

A1M Pharma

Sector: Biotech

A bright future ahead

Despite its past disappointments, we see real potential in A1M Pharma's pivot to develop ROSgard for acute kidney injury (AKI). New CEO Tobias Agervald is moving the company forward with a viable clinical plan to address an important area of unmet medical need with blockbuster sales potential.

Pre-clinical push and positive phase I

A1M's significant pre-clinical data for ROSgard gives valuable insight into its mechanism of action. Since 2018 the company has drawn on this to complete multiple positive studies of the drug's impact on AKI. Last week A1M Pharma reported positive result from their phase I single dose trial, next step will be a multiple dose study followed with a phase Ib study in patients.

Substantial benefits

AKI can be deadly and is a very costly burden on public health spending. Yet no treatment is available for the disease currently. Accordingly, a breakthrough in AKI would bring substantial benefits - both for patients and for society – **and has scope to achieve blockbuster peak sales of some USD 1.4 billion.**

Strong owner

A1M Pharma have in the last year attracted a lot of professional investors in their capital raises. A few that stands out is Rutger Arnhult, Max Mitteregger (Hedgefund manager at Gladiator) and Jan Sthålborg (EQT founder).

Upside potential

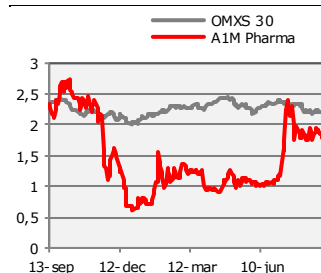
Redeye initiates coverage with a Base Case of SEK 2,3 per share. We want to point out the coming catalyst in data from phase I MAD and phase Ib, which we expect in Q1 2020 respectively Q3 2020. Our Bull Case of SEK 5 factors in positive data from phase IIa study with potential partner deal on the table. A unclear outcome in the phase Ib study next year would take the stock into our Bear Case (SEK 0,4) territory – which would need A1M pharma to perform more studies before entering phase II. This would probably leading to severe dilution through future capital raises.

KEY FINANCIALS (SEK)	2017	2018	2019E	2020E	2021E	2022E
Net sales	0	0	0	0	0	0
EBITDA	-68	-87	-14	-29	-27	-28
EBIT	-68	-87	-14	-29	-27	-28
EPS (adj.)	-8,2	-4,2	-0,1	-0,2	-0,2	-0,2
EV/Sales	N/A	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	N/A	N/A	N/A	N/A	N/A	N/A
EV/EBIT	N/A	N/A	N/A	N/A	N/A	N/A
P/E	N/A	N/A	N/A	N/A	N/A	N/A

FAIR VALUE RANGE

BEAR	BASE	BULL
0,4	2,3	5

A1M.ST VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	A1M.ST
Market	First North
Share Price (SEK)	1,6
Market Cap (MSEK)	201
Net Debt 19E (MSEK)	-20
Free Float	90 %
Avg. daily volume (MSEK)	0,82

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Investment Case

A bright future

While A1M Pharma has struggled to find the optimal path forward for ROSgard over its long history, it now benefits from a clear story. Under new CEO Tobias Agervald and other new members of senior management, plus new board members Göran Forsberg and Johannes Hulthe, the new organization is capable of taking A1M in the right direction, we believe.

We estimate that ROSgard can reach a peak sale of USD 1.4 billion and that a licensing deal could be done after a successful phase IIb study. According to us, A1M Pharma has an upside of some 45%.

Strong pre-clinical data, well defined clinical path

Thanks to the company's long history, there is also a solid pre-clinical portfolio for ROSgard. Because of this A1M has strong insights into how ROSgard works and where it would be optimally applied. Since 2018 the focus has been on acute kidney injury (AKI), which has produced positive pre-clinical data across multiple studies. Last week positive study data were presented from the phase I study with single dose. ROSgard was well tolerated and showed a good pharmacokinetic profile. The results justify continuing studying ROSgard in a multiple-dose study.

Strong owners

With shareholders, including professional investors such as Rutger Arnhult, Max Mitteregger, Jan Sthålborg, and Unionen, to name a few, we assume that there will be no problem to raise further capital.

Unmet medical need

Today there is no treatment for AKI and the disease carries substantial costs for hospitals. Around 1% of the UK National Health Service budget (around GBP 1.3 billion) is associated with AKI. A comparable figure for the US is more than USD 5 billion per year according to industry sources. Apart from its financial cost, AKI is also deadly with a mortality rate in severe cases of around 50%.

Upside potential

Redeye initiates coverage with a Base Case of SEK 2,3 per share. Our Base Case represent a potential upside of some 45% from share's current levels. We see data from phase I MAD in Q1 2020 and phase IIb in Mid 2020 as interesting catalyst.

Our Bull Case of SEK 5 factors in positive data from phase IIa study in 2022. We assume that a partner deal can be reached around 12 months after successful data and estimates a deal value of 200 million USD.

A negative outcome in the phase IIb study next year would take the stock into our Bear Case (SEK 0,4) territory – which would need A1M pharma to go back to the drawing board and probably leading to severe dilution through future capital raises.

Counter thesis

Early-stage development

- ROSgard presented positive result from their phase I single-dose study last week which is a good first step. But this is early clinical development, the prospects of success are still low - we estimate a 15% likelihood of it reaching the market from here.
- Developing new drugs is a high-risk business and requires a hefty budget. We assume that a phase IIa trial would cost around SEK 40-50 million and IIb SEK 150-250 million.
- At the moment the cash position is around SEK 50 million with an additional SEK 25 million to be included if the warrant in October is fully subscribed. Thus A1M Pharma is financed until start of phase IIa, and we assume a capital raise in late 2020.

Competitors way ahead

- Three competitors are in phase II or III in the same indication. We see it as likely that at least one of these candidates could reach the market in the coming years.
- If more than one of the competitors gains approval, the niche could become less attractive for new candidates. A new candidate would need to bring something new to the table - either in effect or safety. It's too soon to tell if ROSgard offers this potential.

Lack of catalyst

- After completing phase Ib, the next major catalyst is data from phase IIa, which in our opinion will be in 2022, thus lack of potential triggers from mid-2020 and forward. This will probably not be in advantage for the stock and could cool the interest for A1M Pharma until data from phase IIa are on the horizon.

Company Description

A1M Pharma is a biotech company focused on developing a preventive treatment for acute kidney injury (AKI) in patients undergoing open-chest cardiac surgery. There are currently no approved therapies for the prevention and treatment of AKI. A1M Pharma's lead drug candidate, ROSgard, is a biologic that mimics one of the body's most powerful and universal defense system against oxidative stress. The company was founded in 2008 by researchers at Lund University and the organization is currently based in Lund, Sweden. A1M Pharma listed its shares on Nasdaq First North in 2013.

ROSGard has multiple molecular mechanisms which individually and synergistically can prevent cell- and tissue damage. Based on integrated assessment of these mechanisms, combined with preclinical pharmacology data and intrinsic drug properties of ROSgard, A1M Pharma recently decided to initially target AKI in cardiac surgery for clinical development.

ROSGard is currently being evaluated in a clinical phase Ia study, and results from the first-in-human single ascending dose (SAD) study was successful. Next step will be a multiple-dose study (MAD).

This year the company has undergone a comprehensive organizational restructuring, including multiple changes in both the management team and the board of directors. The new leadership aims to successfully implement the company's new strategy, to execute the early phase clinical program of ROSgard, and, in the future, potentially enter into value-adding partnerships and licensing agreements. An deal would probably be an alternative after the completion of phase IIa or IIb.

Furthermore, the company recently completed a directed share issue of SEK 27.2 million to fund the first planned study of ROSgard in patients undergoing cardiac surgery. The directed share issue included several professional investors and an institution, which strengthened A1M Pharma's ownership structure significantly. Going forward, the company's short-term focus will be on finishing the early phase clinical program in healthy subjects and the phase Ib study in patients.

Historical Milestones

A1M Pharma has a long history but should be considered almost a new company as of this year, with fresh goals and a lot of new faces in the management team and board. Regardless, the company's milestones, as summarized below, provide an interesting history of A1M Pharma. In our view, investors should focus on the new goals and not so much on the company's history. The milestones achieved before mid-2018 are almost those of another company, and in our opinion, don't represent the new A1M Pharma. We believe the stock is still being viewed in the context of this history and is not judged according to its renewed potential.

A1M Pharma: Historical Milestones

1974	- Bo Åkerström, one of the company's founders, initiates research on the endogenous protein A1M.
2008	- The company is founded as Praelumina AB with the purpose of developing new treatments and diagnostics for preeclampsia.
2010	- Praelumina AB changes its name to A1M Pharma.
2013	- A1M Pharma lists its shares on Spotlight Stock Market (previously AktieTorget).
2014	- A1M Pharma receives Orphan Drug Designation in Europe for preeclampsia. - The company decides to complement its drug development regarding preeclampsia by adding a focus on kidney diseases.
2015	- A1M Pharma initiates preclinical studies in acute kidney disease in collaboration with Professor Faikah Güler from the research organization Phenos, originating from Hannover Medical School. - A rights issue generating SEK 31,9 million is conducted along with a capital raise of SEK 15,5 million through exercised warrants of serie TO1. - The company initiates a development collaboration with CRO Richter Helm BioLogics regarding technology, process development and preparation of large scale production of A1M Pharma's drug candidate according to GMP.
2016	- A rights issue generating SEK 39,7 million is conducted. - A preclinical short-term study in an animal model shows a solid kidney-protective effect with ROSgard's active substance in connection with radiation therapy.
2017	- A1M Pharma conducts initial immunogenicity studies for ROSgard's active substance in an animal model, which show promising results and indicate further development of the candidate. - A rights issue generating SEK 65,8 million is carried out. - The company finishes all preparations necessary to apply for initiation of clinical studies, including CRO partnership, large scale GMP production and GLP-toxicology studies. - A1M Pharma conducts a list change from Spotlight Stock Market to Nasdaq First North. - A1M Pharma applies, with the Swedish Medical Products Agency, for approval to start a clinical phase I trial. SMPA requests additional information, which cause a delay, but the application is finally approved in November.
2018	- A rights issue generating net proceeds of SEK 48,5 million is conducted. - Positive results from preclinical studies in acute kidney disease are reported. - A1M Pharma presents a clinical development plan for ROSgard focused on acute kidney disease associated with cardiac surgery.
2019	- A rights issue generating SEK 70,5 million before transaction costs is conducted, followed by a directed share issue of SEK 27,2 million a few months later. Among the investors participating in the directed issue were Max Mitteregger, Rutger Arnhult, Unionen and EQT-founder Jan Ståhlberg. - The company carries out a thorough organizational restructuring of both the management team and board of directors. - A1M Pharma initiates the clinical phase I study for ROSgard. - A1M Pharma presents positive result in phase I single dose.

Board and management

Following the restructuring and organizational changes conducted during 2019, both the management and the board of directors are now focused on bringing success to A1M Pharma and we believe they have a big opportunity to do so based on their historical achievements. Since the inception of the "new" A1M Pharma, the company has developed in a positive direction, which, combined with management and the board's strong personal track records, leaves us with confidence in the current leadership. CEO Tobias Agervald joined A1M Pharma from his previous role as Senior Medical Director at Astellas Pharma Global Clinical Development. Chairman of the board Cristina Glad has more than 25 years of research and business development experience in the pharmaceutical industry, as well as extensive board experience from biotech companies such as Rhovac

A1M Pharma- Board of Directors	Position	Experience
Cristina Glad (1952)	Chairman	Cristina Glad was appointed Chairman in 2019 after having been a board member since 2012, while simultaneously performing consultancy work for the company. She has more than 25 years of research and business development experience in biotech and diagnostics. Ms. Glad holds a PhD in biochemistry, an Executive MBA and is a member of the Royal Swedish Academy of Engineering Sciences.
Göran Forsberg (1963)	Board member	Göran Forsberg joined the board of A1M Pharma in 2019. He has extensive experience in a number of areas of pharmaceutical development and is currently CEO of the Swedish biotech company Cantargia. Mr. Forsberg holds a PhD in Biochemistry and is an Associate Professor at KTH Royal Institute of Technology.
Johannes Hulthe (1970)	Board member	Johannes Hulthe is Co-founder, CEO and board member of the medtech company Antaros Medical AB. He holds a PhD in Cardiovascular prevention and a MSc in Economics. Mr. Hulthe has more than 17 years of experience in the pharmaceutical industry, mainly from AstraZeneca where his last role was vice president. Johannes joined the board of A1M Pharma in 2019.

A1M Pharma - Management	Position	Experience
Tobias Agervald (1976)	CEO	Tobias Agervald took office as CEO of A1M Pharma in January 2019. Tobias Agervald is an associated professor and specialist in internal medicine and nephrology with extensive experience in global research and development of pharmaceuticals in both early and later clinical stages. Furthermore, Mr. Agervald has extensive experience in the pharmaceutical industry from executive positions and advisory board work at large pharma companies such as AbbVie, Sanofi, Astellas and SOBI.
Magnus Gram (1980)	CSO	Magnus Gram is one of the inventors and founders of A1M Pharma. He is also the originator behind several of the medical applications of A1M and is listed as an inventor on several of the company's medical patents and patent applications. Mr. Gram holds a PhD in Medical Science and was appointed CSO of A1M Pharma in June 2019.
Torun Labeledzki (1970)	CFO	Torun Labeledzki joined as CFO of A1M Pharma in August 2019 from her previous position as Business Controller at Apoteket AB. She has more than 20 years of experience in business and finance from several industries such as health care, TMT and consumables. Ms. Labeledzki holds a degree in Business and Administration from Stockholm University.

Ownership

Avanza Pension is the largest shareholder in the company (through nominee registered accounts) with 10%-plus of the capital, which indicates a large number of retail investors. Following Avanza Pension are many qualified private investors, including Rutger Arnhult (M2 Asset Management), Max Mitteregger (Galba Holding), Jan Ståhlberg, and Axel Karlsson. Furthermore, in the recent directed share issue, A1M Pharma attracted its first institutional investor, Unionen.

Ownership structure per 19/7 2019	Holdings	Capital	Votes
Avanza Pension	13 955 857	10,76%	10,76%
M2 Asset Management AB	13 097 776	10,10%	10,10%
Jan Ståhlberg	9 523 810	7,34%	7,34%
Unionen	4 000 000	3,08%	3,08%
Galba Holding AB	3 150 000	2,43%	2,43%
Axel Karlsson	2 504 977	1,93%	1,93%
Nordnet Pension	2 180 886	1,68%	1,68%
John Fällström	1 800 000	1,39%	1,39%
Wilhelm Risberg	1 590 224	1,23%	1,23%
UBS Switzerland AG	1 535 836	1,18%	1,18%
Håkan Nilsson	1 339 396	1,03%	1,03%
Other shareholders	74 988 983	57,83%	57,83%
Total	129 667 745	100,00%	100,00%

The management team and board of directors own 0.52% and 0.05% of the company's shares respectively, with CEO Tobias Agervald having by far the largest insider holdings in terms of both shares and warrants. We view the insider ownership as clearly inadequate, but we take management's short time at the company into consideration. However, we would welcome an increase in insider ownership in the coming months. Investors should, however, bear in mind that insiders only have certain windows of opportunity in which to invest, and such windows could be closed on account of upcoming study data.

Ownership per 31/8-2019	Position	Holdings	% of Total	Warrants
Management				
Tobias Agervald	CEO	588 240	0,45%	196 080
Magnus Gram	CSO	61 044	0,05%	7 844
Torun Labedzki	CFO	30 009	0,02%	-
Total holdings of Management		679 293	0,52%	203 924
Board of Directors				
Cristina Glad	Chairman	45 705	0,04%	12 188
Göran Forsberg	Board member	25 000	0,02%	-
Johannes Hulthe	Board member	-	-	-
Total holdings of Board of Directors =		70 705	0,05%	12 188

Upcoming catalysts

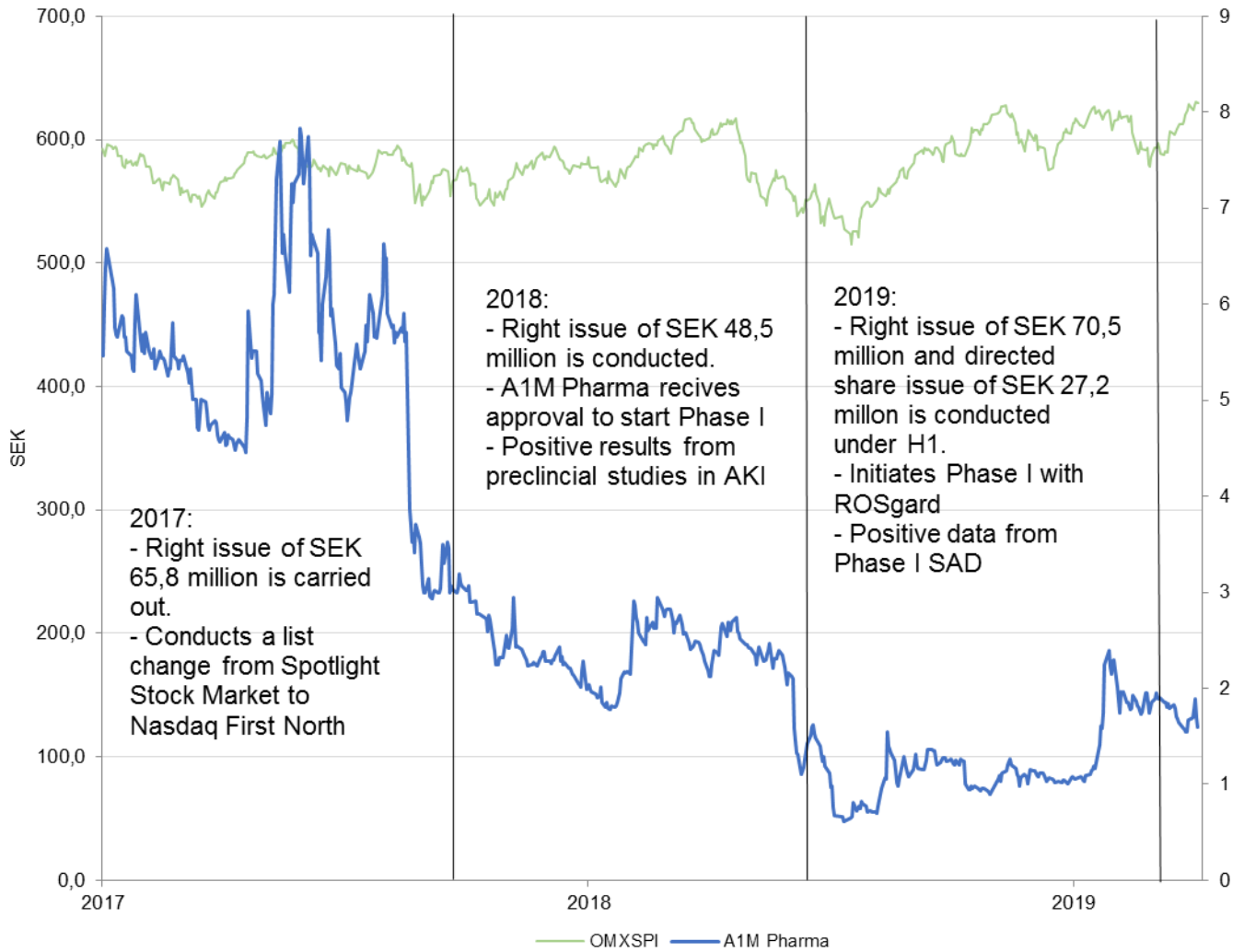
Catalysts are vital for small biotech companies as they draw attention to the company and potentially affect the stock price. We foresee stable news flow for A1M in the coming two years, with the most important catalysts shown below. The key catalyst in the coming 12 months is top-line data from the phase Ia MAD and Ib trials. Afterward, the newsflow will most likely be more modest until topline of phase IIa.

Catalyst	Likelihood	Impact	Timeframe
Start of Phase Ia MAD	Highly	Minor	< 6 months
Topline Phase Ia MAD	Likely	Important	6-9 months
Start of Phase Ib	Likely	Minor	6-9 months
Topline of Phase Ib	Moderate	Very important	9-12 months
Start of Phase IIa	Highly	Modest	>12 months
Topline Phase IIa	Moderate	Very important	24 months
Start of Phase IIb	Moderate	Modest	>24 months
Topline Phase IIb	Moderate	Very important	>24 months
Partnership for Phase III	Moderate	Very important	>24 months

Source: Redeye Research

Stock history

A1M Pharma has a long but shaky history, with various changes to the business plan and clinical focus. In our view, however, A1M Pharma should be looked at with fresh eyes as of mid-2018, following the company restructuring and strategic shift towards a clinical focus on AKI.



Source: Redeye Research

Projects

A1M Pharma is focused on developing its lead drug candidate ROSgard – a recombinant and modified variant of the endogenous protein alpha-1-microglobulin (A1M). ROSgard has multiple molecular mechanisms which protect DNA, mitochondria, cells, and tissues against oxidative stress.

In brief, ROSgard can capture and neutralize harmful and reactive free radicals (including reactive oxygen species, or ROS) that form during oxidative stress. It can also bind to heme (the oxygen carrying molecule in red blood cells) which at high concentrations are toxic to the kidneys. Finally, ROSgard can bind, protect and improve mitochondrial function during oxidative stress. Overall, this enables protection of exposed tissue and support of reparative processes.

ROSGard is currently being developed for the prevention and treatment of AKI in cardiac surgery, for which there is currently no available treatment. Approximately 2 million patients performed cardiac surgery per year and of these around 30% is in high risk of developing AKI according to Meersch et al. (2017). Thus approximately 600,000 patient's sufferers from this condition each year and the outcome of AKI is significant morbidity and mortality, while patients who survive also have a risk of developing chronic kidney disease (CKD). CKD can progress towards end-stage renal disease (ESRD), also called kidney failure. In such cases, the patient needs either dialysis or a kidney transplant to survive. However, many patients die before they develop ESRD because of other risk factors.

Pipeline

A1M Pharma has one drug candidate in development, but no other candidates in the pipeline – at least none it has communicated to the market. Although the drug candidate is initially focused on a niche market, there is potential to broaden the indication further, especially into other AKI segments – for example, into sepsis or delayed graft function in kidney transplant recipients – if A1M Pharma can produce solid study data. Potentially broadening the pipeline in the future could create even more value for shareholders.

Acute kidney injury

Acute kidney injury (AKI) is a state where the kidneys suddenly stop working. It is a life-threatening condition and requires immediate treatment. It may be reversed though, and patients who are otherwise in good health have a good chance of recovering normal or nearly normal kidney function. AKI is most common in patients who are already sick and often hospitalized, with critically ill patients in intensive care representing a high-risk group.

AKI causes the kidneys to suddenly lose their ability to filter waste products from the blood. Without this filtering ability, there is a chance that levels of waste may accumulate to a dangerous level, with blood levels potentially getting out of balance. Principal causes of AKI include:

- A condition that slows blood flow to the kidneys, such as low blood pressure, heart disease or heart attack, infection, or excessive bleeding (pre-renal AKI)
- Intrinsic kidney damage caused by e.g. toxins, drugs, harmful antibodies and immune reactions (intra-renal AKI)

- Blockage of the kidneys' urine drainage tubes, this prevents waste products from being excreted from the body in the urine, which can be caused by cancer, kidney stones or bladder problems, for example (post-renal AKI)

Symptoms of AKI can be hard to spot at first but can include not enough urine, or swelling in the legs, ankles or feet. The patient may feel tired or having trouble catching their breath. Severe AKI can cause seizures or coma.

Treatment of AKI usually requires the patient to stay in hospital, although most patients with AKI are already in a hospital for another reason. Severe AKI requires treatment with dialysis to replace the kidney function until the organ recovers. The aim is to treat what caused the kidney to fail and for the kidney to recover to normal functionality.

More than 13 million people are affected by AKI every year. Suffering from AKI increases the chances of other health problems, with a higher risk for subsequent kidney failure. Severe cases of acute renal failure can result in death. Studies on long-term follow-up (one to ten years) have shown that around 12.5% of AKI survivors require dialysis, and 19-31% of them will develop CKD. For already hospitalized patients, the mortality rate of AKI is 40-50%, and around 2 million people worldwide each year die from the condition.

Oxidative stress and AKI

Oxidative stress occurs when the body transforms oxygen to substances that have the potential to be extremely harmful to organs and tissue. Acute oxidative stress often arises in connection with e.g. major surgery, transplantation, chemotherapy or sepsis. ROS is the name for some of the toxic molecules that can be formed during oxidative stress and which may react uncontrolled with endogenous molecule of blood, tissue, or cells. The kidneys are for several reasons particularly vulnerable to damage caused by oxidative stress, and AKI is therefore a relatively common clinical manifestation.

The medical costs associated with AKI

The costs associated with AKI are very high for hospitals. AKI consumes 1% of the National Health Service (NHS) budget in the UK. In 2018/2019, the NHS's budget was around GBP 129 billion, implying costs associated with AKI of around GBP 1.3 billion. In the US the cost for hospitalization owing to AKI is USD 5-24 billion. Patients who require dialysis are the most expensive, costing somewhere around USD 11,000-42,000 more per hospitalization than a patient without AKI. These estimates only account for the costs incurred during hospitalization and do not include the costs that can result as a long-term consequence of AKI.

Based on these estimates, we see the potential market for treatment of AKI as huge, as today there is no approved treatment to prevent it. A treatment that could prevent AKI from developing could potentially save many lives, and the benefit is easy to calculate using today's costs for intensive care.

ROSGard

ROSGard is a recombinant and modified variant of the endogenous protein A1M. Endogenous A1M was discovered more than 40 years ago and has been subject to extensive research during the last decades. ROSGard mimics one of the body's own and most powerful protection against oxidative stress. It also harbors significant advantages compared to other traditional anti-oxidants such as vitamins C and E:

- It is more efficient in radical binding than other antioxidants
- It does not present an oxidative threat after binding of radicals and/or reducing oxidants
- It is subject to a "homing mechanism" to the kidney, making the kidneys an attractive target for protection

ROSGard represent a treatment paradigm based on augmentation of the body's own defense system in acute clinical conditions when the body is unable to manage the acute burden of oxidative stress, such as during AKI.

ROSGard is being developed for the prevention and treatment of AKI in cardiac surgery. This is considered an attractive first indication, also backed up by industry sources, due to ROSGard's ability to target several important pathways of AKI in the setting of cardiac surgery.

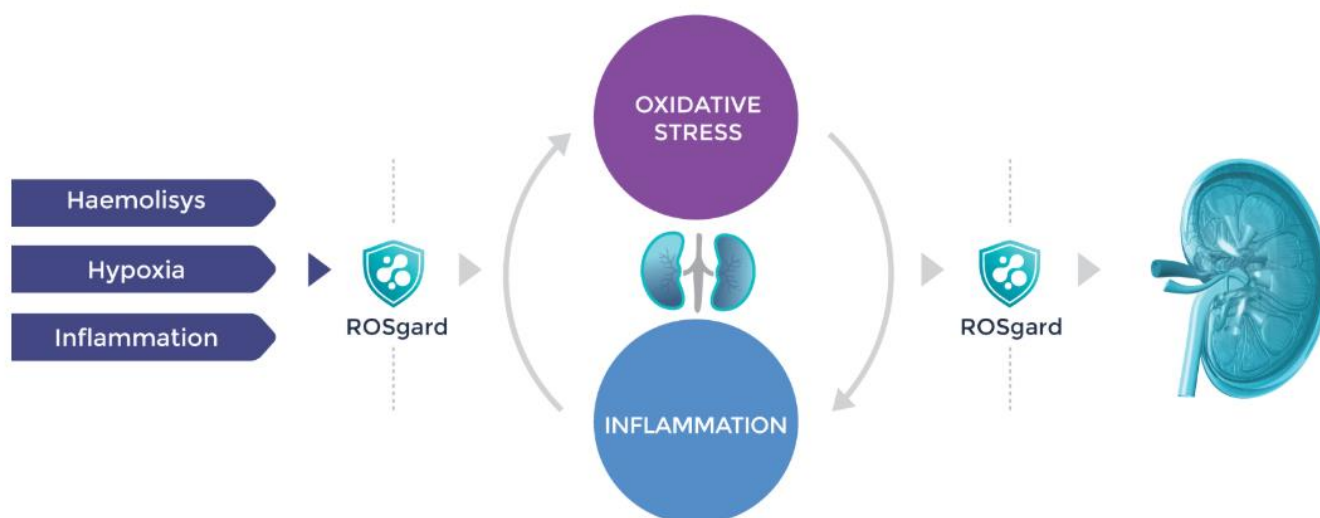
How ROSGard works in cardiac surgery

A heart-lung machine is used during open-heart surgery, creating hypoxia when connected. During the operation, when the patient is connected to the heart-lung machine ("on-pump"), the kidneys suffer repeated minor ischemic damage. Once disconnected ("off-pump"), the kidneys enter a state of severe oxidative stress with subsequent risk for AKI development during the initial 48-72 hours after surgery.

Hemolysis is a complication related to the use of a heart-lung machine, which means red blood cells (RBC) rupture, releasing heme (part of hemoglobin). Hemoglobin is a protein that normally transports oxygen in the blood. However, studies have shown that rupture of RBCs and the release of free heme is toxic to the kidneys and an important contributor to AKI in cardiac surgery.

Thus, oxidative stress combined with release of free heme are considered important steps towards AKI development in cardiac surgery. These events trigger an inflammatory process which fuels additional damage to the kidneys. ROSGard can effectively prevent the deleterious effects of oxidative stress and free heme and is therefore a promising therapeutic candidate in AKI.

In the proposed treatment regime ROSGard will be given as an intravenous dose shortly before surgery, followed by a few doses after surgery, allowing it to protect the kidneys before and during the generation of oxidative stress. ROSGard will also counteract toxins, e.g. heme, in the blood before they reach the kidney. Furthermore, ROSGard will be distributed to the kidneys and protect them against the oxidative stress that is generate during cardiac surgery. The process is illustrated below.



Source: A1M Pharma

Patent

A1M Pharma has approved patents in all major regions for the medical use of A1M and A1M-based therapies. These patents cover a broad range of clinical conditions characterized by abundant oxidative stress, including their lead indication AKI. The company also has pending patents related to composition of matter for their lead compound ROSgard. The patent portfolio beyond these core families is diverse, and we assume that the new management will streamline the portfolio to match the new strategic and commercial objectives for A1M Pharma.

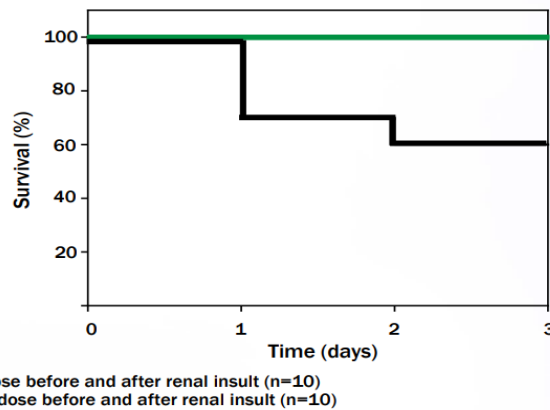
Patent group	Approved in geographical zone	Expiration date
Medical use of A1M	EU/US/AU/JPN	2029
Diagnosis and Treatment of Preeclampsia	EU/US/AU/JPN/CA/MX/KR/NZ/ZA	2028 and 2030 (US)
Biomarkers for Preeclampsia	EU/AU/JPN/CA/MX/NZ/ZA	2031
α -1-Microglobulin for use in treatment of Mitochondria-Related Diseases	EU/AU/MX/NZ	2033

Source: Redeye Research

Solid preclinical data

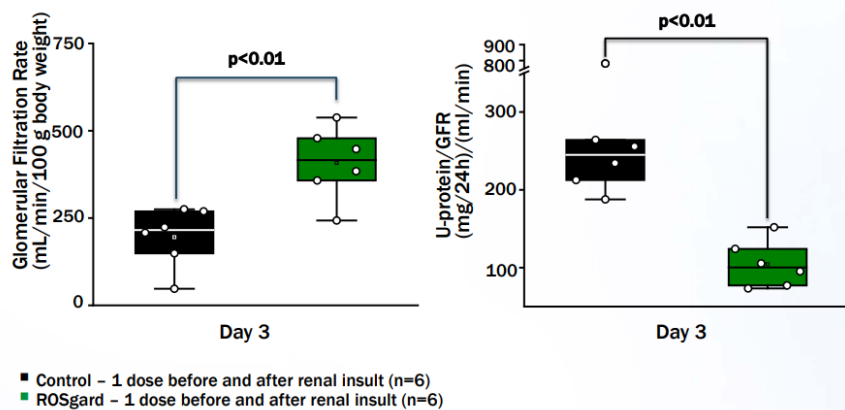
Since 2018, A1M Pharma has built up a solid preclinical data portfolio in AKI, leading the company to believe that ROSgard could have significant potential in AKI.

In a study performed by a CRO in Germany on 20 mice, ROSgard (ten mice) or placebo (the other ten) were administered to animals in conjunction with renal ischemia reperfusion injury. All the mice injected with ROSgard survived. Mortality in the placebo arm was 40%. Although a small preclinical study, it does indicate that ROSgard could act to protect against AKI. Improvements in renal function and various biomarkers of renal damage was also observed in the group who received ROSgard as compared to placebo



Source: A1M Pharma

Another preclinical study was carried out in the US together with a highly recognized Professor of Nephrology. Using a rat AKI model of ischemia reperfusion injury, this study observed that, following renal injury, kidney function was almost two times higher in the group that received ROSgard compared to placebo. It also demonstrated an approximately 70% reduction in the proteinuria in animals treated with ROSgard compared to placebo.



Source: A1M Pharma

ROSGard focus going forward

Primary focus for clinical development of ROSGard will initially be on prevention of AKI in patients undergoing cardiac surgery, an indication that, based on the substantial preclinical package, seems particularly suitable for the company to exploit. There is currently no approved treatment against AKI in association with cardiac surgery, which suggests a golden opportunity for A1M Pharma. Furthermore, the indication offers various advantages during development, such as a large patient base, short duration of treatment, and well-defined regulatory requirements from the authorities. Given the unmet medical need and relatively easy setup for clinical studies, the indication appears a good first test for the candidate, with the potential for broader aims in the future.

A straightforward clinical programme

A1M Pharma is underway with a phase Ia study in healthy subjects who will be given single ascending doses (SAD) first and then multiple ascending doses (MAD) of ROSGard. The primary goal of the study is to show that ROSGard is safe and tolerable in humans, with a secondary goal of assessing the pharmacokinetics under various dosing conditions.

Last week A1M Pharma presented positive phase I (SAD) data. ROSGard was well tolerated and showed a promising pharmacokinetic profile. The study also showed a plasma concentration that is expected to have a therapeutic effect with no serious side effects reported. The result from the study justifies continuing study ROSGard in a multiple-dose study, to complete the phase Ia program.

If phase Ia is successful, the next step will be to perform a small phase Ib study in around 20 patients undergoing open-chest cardiac surgery with the use of a heart-lung machine. The primary and secondary goals in this study will be the same as in phase Ia but also closely evaluating the patients to gain important understanding of how to design the phase II study. Vital information on doses, frequency of dosing, and safety profile could be generated from this study ahead of a phase II study, de-risking the clinical programme.

These three studies are estimated to be completed in Q3 20, with the first part of the phase Ia already completed successfully and second part to start in Q4 19, with data to be presented in late Q1 20. After that, it is assumed that the phase Ib will start in Q2 2020 and to report data in Q3, totaling about six months, which is a relatively short and effective study.

So far, the company has only obtained regulatory approval for the phase I SAD; approval for the phase I MAD and phase Ib will most likely be obtained as the clinical programme progresses. A1M Pharma has finances for both phase Ia and Ib, and thanks to its solid ownership base, we believe it could conduct a directed share issue in a swift manner should the need for more capital arise.

If all goes to plan with the development, phase IIa will start in late 2020/early 2021, and the study will take approximately 1-1.5 years to complete. The company believes after phase IIa could be an appropriate time to make a deal for the candidate before moving to the next step. We, however, estimate that also a phase IIb will be conducted before a potential deal, this will most likely raise the deal value significant. There is a variety of options after phase IIa in terms of clinical trials: including either a phase IIb/III or a phase III. The final decision will probably depend on the data obtained from the phase IIa study. In our opinion a phase IIb will be conducted followed by an extensive phase III which will be financed by a partner.

Big potential market

More than 13 million people each year are diagnosed with AKI, with high mortality and the chance of developing chronic renal impairment, leading to further sickness and a poorer quality of life. The global market is estimated to be worth more than USD 2.6 billion and is seeing annual growth of 11%. This indicates the huge potential in acute kidney injuries. Around 3 million patients are affected by AKI annually in Europe, the US and Japan, and mortality rates are high, at about 700,000 patients annually. In the US alone, AKI treatment affects hospital bills by around USD 10 billion each year. In the UK, AKI healthcare costs are estimated at SEK 4.4-6.4 billion per year, which is more than the healthcare costs for breast, lung and skin cancer combined.

We estimate the market for AKI in cardiac surgery is around 400,000-600,000 patients each year, based on two million cardiac surgeries performed globally. There are currently no drugs approved to treat AKI following cardiac surgery and so no historical sales are available for the indication.

Competitors to ROSgard

A1M Pharma has a few competitors trying to develop a treatment to prevent AKI following cardiac surgery, one of which is currently in phase III. Quark Pharmaceuticals is developing QPI-1002, a small interfering RNA (siRNA) targeting the pro-apoptotic gene P53 and temporarily inhibiting the expression of the gene. Both primary and multiple secondary endpoints were successful in a phase II clinical study of 314 patients. The primary endpoint was to investigate the proportion of patients developing AKI in the post-operative period until day 5, and the study showed that treatment with QPI-1002 significantly reduced the incidence of AKI.

In 2018 Quark Pharmaceuticals started a pivotal phase III study in AKI following cardiac surgery, enrolling 1,038 patients at high risk of AKI following cardiac surgery at 115 sites globally. The phase III study is a double-blind, placebo-controlled, multi-center study to evaluate the efficacy and safety of QPI-1002 in patients undergoing cardiac surgery. The primary endpoint will be the proportion of subjects who develop any of the components of major adverse kidney events at day 90 (MAKE90), defined as death up to day 90, initiation of renal replacement therapy (RRT) up to day 90, or an equal to or greater than 25% reduction in estimated glomerular filtration rate at the day 90 visit. This new primary endpoint is based on Quark's phase II study. According to industry sources, the primary completion date for the phase III study is expected during July 2021.

Angion Biomedica is another competitor, currently enrolling patients in a phase II study with its drug candidate ANG-3777. The study will examine patients with a high risk for AKI following cardiovascular surgery. ANG-3777 is a potent, small molecule mimetic of hepatocyte growth factor, the sole ligand of the c-Met receptor. A reduction of acute organ damage has been shown if the HGF/c-Met pathway is activated, prompting Angion to start two separate phase II trials in different indications, one in patients with presumptive delayed graft function post-transplant and another in AKI following cardiovascular surgery. There is no information on when study data will be available, but considering the other competitors, we believe Angion's data should be available during 2019 or 2020.

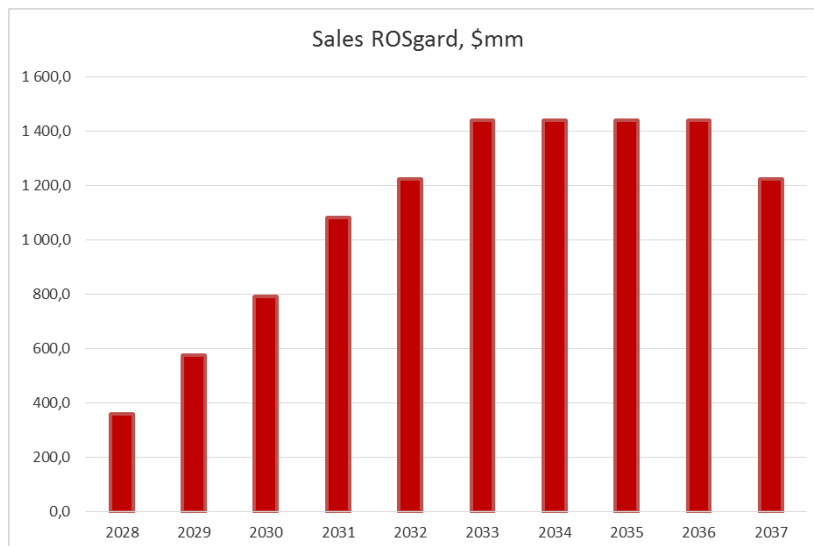
In 2018 Astellas Pharma acquired Mitobridge for USD 225 million. It is currently enrolling patients for a phase II study including 220 subjects. The purpose of the study is to evaluate the efficacy of post-surgery treatment with ASP1128 in subjects at risk of developing AKI following coronary artery bypass graft (CABG). The primary endpoint in the study examines the proportion of participants developing AKI based on serum creatinine criteria within 72 hours. According to industry sources, the primary completion date is expected in July 2020.

These three are, in our opinion, the main competitors to A1M Pharma for the unmet medical need of preventing AKI. Investors should keep an eye on these studies as the competitive landscape could swiftly change should any of them fail in their studies or gain market approval. A1M Pharma is somewhat behind its main competitors, but if all goes as planned, we still expect this to be a big enough market to share among the lucky ones gaining approval.

Investors should also note that none of competitors mentioned here are not targeting the same mode of action as A1M Pharma which could be a significant advantage and offers opportunities for competitor differentiation. At present, there is no approved treatment to prevent AKI; the only treatment options available are dialysis and supportive care.

Market Opportunity and Estimates for ROSgard

There is still a long way to go before A1M Pharma will receive any revenue from ROSgard. In our estimates, we have the first sales in 2028 but with potential upfront and royalties from 2024. We expect that ROSgard will reach its peak sale of 1,4 billion after five years in the market.



Source: Redeye Research

Our valuation in A1M Pharma is based on the global potential and that ROSgard has the potential to be one of several other drugs on the market in 8 years. We also predict that A1M Pharma will license out ROSgard after a successful phase IIb, and thereby assume that no further investment will be needed from A1M Pharma. We assume that the target population is around 600 000 patients per year who develops AKI in associating with cardiac surgery. According to us, ROSgard has the potential to take 30% of the market, thus a peak penetration of 180 000 patients. We assume that there will be at least two competitors on the market before ROSgard reaches it and therefore we see a markets penetration of 30% as reasonable. Based on discussion with the company and research we estimate a price per year for ROSgard of 8000 USD. Based on these assumptions we estimate that ROSgard will be launched in 2028 and reach a peak sale of 1.4 billion USD.

Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036
Upfront														
Cash flow MSEK		285												
Probability		30%												
Risk-adjusted CFs		85,5												
Milestone Ph. III														
						NDA	1st sale							
Cash flow MSEK		95				237,5	332,5							
Probability		30%				20%	10%							
Risk-adjusted CFs		28,5				47,5	33,25							
Sales/royalties														
Cases	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000
# pts with ,	600 000	600 000	600 000	600 000	600 000	600 000	600 000	600 000	600 000	600 000	600 000	600 000	600 000	600 000
# pts treated with ROSgard						45 000	72 000	99 000	135 000	153 000	180 000	180 000	180 000	180 000
ROSGard market share						7,50%	12,00%	16,50%	22,50%	25,50%	30,00%	30,00%	30,00%	30,00%
launch curve						25,00%	40,00%	55,00%	75,00%	85,00%	100,00%	100,00%	100,00%	100,00%
ROSGard yearly cost \$						8 000	8 000	8 000	8 000	8 000	8 000	8 000	8 000	8 000
Net sales, ROSgard, \$mm						360	576	792	1 080	1 224	1 440	1 440	1 440	1 440

Source: Redeye Research

ROSGard – Licensing and partner deal assumptions

We see a future partnership deal as vital for A1M Pharma and our valuation. In our opinion, the most likely partner scenario would be after a successful phase IIb, however partner deal can be reached in an earlier stage as well all depending on the data.

There is a huge unmet medical need in the indication, and in our view, there should be significant interest from partners for ROSGard if everything plays out correctly. It will be important for A1M Pharma to get a partner that will be available to finance further study and preferably have experience from regulatory processes. Apart from this, the partner would also need resources to commercialize ROSGard in US and EU and an attractive network of key individuals from the medical field, payers and key opinion leaders.

In our opinion, A1M Pharma could finance their development in phase IIa and IIb, but for phase III, which will enroll around 1000 patients, a partner would be needed. Thus we expect a partner deal during 2024 of 100 million USD, which would generate an upfront payment of 30 million USD and follow shortly after with a milestone of 10 million USD in association with the start of phase III. Apart from these two potential payments, we have estimates royalty of 25 million USD for NDA and 35 million USD at the launch of ROSGard. Furthermore, we estimate that A1M Pharma would have a royalty share of 18% from sales.

We argue that 100 million USD would be reasonable value for a partner deal since Astellas Pharma acquired Mitobridge for 225 million USD. We take a conservative stand and therefore assume around half of that deal value.

With a high interest in the field we also see the potential of A1M Pharma being acquired by a smaller pharma company or specialty company if the phase IIb would be successful. A potential speculator could be Astellas Pharma if their candidate for AKI (ASP1128) were to be proven not suitable for the intended indication. In that case, Tobias Agervald historical connections with Astellas Pharma could come in handy.

ROSGard		
Deal assumptions	Year	\$mm
Upfront	2024	30
Phase III start	2024	10
NDA	2027	25
First Sale	2028	35
Total		100
Royalty Rate		18%

Source: Redeye Research

Financials

Research & development and other costs

We estimate that A1M Pharma needs to invest around SEK 190-300 million from now until the top-line data from its phase IIb study is released. After this event, we assume that a partner would take on the cost for further development of ROSgard. We estimate that the phase IIa trial will cost around SEK 30 million and a phase IIb around SEK 110 million, risk-adjusted.

Other costs we estimate at around SEK 10 million per year because of the slim organization. According to the Q2 19 report, the cash balance was SEK 52 million, while A1M Pharma has an outstanding warrant that could bring in around SEK 28 million before transaction fees in October 2019. The warrant invites owners to buy new shares in A1M Pharma for SEK 1 per share, making it well in the money at present. In our opinion, the company's current cash position is thus around SEK 65 million, including the warrant.

Capital

We see a need for capital of around SEK 40-50 million to conduct the phase IIa study which we risk-adjust with 60% to SEK 24-30 million. The phase IIb we estimate to SEK 150-250 million with a risk-adjustment of 45% to SEK 70-110 million. Based on the capital need we expect A1M Pharma to initiate a capital raise during 2020 of around SEK 50 million. The company has conducted two directed share issues in the last six months targeting professional investors, and we believe further capital raises will be carried out in the same manner or as a rights issue.

Valuation

- The target population of 600 000 patients per year with a high risk of developing AKI
- ROSgard could achieve a 30 percent market share, we judge – around 180 000 patients per year at the peak
- We estimate ROSgard will cost USD 8,000 per year
- Peak sale of USD 1.4 billion
- A1M entitled to a royalty of 18 percent of sales, translates to SEK 2.5 billion at peak sales
- We assume a 15 percent chance of success from this stage, we risk-adjust potential revenue
- We assume a partner deal after a successful phase IIb in 2024
- Deal value of 100 million USD including 30 million USD upfront
- All in all, this leads us to a risk-adjusted net present value at SEK 423 million or SEK 3,3 per share
- Factor in future cost though our sum-of-the-parts analysis leads us to set a fair value at SEK 2,3 per share

A1M Pharma Valuation				
Project			Valuation	Per Share
ROSGard			423	3,3
Cost			-190	-1,5
EV			233	1,8
Cash			65	0,5
Fair value			298	2,3
Source: Redeye Research				

Bull

- In our Bull case, we assume 40% penetration of ROSgard
- We estimate that 240 000 patients will be treated per year at the peak
- Peak sale of 1.9 billion USD
- A1M Pharma entitled to a royalty of 20 percent of sales, translates to SEK 3.5 billion at peak sales
- Partner deal after positive phase IIa in 2022 with 200 million USD in value, 60 million USD upfront
- 15 percent chance of success from phase I
- We see a Bull Case of SEK 653 million or SEK 5 per share

Bear

- In our Bear Case, we assume that the data from phase Ib will be in a grey area which would require more studies before entering phase II
- A1M Pharma will have to go back to the drawing board and re-run the phase I program
- The need for more capital will arise and with that potential to multiple dilutions before the project is back on track
- We see a Bear Case of SEK 47 million or SEK 0,4 per share

A1M Pharma: Summary of scenarioanalysis

	Bear	Base	Bull
SEK per share	0,4	2,3	5
Potential / Risk*	-75%	45%	214%

* Base on closing price 20 Sep 2019: SEK 1,59

Source: Redeye Research

Peer Valuation

Our peer-valuation don't impact our Base Case; thus, it's only a way for investors to get some perspective about how similar companies are valued. Investors should also bear in mind that peer-valuations should only be seen as indicative because companies and projects can vary greatly. Also, peers are only interesting if you could find relevant peers. With this in mind, we present a few peers that, according to us, is in a similar stage as A1M Pharma.

All of our peers are in preclinical or phase I with its main candidate (Cyxone have a candidate that may enter phase II in 2020 but need to complete toxicity study first). However according to us the market mainly looks at the three peers as company in phase I, and therefore it is a relevant comparison.

Based on our peer valuation, we argue that our Base Case is realistic and that there is clear upside potential in A1MPharma, especially as A1MPharma has presented positive data in their first phase I trial.

A1M Pharma: Peers

	Market cap (SEKm)	Cash*	EV	Clinical Stage	# Projects
Cyxone	218	24	194	I	2
Corline Biomedical	236	33	203	I	1
Kancera	167	9	158	I	4
		Mean	185		
		Median	194		
A1M Pharma	220	65	155	I	1

* Based on latest interim report

Source: Interim reports, Redeye Research

Sensitivity analysis

LoA, WACC, and penetration are three of the key variables which impact our valuation. We, therefore, provide two sensitivity analysis to illustrate this.

A1M Pharma sensitivity anlysis, share price

		LoA				
		5%	10%	15%	20%	25%
WACC	10%	3,9	3,9	3,9	3,9	3,9
	12%	2,9	2,9	2,9	2,9	2,9
	14%	2,1	2,1	2,1	2,1	2,1
	16%	1,5	1,5	1,5	1,5	1,5
	18%	1,1	1,1	1,1	1,1	1,1

A1M Pharma sensitivity anlysis, share price

		LoA				
		5%	10%	15%	20%	25%
Penetration %	10%	-0,3	0,0	0,3	0,6	0,9
	20%	0,0	0,6	1,2	1,8	2,4
	30%	0,3	1,2	2,1	3,1	4,0
	40%	0,6	1,8	3,1	4,3	5,5
	50%	0,9	2,4	4,0	5,5	7,0

Source: Redeye Research

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

CEO Tobias Agervald has experience from Astellas Pharma and drug development which will be useful for A1M Pharma. Management is backed by a lot of experience from the board. In 2019 both Göran Forsberg, extensive experience from pharmaceutical development and currently CEO of Cantargia, and Johannes Hulthe, over 17 years of experience from the pharmaceutical industry and previously vice-president at AstraZeneca.

Business: 2

There is a huge unmet medical need for a treatment against AKI, and a potential candidate to prevent this will be a blockbuster. A1M Pharma, therefore, has started to take a position in a very attractive field however its a long way to go.

Financials: 1

A1M Pharma's is a biotech company which will be without stable revenue until their candidate can reach the market. They will need regular capital injections from the capital market until an eventual partner decided to finance further development.

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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Redeye Rating (2019-09-22)

Rating	People	Business	Financials
5p	11	8	1
3p - 4p	62	51	28
0p - 2p	13	27	57
Company N	86	86	86

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Jakob Svensson owns shares in the company : No

Anders Hedlund owns shares in the company : No

Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.