A1M Pharma

On the verge of entering a new phase

Emerging from research project to treatment platform

A1M Pharma is a preclinical stage biotech company focused on establishing a treatment platform with ROSgard, a recombinant version of the endogenous A1M protein. The protein fulfils various important bodily functions, including working as a protector against free haemoglobin, an antioxidant, as a radical inhibitor and as a tissue-repair agent. It can thus potentially be used in multiple therapeutic and diagnostic settings.

Biological drug based on an endogenous protein

As ROSgard is a biological drug based on the endogenous A1M protein, it could mitigate the risk of safety issues in the coming clinical trials. In a preclinical setting, A1M Pharma has so far been able to demonstrate a solid safety profile in different animal models. It also has an extensive scientific foundation built on more than 40 years of university research on the A1M protein.

Clinical trials to commence in 2018

The company currently targets two indications: kidney protection in radiation therapy (PRRT) and pre-eclampsia (toxaemia in pregnancy), two areas with unmet medical needs. We estimate the market opportunity within PRRT in the range of USD 560m-1,960m and pre-eclampsia at USD 1,200m-3,200m. ROSgard should enter an adaptive phase I/II study in PRRT in 2018 followed by studies in pre-eclampsia in H2 2019. We see a need for additional financing to finalise the PRRT study, the amount and timing depending on outstanding warrants and potential strategic partnerships.

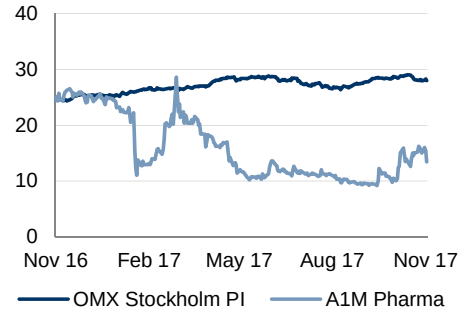
Valuation

Based on our fundamental DCF approach, with variations in sales growth, EBIT margin and WACC assumptions, we derive an equity value per share of SEK 11.0 to SEK 28.0.

Key data

Country	Sweden
Bloomberg	A1M SS
Reuters	A1M.ST
Share price	13.45
Free float	80%
Market cap (m)	SEK 108
Website	www.a1m.se
Next report date	23 February 2018

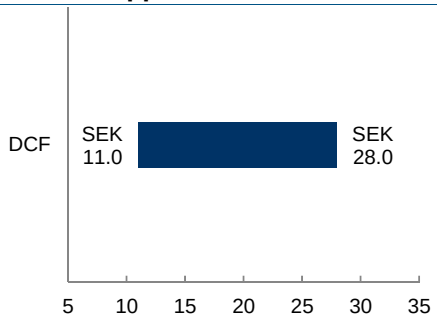
Absolute and relative performance



	-1M	-6M	-12M	YTD
Absolute	28%	12%	-46%	-45%
Relative	30%	12%	-59%	-54%

Source: FactSet

Valuation approach



Source: Nordea Markets

Summary table - key figures

SEKm	2014	2015	2016	2017E	2018E	2019E	2020E
Net sales	0	0	0	0	0	31	52
- growth		n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBIT	-14	-30	-54	-70	-81	-30	-3
- margin		n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EPS	-9.66	-15.90	-19.07	-7.18	-8.24	-3.08	-0.30
- growth		n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
DPS	0.00	0.00	0.00	0.00	0.00	0.00	0.00
P/E	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EV/EBIT	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EV/Sales	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
RoE	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Div. yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
FCF yield	-16.6%	-15.4%	-43.8%	-56.8%	-61.1%	-27.6%	-7.3%
ND/EBITDA	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

Source: Company data and Nordea Markets

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Factors to consider when investing in A1M Pharma

A1M Pharma is on the path to transforming from a university research project to achieving its long-term ambition of building a treatment platform based on the endogenous A1M protein. Preclinical trials have indicated that the company's lead product candidate ROSgard could restore impaired kidney functions by repairing damaged tissue and protecting against oxidative stress, which could be useful in multiple indications. It currently targets two indications, kidney protection in PRRT for NETs and pre-eclampsia, and seeks to start an adaptive phase I/II study in radiation-induced kidney damage in 2018. Its commercial strategy is to form strategic partnerships to take ROSgard to market.

We identify a number of key themes describing the investment case in A1M Pharma

We consider the following factors key when evaluating an investment in A1M Pharma:

- A1M Pharma is on a journey to build a treatment platform based on the product candidate ROSgard that could be used in multiple settings to protect cells and tissue from damage induced by oxidative stress and other toxic substances.
- The company is focusing on kidney protection in radiation therapy (PRRT) and pre-eclampsia (toxaemia in pregnancy), areas with unmet medical needs due to a lack of treatment options, and which thus represent promising market opportunities. We estimate the market opportunity in PRRT in a range of USD 560m-1,960m and in pre-eclampsia at USD 1,200m-3,200m.
- The nature of the ROSgard product candidate, as a recombinant drug based on endogenous protein A1M, could offer potential safety benefits in coming clinical trials. ROSgard is also based on a solid scientific foundation with more than 40 years of research underpinning the mechanism of action.
- New clinical strategy could facilitate a more optimal path to show clinical proof of concept and later expand ROSgard into other indications with support from strategic partners.
- Next year represents a paradigm shift for the company as it enters clinical trials with its product candidate ROSgard after the timely execution of the preclinical development plan.

Key risk factors:

- Dependent on regulatory approvals and successful commercialisation of the product candidate ROSgard.
- Clinical trials are risky and have no guarantee of success, despite promising results in a preclinical setting.
- The company is in the preclinical stage and the value of preclinical assets is often hard to assess.
- A1M Pharma is in need of additional funding to complete its planned activities over the next 12 months.
- The company is highly dependent on a number of key employees.

Properties of the A1M protein could enable it to be used across multiple medical applications

Powerful protective and regeneration stimulating properties

A1M Pharma hopes to fulfil its long-term ambition of establishing a treatment platform based on the natural endogenous A1M protein that can be found in all vertebrates. Its lead product candidate is called ROSgard, due to its potential to protect against reactive oxygen species (ROS), a recombinant version of the A1M protein.

In different preclinical settings it has been indicated that the product candidate could have the potential to protect the body against harmful oxidative stress in the organs and other tissues. If the company were able to establish the protective and healing effects in a clinical setting, it could be applied in a broader sense across other indications.

New clinical strategy to optimise long-term ambitions

New clinical strategy introduced in 2016

A1M Pharma was founded in 2008 with the intention of focusing its activities on pre-eclampsia, an area of significant unmet medical need to which there is no cure today other than symptomatic treatment and terminating the pregnancy. In 2016, the company initiated a strategic review and decided to alter its clinical strategy and chose kidney protection in PRRT for NETs as the first indication to enter clinic with ROSgard. This means that A1M Pharma is developing ROSgard for two indications, both areas with unmet medical needs.

PRRT initially seen as a quicker way to validate the platform

In PRRT, the treatment potential with radioactive isotopes is limited by its harmful effect on the kidneys and bone marrow and ROSgard's protection of these organs could therefore improve the efficacy of the current treatment regime.

It also represents a meaningful market opportunity on its own merits

Although PRRT was initially seen as a means to speed up and facilitate ROSgard's path through the clinical stage, the PRRT indication itself represents a significant market opportunity. In November 2017, the company announced that, in addition to its protective effect on the kidneys, preclinical studies on ROSgard also indicate a protective effect on bone marrow during radiation treatment. If this dual protection against two of the most central damaging effects in connection with radiation treatment can be replicated in clinical trials, it could generate interest and potentially fuel licensing discussions.

PRRT offers a well-specified patient population, which could facilitate patient recruitment

Another key benefit of the strategy shift is that PRRT has a small and well-specified patient population. This facilitates recruitment for a clinical study, a factor that posed a potential issue in a pre-eclampsia clinical study where the patient population consists of pregnant women. The adaptive phase I/II study in PRRT could also generate safety data that could be used in future pre-eclampsia studies.

Market opportunity within PRRT	
NETs prevalence in the US and Europe	200,000 - 350,000
PRRT potential patient pool	70,000 - 122,500
ROSGard treatment cost	USD 2,000 - 4,000
Value per patient	USD 8,000 - 16,000
Market opportunity	**USD 560m - 1,960m**

Source: Company data and Nordea Markets

Market opportunity within pre-eclampsia	
Annual pre-eclampsia incidence in the US and Europe	300,000 - 400,000
ROSGard treatment cost	USD 2,000 - 4,000
Value per patient	USD 4,000 - 8,000
Market opportunity	**USD 1,200m - 3,200m**

Source: Company data and Nordea Markets

Pre-eclampsia and PRRT alone offers major market opportunities

We estimate the market opportunity for kidney protection in PRRT for NETs is worth USD 560m-1,960m. Assuming a market share for ROSgard of 35%, this yields a market potential of USD 196m-686m. For pre-eclampsia, we estimate a market potential of USD 1,200m-3,200m.

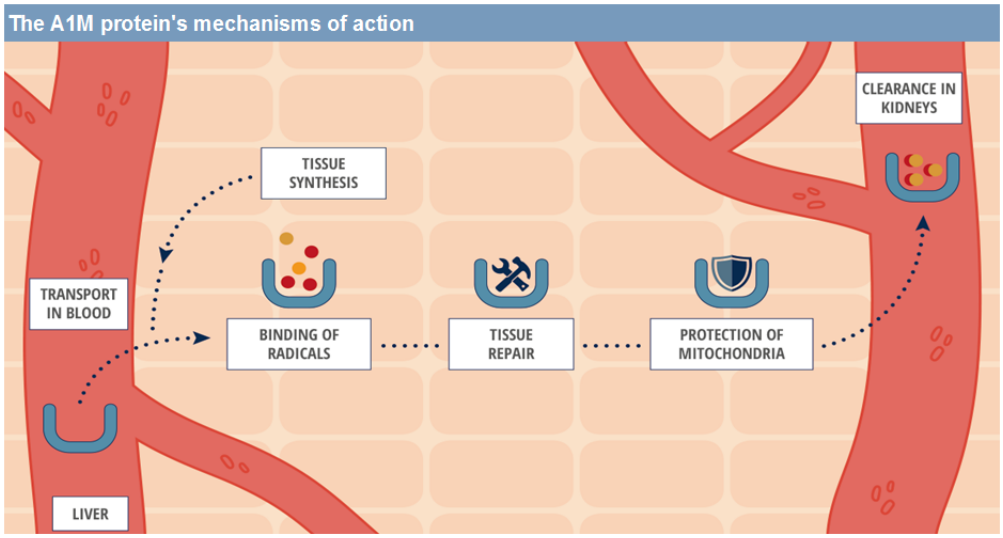
Replicating a natural process

A1M is an natural endogenous protein found in all vertebrates

A1M Pharma's product candidate ROSgard is a recombinant version of the natural endogenous A1M protein. Its mechanism of action can best be described as a "circulating wastebasket" that plays a key role in the body's defence against oxidative stress and toxic substances. With ROSgard, A1M Pharma is thus essentially replicating and amplifying nature's own defence mechanism. The natural A1M protein has the following main mechanisms:

- It binds and transports radicals and heme.
- It repairs oxidation damage and stimulates the healing processes.
- It protects the mitochondria – the cells' built-in power plants.

The A1M protein can be illustrated as a circulating waste bin



Source: Company data and Nordea Markets

ROSgard could potentially exhibit a strong safety profile

As ROSgard is based on an endogenous protein, ie is generated by the body itself, it could generate a strong safety profile. A1M Pharma has so far been able to demonstrate this in preclinical studies in six different species. This safety aspect is especially important in the pre-eclampsia indication, where the patient population consists of pregnant women.

Extensive background research on the properties of A1M

The research on the A1M protein was initiated in 1974 by one of the company's founders, Bo Åkerström, who was assigned the protein as a doctoral project. It has since occupied much of his career and more than 40 years of background research underpins the potential applications for ROSgard.

Entering a new phase in 2018

Transforming from a university research project to clinical research company

A1M Pharma has evolved from essentially an externally funded research group to a clinical research company in quite a short period of time. The company has so far delivered on the final stages of preclinical development without setbacks and is expected to enter clinic in the beginning of 2018.

Expected to enter clinic in PRRT in the beginning of 2018

Its clinical strategy for the development of ROSgard is to adopt an adaptive phase I/II study design in PRRT. Depending on the outcome of the PRRT study, a phase I or II study in pre-eclampsia is scheduled to start in the second half of 2019.

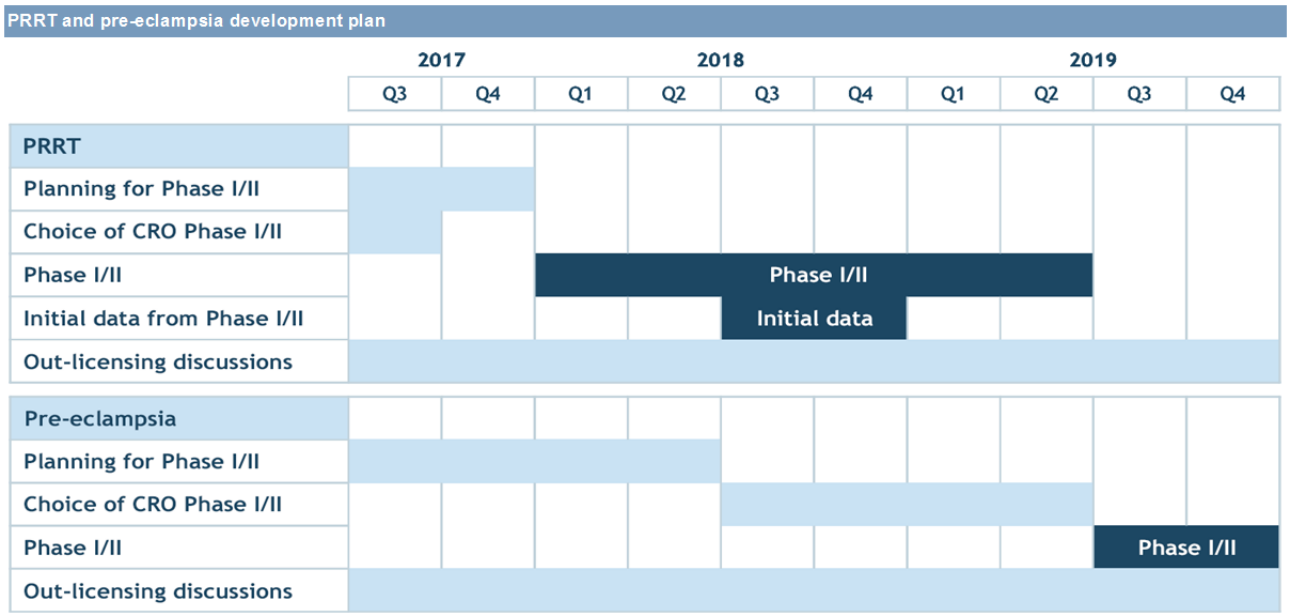
Followed by pre-eclampsia studies in 2019

A1M Pharma's commercial strategy is to formulate strategic partnerships to facilitate later-stage research and help to bring the product to market. Such agreements could provide a validation of the ROSgard platform and bring shareholder value relatively early in the process, as opposed to the riskier and financially more demanding path of going through the entire clinical process by itself.

Commercial strategy licences the technology to strategic partners

The company plans to have ongoing partnership discussions during the clinical work and initial data from the PRRT phase I/II study is expected in the second half of 2018. An early deal could act as a validation of the technology platform and would mitigate the need for additional funding. There is a trade-off, however, between the timing of a deal and its size, with the size increasing as a function of a product's progression in clinical development.

Financing, inherent in the nature of an early-stage life science company with no sales and resource-demanding research activities, is a recurring issue. We include a need for additional equity financing of SEK 150m in 2018E and estimate it to be enough to cover the company's cash burn to finalise the phase I/II study, initiate clinical studies in pre-eclampsia and create a strong negotiation position with potential partners. The actual amount needed is highly dependent on the exercise of the outstanding warrants, which expire on 8 December and have a strike price of SEK 15. If fully exercised, they could provide the company with SEK 27m before costs. Furthermore, a potential strategic partnership based on preliminary phase I/II data could provide some relief in terms of near-term cash flows.



Source: Company data and Nordea Markets

Valuation

Our DCF valuation indicates an fair value range of SEK 11.0-28.0 per share

Based on the assumption that the company can deliver in line with our expectations, we estimate a fair value range of SEK 11.0-28.0 per share based on variations in sales growth, EBIT margins and WACC. We derive our fair value from our fundamental DCF framework.

Risk factors

A1M Pharma is dependent on regulatory approvals and the successful commercialisation of its product candidate ROSgard. Failure to receive approval for one or several product candidates could affect the prospects of strategic collaborations and funding, as well as limit future earnings potential.

A full description of the risk factors we find most relevant for A1M Pharma can be found on pages 46-47

Clinical trials are risky and there are no guarantees they will be successful despite promising results in previous trials. Even in the case of positive results, there is a risk that regulatory bodies, such as the FDA and EMA, might have another interpretation of the results. Trials are time consuming, expensive and require certain expertise. It can take several years to complete a trial, and regulatory bodies may delay or terminate trials at any time.

ROSgard has just finalised the preclinical phase, and the value of assets in this early stage of development is often difficult to assess. The benefits still need to be confirmed in a clinical setting and as the product is still years from potentially reaching the market, it is difficult to predict pricing and demand for the product candidate.

A1M Pharma is still in the development phase and is not generating any sales. As there is not enough cash on hand to support the planned activities for the next 12 months, the company is likely to raise new funds in the near term.

The company's future success is dependent on its ability to keep, motivate and attract key personnel. This includes senior scientists and senior management. We provide a full description of the main risk factors we find relevant for A1M Pharma on pages 46-47.

Valuation

Based on a fundamental discounted cash flow (DCF) approach and assuming a weighted average cost of capital (WACC) of 10-12%, we derive an equity value range of SEK 11.0-28.0 per share. Note that the valuation is based on a long-term analysis and is not linked to a near-term assessment of the performance of the company.

Our valuation approach is primarily based on a DCF framework

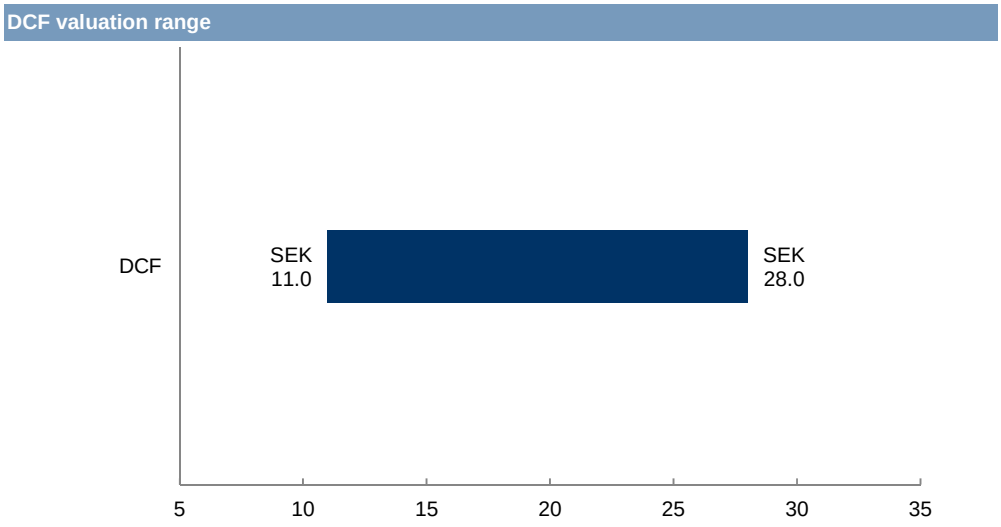
One of the most common ways to value the attractiveness of an investment opportunity is the discounted cash flow (DCF) method. A DCF model discounts all available cash flows for equity, bond and non-equity holders at the weighted average cost of capital (WACC). In other words, WACC represents a blended cost of capital for all invested capital in the company. In fundamental terms, a DCF framework is built on three parts:

- Discounting the company's free cash flow at WACC.
- Identifying the value of debt and other non-equity claims on the enterprise value.
- Deducting all claims to determine the value of the common equity. The fair value per share is then simply calculated by dividing the equity value by the number of outstanding shares.

A DCF valuation is commonly considered among academics and practitioners to be the best way to capture the underlying fundamental drivers of a company such as cost of capital, growth rates, reinvestment rates etc. If applied correctly, it represents the best way to approximate the true intrinsic value of a company. The main appeal of a DCF framework compared with other valuation methodologies is that it also focuses on streams of cash rather than accounting earnings. Its main disadvantage is its relative sensitivity to changes in input values.

We derive an equity value of SEK 11.0 to SEK 28.0 per share for A1M Pharma

Based on a DCF framework, we derive an equity valuation range of SEK 11.0-28.0 per share for A1M Pharma. Our forecast model is based on risk-adjusted NPV, where cash flows for the product candidates are adjusted to reflect the probability at each phase of clinical development. This implies that clinical achievements could have a significant impact on the valuation, positively or negatively.



Source: Nordea Markets

Near-term valuation triggers

A number of near-term events could impact the valuation of the company

A1M Pharma is on the verge of entering the clinic next year with its product candidate ROSgard in PRRT. The main uncertainty in the near term relates to financing, as the preclinical work has now been finalised and the company does not have sufficient resources to complete its clinical development. One short-term relief factor could be provided by the outstanding warrants that are not in the money and could, if fully exercised, raise SEK 27m. We believe the company will have a burn rate of at least SEK 80-90m and it is likely feasible to raise sufficient funds to have a strong negotiation position in potential partner discussions.

Preliminary data from PRRT study expected in H2 2018

The next potential near-term trigger would be preliminary phase I/II data in PRRT, with expected read-out in second half of 2018, followed by final data at year-end. Potential licensing discussions would likely be ongoing during the period and could provide some financial relief given positive data read-out and allow for further studies in other indications, primarily pre-eclampsia. In line with management communication, we expect clinical studies in pre-eclampsia to commence in the second half of 2019.

Upcoming valuation triggers	
Event	**Expected**
Initiation of phase I/II study in PRRT	Q1 2018
Financing/Equity issue	Q1 2018 - Q2 2018
Initial data from phase I/II study in PRRT	Q3 2018 - Q4 2018
Final data from phase I/II study in PRRT	Q2 2019 - Q3 2019
Potential out-licensing discussions	Q3 2018 - Q2 2019
Initiation of clinical studies in pre-eclampsia	H2 2019

Source: Company data and Nordea Markets

Valuation distribution

Our valuation only incorporates the potential in PRRT and pre-eclampsia

On an indication level, our valuation of the company is based on implicit values of SEK 145-211m and SEK 210-320m in PRRT and pre-eclampsia, respectively. Note that successful clinical proof of concept could validate the treatment platform and allow for expansion into new indications, potentially offering valuation upside. These potential indications include cardiovascular diseases (hardening of the arteries) and eye diseases. Radiation therapy in a broader sense, such as PRRT in treatment of prostate cancer, could also offer further applications of ROSgard. We do not assign any value to other indications apart from pre-eclampsia and PRRT in NETs in our current numbers.

Relative valuation and benchmarking

Difficulties finding relevant peers as it is a novel treatment

While it is generally advisable to attempt to provide a relative valuation approach, as a sanity check if nothing else, the early stage and the nature of the business that A1M Pharma is active in makes it very difficult to find a suitable peer group. The valuation for such a company is highly dependent on company-specific factors such as long-term market potential and probability of reaching that market, something that differs greatly between different medicinal focus areas. Considering the pioneering nature of A1M Pharma's platform against oxidative stress, we will therefore value the company solely on its own merits.

Fundamental valuation

Our DCF valuation range is based on variations in sales, EBIT margin and WACC assumptions

In the table below, we set out the general assumptions that we use to calculate our DCF value. Based on the assumption that A1M Pharma can deliver broadly in line with our forecasts, with variations in sales growth, EBIT margin and WACC assumptions, we arrive at a fair equity value range of SEK 11.0-28.0 per share. In the terminal period, we model WACC equal to ROIC and 2.5% growth.

DCF valuation		
DCF value	**Value**	**Per share**
NPV FCFF	91-246	9.2-25.0
(Net debt)	7	0.7
Time value	10-22	1.1-2.3
DCF Value	**109-275**	**11.0-28.0**

Source: Nordea Markets

Averages & assumptions					
Averages and assumptions	**2017-30**	**2031-37**	**2038-42**	**2043-47**	**Sust.**
Sales growth, CAGR	n.a	-25.0%	-20.0%	2.5%	
EBIT-margin, ex. associaties	56.9%	52.8%	48.0%	38.0%	
Capex/depreciation, x	1.5	1.0	1.0	1.0	
Capex/sales	5.7%	3.0%	3.0%	2.5%	
NWC/sales	13.5%	5.0%	5.0%	5.0%	
FCFF, CAGR	n.m.	-18.5%	-23.0%	-14.6%	2.5%

Source: Nordea Markets

To highlight the sensitivity of the DCF valuation, we also provide sensitivity matrices modelling variations in revenue growth, margin assumptions and cost of capital.

WACC

We apply a WACC range of 10%-12%

We apply a range of cost capital (WACC) of 10-12% as the input for our DCF valuation. The assumptions behind our WACC are outlined in the following table.

WACC assumptions	
WACC components	
Risk-free interest rate	1.5%
Market risk premium	5.5%
Forward looking equity beta	1.6-1.9
Cost of equity	10%-12%
Cost of debt	10.0%
Tax-rate used in WACC	22.0%
Equity weight	100%
WACC	**10.0%-12.0%**

Source: Nordea Markets

DCF sensitivity

In the following table, we provide a sensitivity analysis of the DCF valuation, with varying EBIT margins and sales growth rates.

Our DCF value with varying EBIT margins and sales growth rates

Sales growth vs EBIT margin						
		Sales growth change				
		-7.0pp	**-3.5pp**		**+3.5pp**	**+7.0pp**
	+7.0pp	15.6	17.0	18.8	21.1	24.2
EBIT margin	**+3.5pp**	15.0	16.4	18.1	20.2	23.2
change		14.5	15.7	17.3	19.4	22.1
	-3.5pp	13.9	15.1	16.6	18.5	21.0
	-7.0pp	13.4	14.5	15.9	17.6	19.9

Source: Nordea Markets

We also illustrate how the equity value varies with changes in WACC and sales growth.

Our DCF value with different WACC and sales growth assumptions

WACC vs sales growth						
		WACC				
		10.0%	**10.5%**	**11.0%**	**11.5%**	**12.0%**
	+7.0pp	28.0	24.9	22.1	19.5	17.1
Sales gr.	**+3.5pp**	24.6	21.9	19.4	17.1	15.0
change		22.0	19.6	17.3	15.2	13.3
	-3.5pp	20.1	17.8	15.7	13.8	12.0
	-7.0pp	18.5	16.4	14.5	12.7	11.0

Source: Nordea Markets

In addition, we provide a sensitivity table illustrating how the equity value varies with changes in EBIT margin assumptions and WACC.

Our DCF value with different WACC and EBIT margin assumptions

WACC vs EBIT margin

		WACC				
		10.0%	**10.5%**	**11.0%**	**11.5%**	**12.0%**
EBIT margin change	**+7.0pp**	23.8	21.2	18.8	16.6	14.5
	+3.5pp	22.9	20.4	18.1	15.9	13.9
		22.0	19.6	17.3	15.2	13.3
	-3.5pp	21.1	18.8	16.6	14.6	12.7
	-7.0pp	20.3	18.0	15.9	13.9	12.1

Source: Nordea Markets

Company overview

A1M Pharma is an early-stage research-oriented company focused on building a treatment platform around its product candidate, ROSgard, which is based on the endogenous A1M protein. Preclinical trials have indicated that A1M can prevent kidney damage by protecting the body from toxic substances that cause oxidative stress and inflammation. In 2016 the company announced a new operational strategy to focus its clinical research on radiation-induced kidney damage, where it saw a faster and more cost-efficient path to show clinical proof of concept and validate the technology, before bridging into other indications such as pregnancy-related diseases.

Swedish biotech with a product candidate that could prevent kidney damage

A1M Pharma is Swedish biotech company founded in 2008 by researchers at Lund University, although the background research stretches all the way back to the 1970s. The company develops the product candidate ROSgard, which is based on the endogenous protein alpha-1-microglublin (A1M). The protein is naturally present in living organisms, including humans, and preclinical trials have indicated that A1M can prevent kidney damage by protecting the body from toxic substances causing oxidative stress and inflammation. This is reflected in the name of the product candidate, ROSgard, which refers to the protection against so-called reactive oxygen species (ROS).

Source: Company data and Nordea Markets

Initial focus on protection against pregnancy- and radiation-induced kidney damage

Acute kidney injuries and pre-eclampsia affect millions of people each year and are conditions for which there is currently no curative care. Therefore, ROSgard could potentially have broad applications for both therapeutic and diagnostic uses and the company is initially focusing on two specific indications:

- Kidney protection in radiation therapy (PRRT) of neuroendocrine tumours (NETs)
- Treatment of pre-eclampsia.

Also developed a diagnostic tool for pre-eclampsia

In addition to ROSgard, the company's fully-owned subsidiary Preelumina Diagnostics AB has developed a diagnostic tool for pre-eclampsia that could have out-licensing potential and/or become a companion diagnostic for a future ROSgard pre-eclampsia treatment.

Source: Company data and Nordea Markets

Clinical trials to start at the beginning of 2018

A1M Pharma has conducted preclinical proof of concept studies in animals for the treatment of pre-eclampsia, acute kidney damage and radiation therapy for neuroendocrine tumours. Phase I/II trials are scheduled to begin in the beginning of 2018 with a safety study in healthy volunteers, followed by safety and efficacy studies in patients receiving PRRT. Upon receiving clinical proof of concept the company aims to attract potential partners to support the development in other indications, in particular in pre-eclampsia.

A1M Pharma has transitioned from a research group into a company ready to enter the clinic

In the past three to four years A1M Pharma has developed from an externally funded research group into a biotech company that is preparing to enter the clinic with its biological drug candidate ROSgard. In relative terms, the transformation process has been reasonably rapid and the SEK 200m spent during the period is quite cost-efficient when benchmarked against similar microcap biotech companies.

In April 2017, the company raised SEK 63m, after fees, in a share issue from existing shareholders. The company's share is listed on Nasdaq Stockholm First North.

Company history

Research on the A1M protein was started in 1974 by one of the company's founders

The history of A1M stretches all the way back to 1974, when Bo Åkerström began his research into the A1M protein. In 2002 the first study results were published in the journal Blood, indicating A1M's protective mechanism against haemoglobin and oxidative stress. Six years later, in 2008, A1M Pharma (formerly Preelumina Diagnostics AB) was officially established and applied for patents for the treatment and diagnosis of pre-eclampsia and the medical use of the A1M protein.

Listed in 2013, it received ODD in Europe in 2014 and signed a manufacturing agreement in 2015

In April 2013 A1M Pharma took a step into the public market, when its share was listed on Aktietorget. The following year was intense in terms of news flow and the company was granted patents for the treatment and diagnosis of pre-eclampsia, initiated a research project with NeuroVive Pharmaceutical, received orphan drug designation in the EU and expanded into its second indication, acute kidney damage. The company took a further step in 2015 by signing a development deal with a leading European contract manufacturer (Richter-Helm BioLogics) to prepare for full-scale production of the product candidate according to good manufacturing practice (GMP).

Equity issue this year raised SEK 63m as last steps before the clinical stage are being taken

Further milestones were reached in 2016 and the company decided to change its clinical strategy to initially target acute kidney damage in radiation therapy, which it sees as a faster and more cost-effective path to show clinical proof of concept and maximise the long-term value of ROSgard. A short preclinical study in animals was also concluded, indicating a kidney-preserving effect from the active substance in ROSgard in radiation therapy, which was later confirmed by a long-term study. The company also raised SEK 39.7m in a new equity issue.

This year the company has raised another SEK 63m after fees to prepare for entering the clinical phase during 2018. Recently, it completed the final two milestones in the preclinical development after announcing that manufacturing of the first large-scale GMP batch to be used in trials has been successful and that the GLP toxicology study reported positive results. A1M Pharma is now finalising the application to initiate clinical studies.

Key events for A1M Pharma	
Key years	
1974	Bo Åkerström starts his research on A1M
2002, 2005 & 2007	Key research results published
2008	A1M Pharma founded
2013	Company goes public with AktieTorget listing
2014	Strategic partnership with NeuroVive Pharmaceuticals
	Receives Orphan Drug Designation in EU
2015	Research collaboration with Fred Hutchinson Cancer Research Center
2016	Research collaboration with CSL Behring
	Extension of manufacturing agreement with Richer-Helm Biologics GmbH & Co. KG
	Rights issue of SEK 39.7m after costs
	Agreement with CRO Research Toxicology Centre (RTC)
	New strategy of initially using ROSGard in PRRT to prove safety
2017	First batch of ROSGard successfully manufactured on a large scale
	Rights issue of SEK 63m after costs
	Listing change to Nasdaq First North

Source: Company data and Nordea Markets

Technology platform

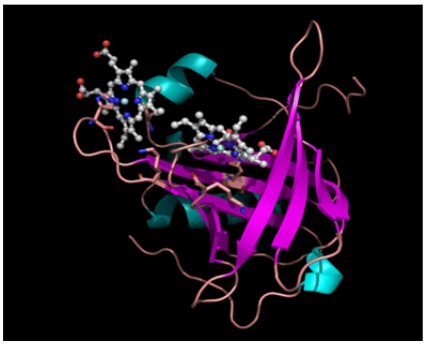
A1M is an endogenous protein playing a vital part in tissue housekeeping

A1M is a small protein found intra- and extracellularly in all tissues of vertebrates. It was first discovered almost 40 years ago, but its physiological role was long unknown. However, recent publications have demonstrated that A1M is a vital part of tissue housekeeping.

Works as a "circulating wastebasket"

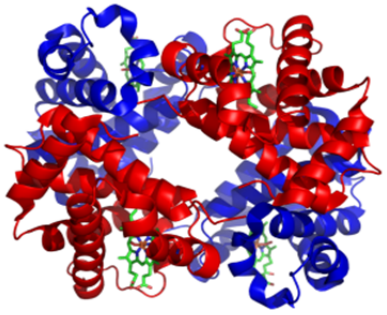
Simply put, A1M can best be described as a "circulating wastebasket" that captures and eliminates toxic substances that are continuously produced as by-products in a cell's metabolism. The protein fulfils various functions in the body, including working as a protector against free haemoglobin, an antioxidant, as a radical inhibitor and as a tissue repair agent. A1M Pharma thus believes the protein can be used in multiple settings in treatment and diagnostics. Preclinical research suggests that it can prevent and mitigate part of the damage caused by hypoxia, oxidative stress and inflammatory conditions. In November 2017, the company announced that, in addition to its protective effect on the kidneys, preclinical studies also indicate a protective effect on bone marrow during radiation treatment. This means that ROSgard could potentially offer dual protection against two of the most central damaging effects in connection with radiation treatment.

Alpha-1-microglobulin with two bound heme molecules



Source: Company data and Nordea Markets

Haemoglobin molecule with the heme groups in green



Source: Company data and Nordea Markets

Patent portfolio

Strong patent portfolio with ODD in Europe

The company's patent portfolio consists of three granted international patent families and two pending applications. In addition, it has been granted orphan drug designation in Europe for the treatment of pre-eclampsia.

Approved patents			
Region/country	**Patent Medical use of A1M**	**Patent Diagnostics**	**Patent Treatment of mitochondria related diseases**
Japan	YES	YES	
Australia	YES	YES	
Europe	YES	YES	YES
Russia		YES	
Mexico		YES	
New Zealand		YES	YES
Singapore			YES
South Africa		YES	
South Korea		YES	
US		YES	

Source: Company data and Nordea Markets

Patent applications		
Region/country	**Protection of the A1M substance and A1M related proteins**	**A1M in kidney diseases**
Japan	Yes, applied 18 February 2016	Yes, applied 16 March 2016
PCT*	Yes, applied 25 February 2016	Yes, applied 16 March 2016
Taiwan	Yes, applied 25 February 2016	Yes, applied 16 March 2016

** The Patent Cooperation Treaty (PCT) is an international agreement allowing the filing of a single application in one language with one international filing date. That means the application is considered as filed in all the PCT contracting states, more than 140, on that date.*

Source: Company data and Nordea Markets

Strategy

Out-licensing strategy to secure company's finances, reduce risk and enable further product development

The company's strategy is to focus on product development and reach an out-licensing deal for ROSgard at an early stage to validate the technology and enable further product development. Such deals are usually struck with a major pharmaceutical company and are commonly structured with an upfront payment followed by milestone payments on continued product development and royalties if the product reaches the market. This could be done for a specific indication, most likely PRRT or pre-eclampsia, and bring revenues to the company years ahead of its product reaching the market. This strategy allows A1M Pharma to bring value to its shareholders early on in its product development, reducing the risk for the company and generating resources to investigate additional indications for ROSgard.

First clinical phase I/II study to begin in Q1 2018

The company is planning to start an adaptive phase I/II study within PRRT in Q1 2018 and will continuously pursue out-licensing discussions for the PRRT and pre-eclampsia indications for ROSgard.

Milestones within PRRT in NETs	
Area	**Status**
Academic collaboration for pre-clinical Proof of Concept for AKI	Completed
Short term follow up of animal study	Completed
Selection of CRO for adaptive phase I/II study	Completed
Long term follow up of animal study	Q1 2017 - Q4 2017
Planning of adaptive phase I/II study	Q2 2016 - Q4 2017
Adaptive phase I/II study	Q1 2018 - Q2 2019
Initial data from adaptive phase I/II study	Q3 2018 - Q4 2018
Out-licensing discussions	Q3 2017 -

Source: Company data and Nordea Markets

Milestones within pre-eclampsia	
Area	**Status**
Pre-clinical Proof of Concept for pre-eclampsia treatment	Completed
Pre-clinical Proof of Concept for pre-eclampsia diagnostic tool	Completed
Planning of phase I/II study*	Q3 2017 - Q2 2018
Selection of CRO for phase I/II study*	Q3 2018 - Q2 2019
Phase I/II study*	Q3 2019 -

** The choice of a phase I or phase II study will depend on the data from the PRRT phase I/II study as well as discussions with regulatory authorities in key markets.*

Source: Company data and Nordea Markets

Financial overview

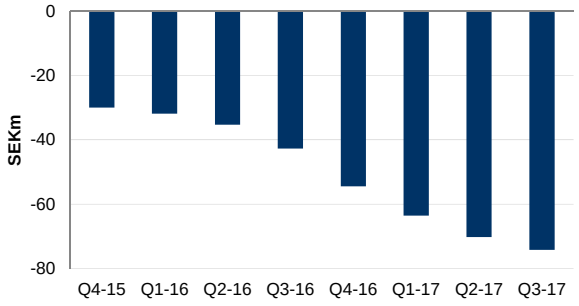
Dependent on external funding during resource-intensive phase

A1M Pharma is in a resource-intensive phase of its product development and is still years away from launching a product on the market. As is the case with most life science companies in early stages, it is dependent on external sources of funding as it is not generating any revenue at this stage.

Current cash burn rate indicates need for equity issue in the near term

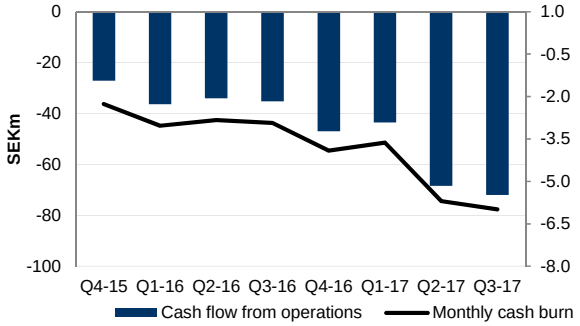
The company's financial position was strengthened with an equity issue that provided it with SEK 63m in Q2. However, with its current cash burn rate, its cash on hand will not last for more than three months and it will likely need to engage in another equity issue in the near term to be able to finalise its first clinical study. The company has outstanding warrants, with a strike price of SEK 15, which could alleviate the short-term funding needs with a potential SEK 27m inflow before costs. The exercise period for the options is between 27 November and 8 December 2017. An out-licensing deal could also improve its financial position but we believe it more likely that such a deal will take place after preliminary data.

Operating income - rolling LTM as of Q3 2017



Source: Company data and Nordea Markets

Cash flow from operations - rolling LTM as of Q3 2017



Source: Company data and Nordea Markets

Executive management and the board of directors

Management and board with relevant capabilities for pharmaceutical development

A1M Pharma has a lean management team headed by CEO Tomas Eriksson, one of the co-founders of the company. He has extensive experience of business development and leading positions in early-stage companies within medtech and diagnostics. Head of Development is Eddie Thordarson, who has a PhD in chemistry and who was most recently CEO of Magle AB.

The chairman of the board is Martin Austin, who is also Business Development Director, a job he carries out on a consulting basis. Board members Bo Åkerström and Stefan Hansson, both co-founders of the company, originated the research into the A1M protein and its potential in pre-eclampsia treatment that forms the basis of the company's foundation. Both are among the pioneers in their scientific fields and are likely to remain essential members of the company in the future.

Our overall impression is that A1M Pharma possesses relevant experience to drive the company's development but could need to add capabilities, such as on the regulatory side and clinical side, to take ROSgard through the clinical stage while engaging in out-licensing discussions. One step in this regard was recently taken with the hiring of Marie Wallén Öhman as Head of Clinical Development.

Executive management

Tomas Eriksson	Eddie Thordarson	Martin Austin
Position	**Position**	**Position**
CEO	Head of Development	Business Development Director
Other appointments	**Other appointments**	**Other appointments**
Board member of Enorama Pharma AB and Kombinator Affärsutveckling AB. Also CEO of A1M's subsidiary Preelumina Diagnostics AB	Owner of Eddie Thordarson Holding AB.	Chairman of Preelumina Diagnostics AB and Zestagen SA, board member of Algipharma SA, Deverex AG, RSA AG and partner in MarraM Sarl
Previous background	**Previous background**	**Previous background**
Experience in business development with a focus on early stage companies within Life Science. Also worked in leading positions within medtech and diagnostics, eg as Area Manager at Gambro AB, Sales & Marketing Director at Magle Life Science and as interim CEO of Lund University Bioscience AB	Ph.D. in chemistry from Lund University. Worked wihin business development, marketing and management of several companies in the last 15 years, most recently as CEO of Magle AB and board member of Nicachet AB	International expert in finance, strategy and business development with over 35 years of experience in the pharmaceutical industry
No. of shares	**No. of shares**	**No. of shares**
50,293 shares, private and through company, and 225,000 of option series 2015/2018 and 84,444 of option series 2017	5,000 shares and 150,000 of option series 2015/2018	4,568 shares and 75,000 of option series 2015/2018 and 22,843 of option series 2017

Source: Company data and Nordea Markets

Board of Directors

Martin Austin

Position
Chairman of the Board
Other appointments
Chairman of Preelumina Diagnostics AB and Zestagen SA, board member of Algipharma SA, Deverex AG, RSA AG and partner in MarraM Sarl
Previous background
International expert in finance, strategy and business development with over 35 years of experience in the pharmaceutical industry
No. of shares
4,568 shares and 75,000 of option series 2015/2018 and 22,843 of option series 2017

Anders Ermén

Position
Board member
Other appointments
Chairman of Enorama Pharma AB, board member of Xintela AB, Baulos Capital Belgium SA and Ermén Produktion & Redovisning AB
Previous background
More than 20 years of experience from the music and media industry as well as extensive experience of taxation issues and deal negotiation
11,673 shares

Cristina Glad

Position
Board member
Other appointments
Chairman of Edvince AB, board member of Aptahem AB, Ideonfonden AB, Medeon Aktiebolag, Öresundståg AB, C Glad Consulting AB and RhoVac AB. Also member of the Royal Swedish Academy of Engineering Sciences (IVA)
Previous background
More than 25 years of experience of R&D within biotech and Life Science, eg as former CEO of BioInvent International AB
No. of shares
3,141 shares and 75,000 of option series 2015/2018

Stefan Hansson

Position
Board member
Other appointments
Vice Dean at the Faculty of Medicine and Professor of Obstetrics and Gynecology at Lund University. Senior physician at the Prenatal Department at Skåne University Hospital. Board member of Preelumina Diagnostics AB and S.R. Hansson Medicinsk Konsult AB
Previous background
Co-founder of the company. Published more than 80 peer-reviewed articles and is listed as inventor in five patents/patent applications
No. of shares
102,480 shares and 25,000 of option series 2015/2018

Christina Östberg Lloyd

Position
Board member
Other appointments
Medical and clinical research director with responsibility also for regulatory affairs, safety and quality management at Novo Nordisk Scandinavia AB. Board member of SWElife and D&C Design & Care AB
Previous background
Physician and specialist within gynecology and obstetrics. Studied Medical Busines Strategy at SIMI in Copenhagen
No. of shares
541 shares

Bo Åkerström

Position
Board member
Other appointments
Board member of Preelumina Diagnostics AB and Head of the Section for Infection Medicine at Lund University.
Previous background
Co-founder of the company. Professor in medical chemistry who has published about 150 peer-reviewed articles and is listed as inventor in eight patents/patent applications within A1M's area as well as three in other areas
No. of shares
132,160 shares and 25,000 of option series 2015/2018

Source: Company data and Nordea Markets

Scientific advisory board

Experienced scientific advisory board with highly relevant expertise

A1M Pharma has a scientific advisory board of six experienced researchers in fields related to that of A1M Pharma, eg pre-eclampsia and oxidative stress. The scientific advisory board supports A1M Pharma's R&D work and participates in long-term strategic discussions about the medical application of the company's product candidate.

Scientific advisory board

Michael Brownstein

Title	Background
Scientific Consultant	Scientist Emeritus at the National Institutes of Health in Bethesda, Maryland, US. Now mainly works as a consultant and has participated in the founding of numerous successful biotech companies. During his academic career he was active in research within neurobiology, pharmacology and genetics.

Gunvor Ekman-Ordeberg

Title	Background
Professor of Obstetrics and Gynecology at the Karolinska Institute, Sweden	Associated researcher at Karolinska Institutet (KI) and senior physician at the Karolinska University Hospital. Her research has focused on connective tissue remodeling in the uterus and cervix during pregnancy and childbirth. Two companies have been founded at KI as a result of her research.

Tony Kettle

Title	Background
Professor of Pathology at the University of Otago Christchurch, New Zealand	Research professor at the Department of Pathology, University of Otago, Christchurch, New Zealand. For more than twenty years he has been studying the enzyme myeloperoxidase och its role in the immune system and inflammatory tissue injuries.

Christopher Redman

Title	Background
Professor emeritus of Obstetric and Gynecology at the Nuffield Department of Obstetrics & Gynecology at Oxford University, UK	Has been active within the field of pre-eclampsia for four decades and has laid the foundation for the understanding of the emergence, diagnosis, prevention and treatment of pre-eclampsia. Considered by many to be one of the foremost researchers within pre-eclampsia in the world.

Henning Schneider

Title	Background
Professor emeritus of Obstetrics and Gynecology at Bern University, Switzerland	Continuing his long career as a researching clinician at the Women's Hospital in Bern by working with a network of research groups in Europe and the US – all focused on the biology of the placenta. One of Schneider's experimental models is built on ex vivo-perfusion to study the function of the placenta, eg in pre-eclampsia.

József Balla

Title	Background
Professor of Medicine at the University of Debrecen, Hungary	Head of Department of nephrology and hemodialysis at University of Debrecen, Hungary. He has taken part in a number of academic collaborations, been the responsible reearcher for clinical studies and is a member of the Hungarian medical authority's scientific council. Balla's research has focused on oxidative stress and the harmful effects of heme

Source: Company data and Nordea Markets

Shareholders

Founders among the top shareholders, and a large retail investor base

Baulos International is the largest shareholder, followed by custodian accounts Avanza and Nordnet, which together represent thousands of primarily Swedish retail investors. Among the top ten shareholders are two of the founders – Bo Åkerström and Stefan Hansson – with ownership of 1.6% and 1.3%, respectively.

Shareholder structure as of November 3, 2017	
Shareholder	**Ownership**
Baulos Capital Belgium SA*	11.0%
Försäkringsbolaget Avanza Pension	6.5%
Nordnet Pensionsförsäkring AB	3.6%
Ålandsbanken (representing other owner)	2.1%
Handelsbanken Liv	1.8%
Bo Åkerström*	1.6%
Lars Thomas Jönsson	1.4%
Stefan Larsson	1.3%
Stefan Hansson*	1.3%
Lars Björkström	1.1%
Others	68.3%
Total	100.0%

**Including related party and companies.*

Source: Company data and Holdings (Swedish ownership database)

Technology platform

A1M Pharma's product development is based on extensive research conducted at Lund University into the endogenous protein alpha-1 microglobulin (A1M). The protein can best be described as a "circulating wastebasket", referring to its ability to capture and eliminate toxic substances that are by-products from cell metabolism. It exhibits many unique properties, and preclinical studies have indicated its effectiveness in preventing and mitigating damage caused by oxidative stress and inflammation. A1M Pharma's lead product candidate is called ROSgard, a recombinant version of A1M, which is primarily targeted at preventing acute kidney damage caused by radiation and pre-eclampsia.

Introduction

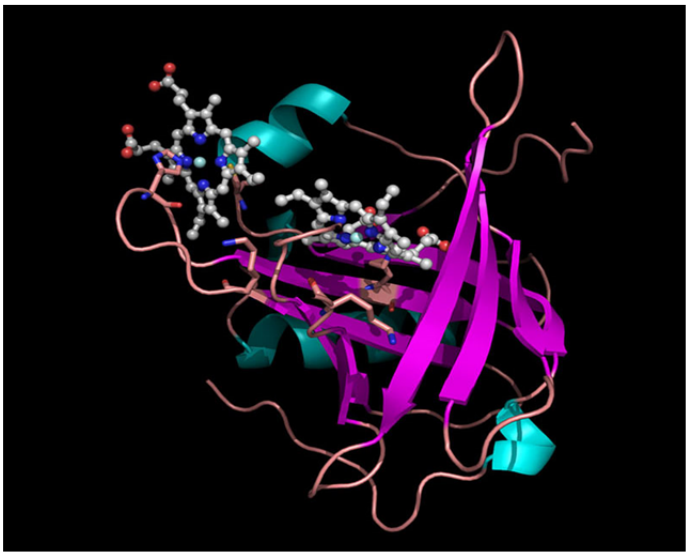
An endogenous protein that absorbs toxic substances

Alpha-1-microglobulin is a small protein found intra- and extracellularly in all tissues of vertebrates, including humans. It was first discovered more than 40 years ago, but its physiological role was long unknown. It has since been demonstrated that A1M has an important part in tissue housekeeping.

A1M is primarily synthesised in the liver, but also to some extent in cells, and is stimulated by the levels of free radicals and heme. It is subsequently distributed through blood plasma and rapidly transported to tissues of all organs. Thereafter, the protein passes through the blood and lymph to the kidneys, where it is broken down into harmless residues and exits through the urine.

Simplified, this process can be described as a five- to ten-minute cycle where the tissues are rinsed with A1M. Consequently, A1M can be said to resemble a waste bin that absorbs toxic substances intra- and extracellularly, mitigating the risk of inflammation and damage in surrounding tissues.

Alpha-1-microglobulin with two bound heme molecules



Source: Company data and Nordea Markets

A1M – a radical scavenger and antioxidant

Free radical formation caused by diseases could trigger a need for additional A1M

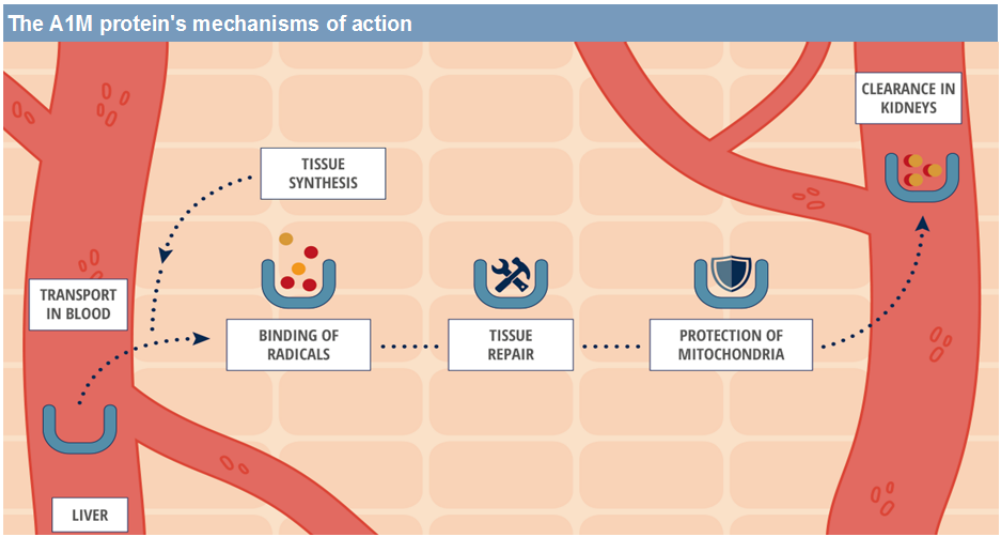
Free radicals are atoms with an odd (unpaired) number of electrons that are formed when oxygen interacts with certain molecules in blood, tissue and cells. They are derived through normal metabolism in the human body, or via external sources such as exposure to X-ray, smoking, pollution, among other factors. Once formed, these radicals are highly reactive and could spark a chain reaction that damages other molecules. Free radical formation occurs continuously, and is a slow process in healthy individuals. However, diseases could disturb the natural balance and trigger a need for additional A1M. In this case, the protein would act as enzymatic reductase, repairing oxidation-damaged molecules by adding electrons to them.

Research has also indicated that A1M has the ability to bind and degrade heme

Research by Bo Åkerström and his team has also indicated that A1M has the ability to bind and degrade toxic heme molecules. Heme is a cofactor consisting of iron that is commonly recognised as a component of haemoglobin, but also other biologically important haemoproteins. Haemoglobin is used to transport oxygen and is composed of four iron-containing heme groups and four peptides that are safely packaged inside the red blood cells. However, free haemoglobin could be harmful to the body because, when it binds to oxygen, it spontaneously generates free oxygen radicals that cause the molecule to break down and release iron, heme and other toxic by-products. This may result in oxidative stress and damage to vessels and kidneys.

A1M has the following main mechanisms:

- It binds and transports radicals and heme.
- It repairs oxidation damage and stimulates the healing processes.
- It protects the mitochondria – the cells' built-in power plants.



Source: Company data and Nordea Markets

ROSgard

Lead candidate, ROSgard, is a recombinant version of A1M

A1M Pharma's lead product candidate is called ROSgard, and is a recombinant version of the A1M protein optimised for large-scale production and medical use. The human body is constantly exposed to internal stress, resulting from reactive oxygen species (ROS) and free radicals that are by-products of metabolism and respiration.

A conceptual way to illustrate the process is with an oxidising apple. Human organs experience a similar reaction, and antioxidants, such as vitamin A and vitamin C, act as one line of defence together with other substances that can be supplemented through food. However, the antioxidants that are part of the body's internal defence system are even more important, including the endogenous A1M protein.

Effect of oxidation

Source: Company data and Nordea Markets

New clinical strategy to fulfil the company's long-term ambition and utilise shareholder value

A1M Pharma's research efforts are focused on preventing kidney damage stemming from pre-eclampsia and radiation. Its first go-to market strategy was to focus its clinical work on pregnancy-related conditions, but due to the difficulties in introducing new drugs to pregnant women, the company recently changed its clinical strategy to target cancer patients treated with a specific form of radiation therapy. This could enable a quicker and more efficient way to market and help A1M Pharma to fulfil its ambition of becoming a universal platform in kidney damage and utilising the broad applicability of the protein.

Kidney damage

Kidneys perform a number of vital tasks…

The kidneys perform a number of important tasks, including blood pressure regulation and, consequently, salt and fluid balance. They also play a central role in filtering the blood and in eliminating residues by producing urine. Kidney failure can thus affect several major body functions. The kidneys are especially sensitive to adverse effects caused by oxidant toxins that can induce permanent damage.

…and are especially sensitive to oxidant toxins

The antioxidant property of the active substance in ROSgard enhances the body's internal defence system and is particularly equipped for the task since it naturally finds its way to kidneys through the blood.

ROSgard in PRRT for NETs

Side effects of PRRT could be mitigated with ROSgard

Peptide receptor radionuclide therapy (PRRT) is radioisotope therapy used to treat neuroendocrine tumours (NETs). It uses a cell-targeting protein (or peptide) called octreotide in combination with radionuclide to create a special type radiopharmaceutical called a radiopeptide. Eventually, most of the radioactive peptides end up in the kidney, causing cell damage. This side effect of PRRT treatment could be mitigated by the active substance in ROSgard. By treating the patient with A1M and increasing protection of the kidneys, it may allow for increased radiation, which implies an overall more efficient treatment.

ROSgard in pre-eclampsia

Free foetal haemoglobin in maternal circulation could cause oxidative stress and damage to the kidneys

Pre-eclampsia, also known as toxaemia in pregnancy, is a condition that occurs during the latter part of pregnancy. Typically, clinical manifestations include high blood pressure and protein in the urine, an expression for kidney damage. Symptoms are often vague and may include diffuse swelling and headaches. Its most severe form, eclampsia, can be life-threatening and is characterised by seizures, high blood pressure and organ failure. Research has suggested that oxidative stress and increased free foetal haemoglobin are formed because of complications in the placenta early in the pregnancy. This could hurt, among other things, the mitochondria. Free foetal haemoglobin is released and leak into the mother's blood circulation, inducing inflammation and vascular injury that cause organ damage in general, and particularly kidney damage.

A1M is able to counteract free haemoglobin-induced placental damage, restore the blood-placental barrier and prevent material tissue damage

There is no cure for pre-eclampsia other than terminating the pregnancy by inducing delivery. Research by Bo Åkerström and Stefan Hansson has indicated that endogenous A1M, with radical and heme binding properties, has the ability to counteract free haemoglobin induced placental damage, restore the blood-placental barrier and prevent maternal tissue damage. ROSgard is intended to act as a preventive treatment for expectant mothers to strengthen their natural defence mechanism. Research has shown that pregnant mothers with pre-eclampsia increase their own natural A1M production but this is not enough to completely eliminate the disease symptoms. A1M Pharma could thus play a role in reinforcing the body's natural defence by supplementing ROSgard.

Preclinical programme

Finalising preclinical work before entering clinical stage in 2018

Research activities have so far focused on establishing preclinical proof of concept for treatment of kidney damage in pre-eclampsia and radiation-based treatment in metastatic cancer with radioactive isotopes. The company is now finalising its preclinical work before entering the clinical stage.

New clinical strategy to show proof of concept in treating kidney damage and attract potential partners

Its early development activities were able to establish preclinical proof of concept in the treatment and diagnostics of pre-eclampsia. In 2016 the company completed its initial preclinical toxicity and safety studies for A1M by establishing maximum dosage in two different animal models. These findings were used in the recently completed GLP toxicology study, which reported positive results in November.

Results from short- and long-term animal studies suggest protective effect to kidney damage in radiation therapy

In late 2016 the company presented positive preliminary results from a short-term animal study with ROSgard in PRRT. The study was designed to establish the protective effect to kidney damage in combination with radiation therapy after one to eight days of treatment. In Q1 2017, results were further confirmed in a long-term preclinical study with follow-up up to six months after treatment. In addition, the company has been able to establish absence of immunogenicity of the active substance in ROSgard in animal models.

In a recent preclinical study, the company announced that ROSgard, in addition to the kidney protection it affords, also shows a protective effect on bone marrow. This result means that ROSgard has the potential to protect against two of the most central damaging effects occurring in connection with radiation therapy.

Patent portfolio

Intellectual property portfolio consist of five patent families

A1M Pharma's intellectual property portfolio consists of five patent families. Its initial strategy was to secure immaterial rights for the medical use of A1M in various settings. To further strengthen its immaterial rights, it has since applied for a substance patent after choosing RMC-035 as the active substance in ROSgard. Substance patents are generally regarded as more solid, which could be helpful in potential licensing discussions. A1M Pharma has also received orphan drug designation in the EU for treatment of pre-eclampsia, granting ten-year market exclusivity. A summary of the geographical scope and approved patents follows below.

Orphan drug designation portfolio		
Region	**Designation**	**Date of designation**
Europe	Treatment of pre-eclampsia	July 4, 2014 EMA/COMP/322623/2014

Source: Company data and Nordea Markets

Patent portfolio		
Claims	**Priority filing (estimated expiry)**	**Application ID (Status)**
Medical use of the radical scavenger and antioxidant alpha-1-microglobulin	July 18, 2008 (July 18, 2028)	PCT/EP2009/05217 (Granted)
Diagnosis and treatment of preeclampsia	Feb 12, 2007 (Feb 12, 2027)	PCT/EP2008/001051 (Granted)
Alpha-1-microglobulin for use in the treatment of mitochondria-related diseases	Sep 05, 2012 (Sep 05, 2032)	PCT/EP2013/068270 (Granted)
Hbf and A1M as early stage markers for preeclampsia	Mar 24, 2010 (Mar 24, 2030)	PCT/EP2011/001458 (Application)
Alpha-1-microglobulin for use in the protection of kidneys in radionuclide therapy	Feb 25, 2015 (Feb 25, 2035)	PCT/EP2016/053904 (Application)
Biomarkers for preeclampsia	Mar 16, 2015 (Mar 16, 2035)	PCT/EP2016/055619 (Application)
Alpha-1-microglobulin for use in the protection of kidneys in connection with use of contrast media	Feb 25, 2016 (Feb 25, 2036)	PCT/EP2017/054349 (Application)

Source: Company data and Nordea Markets

We summarise the different patent groups

Medical use of the radical scavenger and antioxidant A1M

The patent covers the medical use of A1M in the treatment or prophylaxis of diseases for which oxidative stress is a responsible factor in the progress of the disease. It covers six broad groups of diseases:

- Infection and inflammation
- Heart and cardiovascular diseases
- Internal bleeding
- Radiation diseases
- Child and women's diseases
- Injuries from premature birth.

Diagnostic and treatment of pre-eclampsia

The second patent family includes three patents. Two relate to diagnostics of pre-eclampsia, while the third regards the use of foetal haemoglobin and A1M as early-stage markers for pre-eclampsia. An extended patent application concerning diagnostics and prediction of pre-eclampsia was filed in 2016.

Treatment of mitochondrial-related diseases

A patent related to the treatment of mitochondrial disease or for use in repairing, restoring or maintaining mitochondrial function.

Protection of A1M and A1M-related proteins (application)

In a move to further strengthen its intellectual property portfolio, A1M Pharma has also applied for a patent regarding the recombinant version of the endogenous A1M protein. The patent was filed during Q1 2016.

Reduce kidney-related side effects in radiation therapy (application)

A patent application regarding A1M's ability to protect the kidneys from damage induced by radiation and other sources during cancer therapy and other medical processes.

Protection of bone marrow during radiation therapy (application)

After a preclinical study showed a protective effect of ROSgard on bone marrow during radiation treatment, the company filed a patent application for this new indication in November 2017.

Market overview: Kidney protection in PRRT for NETs

Peptide receptor radionuclide therapy (PRRT) in neuroendocrine tumours (NETs) is a novel treatment for a specific form of cancer. It consists of a peptide that attaches to a tumour with an attached radioactive compound that subsequently kills the tumour. However, a potential side effect of the treatment is kidney damage, which limits the amount of radiation used and thereby limits the efficacy of the treatment. A1M Pharma's ROSgard candidate has been shown to afford kidney protection in preclinical studies and could thus be used as a companion drug to PRRT, potentially increasing its efficacy.

Neuroendocrine tumours (NETs)

Cancer is among leading causes of death globally

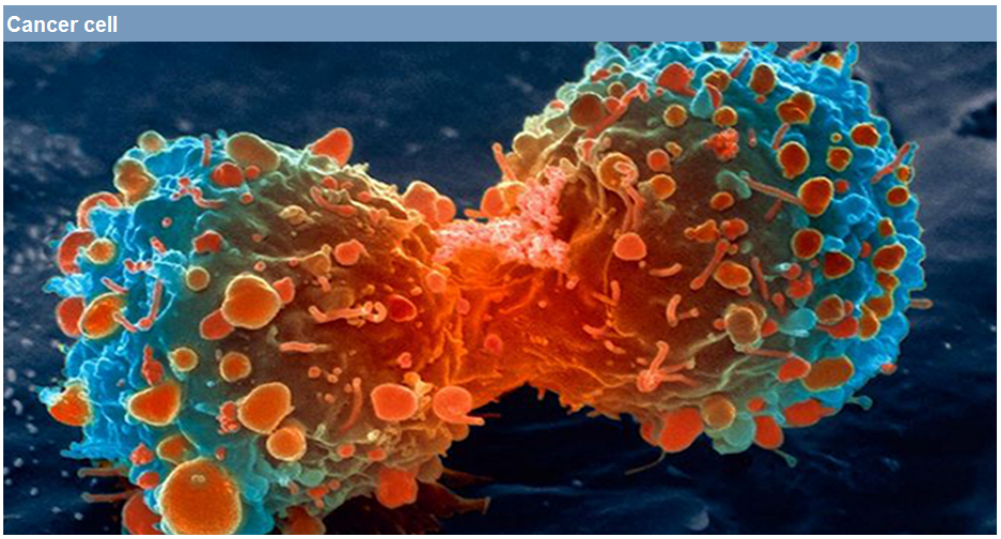
Cancer is among the leading causes of death, accounting for about one in every seven deaths worldwide. The WHO's most recent global data compilation found that there were 14.1 million new cases in 2012 and 8.2 million cancer-related deaths worldwide.

NET is a specific form of cancer that occurs in hormone producing cells found throughout the body

Neuroendocrine tumours, or NETs, are a specific form of cancer occurring in the hormone-producing cells of the body's neuroendocrine system. Neuroendocrine cells are found throughout the body in organs such as the lungs and gastrointestinal tract, including the stomach and intestines. They perform specific functions, such as regulating air and blood flow through the lungs and controlling how quickly food moves through the gastrointestinal tract.

Many variations of NETs

There are many different types of neuroendocrine tumours. They vary in size and speed of growth. Neuroendocrine tumours can also spread (metastasise) to other parts of the body, such as the liver or bones.



Source: National Cancer Institute

Proliferation in NETs is slow and it is hard to identify, making late-stage diagnosis common

The symptoms of NETs, including tiredness, asthma and digestion problems, can easily be mistaken for other diseases, making it hard to identify the disease. As diagnostics have improved over the years, the incidence of new or newly diagnosed cases has increased. In the US, NETs incidence increased 6.5x from 1.09 to close to 7 per 100,000 people from 1973 to 2012. The slow proliferation of the disease, however, means that the prevalence (actual number of people living with the disease) is high compared with incidence. In many cases, NETs is diagnosed at a late stage, when some of the treatment options, such as surgery, are no longer available.

The main treatment strategy for NETs today is surgery, controlling tumour growth, symptomatic treatment and providing life quality to patients. Besides surgery, PRRT

Main treatment option is surgery but other alternatives are available, largely depending on tumour location

using radioactive somatostatin analogues has been in use for the past 20 years. Chemotherapy and embolisation are other alternatives, but are rarely used. The appropriateness of each option depends largely on where the tumour appears, eg embolisation is performed if the tumour has spread to the liver.

Since ROSgard is being prepared for an adaptive phase I/II study as a complement to PRRT, we will focus on that market.

Peptide receptor radionuclide therapy (PRRT)

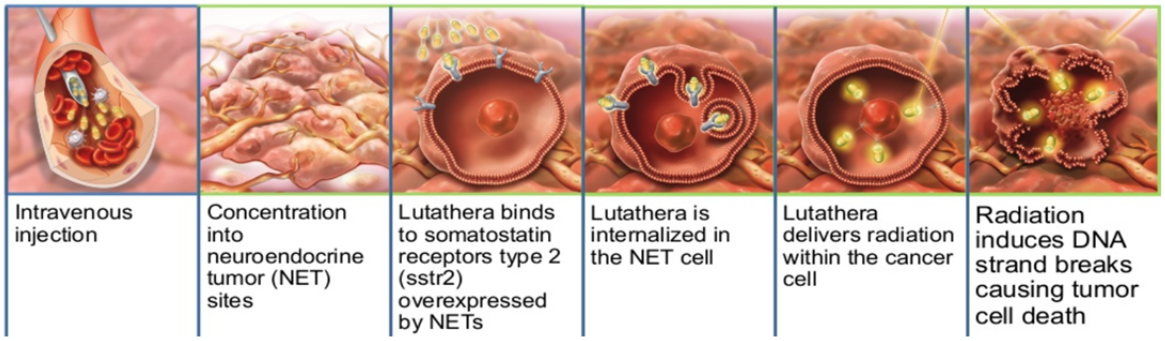
PRRT is a target-seeking radiation therapy

PRRT stands for peptide receptor radionuclide therapy. It is a molecular "target-seeking" radiation treatment combining a peptide with a radioactive component (Lutetium 177). The peptides accumulate in the neuroendocrine tumours and the radiation from the radioactive component slows, stops or, hopefully, kills the cancerous tumour cells.

A limitation in PRRT is its harmful effect on the kidneys – this is where ROSgard comes in

There is a limitation with the PRRT approach as a substantial part of the radioactive substance ends up in the kidneys, making kidney damage a common side effect of PRRT. The current approach among oncologists is to limit the amount of radiation but this also reduces the potential efficacy of the PRRT treatment. With ROSgard's kidney protection potential, oncologists could increase the number of PRRT courses in a treatment (from the current standard of four), thereby increasing the efficacy of the treatment. In addition to its protection of the kidneys, ROSgard has also recently been shown to protect the bone marrow during radiation treatment in preclinical studies, a potentially highly important result considering that the kidneys and the bone marrow are among the most exposed organs to radiation damage.

Approved PRRT drug Lutathera's mechanism of action



Source: Advanced Accelerator Applications

The first PRRT product on the market was recently approved in Europe

PRRT is a novel form of treatment and has until recently only been used in specialised clinics in the EU at an out-of-pocket expense for patients and offered under a "compassionate use" exception due to the lack of approved products on the market. In October, however, Advanced Accelerator Applications' Lutathera product, with Lutetium 177 as its radioactive substance, was approved in Europe. The same product is awaiting approval in the US and is still at the clinical stage in Japan.

Large and growing interest from the pharma industry in the field

There is a growing interest in PRRT in the pharmaceutical industry, as evidenced by Novartis' USD 3.9bn bid for Advanced Accelerator Applications on 30 October 2017, only weeks after Lutathera was approved in Europe. This bodes well for the future potential of the treatment and, by extension, A1M Pharma's ROSgard product candidate.

Market opportunity

NETs prevalence is much higher than incidence

Advanced Accelerator Applications has estimated the annual incidence of NETs at around 48,000 patients in the US and Europe, with a prevalence of approximately 232,000 cases, of which the US accounts for 111,000.

171,000 cases estimated in the US in recent study

A recent study published in the SEER database estimated that the prevalence of NETs in the US is roughly 171,000 – a substantial increase from the 2008 estimate of 100,000 people.

Ipsen estimates that NETs is a USD 1bn market

These estimates are also in line with market forecasts from Ipsen, a French pharmaceutical company active in the NETs field. It estimates prevalence of 120,000 for gastroenteropancreatic (GEP) NETs in Europe and the US, which accounts for roughly 60% of total NETs. Ipsen translate this into an USD 1bn market opportunity annually for this specific NETs indication in the US and Europe alone, with the under-served US market accounting for USD 600m and Europe for the remaining USD 400m.

While estimates vary, we believe the NETs population in the US and Europe is likely in the range of 200,000-350,000 cases.

PRRT treatment is an option for 35% of total, translating into a 70,000-122,500 target population

PRRT is primarily a treatment option for patients with aggressive or late progressed NETs not treatable with surgery or other alternatives, such as chemotherapy. This is partly due to the harmful kidney effects that PRRT treatment entails. This could change if ROSgard proves capable of replicating its preclinical results in humans and can improve the applicability and efficacy of PRRT treatments. A1M Pharma estimates a potential penetration rate of about 35% in the current target population for PRRT within NETs. This translates into a potential patient pool of 70,000-122,500.

ROSgard treatment cost unclear but PRRT treatment is in the range of USD 30,000-50,000

The potential treatment cost for ROSgard has not been communicated by the company and is likely not yet set at this early stage in the product's development. However, we expect it will come in substantially below its future companion drugs that directly target cancer. Zurich Health, a Swiss medical consultancy, estimates that the cost of a PRRT treatment is typically in the USD 30,000-50,000 range, depending on country, clinic and tumour.

Estimated treatment cost range of USD 2,000-4,000 per cycle (four in total)

We believe a course of ROSgard will likely end up in a range of single-digit thousand dollars, around USD 2,000-4,000, with some variation between Europe and the US (where drug prices are generally higher). Considering that a standard PRRT treatment consists of four courses, this translates into a value per patient of USD 8,000-16,000.

We see a market opportunity of USD 560m-1,960m, where a 35% share for A1M yields USD 196-686m

This would represent a meaningful increase to the cost of a PRRT treatment, but we find it warranted given that it addresses two of the most central damaging effects in connection with radiation therapy. As such, ROSgard could improve the efficacy and applicability of PRRT, ie by allowing for more therapy sessions in a shorter amount of time, resulting in a more effective treatment.

Given a market of 200,000-350,000 NETs patients, of whom 70,000-122,500 are candidates for PRRT treatment, and a treatment cost per patient of USD 8,000-16,000, the market opportunity for ROSgard within PRRT is in the range of USD 560-1,960m. The market share of ROSgard in this context is difficult to estimate but could plausibly go as high as 35%, considering the lack of direct alternatives, indicating an opportunity for A1M Pharma of USD 196-686m.

Market opportunity within PRRT	
NETs prevalence in the US and Europe	200,000 - 350,000
PRRT potential patient pool	70,000 - 122,500
ROSGard treatment cost	USD 2,000 - 4,000
Value per patient	USD 8,000 - 16,000
Market opportunity	**USD 560m - 1,960m**

Source: Nordea Markets

Market overview: Pre-eclampsia

Today, there are no existing cures for pre-eclampsia, a condition also known as toxaemia in pregnancy, except for induced childbirth or caesarean section, which result in babies being born prematurely. As care of premature babies remains expensive, any drug that is able to moderate the condition and delay births could contribute to considerable cost savings for the healthcare system. Consequently, A1M Pharma's drug candidate ROSgard could attractively position itself to target a patient group with a large unmet medical need.

Pre-eclampsia

Pre-eclampsia affects 8.5 million women globally, causing about one-fifth of all maternal deaths

Pre-eclampsia, also known as toxaemia in pregnancy, is a condition that occurs during the latter part of pregnancy. Globally, about 8.5 million pregnant women suffer from pre-eclampsia on a yearly basis, according to a study conducted at Lund University in 2012. The study also concludes that this corresponds to 3-8% of all pregnant women in the world. Moreover, the condition is estimated to cause up to 40% of deaths among foetuses and about 18% of all maternal deaths.

In Sweden, pre-eclampsia affects 5,000 women yearly, corresponding to 3-7% of all pregnant women. While it is far less lethal in Sweden than globally, the condition still causes 15% of all premature births.

It can develop into eclampsia, causing seizures and even coma

The condition, which generally starts after 20 weeks of pregnancy, is usually detected due to high blood pressure and protein in the urine arising from reduced kidney functions. If left untreated, it may develop into eclampsia – a life-threatening condition characterised by seizures, high blood pressure and general organ failure.

Source: Company data

The root cause of pre-eclampsia remains unknown, although one generally accepted theory is that it relates to underdevelopment of the placenta. Such a deficiency may cause inadequate blood supply and subsequent oxidative stress. These conditions can be followed by kidney damage as well as damage to other organs associated with pre-eclampsia.

The cause of the condition remains unknown, but A1M appears to delay the symptoms

While the cause of the condition remains unknown, certain risk factors have been identified that increase the risk of being affected. These include chronic high blood pressure, obesity and a family history of the condition. According to the WHO, about 20-40% of daughters are affected when their mothers have experienced the same condition. The corresponding level among sisters is 11-37%.

Research also suggests that the kidneys of pregnant women affected by pre-eclampsia increase the production of the A1M protein. This process appears to delay the outbreak of the symptoms associated with the condition.

Treatment

No cure exists except for induced delivery or caesarean section

As the cause of pre-eclampsia remains unknown, there is no medical drug that can cure the disease and therefore only symptomatic treatment is currently being used. The only real 'cure' today is to terminate the pregnancy early by induced delivery or caesarean section, thereby resulting in premature births. This usually happens after 37-38 weeks of pregnancy but can occur earlier. Blood pressure medicines are sometimes prescribed before delivery to improve the mother's condition.

The company sees potential for ROSgard to prevent and/or lower the harmful oxidative stress that characterises pre-eclampsia. In the longer run it could also prevent or restore placental damage and prevent and/or mitigate the risk of development of subsequent clinical conditions.

Market opportunity

Globally, about 8.5 million pregnant women are affected on an annual basis by pre-eclampsia and there is currently no medical cure except for induced delivery or caesarean section. Such treatments are associated with potential discomfort for patients and considerable costs related to premature delivery. Consequently, if approved and affordable, ROSgard could gain notable market penetration.

Total healthcare cost of pre-eclampsia is estimated at USD 2.2bn in the US

The short-term total cost of pre-eclampsia in the US was estimated at USD 2.2bn in a 2012 study conducted jointly by researchers at Stanford Medical School, Harvard Medical School and multiple other institutions. All natural costs associated with childbirth were explicitly excluded from the total cost number.

Similar total cost estimates have been suggested in a meta-analysis commissioned by A1M Pharma and conducted by Professor Lars Holger Ehlers, currently at Aalborg University. According to these estimates, the total cost of pre-eclampsia is approximately SEK 19bn and SEK 20bn in the US and Europe, respectively.

Using the 141,830 cases of pre-eclampsia recorded in the US during 2012, the estimated total cost per pre-eclampsia case would have been about USD 15,400. This would place the inflation-adjusted cost as of 2016 at approximately USD 16,000. As pre-eclampsia treatment is expected to require at least two doses, the effective price ceiling of a dose of ROSgard is USD 8,000. Adding a floor price of USD 2,000 and using conservative estimates, we expect that the price range for a dose of ROSgard could be USD 2,000-4,000.

The total market opportunity in pre-eclampsia ranges between USD 1,200m and USD 3,200m

Given an estimated 300,000-400,000 cases in the US and Europe annually and an average of two treatments per individual, in the price range of USD 2,000-4,000 per dose, the implied annual market opportunity for ROSgard is USD 1,200–3,200m. Since there is no other treatment available on the market, ROSgard could capture a substantial share of this market. The company itself estimates that ROSgard sales could amount to USD 1.2bn in its fifth year of sales.

Market opportunity within pre-eclampsia	
Annual pre-eclampsia incidence in the US and Europe	300,000 - 400,000
ROSGard treatment cost	USD 2,000 - 4,000
Value per patient	USD 4,000 - 8,000
Market opportunity	**USD 1,200m - 3,200m**

Source: Nordea Markets

Competition

Limited competition considering no other company has been successful with its drug candidate

Within the field of pre-eclampsia drug development, the competition faced by A1M Pharma remains limited. The most developed drug candidate, ATryn from the US-based rEVO Biologics, was found to have no effect in large randomised trials with human patients in early 2017.

Israeli drug development company Pluristem gained considerable coverage for its initially positive results from placental cell treatment of pre-eclampsia in preclinical trials. The treatment gained orphan drug status from the FDA in late 2015, but no new developments have been reported since then.

Like Pluristem, Glenveigh Medical, another potential competitor has reported no activity since 2015.

Strategy

Following a shift in the strategic plan, A1M Pharma changed the indication for its first clinical study for ROSgard from pre-eclampsia to PRRT. The rationale was that this would maximise the long-term potential and validate the A1M platform. It can also facilitate later studies within pre-eclampsia as the PRRT study could generate useful safety data. With PRRT, the company is able to go directly to an adaptive phase I/II study, potentially reducing the time to market. In addition, it could allow ROSgard's platform against oxidative stress to be used in other types of radiation treatment. With the preclinical phase in its final stages, clinical trials are expected to be initiated in the first quarter of 2018. Out-licensing discussions will start concurrently with the medical development.

Strategic overview

A1M Pharma is currently finalising its preclinical stage

With multiple patent applications pending or already approved, A1M Pharma is currently pushing forward with the development of its drug candidate ROSgard. The majority of the preclinical work has been completed, and the company recently announced that large-scale production of the active substance in ROSgard has been validated.

The first indication changed from pre-eclampsia to PRRT due to a number of realised benefits such as faster path to market

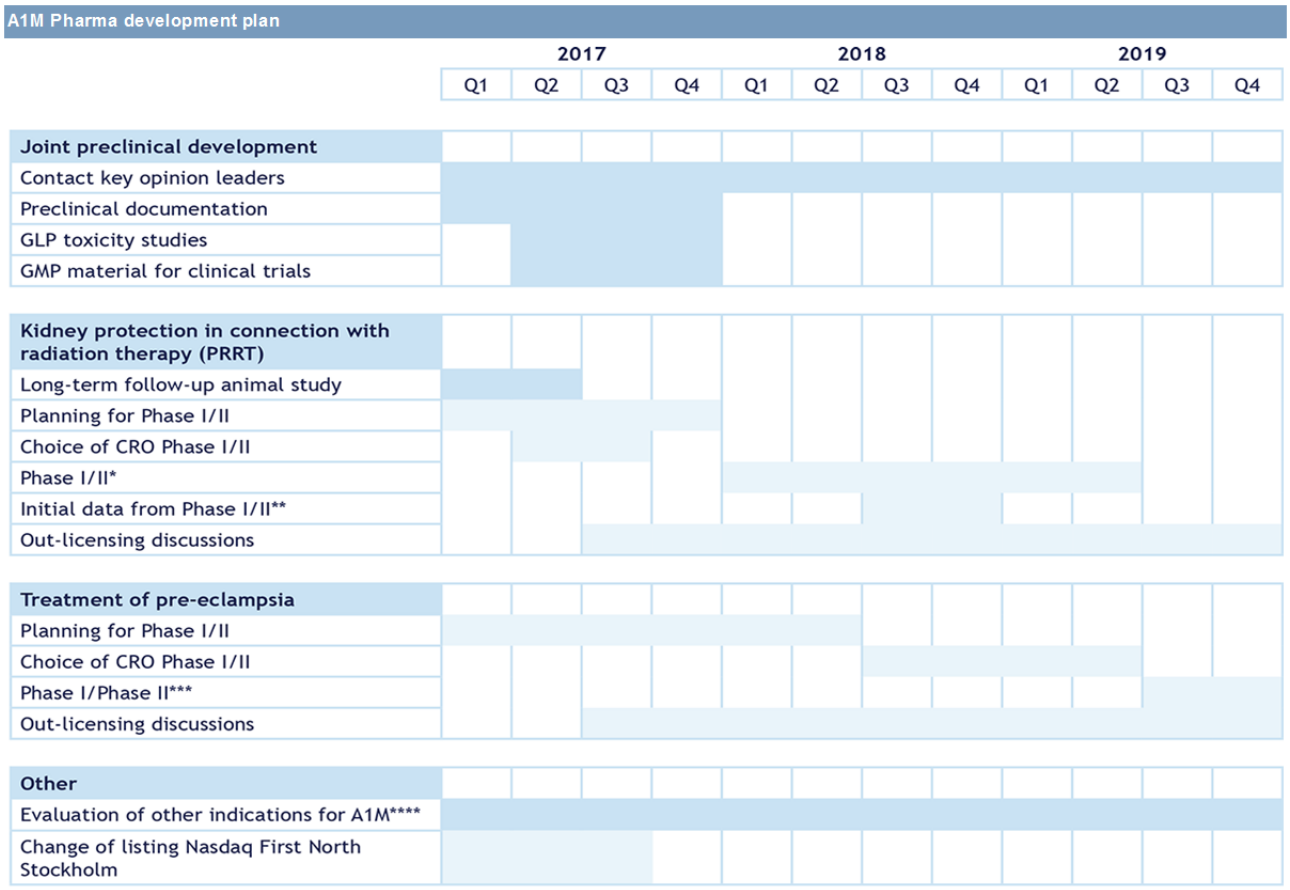
After identifying the key benefits of changing the clinical strategy for ROSgard, the company decided upon a shift in its strategic plan in 2016. Specifically, the company is now planning on first using ROSgard for kidney protection during radiation treatment of cancer patients instead of in pre-eclampsia treatment and diagnostics. The radiation treatment, known as peptide receptor radionuclide therapy (PRRT), will thus be the first indication for ROSgard's clinical trials. Safety data from a PRRT study can facilitate future pre-eclampsia studies and the new indication enables the company to go directly to an adaptive phase I/II study, a potentially faster and more cost-efficient path to the market. PRRT targets a more specific population than pre-eclampsia, making it easier to find and recruit patients to clinical studies. If proven in the PRRT indication, the ROSgard platform and the kidney protection it affords could also potentially be applicable in other indications where radiation therapy is used.

Phase I/II study planned to start in Q1 2018 for PRRT

ROSgard is currently planned to go into clinical trials in Q1 2018, and the company expects its phase I/II study for PRRT to be completed in Q2 2019. For the pre-eclampsia indication, A1M Pharma is planning a phase I or II study to start during H2 2019, depending on the outcome of the PRRT study.

Ambition to find a licensing partner to take ROSgard to the market – likelihood of deal increases after initial data from PRRT study in Q3-Q4 2018

A1M Pharma's ambition is not to take ROSgard to the market on its own but to find a partner with which it can reach an out-licensing deal. This could bring shareholder value, reduce the risk to the company and generate external validity for the company's mechanism of action against oxidative stress. There is, however, a trade-off between the size of an out-licensing deal and the stage of clinical development. A product that has advanced further in the clinical stage is likely to result in a larger deal as the odds of a product reaching the market increase with each successful clinical trial, thus reducing the risk for the licensee. The likelihood of an out-licensing deal should increase after a successful clinical study and could thus come after the expected initial data from the first phase I/II study in Q3-Q4 2018, which could result in clinical proof of concept for ROSgard.



* The planned Phase I/II trials will begin with a safety study in healthy volunteers, followed by safety and efficacy studies in sick patients with an adaptive study design. An adaptive study design enables the study protocol to be updated based on preliminary results during the course of the study.

** Presentation of initial data for proof of concept (PoC) from Adaptive Phase I/II, which may be used in out-licensing discussions.

*** Phase I/II within Treatment of pre-eclampsia will be partially based on data from Phase I/II within Kidney protection in connection with radiation therapy (PRRT).

**** The active substance in ROSgard™ has, in early trials, exhibited potential within cardiovascular diseases and eye diseases.

Source: Company data and Nordea Markets

Achievements

Large scale GMP manufacturing recently completed

A1M Pharma is currently in the final stages of the preclinical phase for its ROSgard product candidate, having just completed manufacturing of the first large scale GMP-batch of the active substance in ROSgard, chosen a contract research organisation (CRO) for the first clinical study and reported positive results from its GLP toxicology study. It is thus now able to finalise its application to initiate clinical studies.

Preclinical proof of concepts established in both indications

Preclinical proof of concept has been established for the active substance in ROSgard in both of the focus areas, PRRT and pre-eclampsia. A preclinical proof of concept results from tests in animals and should not be confused with the standard proof of concept, which is established in the clinical stage of the drug development process.

Milestones in the preclinical development

The preclinical development phase is coming to a close with the company finalising the application to initiate clinical studies

A1M Pharma is currently finalising the preclinical phase of its drug development. Contracts for production have been signed under good manufacturing practice (GMP), a minimum requirement guideline. In 2016, the first large-scale batch of the active substance in ROSgard was produced. The batch was produced without intermediary steps and was 100 times larger than previously produced batches. In October 2017, the company announced that the first large-scale manufacturing of the active substance in ROSgard under full GMP compliance had been completed. In November 2017, the company reported positive results from its GLP toxicology study, meaning that the final preclinical milestone has been achieved and that it is now finalising the application to initiate clinical studies.

Multiple studies have been conducted already, such as pilot studies on optimal dosage and studies on immunogenicity in animals. The latter is a key milestone for biological drugs like ROSgard, which could potentially activate the body's immune system. Relevant contacts with government agencies and key decision makers have been established. Moreover, documentation in accordance with government requirements is expected to be finalised by year-end 2017.

Milestones within kidney protection in PRRT for NETs

Preclinical proof of concept established and extensive planning for adaptive phase I/II study scheduled for Q1 2018

After forming an academic collaboration to determine preclinical proof of concept, short-term animal tests on mice were conducted. The mice were provided with an anti-cancer treatment and, at a later stage, the active substance of ROSgard. Their kidney functions were then analysed six months after treatment. The study is being supplemented with a longer-term study.

Extensive planning has been conducted for the coming phase I/II clinical trial, and the selection process for the CRO was completed in October.

Milestones within PRRT in NETs	
Area	**Status**
Academic collaboration for pre-clinical Proof of Concept for AKI	Completed
Short term follow up of animal study	Completed
Selection of CRO for adaptive phase I/II study	Completed
Long term follow up of animal study	Completed
Planning of adaptive phase I/II study	Q2 2016 - Q4 2017
Adaptive phase I/II study	Q1 2018 - Q2 2019
Initial data from adaptive phase I/II study	Q3 2018 - Q4 2018
Out-licensing discussions	Q3 2017 -

Source: Company data and Nordea Markets

Adaptive phase I/II study to start in Q1-18

The development of the PRRT application of ROSgard is expected to enter an adaptive phase I/II study in Q1 2018. Such a process would be started with a safety study on seven to ten healthy volunteers, followed by a safety and efficacy study on 15-20 patients. Compared with pre-eclampsia patients (pregnant women), PRRT patients have previously shown higher willingness to participate in drug development studies.

Initial data expected Q3-Q4 2018 and study completion in Q2 2019

This phase of the development process is expected to be completed by Q2 2019, with initial data from the study becoming available in Q3-Q4 2018, which can potentially be used in out-licensing discussions.

Milestones for pre-eclampsia

Has developed both a treatment and a diagnostic tool for pre-eclampsia

Within the focus area of pre-eclampsia, two applications are under development: a treatment for the negative effects of pre-eclampsia on kidneys and a diagnostic tool for the disease. Preclinical proof of concept has been established for both applications.

Milestones within pre-eclampsia	
Area	**Status**
Pre-clinical Proof of Concept for pre-eclampsia treatment	Completed
Pre-clinical Proof of Concept for pre-eclampsia diagnostic tool	Completed
Planning of phase I/II study*	Q3 2017 - Q2 2018
Selection of CRO for phase I/II study*	Q3 2018 - Q2 2019
Phase I/II study*	Q3 2019 -

** The choice of a phase I or phase II study will depend on the data from the PRRT phase I/II study as well as discussions with regulatory authorities in key markets.*

Source: Company data and Nordea Markets

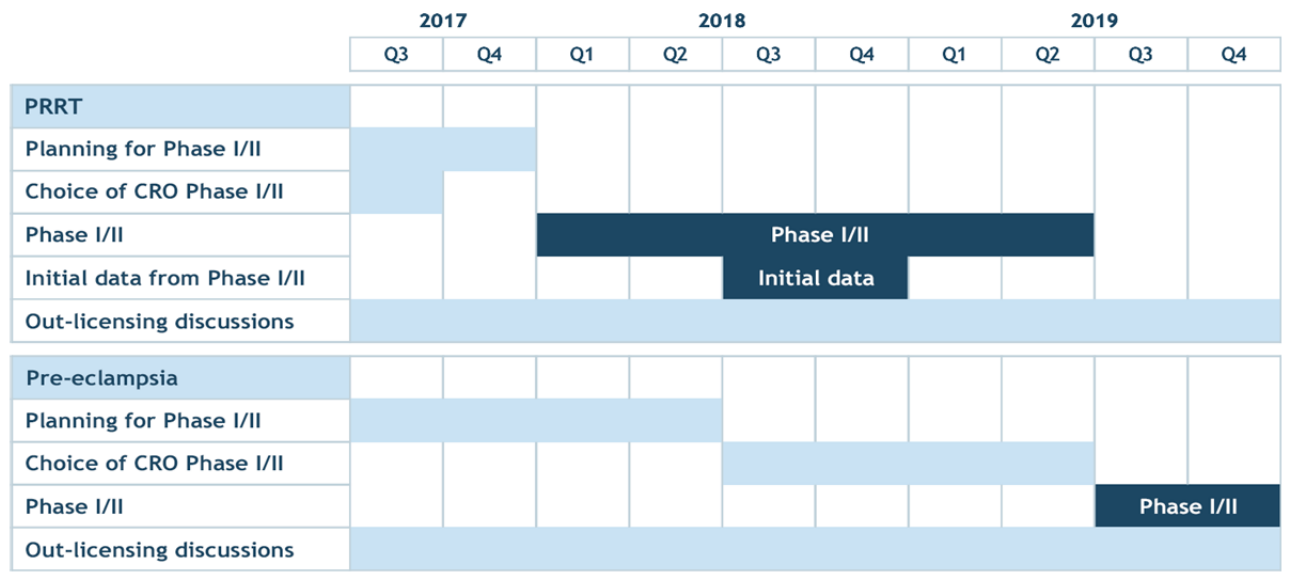
Clinical trials are scheduled for H2 2019 with specifics dependent on PRRT study

Clinical trials for the pre-eclampsia treatment are currently planned to start in H2 2019. The specifics of the study, ie whether it will enter phase I or phase II directly, will be highly dependent on data from the PRRT phase I/II study and decisions made by regulatory bodies in the major regions. Until then, A1M Pharma is focusing on identifying a CRO.

Diagnostics tool likely to become a companion to the pre-eclampsia treatment

Regarding the diagnostics tool, which was previously discussed as a future out-licensing candidate, the company is still considering the possibility of entering an out-licensing agreement at an early stage. However, it may be more likely that it will be part of a future ROSgard deal as a companion diagnostic to the drug treatment. According to the company, any final decision will be made in order to maximise shareholder value.

Development plan for PRRT and pre-eclampsia



Source: Company data and Nordea Markets

Other potential indications

ROSgard has demonstrated potential in numerous indications

While mainly focusing on the development of the PRRT and pre-eclampsia indications, A1M Pharma is also evaluating other applications of the active substance. Studies conducted with other genetically modified (recombined) versions of A1M, also known as rA1M, indicate efficacy against cardiovascular disease (arteriosclerosis) as well as eye diseases. Research collaboration with NeuroVive Pharmaceutical showed that ROSgard has a protective effect on mitochondria, the "power plants" of the cells. Validating the technology in PRRT and pre-eclampsia could allow A1M Pharma to establish a platform for acute kidney injuries. Following the recently announced bone marrow protection that ROSgard showed in a preclinical study, the company is planning to include biomarkers for bone marrow protection in the coming PRRT study. In addition, a recent study published in the Journal of Nuclear Medicine showed that the active substance in Lutathera, a PRRT drug, increased survival for patients in the treatment of castration-resistant prostate cancer, which represents a much larger market than NETs.

The road ahead

Phase I/II in PRRT approaching fast, with pre-eclampsia studies to follow in the coming years

Going forward, A1M Pharma is expected to finalise the preclinical phase of its drug development before year-end 2017. This would effectively allow the company to move ahead with clinical trials of ROSgard for PRRT treatment in Q1 2018, a process that is expected to be completed by mid-2019.

If regulatory approval is given for the use of PRRT test results in pre-eclampsia trials, the company could be able to advance to a phase I/II study for the pre-eclampsia indication by H2 2019.

Historical financials

A1M Pharma is in the early stages of its development and does not generate any revenue yet. Costs are on the rise as operational activities are being ramped up to prepare for clinical trials. The company's funding has historically been dependent on issuing new equity to its investors and its cash position was strengthened this year with a SEK 65m rights issue in Q2.

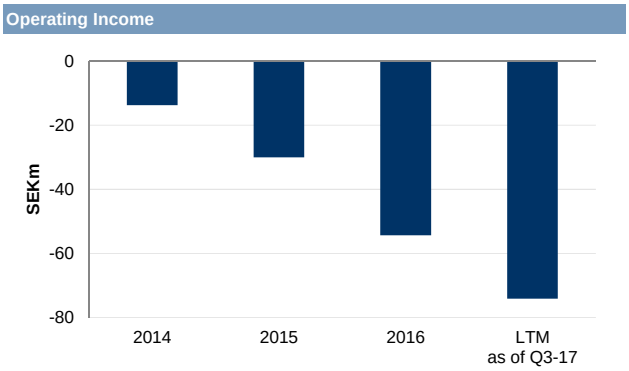
Group financials

A1M Pharma is in a resource-intensive phase with clinical stage approaching

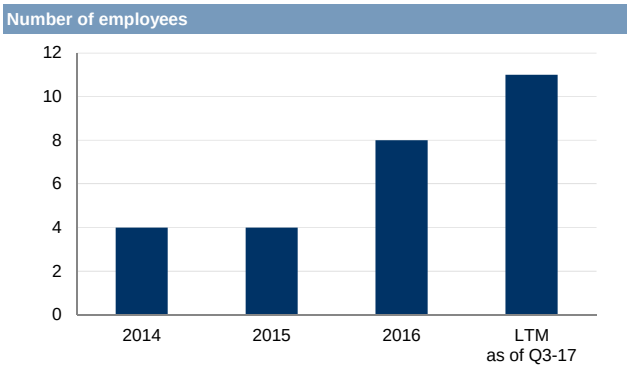
As A1M Pharma is a life science company in the early stages of its development, it does not generate any revenue yet. It has thus reported losses since its inception and costs are trending upwards, as activities are being ramped up to prepare for taking the ROSgard product candidate to clinical stage in 2018. Operating income has thus steadily declined, from SEK -14m in 2014 to SEK -74m in the last 12 months as of Q3 2017.

Employee base doubled in 2016, currently 11 FTEs

A1M Pharma's employee base doubled between 2015 and 2016, going from four to eight employees, and has since increased further. On 12 October 2017, the company announced the addition of a project manager for its clinical development, bringing the total to 11 FTEs as of Q3 2017.



Source: Company data and Nordea Markets

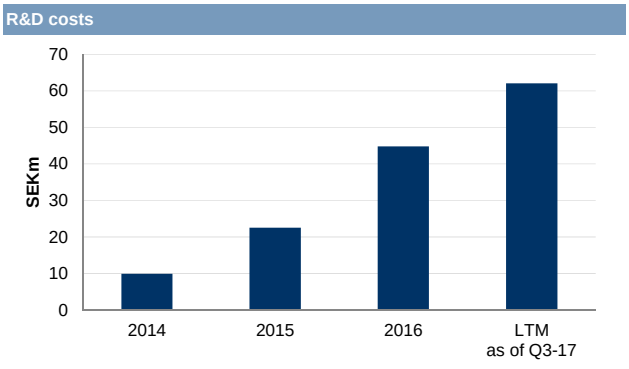


Source: Company data and Nordea Markets

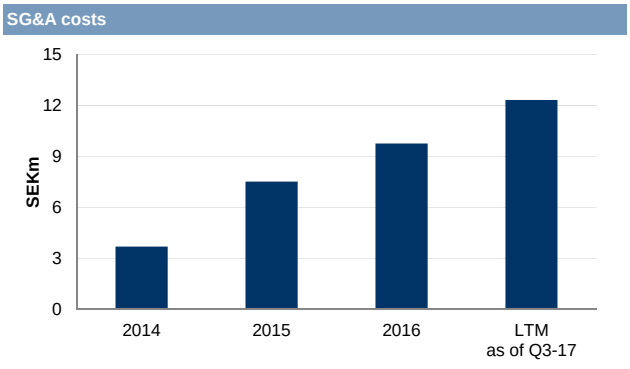
Group cost structure

Costs are trending upwards, as the company is ramping up its operations

A1M Pharma's operational costs have been rising over the past few years, as its preclinical efforts have been intensified and ROSgard is nearing clinical stage. Both R&D and SG&A costs are subsequently on the rise: R&D costs increased from SEK 9.9m in 2014 to SEK 62.0m in the last 12 months as of Q3 2017; and SG&A costs went up from SEK 3.7m to SEK 12.3m in the same period.



Source: Company data and Nordea Markets



Source: Company data and Nordea Markets

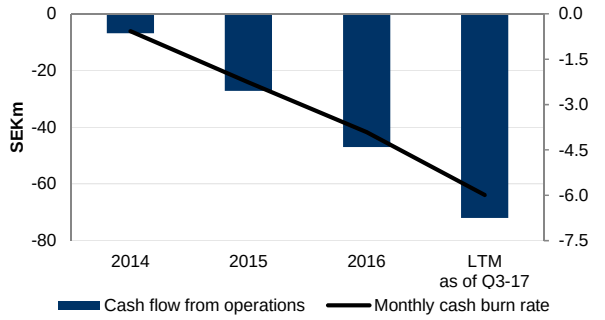
Group cash flow

The company's cash burn rate has steadily increased to a monthly burn of SEK 6.0m LTM

A1M Pharma's cash flow from operations closely tracks its operating income and has thus seen the same negative trend, going from SEK -6.9m in 2014 to SEK -71.9m in the last 12 months as of Q3 2017. This is also reflected in the monthly cash burn rate, which went from SEK -0.6m to SEK -6.0m in the same period.

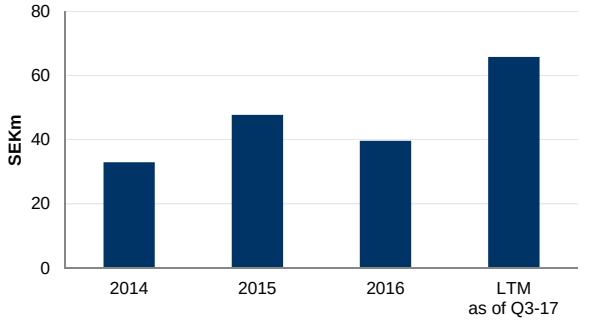
To cover the cash outflow from operations, the company has relied on frequent equity issues, most recently closing a rights issue in Q2 2017, which provided the company with SEK 65m.

Cash flow from operations



Source: Company data and Nordea Markets

Cash flow from equity issues



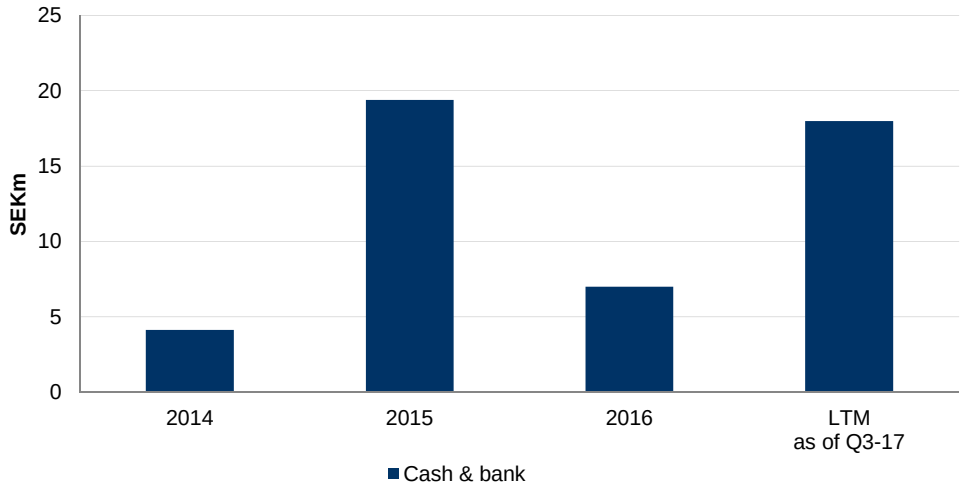
Source: Company data and Nordea Markets

Group financial position

Currently net cash position, but further financing is needed

Similar to most of its peers, A1M Pharma has relied on financing from the equity markets and is essentially debt-free. This has resulted in a net cash position, but considering its current cash burn of about SEK 6m per month, its cash at hand (SEK 18.0m as of Q3 2017) will only last for about three months, assuming a constant burn rate and no exercise of the option programme, which could generate SEK 27m before costs. The exercise period is between 27 November and 8 December 2017 with a strike price of SEK 15.

Cash & bank



Source: Company data and Nordea Markets

Estimates

We use a royalty-based revenue model to estimate A1M Pharma's earnings potential. Our estimates are based on the assumption that the company achieves its goal of finding a strategic partner that can support the commercialisation of ROSgard and share the clinical development costs. We see non-risk-adjusted royalty sales of SEK 528m and SEK 960m in PRRT and pre-eclampsia respectively in 2030E. However, adjusting for the risks inherent in the clinical stage, we calculate total risk-adjusted royalty sales for the company of SEK 227m in 2030E.

A1M Pharma aims to commercialise products through partnerships

A1M Pharma's operational strategy is to become a lean development organisation that can commercialise its products through strategic partnerships. The first step in the process is to enter the clinical stage and show proof of concept in PRRT to attract interest and later expand into other indications, primarily pre-eclampsia in the short term.

We use a royalty based revenue model to estimate earnings potential

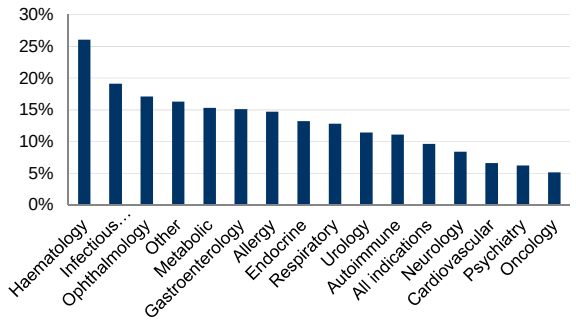
To estimate the earnings potential we use a royalty-based revenue model that assumes the company is able to find a strategic partner. The design of such partnership deals depends on numerous factors, such as market potential, competition, relative bargaining power and the stage of development. Generally, there is a balance between signing an early deal to de-risk operations and validate the technology, and a deal in a later stage that can induce a higher value. Deal structure can also vary, being either front-end loaded, including a high upfront payment and a low royalty rate, or back-end loaded, including low upfront payment and a high royalty rate. Milestone payments can also be included, with payment upon certain conditions being met.

Estimates are based on the market potential of the two current indications

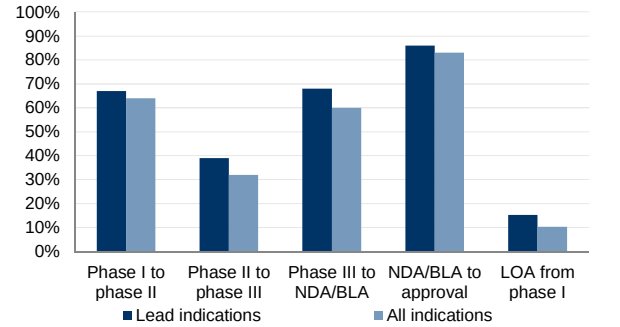
Our estimates are based on the market potential within PRRT and pre-eclampsia. Hence, we do not assign any value to other potential applications for A1M. We use risk-adjusted sales, adjusting sales to reflect the probability of approval. This implies that clinical results could alter the valuation.

Studies in the US estimate that the likelihood of approval from phase I to market authorisation is about 10% across all indications, while it is slightly higher in the lead indication of the drug candidate (15%). Depending on the type of indication, the likelihood of approval is about 5-26%. The biggest threshold is between phase II and phase III, as the majority of the drug candidates do not make it to the final stage of clinical trials.

Likelihood of approval from phase I by field



Probability of success in the clinical stage



Source: "Clinical Development Success Rates 2006-2015", Hay et. al (both graphs) and Nordea Markets

Kidney protection in PRRT

We estimate clinical studies to start in 2018, with phase III in mid-2019

Below we list the main assumptions behind our sales forecasts within PRRT. We expect A1M Pharma to commence clinical studies in 2018, enter phase III in mid-2019 and possibly have an approved product on the market by 2023. We assign likelihood for approval of 15% (phase I upon market authorisation) based on ROSgard being a biological drug candidate.

The market opportunity in PRRT estimated at USD 0.6-2.0bn, based on our assumptions

We estimate the addressable market in PRRT at USD 560m-1,960m, based on a price for ROSgard in PRRT of USD 2,000-4,000 per cycle and NETs prevalence of 200,000-350,000 patients in the US and the EU. We assume four treatment cycles, implying a value per patient of USD 8,000-16,000. This would represent a meaningful increase to the cost of a PRRT treatment, but we find it warranted given that it addresses two of the most central damaging effects in connection with radiation therapy. As such, ROSgard could improve the efficacy and applicability of PRRT, ie by allowing for more therapy sessions in a shorter amount of time, resulting in a more effective treatment. We use the midpoint as the baseline scenario in our forecasts, yielding an addressable market of USD 1,260m.

Main assumptions - PRRT	
Number of treatments	4
Price in USD	3,000
Royalty	10%
Patient growth	3%
Price inflation	3%

Source: Nordea Markets

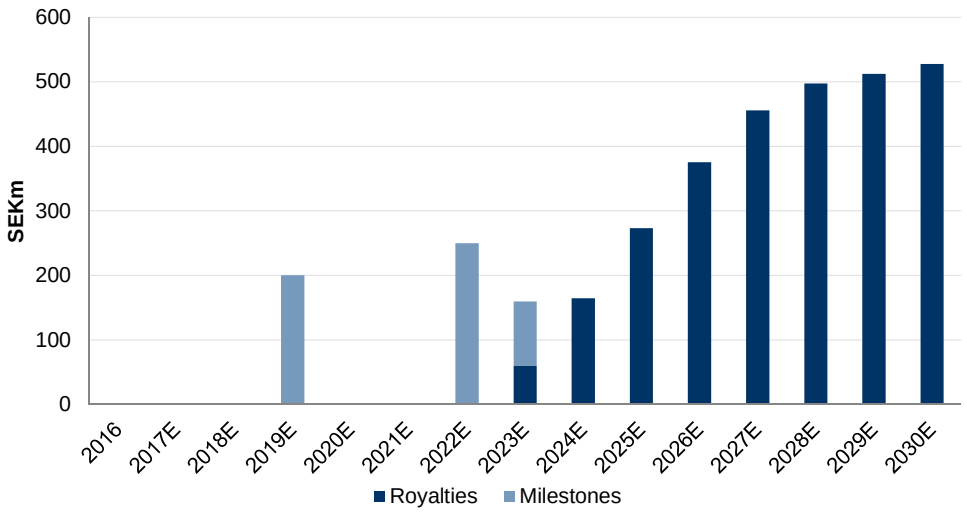
Orphan drug designation and biological exclusivity could further strengthen a favourable patent situation

In 2016 A1M Pharma applied for a substance patent regarding the A1M protein and protection of the kidneys in radionuclide therapy. In addition, it has been assigned orphan drug designation in the EU in pre-eclampsia, allowing for ten years' market exclusivity for the molecule upon approval. The company could also apply for orphan drug status in the US and Japan, which provides seven years' exclusivity. Since the molecule is biological, there could also be an opportunity to gain biological exclusivity, granting 12 years' protection in the US and a decade in Europe. The company is currently evaluating the possibilities of gaining orphan drug designation in the US and the EU for PRRT. Overall, we view the patent situation as favourable, implying potential peak sales beyond 2028. We forecast a peak market share of 35% in the target population.

We see a potential to reach sales of SEK 528m (non-risk-adjusted) in 2030E

Based on the assumptions that the company can deliver on our forecasts, we see a potential to reach royalty-based sales of SEK 528m (non-risk-adjusted) in 2030E, assuming a 10% royalty rate. Our estimates include an upfront payment of SEK 200m upon final phase I/II data in the beginning of 2019 and milestone payments of SEK 250m and SEK 100m, respectively, upon completion of phase III trials in 2022E and subsequent market authorisation in 2023E. In the potential phase III study, we assume research collaboration between A1M Pharma and a potential partner with a 50/50 cost split. Milestones are risk-adjusted to reflect the success probability in each clinical stage of development.

PRRT royalties and milestones - non-risk-adjusted



Source: Nordea Markets

PRRT	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
NETs prevalence in the US and EU ('000s)	275	283	292	300	310	319	328	338	348	359	370	381	392	404	416
PRRT potential patient pool (000's)	96	99	102	105	108	112	115	118	122	126	129	133	137	141	146
Global market, USDm	1,155	1,190	1,225	1,262	1,300	1,339	1,379	1,421	1,507	1,552	1,599	1,647	1,696	1,747	1,799
A1M market share	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	13.0%	21.0%	28.0%	33.0%	35.0%	35.0%	35.0%
A1M sales, USDm	-	-	-	-	-	-	-	71	196	326	448	543	594	611	630

Source: Nordea Markets

PRRT - sensitivity analysis of non-risk-adjusted 2030E royalty sales in SEKm

		Royalty rate				
		8%	9%	10%	11%	12%
Price (USD)	1,000	138	155	176	190	207
	2,000	276	311	352	380	414
	3,000	414	466	528	569	621
	4,000	552	621	704	759	828
	5,000	690	776	880	949	1,035

Source: Nordea Markets

Pre-eclampsia

We estimate market opportunity in pre-eclampsia at USD 1.2-3.2bn, based on our assumptions

In line with management communication, we expect clinical studies in pregnancy-related kidney damage to be initiated in H2 2019. As a baseline for our patient population we use the midpoint of the estimated annual incidence rate of 300,000-400,000 in the US and the EU. Based on the potential direct savings from A1M of about SEK 0.1m per patient, not including factors such as long-term effects and patient wellbeing, we see potential for a price in the region of USD 2,000-4,000. We assume two treatment cycles, which yields a value per patient of USD 4,000-8,000 and a market opportunity of USD 1,200-3,200m. We use the midpoint as the baseline scenario in our forecasts.

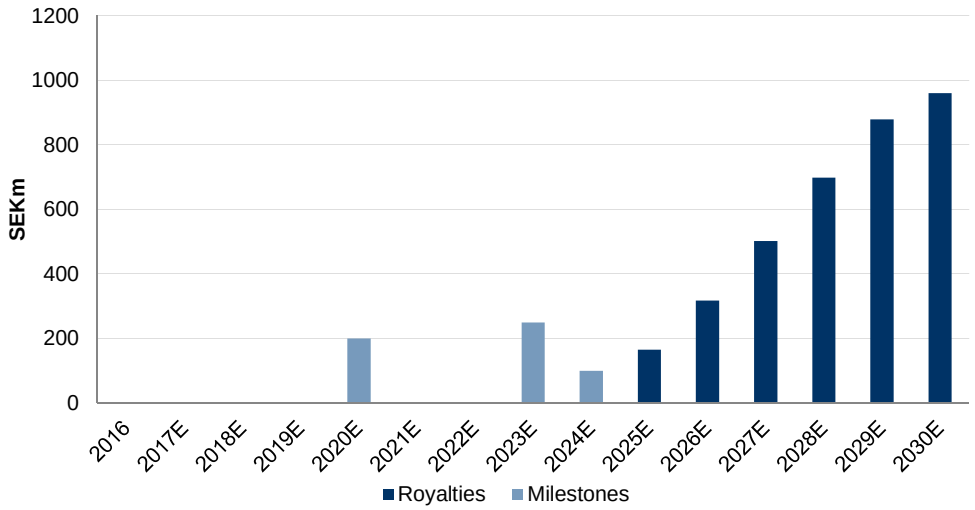
Main assumptions - Pre-eclampsia	
Number of treatments	2
Price in USD	3,000
Royalty	10%
Patient growth	3%
Price inflation	3%

Source: Nordea Markets

We see potential to reach sales of SEK 960m (non-risk-adjusted) in 2030E

Based on our forecasts, we see potential to reach royalty-based sales (non-risk-adjusted) of SEK 960m in 2030E, based on a royalty rate of 10%. Our estimates include an upfront payment of SEK 200m and milestone payment of SEK 250m and SEK 100m, respectively, upon potential successful phase III and subsequent market approval. Note that these forecasts are based on a partnership deal and the company being successful in raising new funds to finalise its research activities. Milestones are risk-adjusted to reflect the success probability in each clinical stage of development.

Pre-eclampsia royalties and milestones - non-risk-adjusted



Source: Nordea Markets

Pre-eclampsia	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence in the US and EU (000's)	350	361	371	382	394	406	418	430	443	457	470	484	499	514	529
Global market, USDm	2,100	2,163	2,228	2,295	2,364	2,434	2,508	2,583	2,660	2,822	2,907	2,994	3,084	3,176	3,272
A1M market share	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.0%	13.0%	20.0%	27.0%	33.0%	35.0%
A1M sales, USDm	-	-	-	-	-	-	-	-	-	198	378	599	833	1,048	1,145

Source: Nordea Markets

Pre-eclampsia - sensitivity analysis of non-risk-adjusted 2030E royalty sales in SEKm

		Royalty rate				
		8%	9%	10%	11%	12%
Price (USD)	1,000	251	282	314	345	376
	2,000	502	565	627	690	753
	3,000	753	847	960	1,035	1,129
	4,000	1,004	1,129	1,255	1,380	1,506
	5,000	1,255	1,412	1,568	1,725	1,882

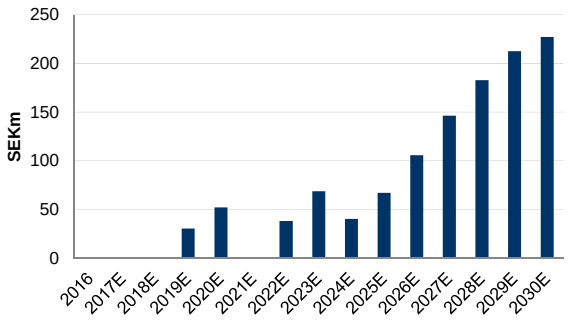
Source: Nordea Markets

Group estimates

We calculate risk-adjusted sales of 227m in 2030E

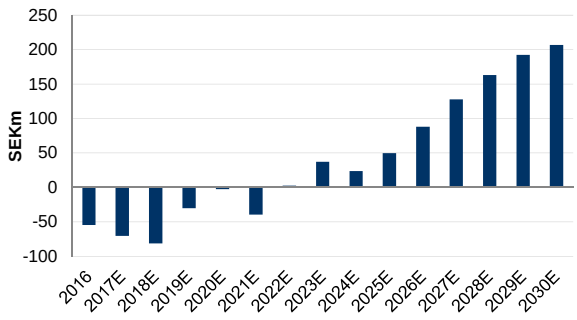
Based on our forecasts, we calculate risk-adjusted royalty sales of SEK 227m on the group level, yielding EBIT of SEK 207m in 2030E. Our estimates imply that PRRT sales constitute 35% of 2030E group sales, with pre-eclampsia representing the remaining 65%. As A1M Pharma has incurred losses during its development phase, we expect taxes carried forward to be used to minimise tax payments. In 2018E, we calculate accumulated losses to amount at about SEK 285m.

A1M Pharma estimated sales



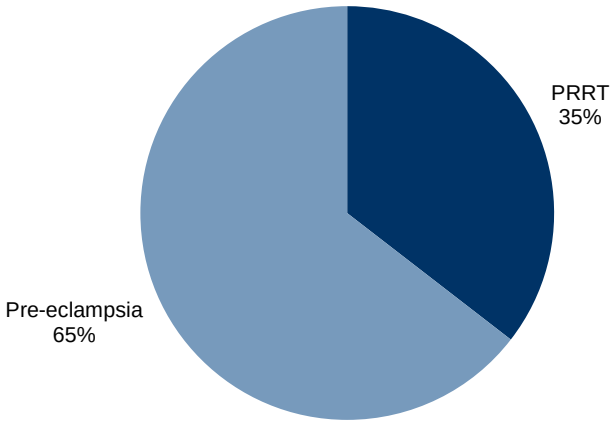
Source: Nordea Markets

A1M Pharma estimated EBIT



Source: Nordea Markets

2030E sales split



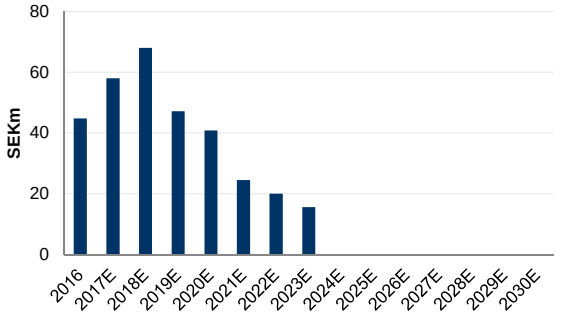
Source: Nordea Markets

Group costs

We estimate operational costs to increase from SEK 55m in 2016 to SEK 81m in 2018

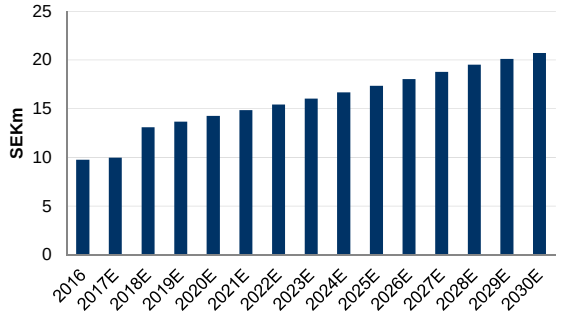
In order to scale up operations and enter clinical phase we estimate operational costs will increase from SEK 55m in 2016 to SEK 81m in 2018. We attribute the main proportion of the cost increase to R&D spending, which we estimate could rise from SEK 45m in 2016 to SEK 68m in 2018. We also see scope for increased sales and administrative costs to scale up operations and prepare for clinical trials, albeit from a low starting point.

A1M Pharma estimated R&D cost



Source: Nordea Markets

A1M Pharma estimated S&GA cost



Source: Nordea Markets

Cash flow

Considering the cash position, we expect the company to raise additional funds

As the company does not have sufficient funds for its planned research activities in the coming 12 months, we include an equity issue of SEK 150m in 2018. We estimate that it will need at least SEK 90m for its planned activities next year. Note that the company has outstanding warrants with a strike price of SEK 15 per share expiring on 8 December 2017. Fully utilised, these options would raise SEK 27m before costs. Our estimates include upfront and milestone payments from a potential partnership deal, which are dependent on positive clinical data. These payments are also risk-adjusted to reflect the probability in each research phase.

Detailed estimates

A1M Pharma - P&L quarterly and annual estimates											
SEKm	**Q1 2016**	**Q2 2016**	**Q3 2016**	**Q4 2016**	**Q1 2017**	**Q2 2017**	**Q3 2017**	**Q4 2017E**	**2017E**	**2018E**	**2019E**
Sales	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**31**
growth (%)	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA	**-6**	**-11**	**-14**	**-21**	**-15**	**-18**	**-18**	**-18**	**-68**	**-79**	**-28**
margin (%)	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBIT	**-7**	**-12**	**-14**	**-22**	**-16**	**-18**	**-18**	**-18**	**-70**	**-81**	**-30**
margin (%)	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net financials	0	0	0	0	0	0	0	0	0	0	0
EBT	**-7**	**-12**	**-14**	**-22**	**-16**	**-18**	**-18**	**-18**	**-71**	**-81**	**-30**
Taxes	0	0	0	0	0	0	0	0	0	0	0
Net income	-7	-12	-14	-22	-16	-18	-18	-18	-71	-81	-30

Source: Company data and Nordea Markets

Risk factors

Below, we list the main risk factors we find relevant for A1M Pharma. The purpose of this is not to provide a comprehensive picture of all of the risks that the company may be subject to, but instead to highlight those that we find most relevant. The main risks we identify relate to the success of clinical trials, regulatory uncertainty, the financial position and the limited commercial history of the company.

A1M Pharma is dependent on the success of its product candidate

Success of its key product candidate

A1M Pharma is dependent on regulatory approvals and the successful commercialisation of its product candidate ROSgard. Failure to receive approval for one or several product candidates could affect the prospects for strategic collaborations and funding, and limit future earnings potential. Risk factors affecting commercial and development success include, but are not limited to, completion of preclinical and clinical trials, regulatory and market approvals from central agencies such as the EMA and FDA, protection and maintenance of intellectual property, competition from other treatments, and licensing discussions with potential partners.

Clinical trials are risky and time-consuming

Clinical studies are risky and time-consuming, and require resources

Clinical trials are risky and there are no guarantees that they are successful despite promising results in earlier trials. Even in the event of positive results, there is a risk that regulatory bodies, such as the FDA and EMA, might have another interpretation of the results. Trials are also time-consuming and expensive, and require certain expertise. It can take several years to complete a trial, and regulatory bodies may delay or terminate trials at any time.

Preclinical assets are difficult to assess

Value of preclinical assets difficult to assess

ROSgard has just finalised the preclinical phase and the value of assets in this early stage of development is often difficult to assess. Its benefits still need to be confirmed in a clinical setting and as the product is still years from potentially reaching the market, it is difficult to predict pricing and demand for the product candidate.

Regulatory outcomes are uncertain and differ between regions

Regulatory approvals

Regulatory processes are also uncertain, demanding substantial time and resources from management. In addition, the requirements might differ between different countries and additional studies could be required to obtain approvals. In the event of approval, products will still undergo continual regulatory overviews covering all parts of the manufacturing process, labelling, packing, distribution, etc. Failure to comply with current regulations could lead to marketing restrictions being imposed and recalls, among other things. Another risk is that the current policies may change in the future.

Pharmaceutical products are governed by strict regulation

Manufacturing

Manufacturing of A1M Pharma's product candidates requires compliance with the EMA, FDA and other international standards, such as current Good Manufacturing Practice (cGMP). If the company fails to meet these standards, this could cause production disruptions, which could delay clinical trials. Increased requirements in the future could also cause disruptions and lead to increased investments.

In addition, A1M Pharma is dependent on third-party manufacturers such as Richer-Helm Biologics GmbH & Co KG, a contract manufacturing organisation that will be responsible for the production of ROSgard.

Competition

A1M Pharma could face competition from companies with extensive experience and resources

The market for pharmaceutical products is highly competitive and A1M might face multiple competitors for its products and product candidates including major pharmaceutical companies, speciality pharma companies and biotechnology companies. Apart from established treatments, A1M Pharma might also face competition from new novel treatments currently under development.

Several of the current and potential competitors also have significant advantages in terms of experience, resources and established market positions.

In addition, early-stage companies might also prove to be a threat, through strategic collaborations with larger players.

Adverse events

Products could cause severe side effects

There is a risk that the company's products and product candidates could cause serious and/or unexpected side effects. If these were to occur, they could cause a delay or stop to clinical trials, lead to negative outcomes in market approval processes, induce labelling requirements, or be the source of legal disputes and reputational damage.

Financial position and capital needs

A1M Pharma does not have sufficient funds to reach the commercial phase

A1M Pharma is still in a development phase and is currently not generating any cash flows. As there is not enough cash on hand to support the planned activities for the coming 12 months, the company is likely to engage in a rights issue in the short term. The company is continually working with several different financing options, eg licensing deals, to ensure that it has enough liquidity until its products are registered and can generate revenue streams. The company believes its prospects of receiving funding are good, but if it was not to receive sufficient funds, it would be difficult for A1M Pharma to continue as a going concern.

Limited operational history to assess long-term viability

Limited history makes it difficult to predict the long-term viability of the business

A1M Pharma has been an active company since 2008, but operations have so far been limited to early-stage development activities such as identifying product candidates, raising capital and conducting preclinical studies. In order to take the next step by entering the clinical stage and later commercialising the product, the company might need to recruit personnel with new areas of competence.

Hiring/maintaining qualified personnel

A1M Pharma depends on key personnel, including scientists

A1M Pharma's future success is dependent on its ability to keep, motivate and attract key personnel. This includes senior scientists as well as senior management. Loss of key individuals could lead to delays to or prevention of the successful development of its product candidates. As previously mentioned, the company might also need to add new capabilities to engage in commercial activities and failure to do so could limit its future success.

Patent

Intellectual property is key to the future success of its product candidates

Intellectual property is crucial in pharmaceutical development and A1M Pharma has a broad portfolio of issued, pending and published patents covering many of the major markets. However, if A1M Pharma is not able to adequately defend its IP, this could affect the future success of its product candidate. The company might also be forced into litigation or it could itself be subject to allegations of patent infringements by a third party.

Glossary

Adaptive study: A study that evaluates a medical device or treatment by observing participant outcomes (and possibly other measures, such as side effects) on a prescribed schedule, modifying parameters of the trial protocol in accordance with those observations.

Clinical phase: Tests of drug candidates on humans (or animals in a veterinary context)

- phase I: test of a drug on a limited number of healthy volunteers (25-100 people) for dose-ranging
- phase II: test of a drug on patients (50-300 people) with the disease to determine efficacy and side effects
- phase III: test of a drug on a larger group of patients (300-3,000 people) with the disease to determine efficacy, side effects and safety profile compared with the current standard treatment
- phase IV: Upon market launch, the drug is monitored with respect to rare side effects.

Contract research organisation (CRO): An organisation that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

EMA: The European Medicines Agency is the EU's medical authority.

FDA: The Food and Drug Administration is the US medical authority.

Free radical: An oxygen-containing molecule that has one or more unpaired electrons, making it highly chemically reactive with other substances. Free radicals can cause serious cellular damage through oxidative stress.

Good Laboratory Practice (GLP): A quality system of management controls for research laboratories and organisations to ensure the uniformity, consistency, reliability, reproducibility, quality and integrity of chemical (including pharmaceuticals) non-clinical safety tests.

Good Manufacturing Practice (GMP): The practices required to conform to the guidelines recommended by agencies that control authorisation and licensing for the manufacture and sale of food, drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public.

Haemoglobin molecule or **heme:** The iron-containing protein in the red blood cells of all vertebrates. The haemoglobin carries oxygen from the respiratory organs (lungs) to the rest of the body. Heme is the iron-containing component of haemoglobin, which binds the oxygen molecule and gives the blood its red colour. Upon combustion in the cells, a few percent of the used oxygen turn into free oxygen radicals.

Mitochondria: Organelles, or parts of a eukaryote cell that are found in the cytoplasm, outside of the nucleus of a cell. The most prominent role of mitochondria is to produce ATP, a molecule that the cells use as a source of energy, in a process called cellular respiration. In addition to supplying cellular energy, mitochondria are involved in a range of other processes, such as signalling, cellular differentiation, cell death, as well as the control of the cell division cycle and cell growth.

NETs or **neuroendocrine tumours:** The generic term for a type of hormone-producing tumour that most commonly occurs in the intestine or the lungs.

Orphan drug designation (ODD): Market exclusivity obtained for a product after market approval even if the relevant patent has expired. ODD gives exclusivity for ten years within the EU from the time of market approval.

Oxidative stress: Imbalance between the production of free radicals and the ability of the body to counteract or detoxify their harmful effects through neutralisation by antioxidants. Oxidative stress occurs when the body produces a surplus of harmful free radicals, or when substances that cause damage enter the body, eg substances

in cigarette smoke. The most important antioxidants that protect the body from oxidative stress are produced in the body itself. One of these is the protein alpha-1-microglobulin, A1M.

Pre-clinical phase: A stage before tests on humans (clinical trials). Identification of drug candidates, study of feasibility and assessment of products' safety profiles.

Peptide Receptor Radionuclide Therapy (PRRT): A form of molecular targeted therapy used to treat neuroendocrine tumours. In PRRT, a cell-targeting protein (or peptide) is combined with a small amount of radioactive material, creating a special type of radiopharmaceutical called a radiopeptide. When injected into the patient's bloodstream, this radiopeptide travels to and binds with neuroendocrine tumour cells, delivering a high dose of radiation to the cancer.

Proof of concept: A method to evaluate the efficacy of a treatment.

Reactive oxygen species (ROS): A number of reactive molecules and free radicals derived from molecular oxygen.

Recombinant: Modified version of an endogenous protein, for example, such as alpha-1-microglobulin (A1M), of which ROSGard is a recombinant.

Reductase: An enzyme that catalyses a reduction reaction.

Toxicology study: A study performed in animals to determine the dose level recommended for the treatment of a disease with a drug. This method enables the identification of potential adverse effects following repeated daily ingestion of a drug.

Reported numbers and forecasts

Income statement									
SEKm	**2014**	**2015**	**2016**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**
Net revenue	**0**	**0**	**0**	**0**	**0**	**31**	**52**	**0**	**38**
Revenue growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	71.0%	n.a.	n.a.
EBITDA	-14	-29	-52	-68	-79	-28	-0	-37	6
Depreciation and impairments PPE	-0	-0	-0	-0	-0	-0	-0	-0	-0
EBITA	-14	-29	-52	-68	-79	-28	-1	-37	5
Amortisation and impairments	0	-1	-2	-2	-2	-2	-2	-3	-3
EBIT	-14	-30	-54	-70	-81	-30	-3	-39	3
of which associates	0	0	0	0	0	0	0	0	0
Associates excl. from EBIT	0	0	0	0	0	0	0	0	0
Net financials	-0	-0	-0	-0	0	0	0	0	0
Pre-Tax Profit	**-14**	**-30**	**-54**	**-71**	**-81**	**-30**	**-3**	**-39**	**3**
Reported taxes	0	0	2	0	0	0	0	0	0
Net profit from cont. operations	-14	-30	-52	-71	-81	-30	-3	-39	3
Discontinued operations	0	0	0	0	0	0	0	0	0
Minority interest	0	0	0	0	0	0	0	0	0
Net profit to equity	-14	-30	-52	-71	-81	-30	-3	-39	3
EPS	**-9.66**	**-15.90**	**-19.07**	**-7.18**	**-8.24**	**-3.08**	**-0.30**	**-4.00**	**0.27**
DPS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
of which ordinary	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
of which extraordinary	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Profit margin in percent									
EBITDA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-0.6%	n.a.	14.7%
EBITA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-1.0%	n.a.	14.2%
EBIT	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-5.6%	n.a.	6.9%
Adjusted earnings									
EBITDA (adj.)	-14	-29	-52	-68	-79	-28	-0	-37	6
EBITA (adj.)	-14	-29	-52	-68	-79	-28	-1	-37	5
EBIT (adj.)	-14	-30	-54	-70	-81	-30	-3	-39	3
EPS (adj.)	-9.66	-15.90	-19.07	-7.18	-8.24	-3.08	-0.30	-4.00	0.27
Adjusted profit margins in percent									
EBITDA (adj.)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-0.6%	n.a.	14.7%
EBITA (adj.)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-1.0%	n.a.	14.2%
EBIT (adj.)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-5.6%	n.a.	6.9%
Performance metrics									
CAGR last 5 years									
Net revenue	n.a.	n.a.	n.a.	n.a.	-58.3%	n.a.	n.a.	0.0%	n.a.
EBITDA	n.a.	n.a.	n.a.	n.a.	55.0%	-1.1%	-72.1%	-14.3%	n.a.
EBIT	n.a.	n.a.	n.a.	n.a.	55.9%	0.3%	-51.9%	-13.5%	n.a.
EPS	n.a.	n.a.	n.a.	n.a.	-3.9%	-33.6%	-64.7%	-13.6%	n.a.
DPS	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Average EBIT margin	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Average EBITDA margin	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

Source: Company data and Nordea Markets

Valuation ratios - adjusted earnings									
SEKm	**2014**	**2015**	**2016**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**
P/E (adj.)	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	50.0
EV/EBITDA (adj.)	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	23.1
EV/EBITA (adj.)	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	24.0
EV/EBIT (adj.)	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	49.0
Valuation ratios/reported earnings									
P/E	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	50.0
EV/Sales	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	2.5
EV/EBITDA	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	23.1
EV/EBITA	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	24.0
EV/EBIT	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	49.0
Dividend yield (ord.)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
FCF yield	-16.6%	-15.4%	-43.8%	-56.8%	-61.1%	-27.6%	-7.3%	-33.4%	-0.2%
Payout ratio	n.a.	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Company data and Nordea Markets

Balance sheet									
SEKm	**2014**	**2015**	**2016**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**
Intangible assets	25	29	32	32	32	34	37	39	42
of which R&D	25	29	32	32	32	34	37	39	42
of which other intangibles	0	0	0	0	0	0	0	0	0
of which goodwill	0	0	0	0	0	0	0	0	0
Tangible assets	1	1	1	1	1	1	1	1	1
Shares associates	0	0	0	0	0	0	0	0	0
Interest bearing assets	0	0	0	0	0	0	0	0	0
Deferred tax assets	0	0	0	0	0	0	0	0	0
Other non-int. bearing assets	0	0	0	0	0	0	0	0	0
Other non-current assets	0	0	0	0	0	0	0	0	0
Total non-current assets	**26**	**30**	**33**	**33**	**33**	**35**	**38**	**40**	**43**
Inventory	0	0	0	0	0	0	0	0	0
Accounts receivable	0	1	0	1	1	8	8	8	10
Other current assets	1	1	2	2	2	2	3	2	2
Cash and bank	4	19	7	24	93	57	47	3	3
Total current assets	**5**	**21**	**9**	**27**	**96**	**66**	**58**	**13**	**14**
Assets held for sale	0	0	0	0	0	0	0	0	0
Total assets	**31**	**51**	**42**	**60**	**129**	**101**	**96**	**53**	**57**
Shareholders equity	**25**	**43**	**30**	**52**	**121**	**91**	**88**	**48**	**51**
of which preferred stock	0	0	0	0	0	0	0	0	0
of which Equity of hyb. debt	0	0	0	0	0	0	0	0	0
Minority interest	0	0	0	0	0	0	0	0	0
Total Equity	25	43	30	52	121	91	88	48	51
Deferred tax	2	2	0	0	0	0	0	0	0
Long term int. bearing debt	0	0	0	0	0	0	0	0	0
Pension provisions	0	0	0	0	0	0	0	0	0
Other long-term provisions	0	0	0	0	0	0	0	0	0
Other long-term liabilities	0	0	0	0	0	0	0	0	0
Convertible debt	0	0	0	0	0	0	0	0	0
Shareholder debt	0	0	0	0	0	0	0	0	0
Hybrid debt	0	0	0	0	0	0	0	0	0
Total non-curr. liabilities	**2**	**2**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Short-term provisions	0	0	0	0	0	0	0	0	0
Accounts payable	1	3	10	5	5	9	5	5	4
Other current liabilities	2	3	3	3	3	2	3	0	2
Short term interest bearing debt	0	0	0	0	0	0	0	0	0
Total current liabilities	**4**	**6**	**12**	**8**	**8**	**11**	**8**	**5**	**6**
Liab.for assets held for sale	0	0	0	0	0	0	0	0	0
Total liabilities and equity	**31**	**51**	**42**	**60**	**129**	**101**	**96**	**53**	**57**
Balance sheet and debt metrics									
Net debt	-4	-19	-7	-24	-93	-57	-47	-3	-3
Working capital	-3	-5	-10	-5	-5	-2	3	5	6
Invested capital	23	25	23	28	28	34	41	45	48
Capital employed	27	45	30	52	121	91	88	48	51
ROE	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
ROIC	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
ROCE	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Net debt/EBITDA	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Interest coverage	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Equity ratio	80.1%	83.4%	71.4%	86.7%	93.8%	89.5%	91.8%	90.6%	89.9%
Net gearing	-16.6%	n.m.	-23.1%	-46.6%	-77.2%	-62.6%	-53.7%	-6.2%	-5.2%

Source: Company data and Nordea Markets

Cash flow statement									
SEKm	**2014**	**2015**	**2016**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**
EBITDA (adj.) for associates	-14	-29	-52	-68	-79	-28	0	-37	6
Paid taxes	0	0	0	0	0	0	0	0	0
Net financials	0	0	0	0	0	0	0	0	0
Change in Provisions	0	0	0	0	0	0	0	0	0
Change in other LT non-IB	0	0	0	0	0	0	0	0	0
Cash flow to/from associates	0	0	0	0	0	0	0	0	0
Dividends paid to minorities	0	0	0	0	0	0	0	0	0
Other adj. to reconcile to cash flow	8	0	-1	0	0	0	0	0	0
Funds from operations (FFO)	**-6**	**-29**	**-52**	**-68**	**-79**	**-28**	**0**	**-37**	**6**
Change in NWC	-1	2	5	-5	0	-3	-4	-2	-1
Cash flow from op. (CFO)	-7	-27	-47	-73	-79	-31	-4	-39	5
Capital Expenditure	-12	-5	-5	-2	-2	-5	-5	-5	-5
Free Cash Flow before A&D	**-18**	**-33**	**-52**	**-75**	**-81**	**-37**	**-10**	**-44**	**0**
Proceeds from sale of assets	0	0	0	0	0	0	0	0	0
Acquisitions	0	0	0	0	0	0	0	0	0
Free cash flow	-18	-33	-52	-75	-81	-37	-10	-44	0
Dividends paid	0	0	0	0	0	0	0	0	0
Equity issues / buybacks	33	48	40	93	150	0	0	0	0
Net change in debt	0	0	0	0	0	0	0	0	0
Other financing adjustments	0	0	0	0	0	0	0	0	0
Other non-cash adjustments	-10	0	0	0	0	0	0	0	0
Change in cash	4	15	-12	17	69	-37	-10	-44	0
Cash flow metrics									
Capex/D&A	n.a.	n.a.	201%	80%	91%	216%	200%	187%	176%
Capex/Sales	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Key information									
Share price year end (current)	3.9	5.6	2.2	13.5	13.5	13.5	13.5	13.5	13.5
Market cap	112	212	119	132	132	132	132	132	132
Enterprise value	107	192	112	108	39	76	85	129	130
Diluted no. of shares, year-end (m)	1.4	1.9	2.7	9.8	9.8	9.8	9.8	9.8	9.8

Source: Company data and Nordea Markets

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Issuer review

This report has been reviewed, for the purpose of verification of fact or sequence of facts, by the issuer of the relevant financial instruments mentioned in the report prior to publication. The review has led to changes of facts in the report.

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