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Valuation brief
A1M Pharma

Gothenburg

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Valuation projects require multiple client interactions, workshops, diligent literature and database reviews and thorough analysis of the company's data and assumptions. In this particular case, however, MSC was requested to do a valuation brief of A1M Pharma's lead program without the normal comprehensive procedure. Results should be interpreted accordingly.

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A high proportion of patients who undergo CABG are at risk of developing AKI and may be thought of as eligible for treatment

- **Large proportion of cardio surgery cases result in AIK:** AKI Acute kidney injury (AKI), or acute renal failure, depending on the specific definition, has been reported to occur in up to 30%^{1,2,3} of all patients who undergo cardiac surgery. The incidence of AKI is dependent on the particular type of cardiopulmonary bypass surgery. Typical coronary artery bypass grafting (CABG) has the lowest incidence of ARF (approximately 2.5%), followed by valvular surgery with an incidence of ARF of 2.8%.
- **Shrinking market:** Research has found that the volume of coronary artery bypass graft (CABG) has decreased by 70 percent from 1997 to 2007, while the volume of percutaneous transluminal coronary angioplasty increased by 20 percent during this same time period, and that CABG procedures decreased by nearly half to 213,700 procedures between 2001-2011 in the US. This results in an annual market decline, expressed in CAGR, of **-6.7%** for the US market. In the UK, there were 17,630 isolated CABG operations in 2013 compared with 23,126 performed in 2004, resulting in a CAGR of **-3%**.
- After discussions with A1M Pharma, two assumptions were decided: 1) **30%** of the patients undergoing CABG would be at risk to develop AKI and thus be eligible to receive drug treatment, 2) the negative market growth was assumed to be cancelled out by population growth and an aging population (**0%**).

Region	Population 2018	Patients undergoing CABG per year	CABG at risk to develop AKI eligible for drug	Target population	Adjustment*: reducing target pop. with 20%	Annual growth rate
USA	329 256 465	213 700⁴	30%	64 110	51 288	-6.7%⁴
EU5	324 505 090	171 382	30%	51 415	41 132	-3.0%
France	67 364 357	43 721 ^{4 ext}	30%	13 116	10 493	-3% ⁸
Germany	80 457 737	37 614 ⁷	30%	11 284	9 027	-3% ⁸
Italy	62 246 674	40 400 ^{4 ext}	30%	12 120	9 696	-3% ⁸
Spain	49 331 076	32 017 ^{4 ext}	30%	9 605	7 684	-3% ⁸
UK	65 105 246	17 630 ⁸	30%	5 289	4 231	-3% ⁸
Total	2 173 066 428	385 082	Assumption: 30%	115 525	92 420	Assumption: 0%

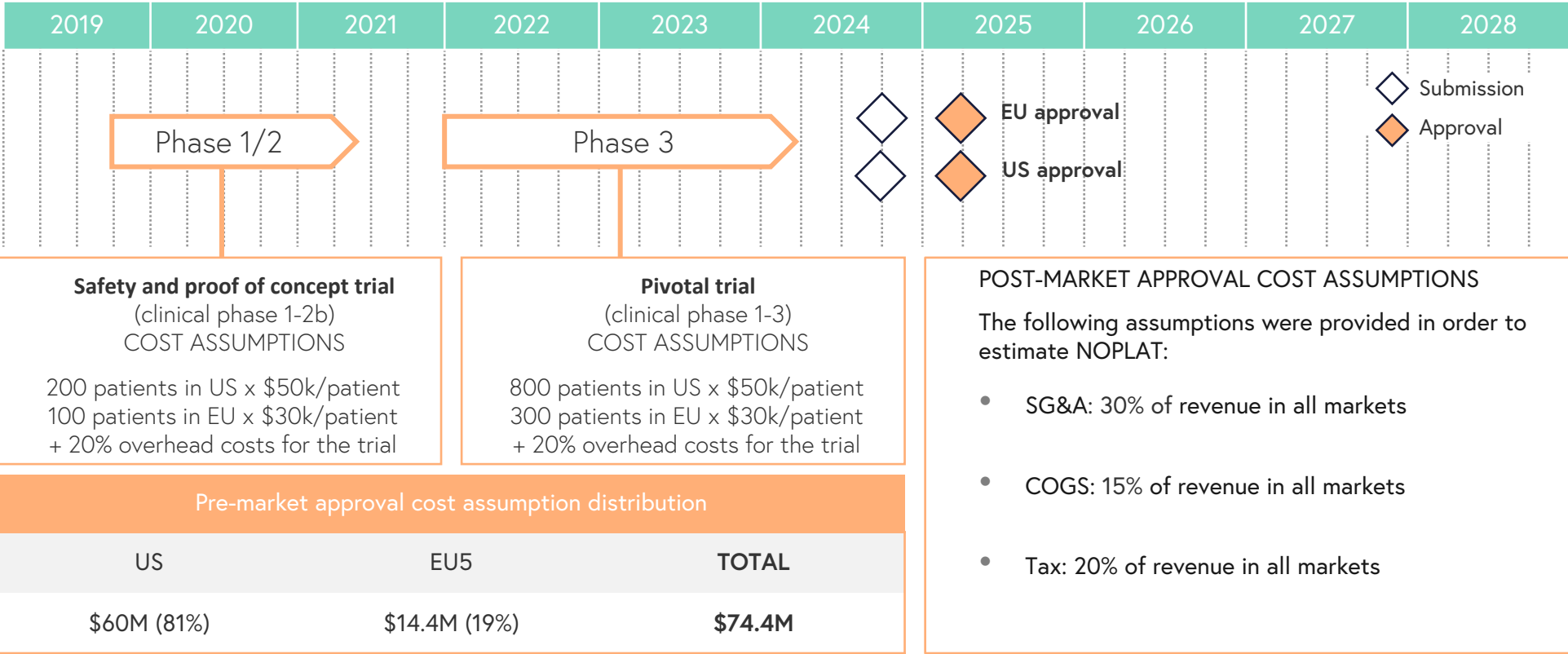
1. Chertow GM et al., Circulation. 1997 Feb 18;95(4):878-84. ([link](#)) 2. Parolari A et al., Ann Thorac Surg. 2012 Feb;93(2):584-91. doi: 10.1016 ([link](#)) 3. Rosner MH et al., CJASN January 2006, 1 (1) 19-32 ([link](#)). 4. Weiss AJ, AHRQ, 2014 (data from 2011) ([link](#)). 5. Castroviejo et al., Rev Esp Cardiol. 2015;68:635-6 - Vol. 68 Num.07 ([link](#)) 6. Nashef et al., European Journal of Cardio-Thoracic Surgery, Volume 17, Issue 4, 1 April 2000, Pages 396–399 ([link](#)). 7. Isolated CABG procedures, Table C1, Beckman et al., Thorac Cardiovasc Surg 2017;65:505–518 ([link](#)). 8. 2013 data, Blue Book Online (UK National Adult Cardiac Surgery Audit) ([link](#)).

* Standard adjustment to reduce the patient population with 20% was applied. This reduction accounts for the 'too old, too frail' population that may discontinue or refuse treatment for different reasons.

Development timeline and costs for clinical program assumptions brings total costs to \$74.4 million and projected approval in 2025

Main development assumptions for the CS1 candidate were established together with the management from A1M Pharma before they were applied in the NPV model. The same development programs were assumed valid for approval in US and EU5. To support development timeline and approval dates, the timelines were modelled based on benchmarking with MA-0217 and QPI-1002 and interviews with the management of A1M Pharma.

Please note that annual attrition was applied for each program based on the highest phase of development for each year.



A set of market assumptions were made for ROSgard

PATENTS AND EXCLUSIVITY OPTIONS

A1M Pharma's patent portfolio includes the following:

- Patents on medical use of A1M
- Patents for diagnostic method and treatment of pre-eclampsia
- Patent for mitochondrial-related diseases
- Patent for protection of the substance A1M and A1M-related proteins – application filed
- A1M for kidney diseases – application filed in 16 Mar 2016

Exclusivities for CS1		
Indication	Reduction of Major Adverse Kidney Event (MAKE) in patients after cardiac surgery	
Geographical market	EU5	US
Estimated market approval	2025	2025
Biologics exclusivity (12 years US in Japan & 10 years EU5)	2035	2037
Patent protection (20 years from filing year)	2036 (assuming no patent term extension)	2036 (assuming no patent term extension)
Orphan drug designation (7 years US & 10 years EU5)	2035	2032

Based on input from the management of A1M Pharma, the following market assumptions were made.

- **Market exclusivity** for ROSgard will mainly be achieved through patent protection with an assumed expiry year in 2036.
- **Market share (at peak)** was assumed to be 30% of CABG patients.
- **Market uptake** was assumed to follow a standard 5 year from launch to peak year (when the full market share is reached).
- As **market growth** was assumed to be 0%, a peak market plateau will result until patent expiry.
- Relatively rapid **sales erosion** post patent exclusivity expiration with 80% erosion 4 years post peak followed by 90% erosion during the next 8 years was assumed. Erosion was modeled to begin on the last year of exclusivity, i.e. in 2036 in the targeted markets.
- **Base case pricing** was assumed to be \$8000 per patient and year and was kept constant (no rebates, prices increases/ decreases, etc., were modeled).
- **Risk adjustment** for clinical attrition was made using the likelihood of approval was modeled based on the Endocrine indication category in Hay M. et al. Nat Biotechnol. 2014 Jan;32(1):40-51. ROSgard was assumed to currently be 90% done with the preclinical phase.
- **WACC** was assumed to be 18%.

rNPV is estimated in a base case to \$23M in 2018, based on projected peak revenues of \$739M and a peak NOPLAT of \$325M in 2030

KEY RESULTS

rNPV 2018: \$23M
NPV 2018: \$222M

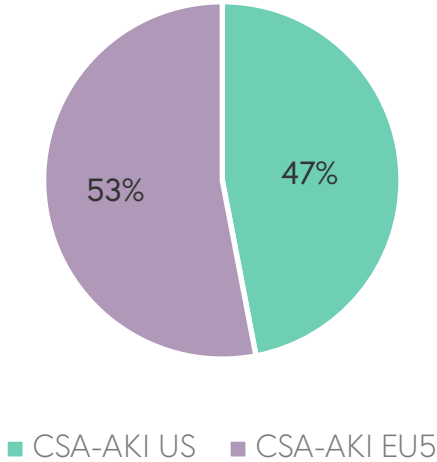
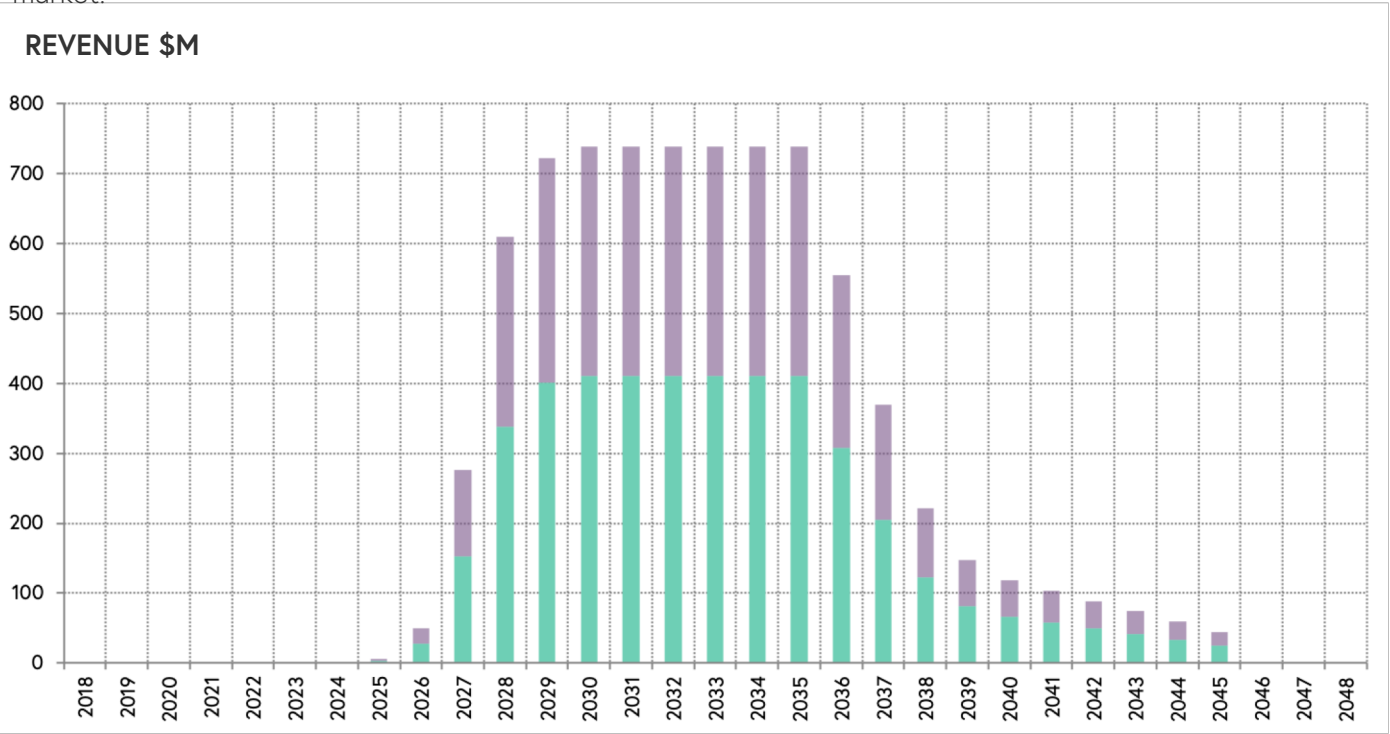
Peak year: 2030
Peak sales: \$739M
Peak NOPLAT: \$325M
Peak population:
92 420 patients
Total NOPLAT: \$3.5B
Total revenue: \$7.9B

MAJOR ASSUMPTIONS

- Modeled cases: 2 (US & EU5)
- Market approval: 2025 (US & EU5)
- Market share (at peak): 30%
- Market growth: 0%
- Price: \$8K (US & EU5)
- R&D costs: \$74.4M
- Tax on sales: 20%
- COGS: 15% of revenue
- SG&A: 30% of revenue
- LoA: 10.4% (Endocrine)
- Current phase: 90% of Phase 1
- WACC: 18%

REVENUE PROJECTION: CSA-AKI IN THE US AND EU5

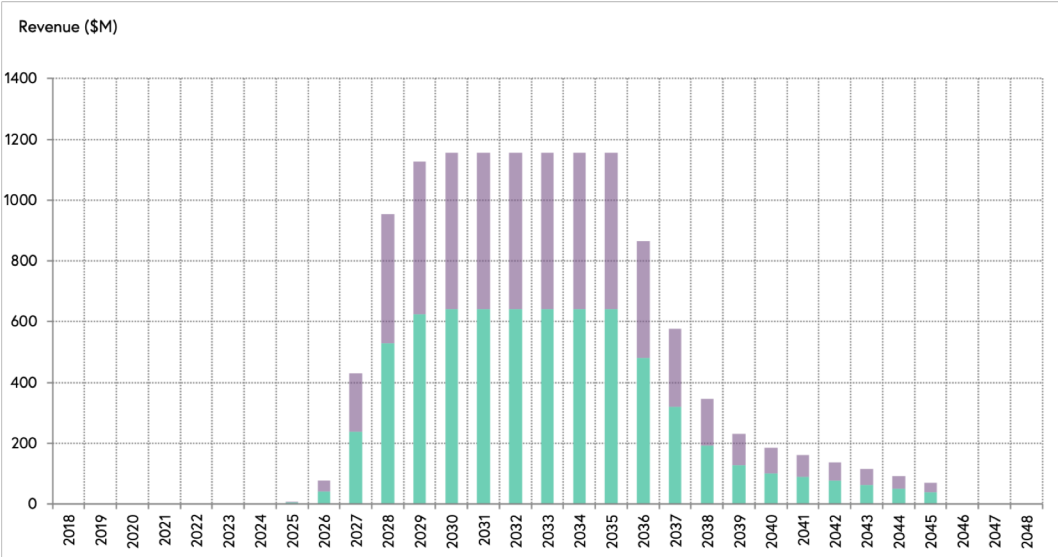
Based on the assumptions, presented in the previous slides, the risk-adjusted NPV (rNPV) for the ROSgard program in patients being treated preventively for AKI before undergoing CABG is \$23M in 2018. The target patient population in the US accounts for \$10.9M (47%) of the asset value and EU5 accounts for \$12.3M (53%). With the same pricing assumption on these two fairly similarly sized markets and with higher costs for a trial in the US, make the scale tip toward a higher value for the European market.



A base case has been estimated to \$23M in 2018, however, modeling with pricing and market share results in a \$10M to \$41M value range

BULL SCENARIO

25% factor increase
Price: \$10k/year/patient
Market share: 37.5%



rNPV 2018: \$41M
NPV 2018: \$389M

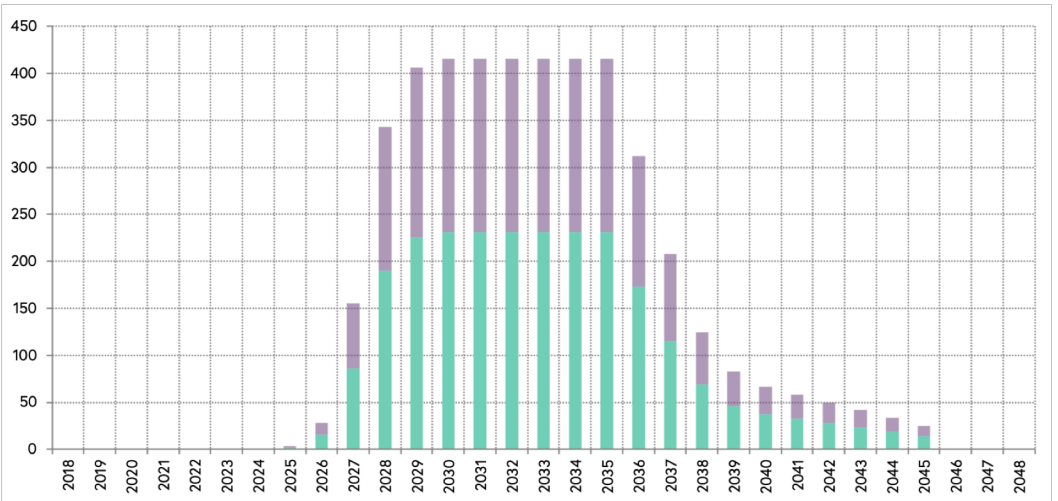
Peak year: 2030
Peak sales: \$1155M
Peak NOPLAT: \$508M
Peak population:
115 525 patients
Total NOPLAT: \$5.4B
Total revenue: \$12.3B

MAJOR ASSUMPTIONS

Modeled cases: 2 (US & EU5)
Market approval: 2025 (US & EU5)
Market growth: 0%
R&D costs: \$74.4M
Tax on sales: 20%

BEAR SCENARIO

25% factor decrease
Price: \$6k/year/patient
Market share: 22.5%



rNPV 2018: \$10M
NPV 2018: \$92M

Peak year: 2030
Peak sales: \$416M
Peak NOPLAT: \$183M
Peak population:
69 315 patients
Total NOPLAT: \$2.0B
Total revenue: \$4.4B

COGS: 15% of revenue
SG&A: 30% of revenue
LoA: 10.4% (Endocrine)
Current phase: 90% of Phase 1
WACC: 18%

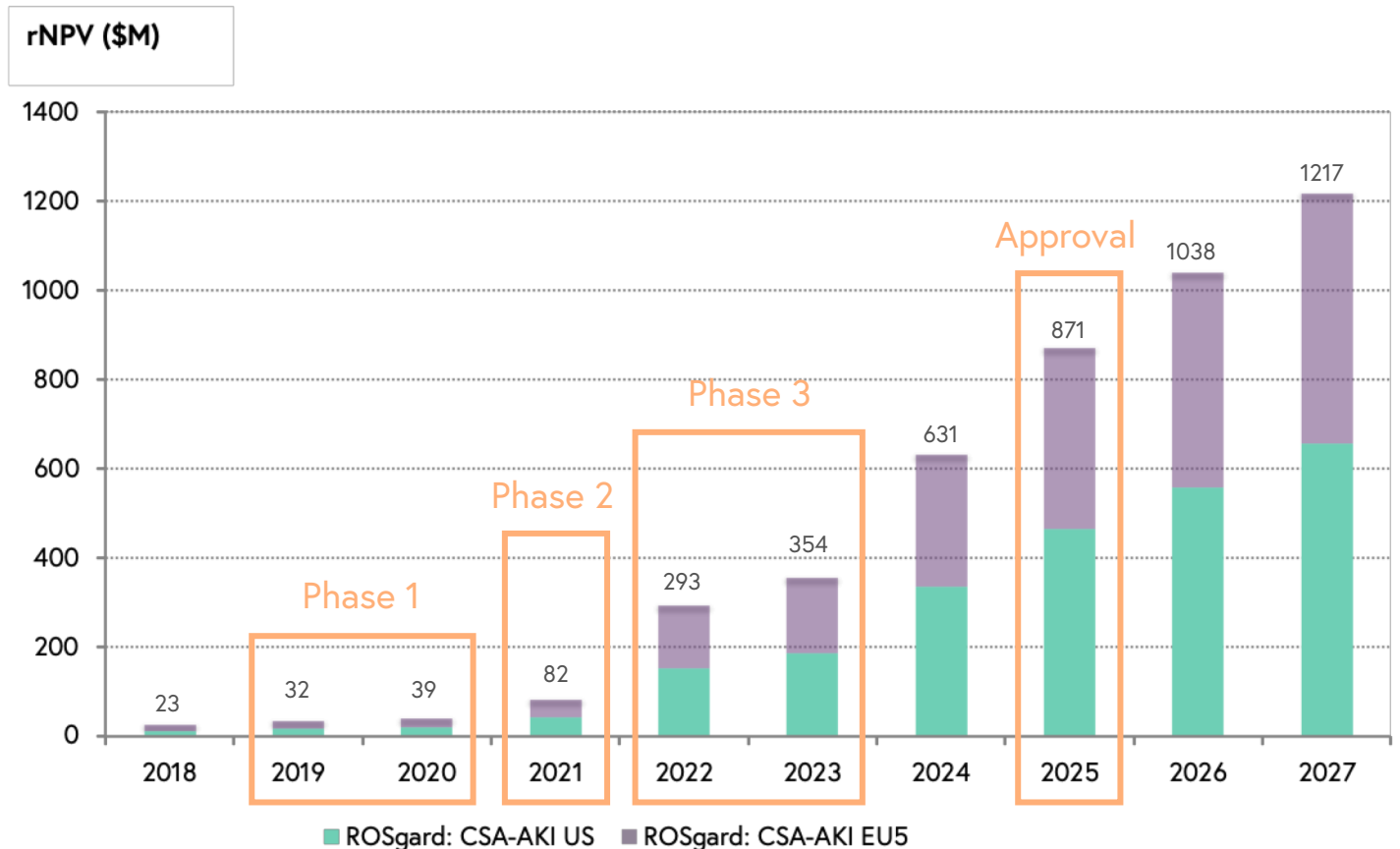
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Significant rNPV increases expected upon advancement into later development stages, as clinical risk is reduced

The risk adjustment that is applied in the financial model is based on clinical attrition data. This means that the rNPV increases significantly every time a new development phase is entered. An overview of the annual value increase, due to the clinical attrition, is shown in the diagram.

While the assumptions in this project result in a current rNPV of \$23M for the current ROSgard program, stakeholders should note the significant value increase that is expected in the future.

Next year, when ROSgard is expected to initiate its phase 1 program the valuation is expected to reach \$32M (39% increase) and will increase all the way to \$82M as it enters phase 2 in 2021 (257%). This may be compared to the clinical cost to go from the current stage to a completed phase 2 study in 2021, which has been assumed to be \$15.6 million (although no costs for company operations, IP, staff, BD, etc, has been assumed).



Executive summary

A brief analysis resulted in a shortlist of 4 licensing and acquisition deals of relevance for benchmarking with A1M Pharma's ROSgard

- Licensing and acquisitions deals related to kidney failure and other kidney related conditions were identified and analyzed. Four deals were considered to be relevant and provide representative benchmark deals based on their indication area. Those four are listed in the table on this slide.
- All the larger deals were identified as being done in clinical phase 2 or 3. The total deal values of these indicate that partners may be willing to pay premiums over the calculated rNPVs that was estimated for ROSgard in phase 2.

Date & Reference	Licensee (Licensor)	Candidate(s)	Indication (phase at deal signing)	Total deal value & geography	Upfront (royalty)
2010-08-18 Ref	Quark Pharma (Novartis)	QPI-1002	AKI in patients undergoing major cardiovascular surgery (Phase 2)	Option deal \$670M	\$10M
2018-05-23 Ref	Cara Therapeutics (Vifor Fresenius Medical Care Renal Pharma)	CR845	Chronic kidney disease-associated pruritus (Phase 3)	\$540M Worldwide, not US, JP, Korea	\$50M + \$20M
2010-09-23 Ref	Reata Pharma (Abbott)	Bardoxolone Methyl	Chronic kidney disease (Phase 2)	\$450M + royalties Worldwide, not US and Asia	Unknown
2015-05-04 Ref	Ionis Pharma (Bayer)	FXI(Rx)	Compromised kidney function and prevention of thrombosis (Phase 2)	\$375M Worldwide	\$100M

Selected public benchmark companies in the AKI space are valued between \$4.1 million to \$1.8 billion

Company	HQ	Drug pipeline: number of candidates, indications, and highest development phase	Clinical phase of similar indication(s) as Client	Market cap (Nov 29, 2018)
Breathtec Biomedical	USA	3 assets, 3 indications, preclinical	Chronic kidney failure	\$5.95M
DiaMedica Therapeutics	USA	20 assets, 4 indications, phase 2	AKI, preclinical	\$52.6M
Dimerix Limited	Australia	8 assets, 8 indications, phase 2	Chronic kidney failure, phase 2	\$10.9M
Ember Therapeutics	USA	15 assets, 11 indications, phase 2	Chronic kidney failure, preclinical	\$4.1M
Reata Pharma	USA	38 assets, 20+ indications, phase 3	Chronic kidney failure, phase 3	\$1884M
Resverlogix Corp	Canada	5 assets, 14 indications, phase 3	Kidney failure, phase 1	\$608M



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