/reward situation

Guard's investment case hinges on the phase IIb POINTER trial with lead candidate RMC-035 for kidney protection following open-heart surgery. The readout, expected in Q4 2025e, is a key trigger and will determine the path forward for RMC-035 and the company. A positive result would not only confirm the RMC-035's potential in cardiac surgery but also open doors to related areas such as renal protection in sepsis patients, while bolstering the case for the company's preclinical GTX platform targeting CKD conditions. However, this is a double-edged sword: if POINTER fails, it would cast serious doubts on the company's other projects, including the GTX platform, leaving Guard's future highly uncertain.

Should the POINTER trial deliver positive results, we believe Guard could secure a substantial licensing agreement in 2026e covering the entire RMC-035 programme. Such a deal would leverage the optionality across multiple indications: cardiac surgery, kidney transplantation, and sepsis.

Our model suggests the market implicitly assigns just above 30% PoS to the POINTER trial, which we consider overly cautious given the encouraging results in the phase IIa AKITA study. Furthermore, industry PoS for phase transition from phase II to phase III stands at 45%, meaning the market not only implicitly disregards the AKITA results, but also sets a large discount to historical success rates. Although trial outcomes are inherently uncertain, we consider Guard to represent a favourable risk-adjusted investment opportunity.

Supportive clinical data

The placebo-controlled AKITA study (n=177) evaluated RMC-035 in patients undergoing open-heart surgery and provided early PoC data on renal protection. The trial demonstrated a statistically significant and clinically meaningful improvement in kidney function, with an average eGFR improvement of 4.3 mL/min compared to placebo in the full population. In the pre-defined subgroup of patients with existing CKD, the benefit was even greater, with an improvement of 7.9 mL/min. Furthermore, RMC-035 reduced the proportion of patients experiencing Major Adverse Kidney Events at day 90 (MAKE90) by 59% versus placebo (p=0,047). As the FDA has indicated that MAKE90 is an acceptable primary endpoint in phase III, where a 20% risk reduction would be considered sufficient for approval, these results provide supportive evidence for the ongoing POINTER study.

The company is financed to summer 2026e, covering the upcoming trial readout and beyond. Should the study succeed, we expect the company to pursue a small, low-discount directed share issue of SEK40m to strengthen its position ahead of partnership discussions, continue preparing for a phase III study and further extend its runway.

Challenge I: Succeeding with clinical development

As with all pre-revenue biotech companies, Guard faces significant development risk, and we estimate a 65% PoS in the POINTER study.

Challenge II: Securing a licensing deal

Guard's strategy is to secure a partner to finance the continued clinical development of RMC-035, including pivotal phase III studies. While the company will carry out preparatory work on its own, the ability to attract a partner will be critical for advancing the programme into late-stage development and realising its full commercial potential.

DCF supports upside

Our valuation derives from a risk-adjusted 2025-2042 DCF model with a 16% WACC. The SEK43 base case assumes a POINTER PoS of 65%, a global 50% risk-adjusted USD650 deal (covering all RMC-035 indications) in 2026e, launch 2028e and peak sales potential of USD0.8bn in cardiac surgery. Our SEK89 bull case sets the phase II PoS to 100%, reflecting the value of Guard following a positive readout. Conversely, the SEK2 bear case assumes a negative readout, with no clinical signal in any subgroup, and a discontinuation of development spanning over all projects.

Sum-of-the-parts

Project	Indication	Phase	Est. Launch	LoA	Peak sales (USDm)	Deal size (USDm)	rNPV (SEKm)
RMC-035	Heart surgery	II	2028	29%	771	650*	**747**
RMC-035	Kidney transplant	I	2031	17%	442		**95**
RMC-035	Sepsis	Preclinical	2032	6%	2701		**177**
Technology value (SEKm)							**1 019**
Net cash (SEKm)							**100**
Shared costs (SEKm)							**-161**
Equity value (SEKm)							**958**
Shares outstanding (million)							**20**
Diluted shares outstanding (million)							**22**
Equity value per share (SEK)							**43**

*Source: Redeye research. *Deal assigned to lead programme for simplicity*

Counter Points

One-trick pony characteristic

The company could be seen as a one-trick pony given its high dependency on RMC-035 and the spillover effect from RMC-035 to the GTX platform. There is a significant risk associated with the upcoming phase IIb trial. If the treatment fails to replicate the promising signs seen in the AKITA study, the candidate and the company face a grim outlook.

Dependency on partners and investors

Guard is a pre-revenue and pre-market company without any established marketing or sales channels. Therefore, it relies heavily on finding a licensing partner for pivotal studies. If no out-licensing is made, the last resort could be for Guard to conduct a phase III study without a partner, which would require around SEK0.5bn. This could lead to dilutive and rebated rights issues in the future.

Catalysts

POINTER readout

The POINTER phase IIb study readout, expected in Q4 2025e, is the primary catalyst for Guard's share performance. Full study data is anticipated in Q1 2026e, which could also serve as a trigger.

Anticipated impact: Major

Time horizon: 1-4 months

Regulatory feedback

If POINTER delivers positive topline data, subsequent triggers could include a potential breakthrough therapy designation (BTD) from the FDA, as well as news regarding an End-of-Phase-2 (EoP2) meeting with the regulatory agency.

Anticipated impact: Moderate

Time horizon: 3-6 months

Out-licensing deal

A successful study readout would significantly improve Guard's chances of securing an out-licensing agreement for RMD-035 or selling the project in a trade sale. We estimate a USD650m deal with an upfront of USD40m and royalties of 15%.

Anticipated impact: Major

Time horizon: 5-12 months

Contents

Company introduction

Background description

Guard Therapeutics is a Swedish biotech company founded in 2008 by researchers from Lund University. Headquartered in Stockholm, the company has a small and focused team of six employees and a small number of permanent consultants.

The company is dedicated to developing innovative therapies for diseases with a significant unmet need, mainly focusing on various forms of kidney disease. Its leading drug candidate, RMC-035, is a biologic derived from a modified form of the body's natural protein alpha-1-microglobulin (A1M), which helps protect against oxidative stress, heme-driven injury, and subsequent tissue damage. The FDA has granted RMC-035 Fast Track Designation to help reduce the risk of permanent kidney failure, the need for dialysis, or death following open-heart surgery in patients at high risk of acute kidney injury (AKI). RMC-035 is currently being tested in a phase IIb trial for this purpose, where no approved renal protection therapies are available. This candidate has multiple potential uses, including in sepsis and kidney transplantation. The rationale for expanding into these areas is based on the fact that the kidneys undergo similar types of damage in these conditions as in open-heart surgery, together with the broad endogenous mechanism of RMC-035, which has demonstrated efficacy in heart surgery.

The company was founded in 2008 under the name Preelumina AB with the goal of developing new treatments and diagnostics for preeclampsia. Two years later, it changed its name to A1M Pharma and subsequently listed its shares on the Spotlight Stock Market (formerly Aktietorget). Since 2018, the strategic focus has been on kidney injury related to open-heart surgery, with initiation of the clinical programme in 2019.

Alongside RMC-035, the company is developing a preclinical platform based on GTX peptides, aimed at chronic kidney conditions and orphan indications such as Alport syndrome. Unlike RMC-035, which is derived from the full-length A1M protein, the GTX peptides are designed to replicate a smaller protein segment. This enables them to be formulated as subcutaneous injections instead of requiring intravenous administration, making them more suitable for at-home use in chronic conditions.

Selected company highlights

Year	Event
2020	
	Receives Ethical Approval for Final Part of Phase Ia Study with ROSgard (RMC-035)
	Positive Top-Line Results from Phase 1a Clinical Study with RMC-035
	SEK66.8m equity issue
	Positive Top-Line Results from Phase I Study with RMC-035 in Patients with Renal Impairment
	Completes Successful Pre-IND Meeting with the FDA regarding RMC-035 in open-heart surgery
2021	
	First Patient Dosed in Phase Ib Study with RMC-035
	Receives U.S. Patent Approval for RMC-035
	Granted European Patent for RMC-035
	Positive Results in Phase Ib study with RMC-035
	SEK180m equity issue
2022	
	First Patient Dosed in Phase IIa study AKITA with RMC-035 in open-heart surgery
	Approval to Initiate Phase Ib Study with RMC-035 in Kidney Transplantation (KTx)
	First Patient Dosed in Phase Ib Study with RMC-035 in KTx
	Receives IND Approval from FDA for RMC-035 in open-heart surgery
	Granted FDA Fast Track Designation for RMC-035 in open-heart surgery
2023	
	Receives Patent Approval for RMC-035 in China
	Positive Results in Phase Ib study in KTx
	Terminates Phase IIa AKITA Trial
	Completes Last Patient Visit in Phase IIa AKITA
2024	
	Receives Regulatory Approval for Phase IIb POINTER Study in open-heart surgery
	Announces Directed Share Issue of SEK60m
	First Patient Dosed in Guard Therapeutics' Phase IIb POINTER
2025	
	Positive Outcomes from Safety Reviews in Phase IIb POINTER Study
	SEK150m equity issue
	Phase IIb study POINTER fully recruited

Source: Guard Therapeutics (data), Redeye research (illustration)

People and ownership

Management and board

Guard is led by a skilled team with extensive experience in clinical development and the biotech sector. Tobias Agervald brings significant expertise in nephrology and clinical drug development, having previously held key roles in clinical development, including Senior Medical Director at Astellas Pharma Global Clinical Development. The company benefits from a management team with diverse experience across the pharmaceutical and biotech industries. Guard's board of directors adds additional strength, with members bringing deep knowledge in drug development, business strategy, and financial management. Many leadership team members have held prominent roles within big pharma, while the chairman and largest shareholder have had central positions at EQT. In combination, we believe this indicates a strong network that could facilitate business development discussions.

The company has demonstrated impressive momentum in its development, progressing rapidly from an initial pre-IND meeting with the FDA in 2021 to potentially being ready for a phase III trial as early as next year. The company has exceeded its own projections, with notable achievements such as the POINTER study's recruitment being completed four months ahead of the initial schedule. This track record highlights Guard's efficiency and ability to execute its plans.

Management and board of directors

Name	Position	Shares	2023 Options	2025 Options
Tobias Agervald	CEO			
	Born in 1976. MD, PhD and associate professor with international experience in nephrology and drug development. Former Senior Medical Director at Astellas Pharma. CEO of Guard Therapeutics since 2019.	33 009	9 450 000	643 647
Karin Botha	Chief Financial Officer			
	Born in 1973. MSc in Business Administration and Economics with more than 20 years of experience in senior finance roles at global pharmaceutical companies including SmithKline Beecham, GSK, Novartis and Sandoz. CFO of Guard Therapeutics since 2020.	5 121	2 520 000	154 475
Thorbjörn Larsson	Head of Chemistry, Manufacturing and Control			
	Born in 1960. BSc in Chemistry with more than 30 years of experience in pharmaceutical development across multiple roles and phases. Former Director of Pharmaceutical Development at Medivir AB and Director of Commercial Production at Aprea Therapeutics AB. Head of CMC at Guard Therapeutics since 2022.	856	1 680 000	115 857
Peter Gilmour	Head of Preclinical Science			
	Born in 1970. PhD in Toxicology with more than 25 years of experience in pharmaceutical discovery, clinical development and drug repurposing. Former pharmacologist at AstraZeneca and Astellas Pharma. Head of Preclinical Science at Guard Therapeutics since 2020.	3 934	1 344 000	77 237
Sara Thuresson	Head of Clinical Operations			
	Born in 1976. MSc in Biomedicine with more than 15 years of experience in clinical drug development and multinational trial management. Former Clinical Operations Director at Oncopeptides. Head of Clinical Operations at Guard Therapeutics since 2021.	3 510	2 100 000	115 857
Michael Reusch	Chief Revenue Officer			
	Born in 1960. MD, pharmacist and physician with more than 30 years of global clinical drug development experience. Former Senior Medical Director at Astellas Pharma. CMO of Guard Therapeutics since 2022.	7 869	2 100 000	128 730

Name	Position	Shares	2023 Options	2025 Options
Johan Bygge	Chairman of the board			
	Born in 1956. MSc in Economics from Stockholm School of Economics with extensive senior executive and board experience, including roles as COO EQT, CFO Investor AB and Deputy CEO Electrolux. Chairman of the board of Guard Therapeutics since 2021.	11 314		
Khatereh Ahmadi	Director			
	PhD in Biochemistry from King's College London and MBA, with more than 20 years of international experience in the pharmaceutical industry. Currently Head of Search and Evaluation Business Development Europe & Middle East at MSD. Former co-founder and CEO of reViral Ltd and senior business development roles at Piramed Ltd (acquired by Roche). Board member of Guard Therapeutics since 2024.			
Göran Forsberg	Director			
	Born in 1963. PhD in Biochemistry and Associate Professor with more than 30 years of experience in pharmaceutical development, business development and investor relations. Former CEO of Cantargia AB (2014–2025) and business development manager at Active Biotech. Board member of Guard Therapeutics since 2019.	5 161		
Hege Hellström	Director			
	Born in 1965. BSc in Medical Laboratory Science with over 30 years of experience in sales, marketing and business management in the pharmaceutical industry, with particular expertise in kidney medicine. Former senior executive at SOBI, Sanofi, Genzyme and Baxter. Currently Chief Commercial Officer at Advicenne. Board member of Guard Therapeutics since 2024.	6 974		
Johannes Hulthe	Director			
	Born in 1970. PhD and MSc in Economics with more than 17 years of pharmaceutical industry experience. Former lecturer in cardiovascular prevention at Sahlgrenska University Hospital and senior clinical drug development roles at AstraZeneca. Co-founder and CEO of Antaros Medical AB. Board member of Guard Therapeutics since 2019.	13 196		
Fredrik Lehmann	Director			
	Born in 1976. PhD in Medicinal Chemistry and Executive MBA with 20 years of experience in the life science sector, including senior roles in research, CMC and management at companies such as Pharmacia, Biovitrum, Recipharm and Oncopeptides. Founder of several biotech companies. Board member of Guard Therapeutics since 2022.			

Source: Guard Therapeutics (data), Redeye research (illustration). Option programme 2023: 0.02 shares/option; 2025: 1 share/option

Business strategy

Guard adopts an out-licensing/M&A strategy and does not intend to undertake further clinical trials in its main scenario. We view this as the most shareholder-friendly approach, as it could, if successful, provide the company with non-dilutive funding. A potential transaction may take various forms: out-licensing of RMC-035 for a single indication, multiple indications, or — what we consider the most likely scenario — a broader agreement covering the entire RMC-035 programme. Such a deal could be arranged on a global or regional scale. There is also the possibility of a trade sale involving the acquisition of the RMC-035 project, the preclinical GTX-platform, or a buyout of the company by a strategic partner.

Competitive advantage

The company's competitive advantage lies in its distinctive mode of action and first-in-class properties. First-in-class refers to a drug that introduces a novel mechanism of action, representing the first therapy of its kind to receive approval. RMC-035 is the only candidate with positive PoC data on renal protection during open-heart surgery, offering a clear differentiation in a field where other programmes are either at earlier development stages or have not demonstrated efficacy in this setting. This first-mover advantage enhances Guard's standing and boosts the chances of attracting a development partner or selling the project. The candidate has been granted Fast Track designation by the FDA in cardiac surgery, a status designed to expedite the development and review of drugs addressing serious conditions with unmet medical needs.

Furthermore, RMC-035 benefits from a composition of matter patent that remains valid until 2037. These patents are the strongest form of intellectual property protection as they protect the active substance itself, regardless of how it is formulated or used therapeutically. The patent protection for RMC-035 has been granted across all key markets, including the US, the EU, Japan, and China.

Beyond patents, RMC-035 will also be protected by regulatory exclusivity if approved. In the US, new biologics receive 12 years of market exclusivity under the Biologics Price Competition and Innovation Act (BPCIA), during which biosimilars cannot be approved. The EU offers a similar system, with 10 years of data and market exclusivity (8+2 years, plus the potential for a 1-year extension for a significant new indication). Japan also provides comparable protection, generally granting an 8-year-long "re-examination" period for new drugs.

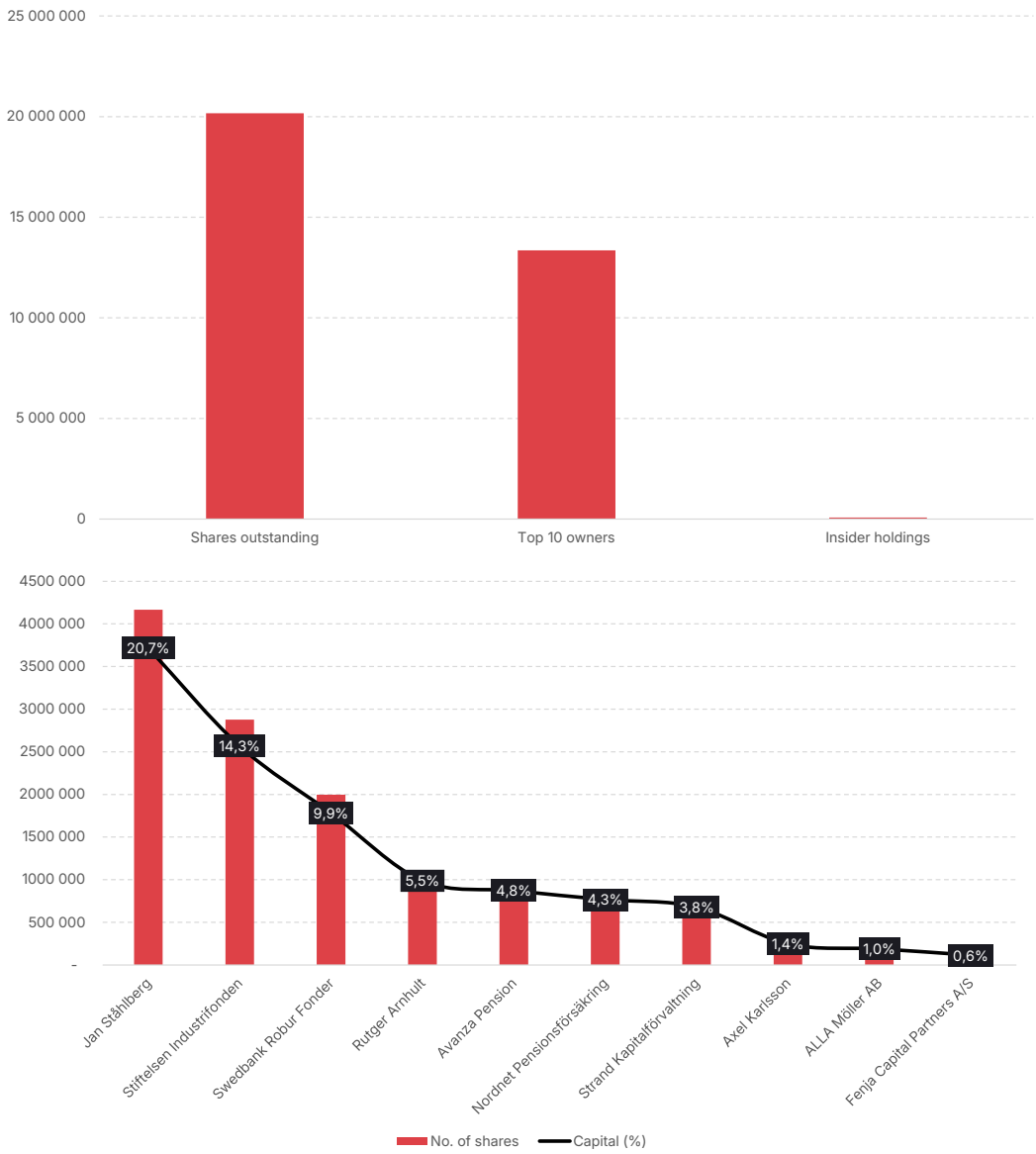
Value proposition

Kidney injury during open-heart surgery can have serious downstream consequences, including the development of chronic kidney disease (CKD) and, in severe cases, progression to end-stage renal disease (ESRD), which may require dialysis or kidney transplantation. These complications are associated with enormous healthcare costs; as a matter of fact, CKD, which may progress to ESRD, accounts for 7% of Medicare expenditures despite affecting only 1% of the population (USRDS, 2024). RMC-035 has the potential to prevent these outcomes, shortening hospital stays, reducing the need for dialysis or organ transplantation, and thereby enabling substantial healthcare savings. For patients, this translates into a lower risk of long-term kidney complications and an improved quality of life.

Ownership

The company has a robust ownership structure compared to other Swedish-listed biotech firms in the clinical stage. The three largest shareholders, who have been very supportive, are EQT founder Jan Ståhlberg, Stiftelsen Industrifonden, and Swedbank Robur Fonder. Insider ownership is low, which is common for biotech companies in clinical phases. Nevertheless, the management team is motivated through stock option programmes, ensuring their interests align with those of the investors.

Shareholder structure

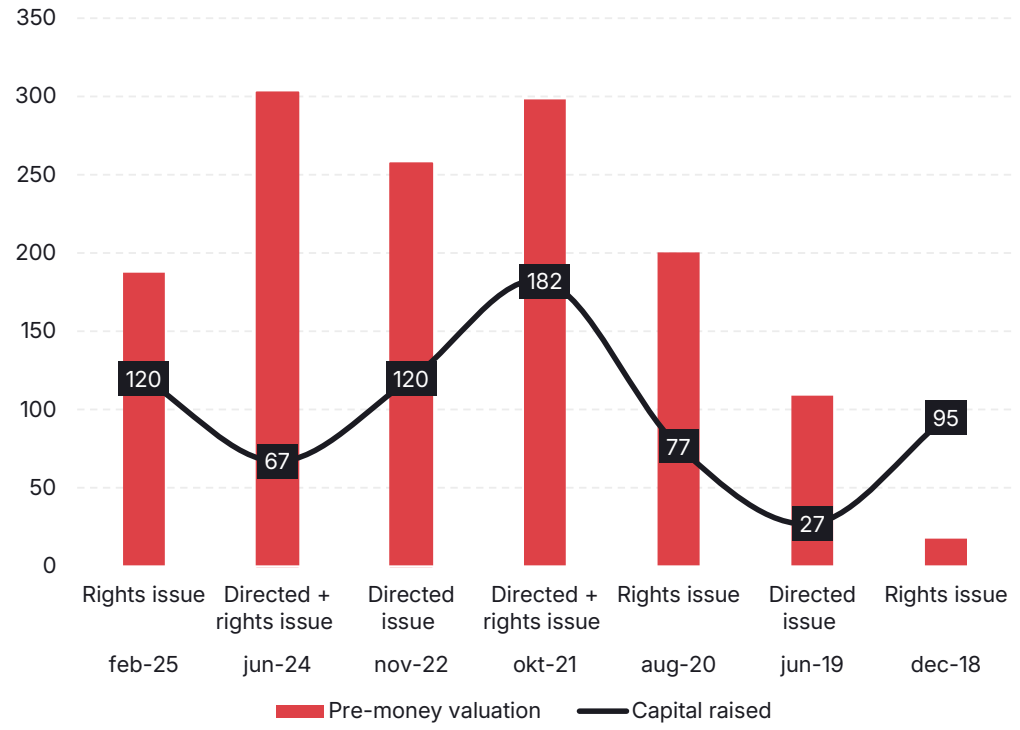


Source: Holdings (2025-09-10), Guard Therapeutics

Financing overview

Guard has raised capital several times the last seven years, in line with the expectations and typical funding needs of a biotech company advancing a therapy through clinical development. These transactions have occurred at pre-money valuations ranging from SEK18m to SEK303m, playing a key role in advancing RMC-035 to its current stage. The most recent capital raise, announced in February 2025, was conducted at a pre-money valuation of SEK187m.

Financing history (SEKm)



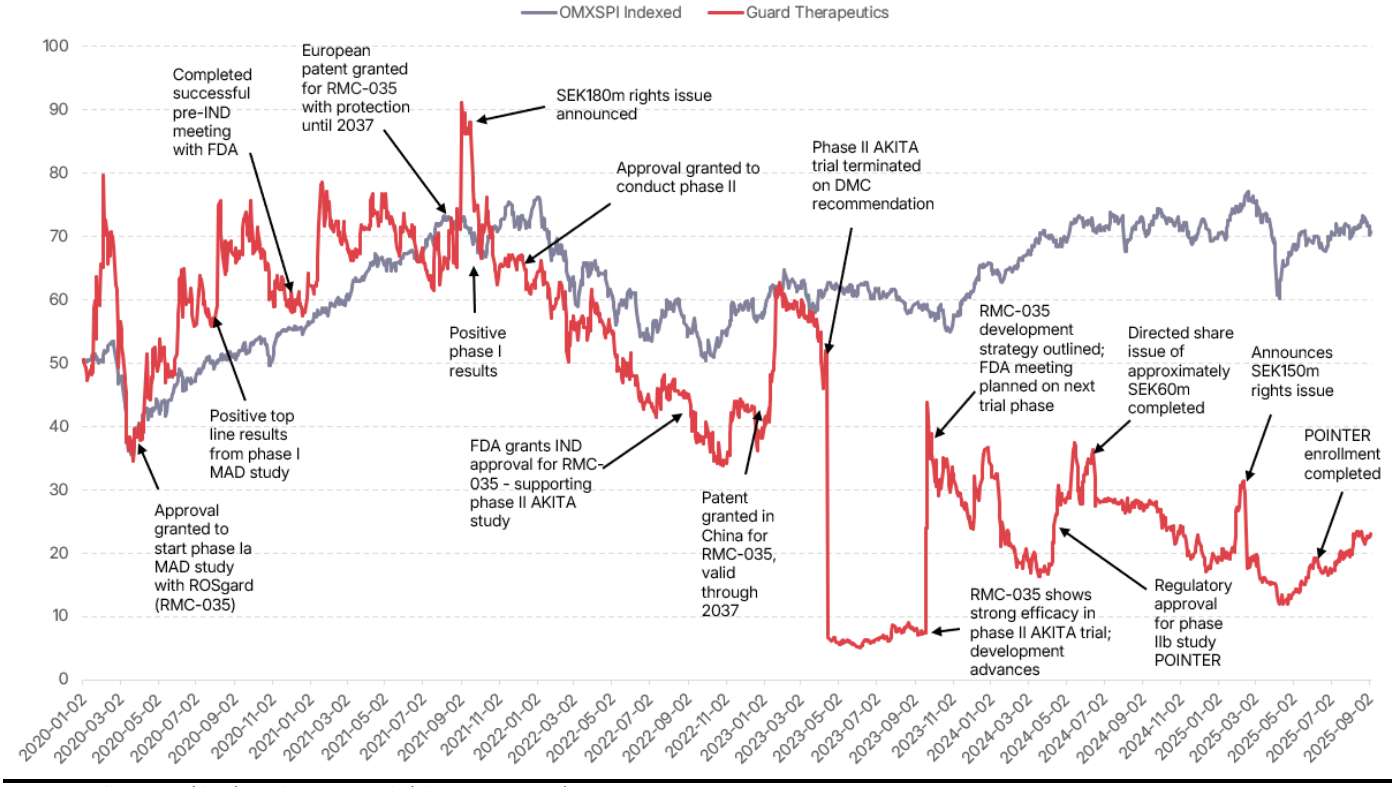
Source: Guard Therapeutics (data), Redeye research (chart structuring, calculations)

From 2018 to 2021, Guard's financing rounds showed a clear correlation between value creation and development progress, with the pre-money valuation rising from SEK18m to around SEK298m during the larger rights issue in 2021. However, this trend has since reversed, showing an inverse relationship between clinical development progress and pre-money valuation. This seems counterintuitive, considering the clinical data for RMC-035 and the company's overall advancements. Normally, such a negative trend would suggest poor data quality or market concerns about a suboptimal funding solution—neither of which we believe applies to Guard. We see this development as mainly driven by two key factors. First, the widespread negative market sentiment towards biotech has heavily impacted valuations across the sector. Second, the market does not fully understand the reasons behind the AKITA study's early halt. While Guard appears to have effectively addressed this in POINTER, investors remain overly cautious.

Share price discussion

Guard's stock price has followed a typical biotechnology pattern, exhibiting a high beta relative to the broader Stockholm OMX index (OMXSPI). The stock has reacted positively to news related to clinical development and patent milestones, while it has shown negative responses to capital raise announcements. A notable outlier was the sharp decline following the early termination of the AKITA study due to a safety signal for the highest dose, which has since been understood to be non-serious and avoidable. As the ongoing POINTER study has passed two planned safety reviews with positive outcomes, it appears this has been effectively addressed. The stock saw a strong surge when positive data from the AKITA study was released. Since late spring 2025, the stock has steadily climbed, driven by the faster-than-expected progress of the POINTER trial, growing investor optimism as expectations rise for the upcoming POINTER data readout in Q4 2025e, and supported by the company's strengthened financial position.

Share price development since 2020



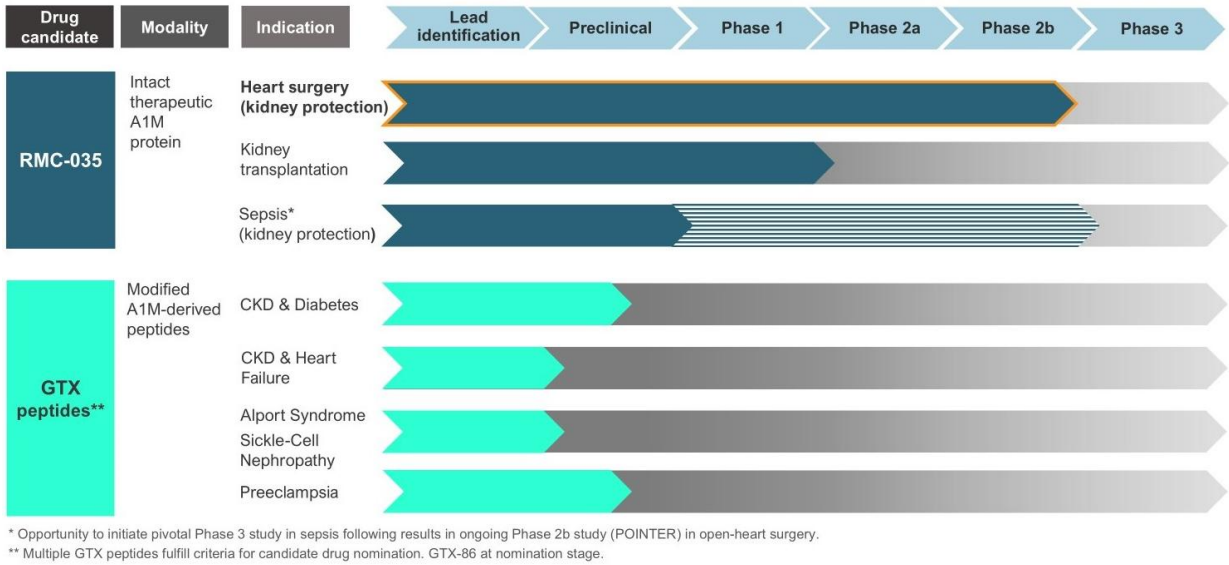
Source: Millistream (data), Redeye research (chart structuring)

The illustration above focuses on the company's lead programme, RMC-035, for kidney protection following open-heart surgery, and the text bubbles refer to this indication unless otherwise specified.

Pipeline

The company's pipeline includes RMC-035 and the GTX-platform. The lead asset, RMC-035, is a full-length therapeutic A1M protein currently being evaluated in an ongoing phase IIb study for renal protection in patients undergoing cardiac surgery. The candidate is also being developed for kidney protection in kidney transplantation and sepsis. Additional candidates are based on the GTX platform, a preclinical programme involving modified A1M-derived peptides that are being developed for various forms of CKD—for example, late-stage CKD due to heart failure and diabetes, as well as orphan indications such as Alport syndrome and sickle cell nephropathy.

Pipeline overview



Source: Guard Therapeutics

In this report, we concentrate on the company's main project, following a brief introduction to kidney diseases and AKI. We also address the potential of RMC-035 in kidney transplantation and sepsis, as well as provide a concise overview of the GTX platform.

Overview – kidney disease and acute kidney injury

Kidney disease presents a major global health challenge, including both acute and chronic types that cause significant morbidity, mortality, and financial burden. According to Chadban et al., the annual direct costs of diagnosed CKD and kidney replacement therapy in 31 developed countries—primarily the largest ones with available data—are projected to increase by 9.3%, from USD372 billion in 2022 to USD407 billion in 2027. These figures do not account for lost income due to reduced working hours, time off for treatment or caregiving, or the risk of premature death.

AKI is characterised by a sudden decline in kidney function within hours to days, causing the kidneys to lose their ability to effectively filter waste products, maintain fluid balance, and regulate electrolytes and acid-base levels. The condition, often triggered by events such as cardiac surgery, sepsis, or transplantation, was long regarded as a temporary complication. Today, science increasingly recognises its lasting effects, including a strong link to CKD and the need for dialysis or transplantation.

Despite growing awareness, there are still no approved therapies that directly protect the kidneys — highlighting a significant unmet medical need and a promising market opportunity.

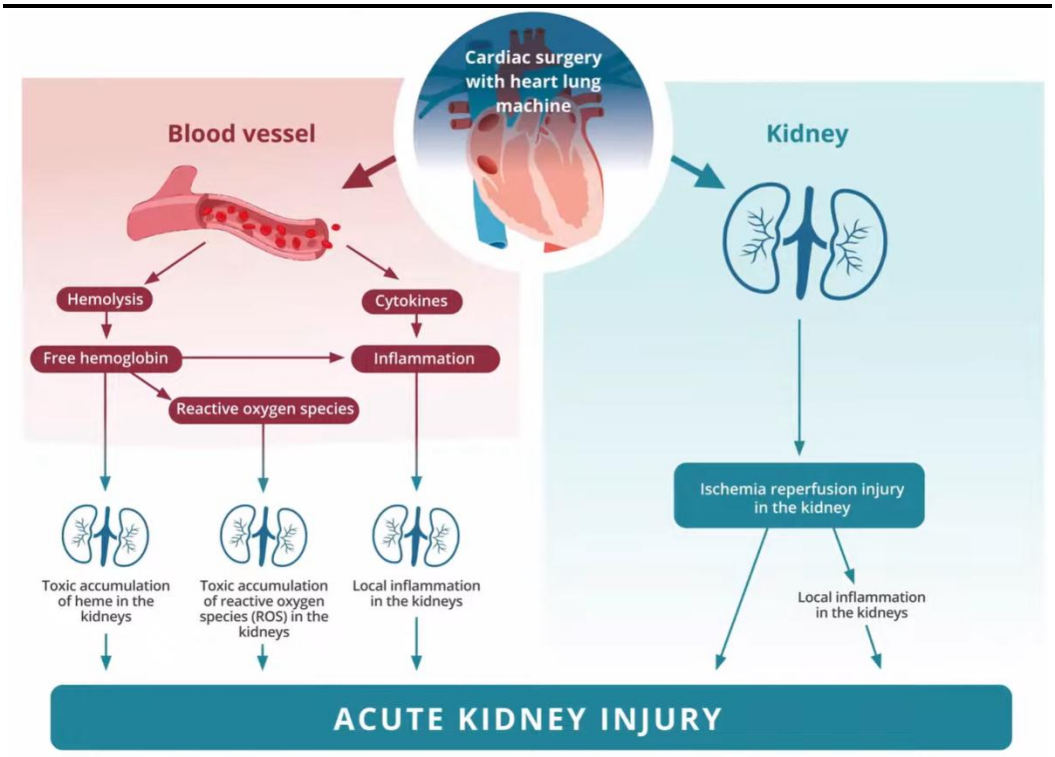
Definition of AKI

AKI can be classified using various systems, with the KDIGO (Kidney Disease: Improving Global Outcomes) criteria being the most commonly used today. This system categorises AKI severity based on changes in serum creatinine (SCr) and urine output. SCr is a waste product produced by muscle metabolism and filtered out of the blood by the kidneys. It is frequently utilised as a marker of kidney function, as elevated SCr levels indicate impaired glomerular filtration.

Kidney damage after open-heart surgery

Open-heart surgery initiates a series of injury processes that can result in AKI. As shown in the image below, cardiopulmonary bypass (i.e., the use of a heart-lung machine during the procedure) contributes to hemolysis, oxidative stress, ischemia–reperfusion injury, and secondary inflammation. These mechanisms operate in parallel and synergistically, potentially leading to both acute and permanent loss of kidney function.

Mechanisms of AKI in cardiac surgery



Source: Guard Therapeutics

Occurrence of cardiac surgery-associated AKI

Historically, establishing an accurate ratio estimate for cardiac surgery-associated AKI (CSA-AKI) has been challenging due to differing diagnostic criteria across studies, variations in surgical techniques, and heterogeneity among patient populations. Reported rates vary widely, with some analyses indicating an incidence from 5% to as high as 43% (Scurt et al., 2024). In enriched patient populations, such as those with pre-operative CKD, the incidence of AKI typically exceeds 50% (McBride et al., 2019).

A large prospective observational study pooling data from 30 countries reported that 25.9% of cardiac surgery patients worldwide developed CSA-AKI (Kamla et al., 2025). Additionally, secondary analyses have shown that approximately 13% of patients experience prolonged CSA-AKI—lasting more than 7 days but less than 3 months—a condition referred to as acute kidney disease (AKD). AKD represents a subacute phase of kidney dysfunction distinct from both AKI and CKD, the latter defined as persistent kidney damage or reduced glomerular filtration rate for at least three months.

Cardiac surgery has been identified as the second most common cause of CSA-AKI in intensive care units, surpassed only by sepsis.

Short-term clinical consequences of CSA-AKI

The short-term effect of CSA-AKI is often reversible but substantial. Patients who develop CSA-AKI are significantly more likely to require longer intensive care stays, prolonged mechanical ventilation, and renal replacement therapy. Machado et al. (2021) showed that patients with CSA-AKI had a 30-day mortality rate of 12.6%, compared to 1.4% in those without. These findings are further supported by Djordjević et al. (2021), who reported a three- to eightfold increase in perioperative mortality among patients with CSA-AKI. Besides the impact on patients, CSA-AKI also imposes a significant economic burden on healthcare systems due to the need for more intensive treatment and longer hospital stays.

Long-term outcomes of CSA-AKI

Beyond the immediate postoperative period, CSA-AKI has lasting effects on kidney health and overall outlook. A study by Horne et al. (2017) showed that after three years of follow-up, 24.6% of patients who experienced CSA-AKI developed CKD, compared with just 7.5% among those without prior CSA-AKI ($p<0.001$). CKD is linked to serious complications, mainly cardiovascular disease and kidney failure.

Expanding on the consequences, one of the most serious clinical outcomes of CSA-AKI is the need for life-saving kidney replacement therapy (KRT), which occurs in approximately 2–5% of affected patients (Kamla et al., 2025). KRT, including dialysis, brings additional challenges that often persist well beyond the acute phase and contribute to substantially higher healthcare costs.

Even when kidney function recovered within three days, CSA-AKI increased the risk of developing acute kidney disease (AKD) and CKD. Patients with early recovery had more than three times the odds of AKD or CKD compared to those without CSA-AKI (Cho et al., 2021). If CSA-AKI persisted, the risks were much higher—over 12 times greater for AKD and more than 10 times greater for CKD. CKD, which may progress to ESRD, accounts for 7% of Medicare expenditures despite affecting only 1% of the population (USRDS, 2024).

A simplifying analogy

Renowned nephrologist Dr. David Goldsmith has notably compared CSA-AKI to a concussion. This analogy highlights how, although initial symptoms may resolve, the organ might not return to its baseline state. Similar to a concussion, knocks can cause irreversible damage that becomes apparent later, such as dementia. An insult leaves the kidneys more vulnerable and gradually speeds up the decline in renal function over time. This deterioration is especially concerning because kidney function naturally decreases with age.

Summary – Impact of CSA-AKI

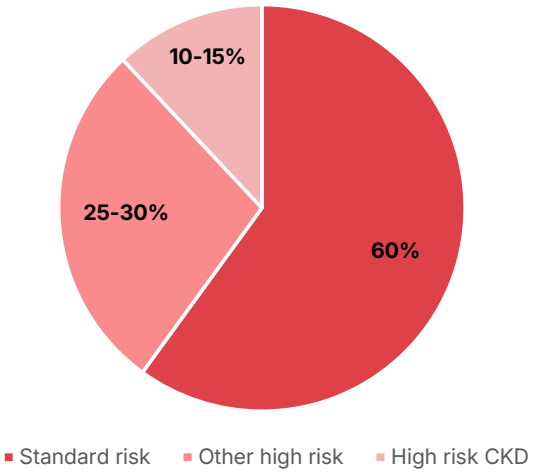
CSA-AKI results in notably worse short-term outcomes, including higher mortality rates, prolonged ICU stays, and increased dialysis requirements—raising healthcare costs. In the long term, it significantly elevates the risk of CKD and heart failure, even in cases of early recovery. With up to ten times the risk of CKD and a high progression to kidney failure (ESRD), CSA-AKI poses a major clinical and economic challenge, emphasising the need for effective therapies to protect the kidneys.

Regarding AKI as an endpoint, changes in SCr that meet AKI definitions can provide supportive evidence but are insufficient for approval. Regulators focus on longer-term outcomes like kidney function, measured by estimated Glomerular Filtration Rate (eGFR), and MAKE90. Severe AKI requiring temporary dialysis is, however, recognised as an important outcome and is therefore included in the MAKE90 composite.

Patient groups with increased risk of developing CSA-AKI

Patients with pre-operative CKD, diabetes mellitus, advanced age (67+), or prolonged cardiopulmonary bypass are at particularly high risk of developing CSA-AKI, with published studies reporting incidence rates of up to 50% (McBride et al., 2019). These patients typically have reduced renal reserve and impaired microcirculation, making them more vulnerable to oxidative stress and ischemia-reperfusion injury. As RMC-035 directly addresses the key injury mechanisms—neutralising free heme proteins, reducing reactive oxygen species, and mitigating inflammation—the treatment effect is expected to be most pronounced in this group. Guard has therefore prioritised these high-risk patients, who are estimated to represent around 40% of the overall cardiac surgery population and constitute the company's addressable market in this indication. Determining an exact figure for high-risk patients is challenging, as there is significant variability in how high-risk is defined across studies and clinical guidelines. Given these differences in definitions, we consider Guard's estimate the most appropriate, as it is based on clear criteria informed by large databases of cardiac surgery patients. Below follows a chart showcasing the distribution of patients' risk of developing AKI after cardiac surgery.

Risk distribution among cardiac surgery patients



Source: Redeye research

Patients with pre-operative CKD – a key risk group targeted by RMC-035

Patients with pre-operative CKD make up about one-third of high-risk patients, or roughly 10–15% of all patients. These individuals are at high risk of developing CSA-AKI and face the most significant lifetime risk of progressing to advanced CKD and ESRD, hence they constitute a key-risk group for RMC-035. While it cannot be ruled out that a future phase III study may focus solely on CKD patients, we do not see this as the primary plan. Ultimately, the outcome of the phase IIb POINTER study will determine this decision. The targeted patient population is discussed in more detail later in this report.

Ageing populations and increasing prevalence are expected to drive significant growth in the burden of CKD in the coming decades. Unlike cardiovascular disease, stroke, and respiratory disease, CKD mortality has been increasing, and currently, kidney disease is the third fastest-growing cause of death worldwide. Furthermore, CKD is projected to become the fifth leading cause of years of life lost (YLL) globally by 2040 and is expected to surpass diabetes as a cause of YLL by then.

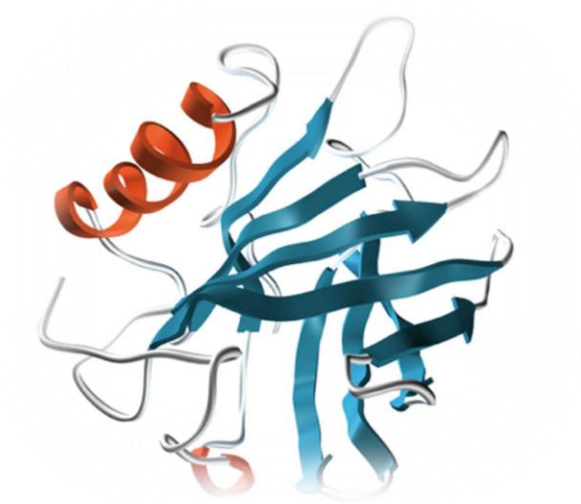
Therapeutic rationale for RMC-035

RMC-035 targets key drivers of CSA-AKI, aiming to safeguard the kidneys. The drug candidate is based on alpha-1-microglobulin (A1M), a native human protein with a natural tissue-protective function.

A1M – Natural. Versatile. Essential.

Alpha-1-microglobulin (A1M) is a naturally occurring, endogenous protein mainly produced in the liver and secreted to almost all organs and cells throughout the body. It features a central binding pocket that binds small, hydrophobic molecules. A key aspect of A1M's function is the presence of a free thiol group at cysteine-34. This thiol group acts as a scavenger of reactive oxygen species (ROS) and free radicals, enabling A1M to neutralise oxidative stress by binding and inactivating free radicals and toxic heme groups—damaging byproducts of haemoglobin breakdown that contribute to cellular and organ injury.

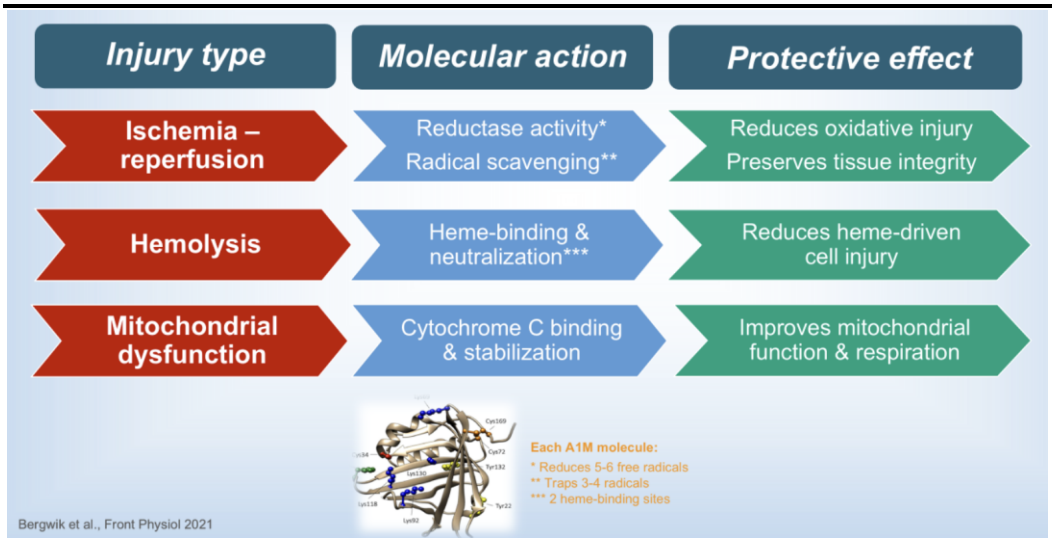
3D structure of native A1M



Source: Guard Therapeutics

A1M also protects vital cellular components such as proteins, DNA, mitochondria, and tissues from these byproducts while supporting the body's regenerative processes. Shown below is an overview of A1M's multifaceted activity.

A1M targets core mechanisms of kidney injury in open-heart surgery



Source: Guard Therapeutics

Thanks to its small size and specific affinity for damaged tissues, A1M is quickly distributed to injury sites, where it helps prevent further cell damage and promotes tissue repair. This unique combination of protective, cleansing, and reparative properties forms the scientific basis for Guards' drug development platform.

RMC-035: a druggable and patent-protected version of native A1M

RMC-035 is a recombinant, chemically modified variant of A1M specifically designed for therapeutic uses. Although it is based on the endogenous protein, it has been optimised to enhance stability and solubility.

RMC-035's properties are relevant in the context of CSA-AKI, where ischemia-reperfusion injury, oxidative stress, and the release of free heme contribute to kidney tubular damage and renal function loss. By scavenging free radicals and binding toxic heme, RMC-035 aims to protect renal tissues during this critical period and reduce the cascade of injury that can cause both immediate and long-term kidney impairment. In preclinical studies, RMC-035 has shown the ability to decrease biomarkers of oxidative stress, tubular cell injury, proteinuria, and to preserve renal function, supporting its potential as a novel intervention to enhance outcomes in high-risk cardiac surgery patients.

In cardiac surgery and kidney transplantation, dosing is expected to be given intravenously around the procedure. In sepsis, however, we believe the treatment regimen may differ, with a higher likelihood of continuous or repeated infusions over several days, given the longer and less predictable disease course.

Clinical validation and development

The company has completed its phase IIa AKITA study and is currently conducting the ongoing phase IIb POINTER trial, evaluating RMC-035 to prevent kidney injury following open-heart surgery.

AKITA study

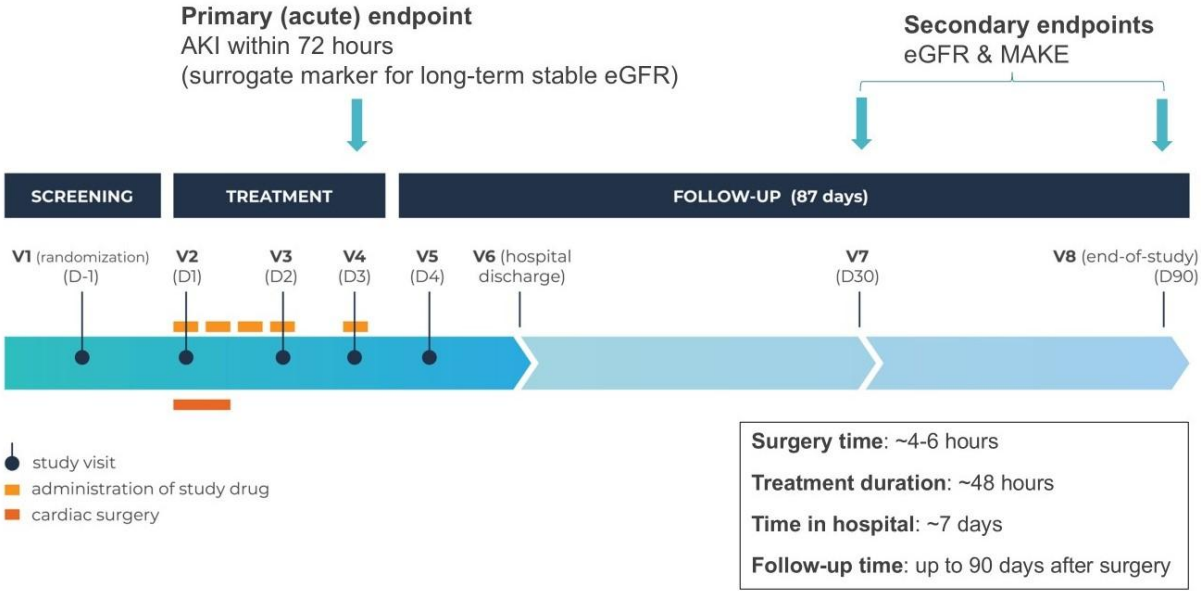
AKITA was a double-blind, placebo-controlled (1:1 RMC-035:placebo) phase IIa study involving patients undergoing open-heart surgery with a higher risk of kidney injury. The primary aim was to demonstrate proof of efficacy to support further development. For this purpose, the maximum dose deemed safe was chosen. Although the primary short-term endpoint—reduction of AKI within 72 hours—was not achieved, several more clinically relevant long-term secondary endpoints were met, including improvements in eGFR and reductions in MAKE90. As mentioned earlier, regulators do not

approve AKI as an endpoint for registration. Instead, they look for evidence of long-term benefits on outcomes such as eGFR and MAKE90. AKI is generally used as a surrogate marker for longer-term outcomes like eGFR and MAKE. Without prior efficacy data on these endpoints, AKI allows for a smaller, more feasible study design, which is why it was selected as the primary endpoint in this trial.

Dosing was based on renal function the day prior to surgery: Subjects with eGFR ≥60 L/min received 1.3 mg/kg per dose for the first and second doses, followed by 0.65 mg/kg per dose for the third, fourth, and fifth doses, while subjects with eGFR <60 L/min received 0.65 mg/kg per dose for all five doses. Dosing took place just before surgery and at 6, 12, 24, and 48 hours afterwards.

eGFR measures how effectively the kidneys filter waste from the blood. It is calculated through a blood test (usually creatinine) and factors such as age, sex, and body size. A lower eGFR indicates decreased kidney function.

AKITA study design



Source: Guard Therapeutics

Outcome of interim analysis

As part of the study design, an independent Data Safety Monitoring Committee (DSMC) conducted an interim review of safety and efficacy concerning the primary endpoint—AKI within 72 hours post-surgery. During this review, the DSMC observed an initial increase in SCr at the highest RMC-035 dose level, which directly confounded the primary endpoint assessment. Based on a futility assessment, the DSMC recommended stopping further patient recruitment. However, all enrolled patients continued to be monitored for efficacy and safety for up to three months post-surgery—a decision that Guard correctly and appropriately followed. Importantly, subsequent analyses demonstrated that the creatinine increase was short-lived, reversible, and limited to the highest dose of RMC-035. It was not linked to any adverse clinical outcomes and, in fact, coincided with improved renal outcomes at three months. It is also important to note that the mechanism behind this transient increase is well understood from preclinical toxicology studies, reflecting overexposure and a temporary "filter blockage" effect in the kidneys. Of the originally planned 268 patients, 177 were randomised and dosed—89 in the RMC-035 group and 88 in the control arm.

Study results

The primary endpoint was AKI within 72 hours after surgery, and key secondary endpoints included eGFR change from baseline after 90 days and MAKE90.

- AKI rate was 50.6% for RMC-035 versus 39.8% for placebo (relative risk [RR]=1.30, p=0.12).

- AKI rate in the pre-defined subgroup of patients having a better kidney function at the time of surgery (eGFR ≥60 mL/min) and who received the higher start dose of 1.3 mg/kg (n=112; 63%):
    - 56.4% for RMC-035 versus 35.1% for placebo (RR=1.66, p=0.01)
- AKI rate in the pre-defined subgroup with worse kidney function at the time of surgery (eGFR <60 mL/min/1.73m2) and who received the lower start dose of 0.65 mg/kg (n=65; 37%):
    - 41.2% for RMC-035 versus 48.4% for placebo (RR=0.85, p=0.57).

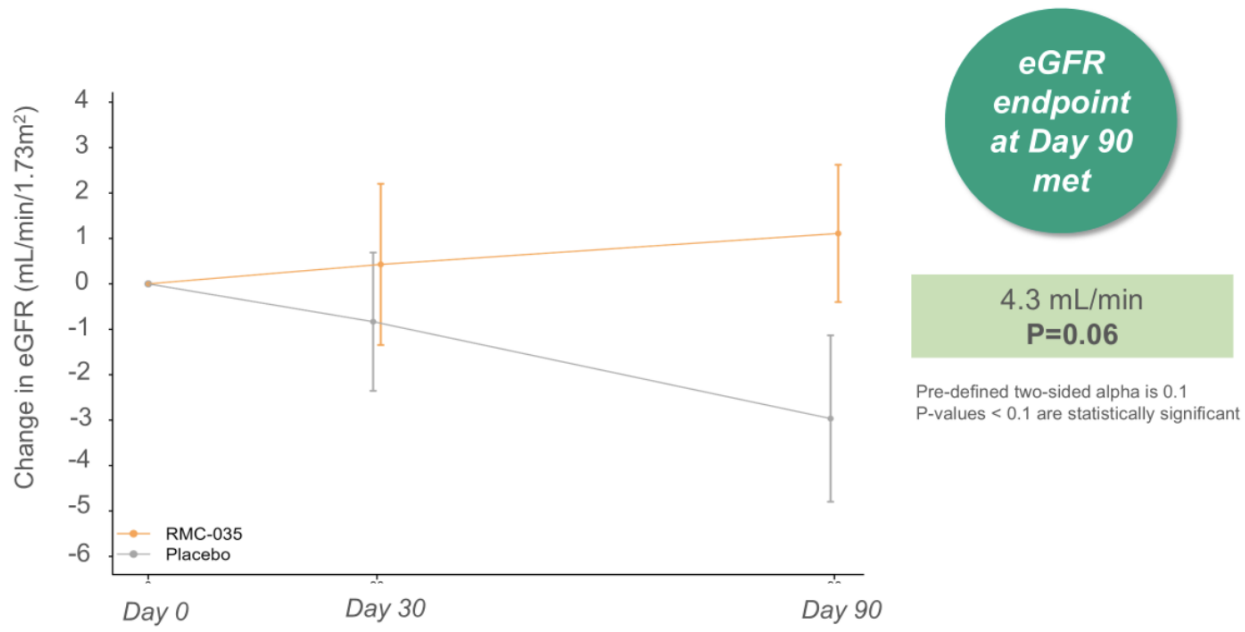
As discussed previously, the higher AKI rate observed at the highest RMC-035 dose is considered to reflect drug overexposure. As demonstrated in the AKITA study, this can be avoided with a lower dose while maintaining efficacy.

Robust efficacy based on assessment of key secondary endpoints

eGFR change from baseline (before surgery):

- In the total study population, the difference in eGFR change from baseline on Day 90 for RMC-035 versus placebo was 4.3 mL/min (p=0.06), favouring RMC-035.

Change from baseline in eGFR: RMC-035 vs Placebo



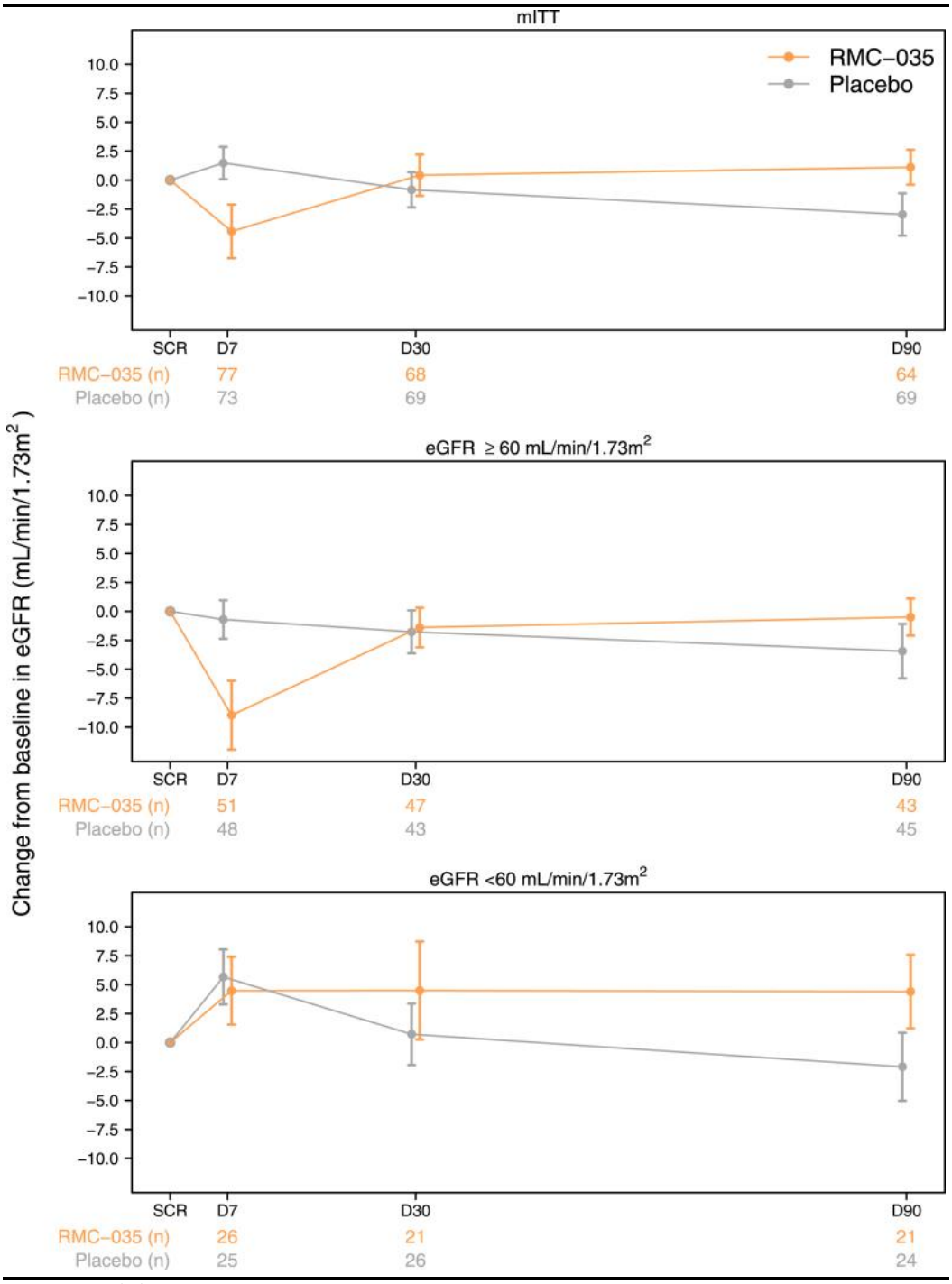
Source: Guard Therapeutics

Although not traditionally significant at the 0.05 level, this result aligns with the predefined alpha threshold of 0.1 and supports the hypothesis that RMC-035 may reduce long-term renal impairment.

The effect was more pronounced in the pre-defined subgroup of patients with reduced kidney function (eGFR <60 mL/min) who received the lower dose, showing an improvement of 7.9 mL/min (p=0.05). In contrast, the effect was weaker in patients with better kidney function (eGFR ≥60 mL/min) who received the higher starting dose, where the improvement was 2.3 mL/min (p=0.41). While it is difficult to draw definitive conclusions about the high-dose cohort due to the limited number of patients enrolled before the study was halted—likely contributing to the higher p-value—we consider it encouraging that the strongest signal was observed in patients with already impaired kidney function, a key segment of the high-risk group with the greatest unmet needs. Furthermore, the observed 7.9 mL/min difference is an exceptionally robust effect size in this context.

Mean eGFR changes from baseline at Days 7, 30, and 90 are shown in the figure below. In patients with preserved kidney function at baseline (eGFR ≥60 mL/min/1.73 m²), who received the higher starting dose, a transient decline in eGFR was observed in the RMC-035 group on Day 7 (likely due to the "filter blockage" we addressed earlier). In contrast, no early decline was seen in patients with impaired kidney function (eGFR <60 mL/min/1.73 m²) who received the lower dose.

Change from baseline in eGFR across patient subgroups (mITT, eGFR ≥60, eGFR <60)



Source: Guard Therapeutics

By Day 90, the most notable treatment effect was seen in the subgroup with reduced baseline kidney function. Overall, these data show that the initial decline did not cause lasting impairment and that RMC-035 delivered a meaningful improvement in long-term kidney function.

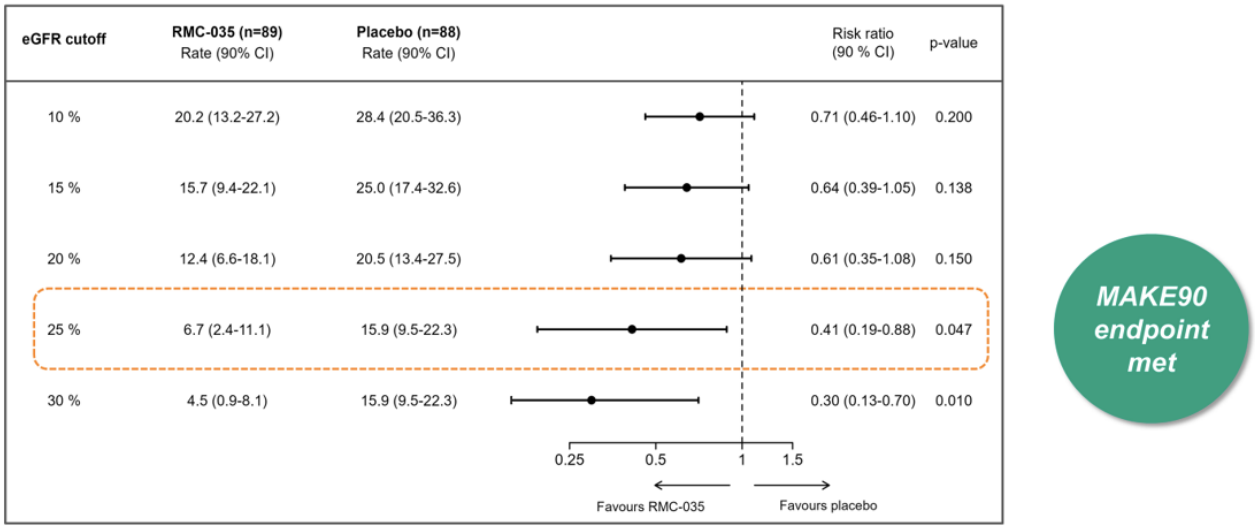
Major Adverse Kidney Events (MAKE):

- The number of MAKE events on Day 90 was reduced with RMC-035 treatment: 6.7% for RMC-035 vs 15.9% for placebo (relative risk 0.41 (p=0.047)). This effect was consistent across the two eGFR subgroups.

MAKE is a composite clinical endpoint that includes death, the need for dialysis, or a ≥25% reduction in kidney function (eGFR) compared to baseline.

In the figure below, the MAKE90 results from the AKITA study are visualised across various thresholds of eGFR decline, ranging from 10% to 30%. While the composite MAKE endpoint is commonly defined using a ≥25% loss of eGFR, the consistency of the treatment effect across all cut-offs enhances the robustness of the findings. Notably, the benefit of RMC-035 becomes more pronounced at higher thresholds, with statistical significance achieved at the 25% and 30% cut-offs (p=0.047 and p=0.010, respectively). Although these findings arise from a post-hoc analysis, apart from the predefined secondary endpoint MAKE90 using 25% eGFR decline, the observed dose-responsive trend indicates a clinically meaningful protective effect on renal function.

MAKE90 at different eGFR cutoffs



Source: Guard Therapeutics (data)

When selecting the appropriate eGFR cutoff to define MAKE, several factors must be considered. Choosing a threshold that is too low may increase the likelihood of capturing minor, clinically insignificant fluctuations in kidney function, thereby introducing noise and diluting the ability to detect meaningful treatment effects. Conversely, selecting a cutoff that is too high can reduce the number of events observed in the study population, potentially limiting statistical power and making it more difficult to draw reliable conclusions. In this regard, the conventional cut-off of 25% eGFR decline appears well balanced and is further supported by regulatory bodies.

Safety

Treatment-emergent adverse events (TEAEs) were generally similar across groups, with most events classified as mild or moderate in severity. In the RMC-035 group, the most frequently reported TEAEs were chills (30.3%), nausea (21.3%), and anaemia (20.2%). For placebo, the most common events included atrial fibrillation (29.5%), anaemia (20.5%), and hypervolemia (14.8%). Notably, the only adverse events that occurred more frequently with RMC-035 compared to placebo were chills, nausea, and pyrexia. These events mainly took place during or shortly after administration of the fourth or fifth dose and were considered infusion-related reactions (IRR).

Severe or life-threatening TEAEs were observed in 29.2% of RMC-035 patients and 18.2% of placebo patients. In the RMC-035 arm, the most common serious adverse events were five cases of hypertensive crisis reported during or shortly after the last dose. No post-treatment adverse events (PTAEs) occurred with a frequency of ≥10% in any treatment group. Overall, aside from the infusion-related reactions, the safety profile was comparable between groups and deemed acceptable given the high-risk surgical population.

POINTER study

The POINTER study is a randomised, double-blind, placebo-controlled phase IIb trial assessing RMC-035 in patients undergoing open-heart surgery. The main aim is to determine the optimal dosing regimen and identify the target population ahead of a future pivotal phase III trial. The primary endpoint is the change from baseline in renal function eGFR at Day 90, and key secondary endpoints include the occurrence of MAKE at Day 90.

As of June 2025, all 170 high-risk patients have been enrolled, of which nearly 30% have pre-existing CKD, defined as an eGFR<60 mL/min. Patients were allocated in a 2:2:3 ratio to receive either 60 mg or 30 mg of RMC-035 or placebo.

In the POINTER study, dosing is given as fixed amounts of active substance rather than being adjusted for body weight. The higher dose of 60 mg corresponds to a level slightly above the median dose in the lower-dose group of the AKITA study (0.65 mg/kg), which was not linked to a drug-induced increase in SCr, offering a relevant reference point for comparison. The 30 mg dose is thought to be slightly above the predicted maximum efficacious dose. Having passed two scheduled interim safety reviews, it seems likely that the doses in POINTER are suitable and pose no risk of an acute increase in creatinine. In the rare event that the AKI rate is higher with RMC-035 than with placebo, we do not expect this to significantly affect the programme. Such a finding would probably be reflected in the product labelling, similar to other kidney-protective drugs.

Results from the 60 mg and 30 mg RMC-035 dose groups will be combined into a single treatment arm for the primary efficacy analysis. This approach offers several advantages. Most importantly, it reduces the required sample size compared to a scenario where each dose arm is individually powered to detect the expected treatment effect against placebo. This strategy has been discussed with the FDA and is enabled by data from the AKITA study. It is also justified because the 30 mg dose is believed to be slightly above the dose needed to achieve maximum therapeutic effect.

The primary endpoint is the change in eGFR from before surgery to 90 days after surgery, while the key secondary endpoint is the incidence of MAKE90. The study is powered to detect a statistically significant eGFR increase of 5 mL/min compared to placebo.

Study recruitment was quicker than expected, with the final patient about four months earlier than planned. We see this as a mark of quality for Guard and its approach to clinical trials. Topline results are anticipated in Q4 2025e.

Designed for success based on AKITA insights

The AKITA study offers valuable risk mitigation insights ahead of the upcoming POINTER results. Although AKITA did not achieve its primary endpoint related to AKI, it showed statistically significant improvements in eGFR on day 90 and MAKE90, which are the primary and key secondary endpoints in POINTER, respectively. Importantly, POINTER is being conducted with generally lower dose levels of RMC-035 compared to AKITA, which reduces the chance of dose-related complications (though reversible) observed previously. The fact that the trial has continued without interruption or early termination indicates that the company has effectively implemented adequate risk mitigation measures, such as those for drug-induced AKI. While the extent of this effect remains to be determined—and regulatory interpretation, especially by the FDA, could depend on the size of the renal signal—the trial seems operationally sound and clinically justified. Overall, AKITA enhances confidence in the mechanism of action, while POINTER could validate its clinical utility with an optimised dosing regimen focused on efficacy and safety in a more controlled and targeted manner.

Regulatory pathways and accelerated opportunities

Given the severity of the condition, the significant unmet need for kidney protection after on-pump open-heart surgery, and the absence of approved therapies, RMC-035 may be well-positioned to qualify for various expedited regulatory pathways. The FDA has already granted RMC-035 Fast Track Designation—a programme for investigational drugs addressing severe conditions with unmet medical needs. This designation recognises the clinical severity and offers Guard more frequent interactions with the agency.

The FDA has also indicated that the programme may qualify for Breakthrough Therapy Designation (BTD). We believe it is very likely that the programme will receive BTD if the forthcoming POINTER study confirms the renal function improvements seen in the AKITA trial. If POINTER yields positive results, we expect Guard to apply for BTD and receive a decision in Q1 2026e, prior to an EoP2 meeting with the FDA.

In an EoP2 meeting, the sponsor (Guard) and the FDA review the phase II data package in detail, including efficacy trends, safety findings, and dose selection. The discussion then shifts to the proposed phase III trial design, addressing key elements such as patient population, primary and secondary endpoints, control arms, sample size, and statistical considerations. Manufacturing and quality aspects (CMC) are also covered. The purpose is to ensure that the development plan aligns with regulatory expectations and that the phase III programme, if successful, can serve as the basis for a future marketing application. We also consider RMC-035 a strong candidate for Accelerated Approval, based on interim analysis of eGFR in a future phase III setting. Read more about the FDA's expedited programmes here.

Selection of the patient group

A key strategic consideration before a possible phase III trial for RMC-035 is deciding on the patient group—whether to include all high-risk patients who undergo open-heart surgery (such as those with CKD, diabetes, or advanced age) or focus specifically on CKD patients. About 40% of patients are considered high-risk, and roughly 10–15% (of all patients) have pre-existing CKD. Ultimately, this decision is likely to be made by a potential partner, as Guard does not intend to conduct a pivotal study itself.

Restricting enrolment to CKD patients could improve the chances of achieving statistically and clinically meaningful results, as this group is both at higher risk of CSA-AKI and more likely to benefit from nephroprotective intervention (as seen in AKITA). A more uniform study population decreases variability and may allow for a smaller, more cost-effective trial. Furthermore, a targeted approach in a clearly defined high-risk group can enhance the health-economic argument, as CKD patients incur substantial downstream costs if kidney injury advances. This could support a value-based pricing strategy and allow for a higher initial price point. Additionally, demonstrating strong efficacy in this cohort may provide a persuasive basis for reimbursement and targeted market entry.

Conversely, adopting a broader inclusion strategy that covers all high-risk patients would better mirror real-world clinical practice and expand the potential market. However, this increased patient heterogeneity may weaken the observed treatment effect, require a larger and more costly pivotal trial, and heighten regulatory uncertainty. Additionally, variability in outcomes among subgroups could complicate negotiations with payers and market positioning.

Ultimately, the decision will depend on the strength of subgroup signals in the POINTER study and the regulatory strategy. Focusing on high-risk patients would strengthen the case for expedited regulatory pathways. Regulatory programmes like BTD are more likely to be granted when a drug targets a clearly defined subpopulation with high unmet medical need and clear therapeutic benefit. We expect that Guard will gain valuable insights into the feasibility of these accelerated regulatory pathways during an EoP2 meeting, and that this guidance will influence the strategic choice regarding the patient population.

For now, we assume that RMC-035 will be developed for all patients with an increased risk of developing CSA-AKI after on-pump open-heart surgery. We estimate that a corresponding phase III trial would involve approximately 600 patients, with direct costs of around SEK400m, and a two year duration.

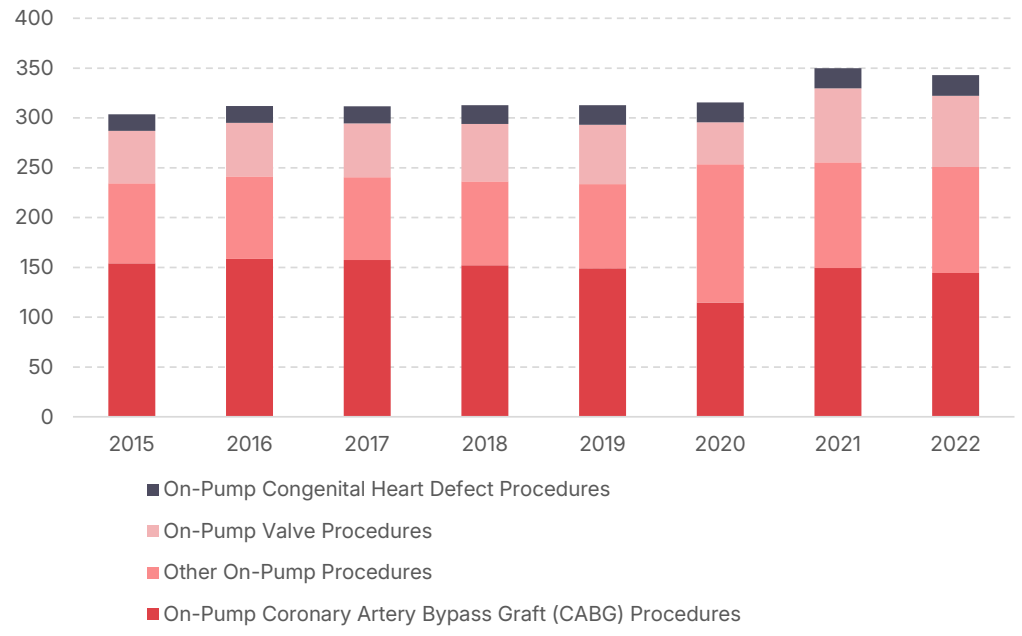
Market overview – open-heart surgery

Procedure volumes and market growth

Open-heart surgeries include coronary artery bypass grafting (CABG), valvular heart surgery, other on-pump heart procedures, and congenital heart defect operations. For Guard, all these procedures target specific patient populations, with the first three—CABG, valvular heart surgery, and other on-pump procedures—being similar and considered part of one market segment for RMC-035. Congenital heart defect procedures vary somewhat, as they are mainly performed in infants, with a median age below one year. This pediatric group is unlikely to be included in a future phase III trial, and therefore not in the initial label. Nonetheless, we see significant potential that if RMC-035 reaches the market, a small bridging study focused mainly on dosing and pharmacokinetics could be sufficient to secure regulatory approval for this patient group. This opportunity is not only commercial but also likely a regulatory expectation. We believe that nearly all patients in this group would be suitable candidates for RMC-035, given the vital importance of preventing kidney injury early in life, as such injury is likely to considerbly increase the risk of developing CKD later.

The illustration with data from GlobalData below displays the number of open-heart surgeries carried out in the United States, highlighting the distribution according to procedure type. Congenital heart surgeries make up approximately 6% of all on-pump surgeries, and a similar pattern is seen in other Western countries.

On-pump open-heart surgeries in the US by type (thousands)

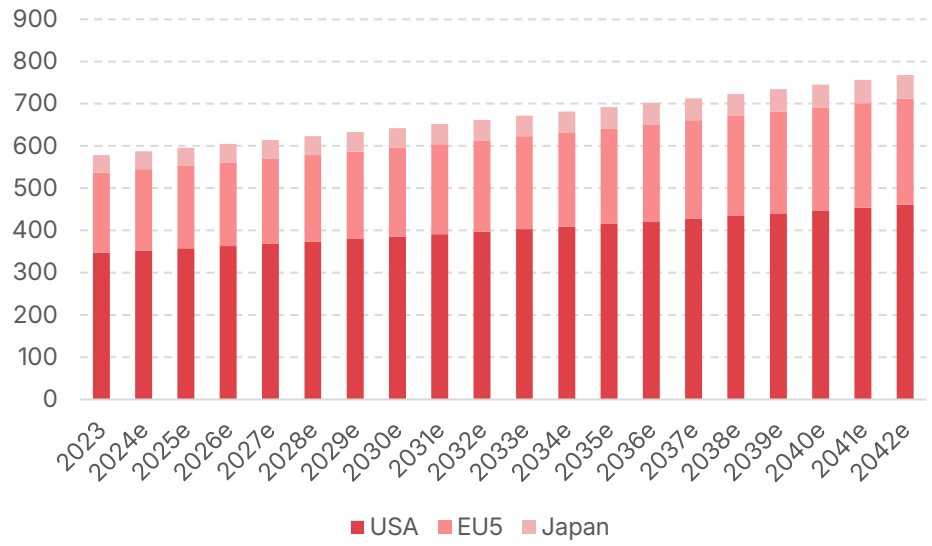


Source: GlobalData (data), Redeye research (chart structuring)

According to GlobalData, the annual incidence of on-pump open-heart surgeries in the 7 major markets (7MM) was approximately 578,000 in 2023. The volume is expected to increase by an average of 1.5% per year until 2030, and we apply the same growth rate across the entire forecast period. The projected trend is shown in the chart below. Additionally, for simplicity, we group all types of on-pump surgeries and assume, as previously mentioned, that 40% involve high-risk patients. Within this group, CKD patients are a key segment for RMC-035, accounting for about one third of high-risk patients, or roughly 10–15% of all patients. Regarding congenital procedures, although we

consider nearly all patients to be high-risk, we still apply the 40% assumption for simplicity. This balances the fact that a pediatric label expansion would likely take several years from initial approval.

Annual number of on-pump open-heart surgeries in the US, EU5 and Japan (thousands)



Source: GlobalData (data), Redeye research (chart structuring)

On a side note, we will briefly review the trends related to on-pump versus off-pump (beating heart) surgeries. Off-pump procedures gained popularity in the 1990s and early 2000s, driven by the belief that avoiding cardiopulmonary bypass could reduce inflammation, neurological complications, and organ dysfunction, including AKI. He et al. (2024) reported in a meta-analysis of 39 articles that off-pump CABG was associated with a 26% reduction in the short-term incidence of stroke. However, the off-pump approach was linked to a 9% increase in long-term mortality and a 49% higher rate of coronary reintervention in the mid-term compared to on-pump surgery, highlighting a trade-off between early neurological benefits and less favourable long-term outcomes. Consequently, the initial enthusiasm for off-pump techniques has waned, and the trend has shifted back towards more routine use of on-pump surgery in most high-income countries. We expect the proportion to continue decreasing over time, especially if protective therapies such as RMC-035 become available in clinical practice.

Competitive landscape

In this section, we examine the competitive landscape. We first outline the current standard treatments and clinical practices before moving on to competing projects in development that seek to meet the same therapeutic need.

Today's treatments

Current strategies to reduce the risk of kidney injury after open-heart surgery are mainly supportive. Standard care involves careful perioperative hemodynamic management to ensure adequate renal perfusion, minimising the duration of cardiopulmonary bypass when possible, and avoiding nephrotoxic drugs. Fluid management and optimisation of volume status — essentially maintaining the correct water balance in the body — are vital for reducing kidney stress caused by ischaemia and reperfusion. Despite these measures, the rate of AKI remains high, and no pharmacological therapies are currently approved specifically for this purpose, highlighting the significant unmet need for effective, targeted treatments that can protect the kidneys in this context.

Competing projects

A key commonality among the competing drug candidates listed is that none have yet demonstrated clinical PoC in the context of open-heart surgery. While several programmes are in advanced

development phases — including two in phase III — none except Guard's RMC-035 have presented efficacy data specific to this setting. This makes RMC-035 uniquely positioned, as it is the only candidate with PoC data in heart surgery and an ongoing phase IIb trial focused explicitly on this indication.

AstraZeneca/Alexion - Ultomiris

Ultomiris (ravulizumab), developed by AstraZeneca/Alexion, is an approved treatment for four rare disorders, including paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uraemic syndrome (aHUS). The ongoing phase III ARTEMIS trial aims to expand its clinical use into the prevention of CSA-AKI. This effort seems to be part of a broader strategy to explore additional indications for Ultomiris, rather than a specific focus on kidney protection. While the drug's established safety profile and regulatory history may support further development, its effectiveness in the context of CSA-AKI remains unproven.

The study specifically focuses on patients with CKD undergoing non-emergent open-heart surgery with cardiopulmonary bypass (CPB). This is a clearly defined but narrower subgroup of high-risk patients compared to RMC-035, which is being developed for a wider segment of patients undergoing cardiac surgery, including those with or without CKD.

ARTEMIS aims to determine whether a single intravenous dose of ravulizumab can lower the occurrence of MAKE90. While the mechanism of action—C5 inhibition—differs fundamentally from RMC-035's approach, both seek to address the unmet need of safeguarding kidney function in a high-risk surgical environment. If successful in CKD patients, we believe ravulizumab will be examined for a wider at-risk population. If approved, Ultomiris could benefit from its established market presence in other indications, potentially enabling quicker uptake and wider adoption in the new setting. A phase III study was initiated in Q2 2023, and is expected to be completed in Q1 2027e.

Genentech – GDC-8264

Genentech's candidate GDC-8264, like Ultomiris, seems to be part of a broader, exploratory development approach. Although the compound is being studied for preventing kidney injury in high-risk cardiac surgery patients—similar to RMC-035—its main focus remains on other inflammatory conditions, such as acute graft-versus-host disease (aGVHD). This development pattern indicates that Genentech is evaluating a wide array of immune-related conditions to find the most promising use for the compound, rather than following a targeted strategy. Therefore, clinical efficacy concerning CSA-AKI has not yet been proven. A phase IIa/b study was started in Q1 2025, with completion expected in Q4 2027e.

AM Pharma – ilofotase alfa

AM-Pharma was developing ilofotase alfa, a recombinant alkaline phosphatase enzyme designed to reduce inflammation and protect organs in patients at risk of AKI. Ilofotase alfa was primarily developed for sepsis-associated AKI, but failed twice in this indication. The company also tested ilofotase in CSA-AKI, but has terminated this indication.

Renibus – RBT-1

Renibus Therapeutics' candidate RBT-1 is a preconditioning agent developed to reduce complications in cardiothoracic surgery patients. The compound, which combines stannous protoporphyrin and iron sucrose, aims to activate the body's antioxidant and anti-inflammatory pathways before surgery. In a randomised, placebo-controlled phase II trial, RBT-1 showed statistically significant improvements in oxidative stress and inflammation biomarkers, along with reduced ventilator time, shorter ICU stays, and fewer hospital readmissions. While these results are promising, the study did not report effects on hard renal endpoints such as eGFR or MAKE. Renibus has since advanced RBT-1 into the phase III PROTECT trial, which seeks to confirm its ability to reduce post-operative complications following cardiac surgery. A total of 423 patients have been enrolled in the trial, with topline results expected in Q3 2025e. This progression highlights the

company's dedication to establishing clinical benefit, but the compound's relevance to CSA-AKI prevention specifically remains to be demonstrated.

Novartis – TIN-816

Novartis was developing TIN-816, a recombinant human CD39 enzyme, to prevent acute complications following cardiac surgery, including AKI. The phase IIa trial involved 120 patients and assessed an acute primary endpoint. However, the study did not achieve its primary endpoint and was terminated early due to futility. This outcome highlights the difficulties in demonstrating significant clinical benefit in this indication and eliminates TIN-816 as a competitor.

Competitive landscape summary

RMC-035 is the only candidate with positive PoC data in open-heart surgery, a key differentiator in a landscape where other drug candidates remain in earlier development stages or have yet to demonstrate efficacy in this particular setting. While we account for potential competition by applying a modest discount to the overall market potential, we will monitor the competitive landscape closely and revise our assumptions as new data becomes available.

Possibilities in additional indications

Beyond its primary programme in open-heart surgery, RMC-035 is also advancing towards kidney transplantation, where a successful phase Ib study has already concluded, and for sepsis, which remains in preclinical development. Guard envisions a possible pathway to progress directly from preclinical studies into a phase III trial in sepsis—pending encouraging results from the ongoing POINTER trial—necessitating only a smaller bridging phase I study. In this section, we explore these indications and their respective market opportunities. We will also briefly mention the company's preclinical GTX platform.

Kidney transplantation

Kidney transplantation is a vital part of renal care, providing patients with end-stage renal disease a better chance for survival and quality of life than dialysis. After a kidney transplant, the new organ experiences a period without blood supply (ischemia) during removal, transport, and implantation. When blood flow is restored (reperfusion), the sudden reintroduction of oxygen can induce oxidative stress, inflammation, and the release of toxic free heme. This process can damage kidney cells, impair early graft function, and lead to delayed graft function or AKI. Additionally, the immune system immediately recognises the donor kidney as foreign, which may necessitate lifelong immunosuppressive therapy to prevent rejection. Collectively, these stressors make the early post-transplant period critical for long-term graft survival.

RMC-035 in kidney transplantation aims to operate through the same biological mechanisms as in CSA-AKI by neutralising free heme and reducing oxidative stress, thereby protecting kidney function during periods of ischemia and reperfusion. The treatment goal is to safeguard long-term graft function and prevent the need for re-transplantation.

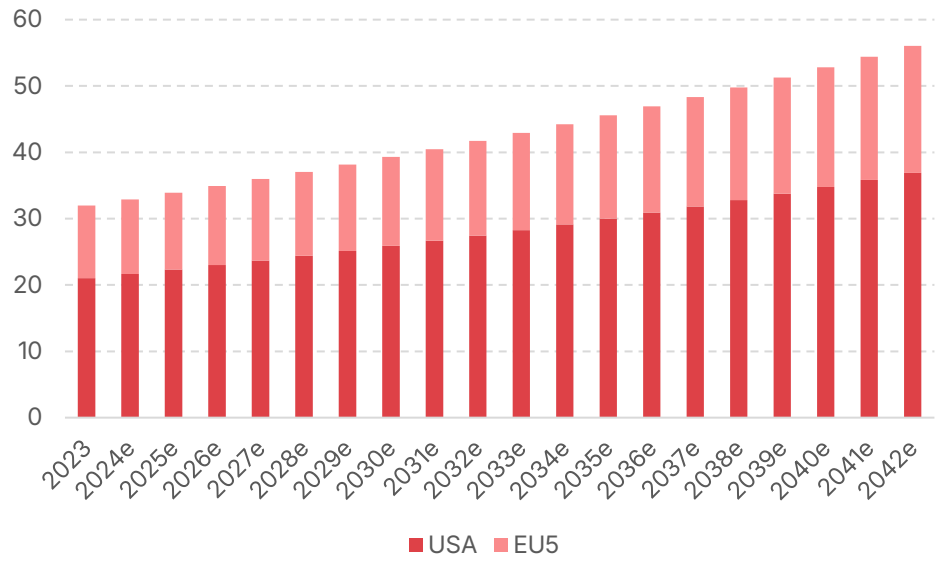
Within the kidney transplantation indication, two potential regulatory pathways exist for RMC-035. The FDA recognises two primary phase III endpoints: Delayed Graft Function (DGF), an acute binary outcome, or eGFR at 12 months post-transplant. We consider an eGFR-based endpoint the more probable scenario for RMC-035, as it would enable the inclusion of virtually all deceased-donor transplant procedures. Conversely, if DGF were chosen as the primary endpoint, the trial population would need to be reduced by at least 50% to enrich patients at higher risk of DGF, thereby ensuring sufficient event rates.

In 2023, the company reported results from a phase Ib clinical study evaluating RMC035 in kidney transplantation. This open-label trial enrolled eight patients who received five daily intravenous doses of RMC035 at 0.3–0.6 mg/kg, including administration during the transplant procedure. The study achieved its primary objectives, demonstrating good pharmacokinetics and a favourable safety and tolerability profile—no serious adverse effects related to the study drug were observed.

Market overview - Kidney transplantation

In 2023, over 27,000 kidney transplants were carried out in the United States, nearly 17,000 across the EU5, and around 2,000 in Japan. The majority of transplanted kidneys come from deceased donors—about 77% in the US and 65% in Europe, while only around 5% in Japan. This very low proportion in Japan reflects cultural traditions regarding the sanctity of the body after death, which have historically restricted organ donation, along with healthier lifestyles that decrease the incidence of end-stage kidney disease. Guard's target population is patients receiving kidneys from deceased donors, as these individuals face the highest risk of developing AKI. The company's addressable patient population encompasses virtually all individuals receiving kidneys from deceased donors, with eGFR serving as a pivotal trial endpoint. Japan is a negligible market, and given the very low rate of deceased donations, we exclude it from our model. Looking ahead, we assume an average annual growth rate of approximately 3% in kidney transplants across the US and EU5, consistent with recent historical trends. Below is a chart showing the number of kidney transplants in the US and EU5.

Annual number of kidney transplantations in the US and EU5 (thousands)



Source: Organdonor.gov, European Commission (data), Redeye research (chart structuring)

In this context, RMC-035 qualifies for Orphan Drug Designation (ODD) in both the US and EU, due to the relatively small patient populations. In the US, orphan status applies to diseases affecting fewer than 200,000 patients per year within the country, while in the EU the threshold is a prevalence of no more than 5 in 10,000 people, corresponding to approximately 250,000 patients across the European Union. Beyond signalling the high unmet medical need, orphan designation offers several strategic advantages, including market exclusivity (7 years in the US, 10 years in the EU), fee reductions, and regulatory support throughout development.

Sepsis

Sepsis remains a leading cause of morbidity and mortality worldwide, with an estimated 1.7 million adult cases annually in the United States alone. It is a major driver of hospital and intensive care unit admissions. Importantly, approximately 40–50% of patients with sepsis develop AKI, a complication strongly linked to prolonged hospital stays, increased risk of death, and long-term renal impairment. Despite the clinical burden, no pharmacological therapies are currently approved to prevent or treat sepsis-associated AKI (SA-AKI), highlighting a significant unmet medical need.

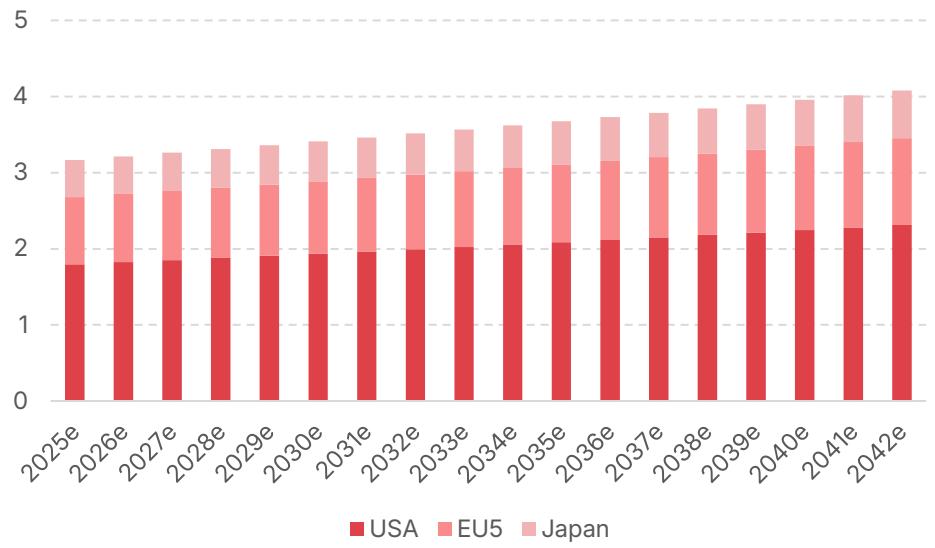
The biological rationale for using RMC-035 in this context is strong. Its antioxidative and secondary anti-inflammatory properties, along with its ability to neutralise free heme, closely align with the underlying mechanisms of SA-AKI. However, developing pharmacological treatments for SA-AKI remains complex. One major challenge is the rapid and unpredictable course of the condition, which requires early intervention, often before irreversible organ damage occurs. Setting appropriate endpoints is also difficult; while mortality is common, it is influenced by many overlapping factors, making it hard to identify the specific therapeutic effect of a renal-targeted agent like RMC-035. Trial design is further complicated by the wide variation in patient characteristics, such as age, comorbidities, and infection causes, which create challenges in patient selection and data analysis. We believe MAKE90 to be the most suitable primary endpoint for a phase III trial. The greater complexity of the sepsis setting was the main reason Guard chose open-heart surgery as the lead indication.

If POINTER achieves the desired results, the company envisions a route from preclinical development to phase III in sepsis, supported by a smaller phase I PK/PD bridging study — a strategy we see as both sensible and efficient.

Market overview – Sepsis

Sepsis constitutes a significant market, with an annual diagnosed incidence of around 1.7 million cases in the US, 882,000 in the EU5, and 487,000 in Japan. Across the 7MM, incidence is expected to increase by approximately 1.5% annually, driven by ageing populations and rising comorbidities such as diabetes and CKD. As illustrated in the chart below, this trend indicates a steadily growing patient pool and a substantial market opportunity for innovative therapies like RMC-035.

Sepsis diagnosed incidence in the US, EU5 and Japan (millions)



Source: GlobalData (data), Redeye research (chart structuring)

Beyond the overall sepsis incidence, we assume patients must have at least one established risk factor for kidney injury or death (age >65, diabetes, CKD, or heart failure). These factors overlap to

some extent but collectively suggest that around 70% of sepsis patients are addressable. Since treatment must be started before AKI develops, and about half of patients already meet AKI criteria at diagnosis, we reduce the target population accordingly. Applying further conservative exclusions for severe comorbidities and ineligible patients brings us to roughly 570,000 addressable patients in the US, 280.000 in the EU5, and 150.000 in Japan.

Preclinical GTX Platform

The company also has a preclinical GTX platform, comprising peptide-based drug candidates designed to mimic smaller fragments of the A1M protein. These candidates are being developed for subcutaneous self-administration and are intended for chronic, long-term treatment. The GTX programme focuses on a range of kidney diseases and serves as a strategic complement to RMC-035, potentially expanding the company's future therapeutic portfolio.

The main difference between acute and chronic kidney conditions mainly relates to the duration and severity of the disease. Several promising GTX peptides have shown strong effects in experimental models, especially in CKD. Strategically, the company considers two development pathways: a general treatment for advanced CKD and disease-specific orphan indications like Alport syndrome, where no effective therapies are available today. GTX peptides could significantly expand the company's addressable market and improve licensing prospects, even at the preclinical stage. The positive long-term efficacy results observed in the AKITA study support the GTX platform, as both RMC-035 and the GTX candidates are derived from A1M. Therefore, positive POINTER data would further validate the GTX platform.

Patent portfolio

RMC-035 benefits from a composition of matter patent that remains valid until 2037. These patents are the strongest form of intellectual property protection because they protect the active substance itself, regardless of how it is formulated or used therapeutically. The patent protection for RMC-035 has been granted across all key markets, including the US, the EU, Japan, and China. Moreover, Guard has secured patents covering its broader GTX peptide platform through 2044, further reinforcing the company's proprietary status and supporting the future development of related drug candidates.

Beyond patents, RMC-035 will also be protected by regulatory exclusivity if approved. In the US, new biologics receive 12 years of market exclusivity under the Biologics Price Competition and Innovation Act (BPCIA), during which biosimilars cannot be approved. The EU offers a similar system, with 10 years of data and market exclusivity (8+2 years, plus the potential for a 1-year extension for a significant new indication). Japan also provides comparable protection, generally granting an 8-year-long "re-examination" period for new drugs.

Estimates and sales model

Our base case valuation includes RMC-035 in open-heart surgery, kidney transplantation, and sepsis. Although it is common practice not to include preclinical projects in valuations due to high uncertainty, we have partly accounted for the sepsis opportunity to reflect the strong optionality involved — specifically the potential to move directly from preclinical development to a pivotal phase III trial. However, we remain cautious by not assigning a likelihood of approval that fully accounts for this, and instead apply a preclinical likelihood of approval (LoA) for the sepsis project. We plan to update this LoA after the POINTER read-out. Additionally, the optionality in sepsis and kidney transplantation is partially reflected in our deal assumptions. With regard to the GTX platform, we see significant long-term potential but have decided not to value it at this stage, choosing to revisit this once the programme reaches greater maturity.

Licensing deal

We believe it is most probable that a potential partner would seek to license RMC-035 for all its possible indications rather than limiting it to a specific setting such as CSA-AKI. A wider licensing agreement increases the commercial potential for both parties and aligns with the drug's prospects across multiple high-value AKI indications. Moreover, this approach reduces the complexity of dividing IP rights. Out-licensing the asset for just one indication might also decrease its appeal to other potential partners.

Identifying a broader range of directly comparable deals within kidney diseases is challenging because kidney-related indications are often secondary to other conditions, such as cardiovascular disease or diabetes. Therefore, we focused on the most relevant transactions in the field and included Hansa Biopharma as a peer, given that its treatment is administered before gene therapy to improve outcomes. Additionally, Hansa Biopharma is a Swedish company, providing further contextual relevance for comparison. A deal is contingent on positive results in the POINTER study, which is why we estimate the project is phase III ready.

Peer deals benchmarks

Licensor	Buyer	Year	Deal type	Upfront (USDm)	Deal size (USDm)	Rights Geography	Royalties	Phase	Comment
AM-Pharma	Kyowa Kirin	2023	Licensing deal	23	287	Japan	Tiered, double digit	Phase III	Iofotase alfa in sepsis associated AKI
Vifor Pharma	Angion	2020	Licensing deal	60	280	Global ex-China	Tiered, up to 40%	Phase III	ANG-3777 in cardiac surgery-associated AKI
Abbott	Action Pharma	2012	Asset transaction	110	110	Global	N/A	Phase II	AP214 in cardiac surgery-associated AKI
Hansa Biopharma	Sarepta	2020	Licensing deal	10	397,5	Global	High single-digit to mid-teens	Pre-Phase I	Imlifidase as treatment before gene therapy
Average				**35**	**243**				
RMC-035		**2026e**	**Licensing deal**	**40**	**650**	**Global**	**15%**	**Phase III ready***	**RMC-035 in all AKI-related indications**

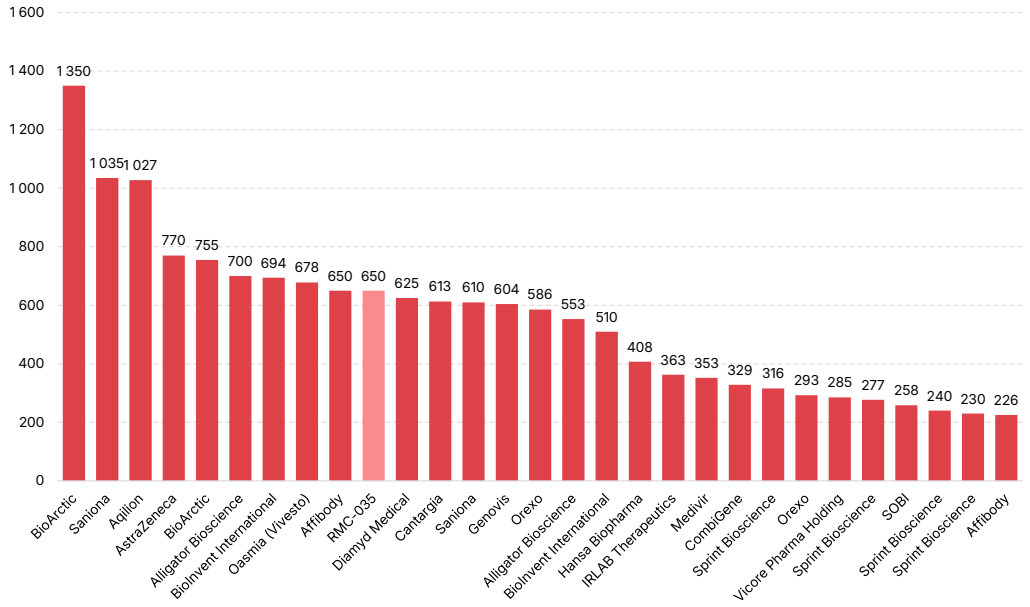
*Source: GlobalData (data), Redeye research (chart structuring). *Phase III ready if POINTER is successful*

Several historical deals in related therapeutic areas provide relevant benchmarks. For this analysis, we focused on the most comparable peer deals, resulting in a smaller but more precise set of references. The 2023 AM-Pharma/Kyowa Kirin licensing deal, worth USD287m with USD23m upfront and tiered double-digit royalties, demonstrates the valuation potential for a phase III asset targeting sepsis-associated AKI in a single indication, within a single geographical area (Japan). The 2020 Vifor/Angion deal, worth USD280m with USD60m upfront and royalties of up to 40%, offers another relevant data point in a single indication, but this time in a global deal. The Abbott/Action Pharma asset transaction in 2012, valued at USD110m, highlights that even phase II assets in AKI can attract significant deal sizes. Lastly, the 2020 Hansa Biopharma/Sarepta agreement, valued at USD397.5m with high single-digit to mid-teen royalties, illustrates a Swedish deal in pre-treatment before intervention.

Drawing on these precedents—particularly the first two deals in the table, which we regard as the most comparable—we estimate a potential global licensing deal for RMC-035, across all indications, to be worth USD650m overall, including a USD40m upfront payment and a 15% royalty rate. We assign a 50% probability to the deal. We note that the deal hinges on positive results from the POINTER study. Moreover, the value could be even higher depending on the data, especially if a competitive bidding process begins.

To validate our assumption and ensure alignment with both local and global deal dynamics, we compare licensing deals in Swedish-listed biotech companies over the past 15 years. On average, deals involving Swedish companies are smaller than larger US-based transactions. This is largely due to better funding in US biotech, which enables larger clinical trials and often allows targeting multiple indications simultaneously, among other factors.

Largest licensing deals in Swedish-listed biotech companies since 2010 (SEKm)



Source: GlobalData (data), Redeye research (chart structuring)

All things considered, the deal assumption discussed above would rank it among the top 10 largest licensing agreements in Swedish biotech since 2010. However, RMC-035's opportunities in several indications support this assumption.

Furthermore, it is important to note that a significant portion of the milestones are typically tied to late-stage clinical development and commercial milestones, often referred to as "Bio-dollars." These represent funding allocated to biotech projects, many of which fail to materialise into successful products due to unmet milestones, regulatory hurdles, or financial challenges, underscoring the high-risk and volatile nature of the industry.

Likelihood of Approval

A key factor in assessing drug candidates during clinical development is the PoS at each phase and the overall LoA. LoA is crucial for risk-adjusting future cash flows, accounting for the inherent uncertainties of clinical trials, and therefore plays a vital role in the valuation of biotech firms. In determining appropriate benchmarks, we have considered both all therapy areas and kidney diseases. The kidney disease dataset mainly reflects chronic conditions, which makes it less directly applicable to AKI as an acute complication. Still, it offers relevant insight given that similar renal endpoints, particularly eGFR, are commonly applied in both settings.

Probability of success across development phases

	Phase I	Phase II	Phase III	Regulatory	Phase II LoA
All therapy areas	70%	45%	49%	83%	18%
Kidney diseases	69%	38%	50%	89%	17%
RMC-035 in CSA-AKI	**100%**	**65%**	**50%**	**89%**	**29%**
RMC-035 in KTx-AKI	**100%**	**38%**	**50%**	**89%**	**17%**

Source: GlobalData (data), Redeye research (chart structuring). KTx abbreviation for kidney transplant

For CSA-AKI, we assign a 65% probability of success (PoS) for phase II, influenced by the favourable safety profile and clear efficacy signals observed in the completed phase IIa AKITA study. For phase III and the regulatory stage, we apply the historical success rates associated with kidney disease,

landing at a LoA of 29%. For kidney transplantation, we apply an assumption in line with kidney disease benchmarks, resulting in an estimated LoA of 17%.

Sepsis is less straightforward. If POINTER delivers supportive results, the company envisions a potential pathway directly from preclinical development to phase III—requiring only a smaller, de-risked PK/PD phase I study. In that scenario, both safety and PoC could be considered indirectly addressed. Nonetheless, we adopt a conservative approach and treat the programme as preclinical at this stage, with plans to reassess our assumptions once POINTER data are available. Based on probability of success benchmarks for kidney disease, infectious diseases, and sepsis, we assign a LoA of 6%. We do not solely use sepsis as a benchmark because there are only 97 benchmark trials, compared to 5,400 in infectious disease and above 600 in kidney disease.

Pricing

Pricing for RMC-035 is expected to reflect its positioning as a hospital-based biologic addressing acute, high-risk complications, to prevent patients from sustaining kidney damage and thereby reduce the need for dialysis or transplantation. To estimate a plausible price point for RMC-035, we have benchmarked against a comparable intravenously administered therapy used in acute, high-risk hospital settings, complemented by a simple health-economic analysis.

Open-heart surgery and sepsis

We assume the same price level for RMC-035 in cardiac surgery and sepsis, as the candidate is expected to provide a comparable clinical benefit in both settings. Indication-based pricing is generally not applied, but if RMC-035 were to demonstrate superior efficacy in sepsis, differentiated pricing could be a possibility—particularly if the product is developed as an infusion-based formulation in sepsis.

We regard Xigris (drotrecogin alfa) as the top benchmark for pricing. It was traditionally used in severe sepsis to prevent organ damage, with a list price of approximately USD8,000 per patient in the US. Although it was eventually withdrawn from the market, Xigris demonstrated that payers are willing to pay premium prices for biologics that can reduce mortality and the burden of critical care.

Additionally, recent health economic analyses by Jha et al. (2023), examining the costs of kidney diseases across 31 countries, further support this pricing range. They showed that an episode of AKI alone carries an average direct cost of around USD6,000, while the long-term consequences are even more costly. Annual healthcare costs increase from about USD3,060 in early-stage CKD to USD49,000–57,000 for dialysis and up to USD75,000 for kidney transplantation in the incident year, before stabilising at around USD16,700 annually in subsequent years due to ongoing immunosuppressive therapy and follow-up care. Even modest reductions in AKI incidence following cardiac surgery could therefore generate significant savings by lowering the risks of dialysis, transplantation, and costly cardiovascular complications. Against this backdrop, we assume a US price of USD7,500 per treatment cycle within open-heart surgery and sepsis, and half that level in EU5 and Japan.

Pricing - Kidney transplantation

Kidney transplantation is an orphan indication with a relatively small patient population, limited by the availability of donor organs. Complications such as delayed graft function or graft loss frequently force patients back to dialysis or necessitate re-transplantation, both of which are highly resource-intensive for healthcare systems. These cost drivers, along with the regulatory and exclusivity benefits associated with orphan drug designation, justify a premium pricing assumption. We therefore estimate a list price of around USD22,500 in the US, and half that level in EU5 and Japan.

Pricing closing remarks

In conclusion, our pricing assumptions should be seen as indicative rather than final. The strength and consistency of clinical outcomes will be the main factors affecting payer perception. Strong data

could support higher prices, while more modest results would naturally lead to lower prices. Additionally, we assume a 2% annual price increase in line with inflation.

Clinical development timeline

In June, Guard announced that all patients had been enrolled and treated in the POINTER study - ahead of schedule. Follow-up data collection is ongoing for three months post-surgery and is expected to be completed in early September. The company anticipates top-line results in Q4 2025e, and a full data readout in Q1 2026e. Guard has already begun planning a phase III study, which we view positively. If the POINTER trial produces positive results, the company intends to accelerate these preparations and its business development activities with the goal of securing a partner to bring the programme into late-stage development. The company does not plan to initiate additional clinical trials until there is a clear path forward for RMC-035, either through an out-licensing agreement or an asset sale – a strategy we support.

Scenarios after POINTER readout

Positive outcome – compelling data

If POINTER demonstrates clear and statistically significant robust effects across the entire high-risk population, RMC-035 would be validated as a first-in-class candidate for protecting kidney function and reducing downstream renal complications following open-heart surgery. Such a result would notably strengthen Guard's bargaining position in partnership discussions, likely leading to a lucrative out-licensing agreement for late-stage development. It would also de-risk expansion into adjacent indications (kidney transplantation, sepsis) and provide validation for the broader GTX platform. In this scenario, investor sentiment and valuation could experience a significant uplift.

Mixed outcome – subgroup signal

If POINTER delivers mixed results – for example, strong efficacy in patients with pre-operative CKD but weaker outcomes in the overall high-risk population – RMC-035 would still retain clinical and commercial relevance. Guard could focus subsequent development on the subgroup with the clearest benefit, designing a phase III study with enriched inclusion criteria. While this would likely support continued development and partnership interest, deal values and investor enthusiasm may be more muted.

Negative outcome – trial failure

If POINTER fails to demonstrate a clinically meaningful effect on kidney protection, Guard would face a challenging outlook. Investor confidence would likely deteriorate, and prospects for out-licensing RMC-035 would diminish. The company would then need to reassess its strategic priorities, though the setback would also negatively spill over onto perceptions of the GTX platform, given its shared mechanistic rationale. In such a scenario, it is not unlikely that Guard may ultimately cease operations and de-list.

Sales model

Below follows our sales models and assumptions for RMC-035 in CSA-AKI, kidney transplantation-associated AKI (KTx-AKI) and SA-AKI.

Assumptions CSA-AKI

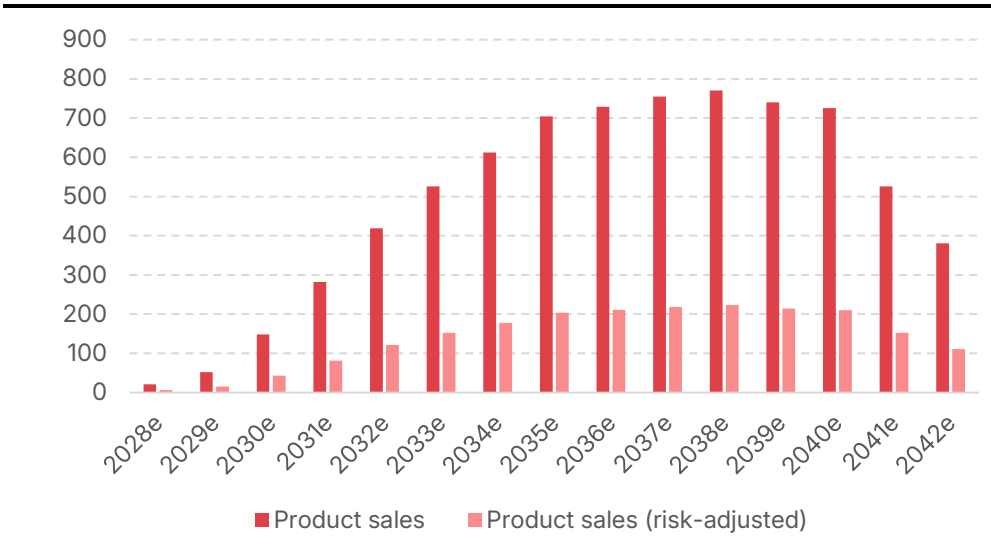
- We base our sales model on the annual number of on-pump open-heart surgeries in the 7MM (US, EU5 and Japan), with 40% assumed to represent the targeted high-risk population
- 50% probability that Guard will secure a USD650m deal (covering all RMC-035's indications), with royalties of 15%, in 2026e
- List price USD7,500 per treatment
- Phase II PoS of 65% and LoA of 29%
- Pivotal trial initiation early 2027e
- Accelerated approval in the US 2028e. Full approval in the US, EU and Japan 2029e
- Peak market penetration of 40%

RMC-035 CSA-AKI market model

		2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	2038e	2039e	2040e	2041e	2042e
Development stage		II	II	III	III/Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market
Probability		100%	100%	65%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%
Diagnosed patients	US	357 710	363 075	368 521	374 049	379 660	385 355	391 135	397 002	402 957	409 002	415 137	421 364	427 684	434 099	440 611	447 220	453 928	460 737
	EU5	195 085	198 012	200 982	203 997	207 057	210 162	213 315	216 515	219 762	223 059	226 405	229 801	233 248	236 746	240 298	243 902	247 561	251 274
	JP	43 176	43 823	44 481	45 148	45 825	46 512	47 210	47 918	48 637	49 367	50 107	50 859	51 622	52 396	53 182	53 980	54 789	55 611
Adressable patients	US	143 084	145 230	147 409	149 620	151 864	154 142	156 454	158 801	161 183	163 601	166 055	168 545	171 074	173 640	176 244	178 888	181 571	184 295
	EU5	78 034	79 205	80 393	81 599	82 823	84 065	85 326	86 606	87 905	89 224	90 562	91 920	93 299	94 699	96 119	97 561	99 024	100 510
	JP	17 270	17 529	17 792	18 059	18 330	18 605	18 884	19 167	19 455	19 747	20 043	20 344	20 649	20 958	21 273	21 592	21 916	22 244
Launch curve	US	-	-	-	0,05	0,09	0,25	0,46	0,66	0,80	0,90	1,00	1,00	1,00	1,00	1,00	1,00	0,70	0,49
	EU5	-	-	-	-	0,09	0,25	0,46	0,66	0,80	0,90	1,00	1,00	1,00	1,00	0,70	0,49	0,34	0,24
	JP	-	-	-	-	0,09	0,25	0,46	0,66	0,80	0,90	1,00	1,00	1,00	0,70	0,49	0,34	0,24	0,17
Market penetration	US	0,0%	0,0%	0,0%	2,0%	3,6%	10,0%	18,4%	26,4%	32,0%	36,0%	40,0%	40,0%	40,0%	40,0%	40,0%	40,0%	28,0%	19,6%
	EU5	0,0%	0,0%	0,0%	0,0%	3,6%	10,0%	18,4%	26,4%	32,0%	36,0%	40,0%	40,0%	40,0%	40,0%	28,0%	19,6%	13,7%	9,6%
	JP	0,0%	0,0%	0,0%	0,0%	3,6%	10,0%	18,4%	26,4%	32,0%	36,0%	40,0%	40,0%	40,0%	28,0%	19,6%	13,7%	9,6%	6,7%
Treated Patients	US	-	-	-	2 842	5 194	14 643	27 349	39 827	49 000	55 951	63 101	64 047	65 009	65 983	66 973	67 977	48 298	34 316
	EU5	-	-	-	-	2 833	7 987	14 915	21 721	26 724	30 515	34 414	34 930	35 454	35 986	25 567	18 166	12 907	9 170
	JP	-	-	-	-	627	1 768	3 301	4 807	5 915	6 754	7 616	7 731	7 847	5 575	3 962	2 814	2 000	1 420
Net price	US	6 867	7 004	7 144	7 287	7 433	7 581	7 733	7 888	8 045	8 206	8 370	8 538	8 709	8 883	9 060	9 242	9 426	9 615
	EU5	3 433	3 502	3 572	3 643	3 716	3 791	3 866	3 944	4 023	4 103	4 185	4 269	4 354	4 441	4 530	4 621	4 713	4 807
	JP	3 433	3 502	3 572	3 643	3 716	3 791	3 866	3 944	4 023	4 103	4 185	4 269	4 354	4 441	4 530	4 621	4 713	4 807
Product Sales (USDm)	US	-	-	-	21	39	111	211	314	394	459	528	547	566	586	607	628	455	330
	EU5	-	-	-	-	11	30	58	86	108	125	144	149	154	160	116	84	61	44
	JP	-	-	-	-	2	7	13	19	24	28	32	33	34	25	18	13	9	7
Product sales		-	-	-	21	51	148	282	419	526	612	704	729	755	771	741	725	526	381
Product sales (risk-adjusted)		-	-	-	6	15	43	82	121	152	177	204	211	218	223	214	210	152	110
Risk-adjusted royalties (SEKm)		-	-	-	8	21	60	114	170	213	248	285	296	306	312	300	294	213	154

Source: GlobalData (data), Redeye research (chart structuring, estimates)

RMC-035 CSA-AKI sales model (USDm)



Source: Redeye research (estimates and illustration)

Assumptions Kidney transplantation

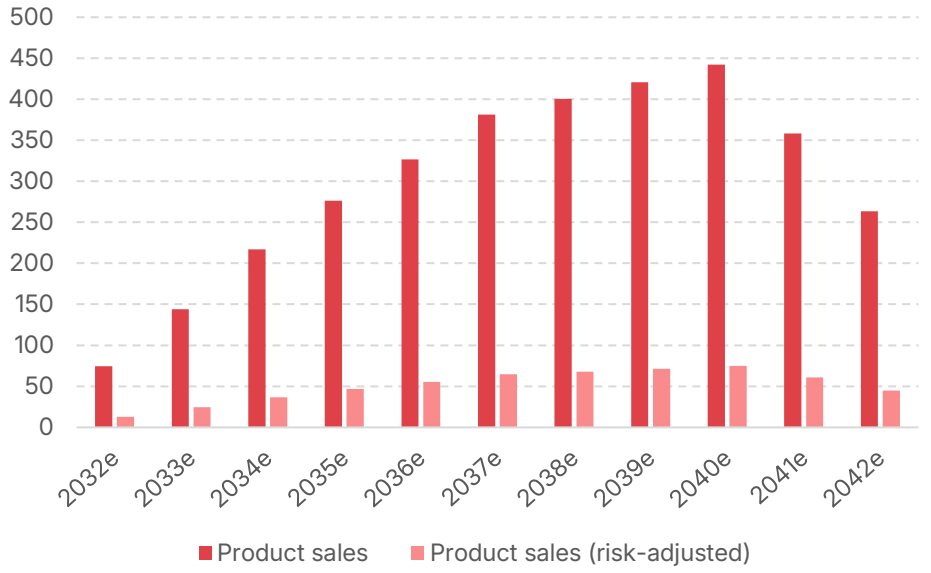
- Our sales model is based on annual kidney transplants in the US and EU5, with 65% constituting the targeted patient population.
- List price USD22,500 per treatment
- LoA of 17%
- Launch 2031e
- Peak market penetration of 45%

RMC-035 KTx-AKI market model

		2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	2038e	2039e	2040e	2041e	2042e
Development stage		I	I	II	III	III	Regulatory	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market
Probability		100%	100%	100%	38%	38%	19%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%
Diagnosed patients	US	28 997	29 866	30 762	31 685	32 636	33 615	34 623	35 662	36 732	37 834	38 969	40 138	41 342	42 582	43 860	45 176	46 531	47 927
	EU5	18 035	18 576	19 134	19 708	20 299	20 908	21 535	22 181	22 847	23 532	24 238	24 965	25 714	26 485	27 280	28 098	28 941	29 810
	JP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Adressable patients	US	18 268	18 815	19 381	19 962	20 561	21 177	21 812	22 467	23 141	23 836	24 550	25 287	26 045	26 827	27 632	28 461	29 315	30 194
	EU5	11 363	11 703	12 055	12 416	12 788	13 172	13 568	13 974	14 394	14 825	15 270	15 728	16 200	16 686	17 186	17 702	18 233	18 780
	JP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Launch curve	US	-	-	-	-	-	-	0,09	0,25	0,46	0,66	0,80	0,90	1,00	1,00	1,00	1,00	0,70	0,49
	EU5	-	-	-	-	-	-	0,09	0,25	0,46	0,66	0,80	0,90	1,00	1,00	1,00	1,00	1,00	0,70
	JP	-	-	-	-	-	-	0,09	0,25	0,46	0,66	0,80	0,90	1,00	0,70	0,49	0,34	0,24	0,17
Market penetration	US	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	4,1%	11,3%	20,7%	29,7%	36,0%	40,5%	45,0%	45,0%	45,0%	45,0%	31,5%	22,1%
	EU5	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	4,1%	11,3%	20,7%	29,7%	36,0%	40,5%	45,0%	45,0%	45,0%	45,0%	45,0%	31,5%
	JP	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	4,1%	11,3%	20,7%	29,7%	36,0%	40,5%	45,0%	31,5%	22,1%	15,4%	10,8%	7,6%
Treated patients	US	-	-	-	-	-	-	839	2 402	4 551	6 725	8 396	9 729	11 134	11 468	11 812	12 167	8 772	6 325
	EU5	-	-	-	-	-	-	523	1 493	2 831	4 183	5 222	6 052	6 926	7 134	7 347	7 568	7 795	5 620
	JP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net price	US	20 600	21 012	21 432	21 861	22 298	22 744	23 199	23 663	24 136	24 619	25 111	25 613	26 126	26 648	27 181	27 725	28 279	28 845
	EU5	10 300	10 506	10 716	10 930	11 149	11 372	11 599	11 831	12 068	12 309	12 556	12 807	13 063	13 324	13 591	13 862	14 140	14 422
	JP	10 300	10 506	10 716	10 930	11 149	11 372	11 599	11 831	12 068	12 309	12 556	12 807	13 063	13 324	13 591	13 862	14 140	14 422
Product Sales (USDm)	US	-	-	-	-	-	-	19	57	110	166	211	249	291	306	321	337	248	182
	EU5	-	-	-	-	-	-	6	18	34	51	66	78	90	95	100	105	110	81
	JP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Product sales		-	-	-	-	-	-	26	75	144	217	276	327	381	401	421	442	358	263
Product sales (risk-adjusted)		-	-	-	-	-	-	4	13	24	37	47	55	64	68	71	75	61	45
Risk-adjusted royalties (SEKm)		-	-	-	-	-	-	-	18	34	51	66	77	90	95	100	105	85	62

Source: Organdonor.gov, European Commission (data), Redeye research (chart structuring, estimates)

RMC-035 KTx-AKI sales model



Source: Redeye research (estimates and illustration)

Assumptions Sepsis

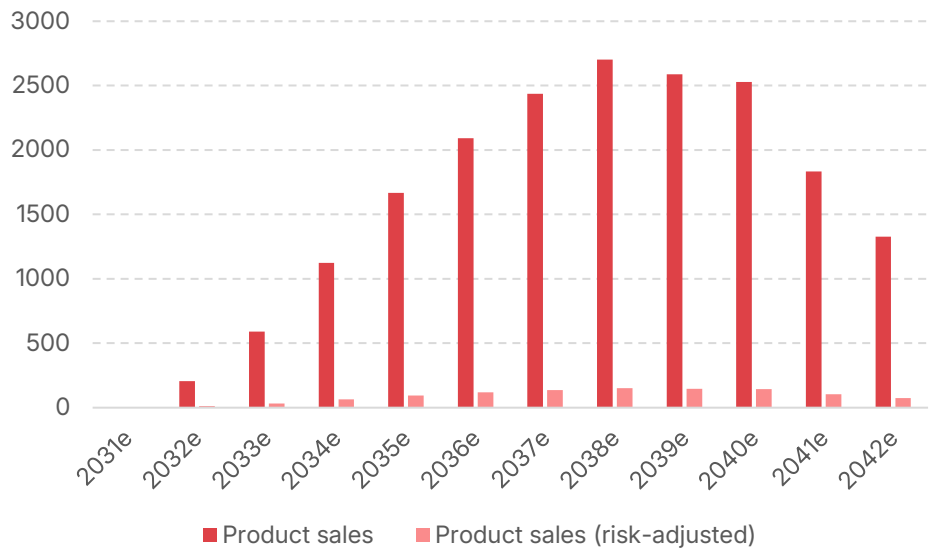
- Our sales model is based on the diagnosed incidence of sepsis across the 7MM, of which we estimate approximately one-third represents the addressable patient population.
- List price 7,500 per treatment
- LoA of 6%
- Launch 2032e
- Peak market penetration of 35%

RMC-035 SA-AKI market model

		2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	2038e	2039e	2040e	2041e	2042e
Development stage		Preclinical	Preclinical	I	III	III	III	Regulatory	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market
Probability		58%	58%	58%	25%	25%	25%	6%	6%	6%	6%	6%	6%	6%	6%	6%	6%	6%	6%
Diagnosed patients	US	1 798 000	1 824 970	1 852 345	1 880 130	1 908 332	1 936 957	1 966 011	1 995 501	2 025 434	2 055 815	2 086 652	2 117 952	2 149 721	2 181 967	2 214 697	2 247 917	2 281 636	2 315 861
	EU5	882 000	895 230	908 658	922 288	936 123	950 164	964 417	978 883	993 566	1 008 470	1 023 597	1 038 951	1 054 535	1 070 353	1 086 409	1 102 705	1 119 245	1 136 034
	JP	487 000	494 305	501 720	509 245	516 884	524 637	532 507	540 494	548 602	556 831	565 183	573 661	582 266	591 000	599 865	608 863	617 996	627 266
Adressable patients	US	566 370	574 866	583 488	592 241	601 124	610 142	619 294	628 583	638 012	647 582	657 296	667 155	677 162	687 320	697 630	708 094	718 715	729 496
	EU5	277 830	281 997	286 227	290 521	294 879	299 302	303 791	308 348	312 974	317 668	322 433	327 270	332 179	337 161	342 219	347 352	352 562	357 851
	JP	153 405	155 706	158 042	160 412	162 819	165 261	167 740	170 256	172 809	175 402	178 033	180 703	183 414	186 165	188 958	191 792	194 669	197 589
Launch curve	US	-	-	-	-	-	-	-	0,09	0,25	0,46	0,66	0,80	0,90	1,00	1,00	1,00	0,70	0,49
	EU5	-	-	-	-	-	-	-	0,09	0,25	0,46	0,66	0,80	0,90	1,00	0,70	0,49	0,34	0,24
	JP	-	-	-	-	-	-	-	0,09	0,25	0,46	0,66	0,80	0,90	0,63	0,44	0,31	0,22	0,15
Market penetration	US	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	3,2%	8,8%	16,1%	23,1%	28,0%	31,5%	35,0%	35,0%	35,0%	24,5%	17,2%
	EU5	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	3,2%	8,8%	16,1%	23,1%	28,0%	31,5%	35,0%	24,5%	17,2%	12,0%	8,4%
	JP	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	3,2%	8,8%	16,1%	23,1%	28,0%	31,5%	22,1%	15,4%	10,8%	7,6%	5,3%
Treated patients	US	-	-	-	-	-	-	-	18 810	53 035	99 048	144 243	177 463	202 641	228 534	231 962	235 441	167 281	118 854
	EU5	-	-	-	-	-	-	-	9 227	26 016	48 588	70 758	87 054	99 404	112 106	79 652	56 592	40 209	28 568
	JP	-	-	-	-	-	-	-	5 095	14 365	26 828	39 070	48 067	54 886	38 997	27 708	19 686	13 987	9 938
Net price	US	6 867	7 004	7 144	7 287	7 433	7 581	7 733	7 888	8 045	8 206	8 370	8 538	8 709	8 883	9 060	9 242	9 426	9 615
	EU5	3 433	3 502	3 572	3 643	3 716	3 791	3 866	3 944	4 023	4 103	4 185	4 269	4 354	4 441	4 530	4 621	4 713	4 807
	JP	3 433	3 502	3 572	3 643	3 716	3 791	3 866	3 944	4 023	4 103	4 185	4 269	4 354	4 441	4 530	4 621	4 713	4 807
Product Sales (USDm)	US	-	-	-	-	-	-	-	148	427	813	1 207	1 515	1 765	2 030	2 102	2 176	1 577	1 143
	EU5	-	-	-	-	-	-	-	36	105	199	296	372	433	498	361	262	190	137
	JP	-	-	-	-	-	-	-	20	58	110	164	205	239	173	126	91	66	48
Product sales		-	-	-	-	-	-	-	205	589	1 122	1 667	2 092	2 437	2 701	2 588	2 528	1 832	1 328
Product sales (risk-adjusted)		-	-	-	-	-	-	-	12	33	63	94	118	137	152	146	143	103	75
Risk-adjusted royalties (SEKm)		-	-	-	-	-	-	-	16	47	89	132	165	193	214	205	200	145	105

Source: GlobalData (data), Redeye research (chart structuring, estimates)

RMC-035 SA-AKI sales model



Source: Redeye research (estimates and illustration)

Financials

Historical financials

Below follows an overview of Guard's financials 2019-2024, as well as estimates for 2025e. The financial performance is expected and aligns with other pre-revenue clinical-stage biotech companies.

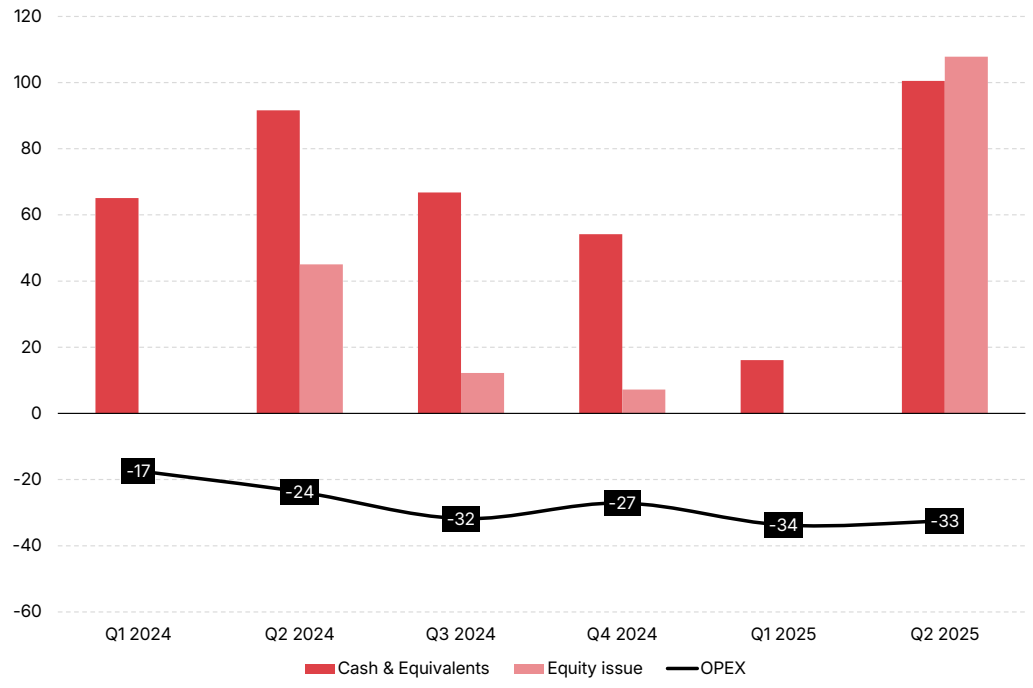
Financial overview

	2019	2020	2021	2022	2023	2024	2025e
Revenues	0	0	0	0	0	0	0
OPEX	-44	-40	-82	-115	-115	-100	-128
R&D costs	-38	-35	-75	-105	-106	-90	-115
SG&A costs	-7	-5	-6	-9	-9	-10	-11
EBIT	-44	-40	-82	-115	-115	-100	-128
EBIT margin							
Net income	-45	-40	-82	-113	-113	-96	-128
Equity issue	101	75	178	114	0	65	107
Net cash flow	40	36	99	10	-117	-32	-25
Cash, End of period	54	90	189	201	84	54	31

Source: Guard Therapeutics (data), Redeye research (chart structuring)

The chart below shows Guard's financial position from Q1 2024 to Q2 2025. In Q2, Guard received net SEK107m proceeds from its recent rights issue.

Liquidity overview



Source: Guard Therapeutics (data), Redeye research (chart structuring)

Cash runway

The company has guided that its cash position will last until summer 2026e, which we view as a reasonable assessment. However, should POINTER deliver positive data, we anticipate a SEK40m directed share issue at a modest discount, primarily to strengthen Guard's position in partner

negotiations, intensify business development efforts, and extend the runway. As a rule of thumb, partnering deals are typically completed 3–9 months after study results, and with a directed of SEK40m, the company would be funded through this period and into 2027e.

Valuation

DCF

At Redeye, we approach the valuation of a company using three scenarios to provide a dynamic view of the case. In complement to our base case valuation, we also model both a pessimistic (bear case) and an optimistic (bull case) scenario. The differences between these scenarios are based on modifications of the assumptions we apply during our valuation process. Our valuation is based on a risk-adjusted 2025-2042 DCF model, using a 16% WACC derived from Redeye's proprietary rating model.

Our sum-of-the-parts valuation (SOTP) follows below. For simplicity, we have assigned the potential deal to the lead indication and will fine-tune its distribution if/when a deal is made.

Base case sum-of-the-parts (SEKm)

Project	Indication	Phase	Est. Launch	LoA	Peak sales (USDm)	Deal size (USDm)	rNPV (SEKm)
RMC-035	CSA-AKI	II	2028	29%	771	650*	**747**
RMC-035	KTx-AKI	I	2031	17%	442		**95**
RMC-035	SA-AKI	Preclinical	2032	6%	2701		**177**
Technology value (SEKm)							**1 019**
Net cash (SEKm)							**100**
Shared costs (SEKm)							**-161**
Equity value (SEKm)							**958**
Shares outstanding (million)							**20**
Diluted shares outstanding (million)							**22**
Equity value per share (SEK)							**43**

Source: Redeye research (estimates)

Bear case SEK2

Our bear scenario assumes that the POINTER readout is unsatisfactory, with no clinical signal in any subgroup. In this scenario, the remaining value would primarily be tied to the remaining cash position. We estimate this value to be approximately SEK2 per share.

Base case SEK43

Our base case builds on the following key assumptions for RMC-035 in CSA-AKI:

- Phase II PoS 65% and LoA 29%
- USD650 deal
- Launch 2028e
- Peak sales USD0.8bn

We also assume a smaller directed share issue of SEK40m, at favourable terms, contingent on a successful POINTER readout.

Bull case SEK89

In our bull case, we mirror the assumptions in our base case with one major deviation: We set the PoS for the POINTER study to 100%, leading to a LoA of 45% in CSA-AKI. Due to cross-read, we also assume a 22% LoA in KTx-AKI, and 25% in SA-AKI.

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Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3

The company is led by visionary CEO Tobias Agervald, supported by a lean and decentralised organisation with a stable management team. Its strategy is clearly focused on advancing RMC-035 as a first-in-class treatment, with well-defined regulatory pathways and expansion opportunities. Innovation is driven through both RMC-035 and the GTX platform, while a strong and diverse board provides expertise aligned with the company's goals and a commitment to gender diversity.

Insider ownership remains relatively low, with management and the board collectively holding less than 1% of shares. In addition, there is limited public evidence of management's candor in acknowledging mistakes or explicitly linking company values to long-term success, reflecting the company's early stage of development.

Business: 2

The company has strong growth potential supported by multiple reinvestment opportunities, secular tailwinds from the rising prevalence of kidney disorders, and a solid patent portfolio that creates barriers to entry. Its products also align with ethical investment considerations by addressing significant medical needs.

At the same time, it remains a pre-revenue biotech with negative cash flow, making it highly dependent on capital markets and regulatory approvals. Like many early-stage biotech companies, it faces a meaningful risk of core business failure, which underscores the high-risk nature of the investment.

Financials: 1

The company currently has no revenues, which is not uncommon for biotech firms at this stage. Financial performance could improve significantly in the future through potential licensing agreements for RMC-035 or other strategic partnerships.

	2024	2025e	2026e	2027e
INCOME STATEMENT				
Revenues	0	0	123	123
Cost of Revenues	0	0	0	0
Gross Profit	0	0	123	123
Operating Expenses	-100	-128	-47	-39
EBITDA	-100	-128	75	83
D&A	0	0	0	0
EBIT	-100	-128	75	83
Net Financial Items	4	0	0	0
EBT	-96	-128	75	83
Income Tax Expenses	0	0	-24	-25
Non-Controlling Interest	0	0	0	0
Net Income	-96	-128	51	58
BALANCE SHEET				
Assets				
Current assets				
Cash & cash equivalents	54	29	116	172
Inventories	0	0	0	0
Accounts Receivable	0	0	0	0
Other Current Assets	1	1	1	1
Total Current Assets	56	31	118	173
Non-current assets				
Property, Plant & Equipmen	0	0	0	0
Goodwill	0	0	0	0
Intangible Assets	0	0	0	0
Right-of-Use Assets	0	0	0	0
Shares in Associates	0	0	0	0
Other Long-Term Assets	0	0	0	0
Total Non-Current Assets	0	0	0	0
Total Assets	56	31	118	173
Liabilities				
Current liabilities				
Short-Term Debt	0	0	0	0
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	9	6	3	1
Other Current Liabilities	8	8	8	8
Total Current Liabilities	18	14	12	9
Non-current liabilities				
Long-Term Debt	0	0	0	0
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	0	0	0	0
Total Non-current Liabilities	0	0	0	0
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	38	17	106	164
Total Liabilities & Equity	56	31	118	173
CASH FLOW				
EBT	-96	-128	75	83
Cash Flow from changes in	nm	nm	nm	nm
Operating Cash Flow	-95	-132	49	55
Capital Expenditures	0	0	0	0
Investment in Intangible As	0	0	0	0
Investing Cash Flow	0	0	0	0
Financing Cash Flow	63	107	38	0
Free Cash Flow	-95	-132	49	55

DCF Valuation Metrics	Sum FCF (SEKm)
RMC-035 CSA-AKI	747
RMC-035 KTx-AKI	95
RMC-035 SA-AKI	177
Technology value (SEKm)	1 020
Net cash (SEKm)	100
Shared costs (SEKm)	-161
Equity value (SEKm)	959
Shares outstanding (million)	20,2
Diluted shares outstanding (million)	22,2
Fair Value per Share	43

	2024	2025e	2026e	2027e
CAPITAL STRUCTURE				
Equity Ratio	0,7	0,5	0,9	0,9
Debt to equity	0,0	0,0	0,0	0,0
Net Debt	-54	-29	-116	-172
Capital Employed	38	17	106	164
Working Capital Turnover	0,0	0,0	0,0	0,0
PROFITABILITY				
ROE	-253%	-764%	48%	35%
ROCE	-263%	-762%	71%	51%
ROIC	-256%	-782%	49%	35%
EBITDA Margin (%)	nm	nm	nm	nm
EBIT Margin (%)	nm	nm	nm	nm
Net Income Margin (%)	nm	nm	nm	nm
VALUATION				
Basic EPS	-7,8	-6,4	2,3	2,6
P/E	neg	neg	9,6	8,5
EV/Revenue	nm	nm	3,1	2,6
EV/EBITDA	neg	neg	5,0	3,8
EV/EBIT	neg	neg	5,0	3,8
P/B	6,0	26,5	4,6	3,0

SHAREHOLDER STRUCTURE	CAPITAL %	VOTES %
Jan Ståhlberg	20,7%	20,7%
Stiftelsen Industrifonden	14,3%	14,3%
Swedbank Robur Fonder	9,9%	9,9%
Rutger Arnhult	5,5%	5,5%
Avanza Pension	4,8%	4,8%

SHARE INFORMATION	
Reuters code	GUARD.ST
List	First North Stockholm
Share price	21,6
Total shares, million	20,2
Total shares, million (diluted)	22,2

MANAGEMENT & BOARD	
CEO	Tobias Agervald
CFO	Karin Botha
Chairman	Johan Bygge

ANALYSTS	Redeye AB
Filip Lindkvist	Mäster Samuelsgatan 42, 10tr
Richard Ramanius	111 57 Stockholm

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories: PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

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Duplication and distribution

CONFLICT OF INTERESTS

Filip Lindkvist owns shares in the company : No
Richard Ramanius owns shares in the company : No
Redeye performs services for the Company and receives compensation from the Company in connection with this.