EDISON

Acarix

FY18 prelims

Favourable market dynamics

Healthcare equipment & services

The CADScor medical device helps doctors rule out coronary artery disease and so avoids complex and costly further testing in 50% of cases. Acarix is in a market development phase; FY18 results show CADScor sales of SEK1m. The application for German public reimbursement is underway; more news is expected in mid-2019. Acarix is focused on the German private market (about 10% of the population) plus public sector sales in Scandinavia. The significant long-term sales potential remains unaltered, but we have adjusted our 2019 and 2020 forecasts for longer market development times. The revised valuation is SEK369m (SEK16/share), formerly SEK448m (SEK19.46/share).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	0.64	(30.74)	(1.29)	0.0	N/A	N/A
12/18	1.02	(42.25)	(1.83)	0.0	N/A	N/A
12/19e	2.62	(43.33)	(1.88)	0.0	N/A	N/A
12/20e	4.11	(44.75)	(1.94)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. The 2016 IPO increased shares in issue.

FY18 CADScor sales

Getting a solid base of CADScor units in place and routinely used is a key to high-margin patch sales to offset cash burn and move to profit. In 2018, there were 19 units sold: 12 in Germany (one a second order), two in Austria and five in Denmark and Sweden. Three sales in Sweden are on trial so are not included in revenues. Some 2,120 patches were sold. Initial medical device sales are slow at first as tests are often not publicly reimbursed and equipment needs to be bought. The incentive for private insurers to pay is greater since much higher costs (from invasive hospital heart tests) are can be avoided in 50% of chest pain patients who are identified by CADScor as not at risk of coronary artery disease (CAD) (96% negative predictive value). Acarix is building wider medical awareness across Europe.

Revised forecasts for 2019 and 2020

Acarix should have German authority feedback by May 2019 on its reimbursement application. The initial view will give more clarity on the possible date of reimbursement. We now assume 2020, so we have reduced our 2019 and 2020 forecasts. Marketing investment in the main European markets (UK, France and Italy) is needed although some of these markets, like the UK, are slow adopters; a UK assessment is underway. A US strategy is being developed but will depend on regulators. Our valuation assumption is that Acarix makes an FDA filing by 2022 and can access the US market from 2023.

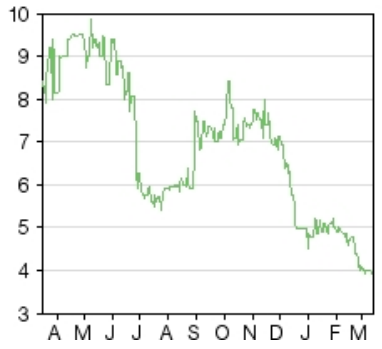
Valuation: Adjusted to SEK16.00 per share

Acarix reported an operational cash use of SEK38m with SEK65m cash remaining as of 31 December 2018. Accordingly, further funding will be needed depending on investment in trials and marketing. Our valuation now assumes 2020 German reimbursement with strong sales from 2021. We now assume US sales from 2023 (formerly 2022). The longer ramp up in sales changes the indicative value before any new funding to SEK369m (SEK16.00 per share), formerly SEK448m (SEK19.46 per share).

14 March 2019

Price	**SEK3.9**
Market cap	**SEK90m**
Cash (SEKm) at 31 December 2018	65
Shares in issue	23.0m
Free float	29.7%
Code	ACARIX
Primary exchange	Nasdaq First North Premier
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(16.8)	(36.3)	(56.1)
Rel (local)	(18.0)	(40.6)	(57.0)
52-week high/low	SEK9.9		SEK3.9

Business description

Acarix, a Swedish company with Danish origins, has developed the CE-marked CADScor to help doctors rule out stable coronary artery disease. About half of patients can be ruled out from further xpensive testing. Full EU sales could start from 2019, with US sales possible from 2022.

Next events

H119 results	16 May 2019

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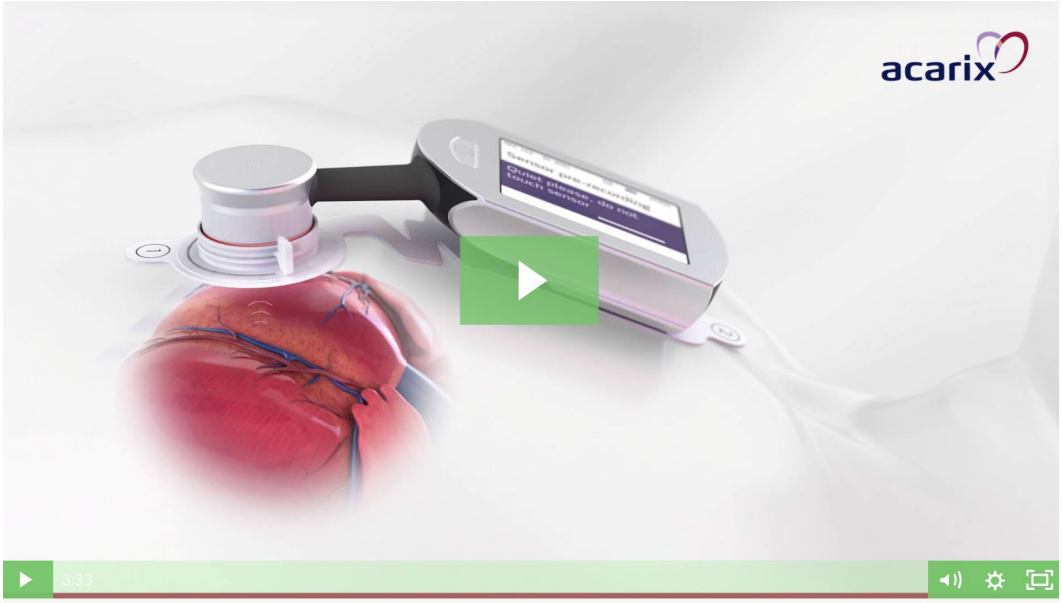
Edison profile page

CADScor to rule out coronary artery disease

Every year, many patients at low and intermediate risk of CAD visit their doctor complaining of non-specific chest pains. These patients may not have angina (chest pain caused by poor blood supply to the heart). Currently, doctors have no easy physical test to separate the worried well from those at high risk of CAD who need further investigation and will be referred for hospital tests. Currently, doctors assess the probability of CAD using questionnaires based on age, gender, clinical risk factors (diabetes, smoking) and immediate symptoms. These tend to overestimate CAD risk.

Exhibit 1 is a video of the CADScor, device and its use, which carries out an independent, patient-specific measurement and analysis of the noise made by the blood flowing in a patient's coronary arteries. The flow at very low noise frequencies is twice as loud due to turbulence if the arteries are partially blocked. Note that the sophisticated algorithm assesses multiple acoustic parameters.

Exhibit 1: Video showing CADScor acoustic device use



Source: Acarix

Simple patient data is entered into the CADScor device before the test. Otherwise, there are no external inputs. CADScor is stuck to the patient's chest using a single-use consumable patch (crucial for performance and as a revenue stream) and uses a sensitive microphone linked to a self-contained processing module to record a patient's diastolic heart sounds. The CAD-score is calculated by the device and displayed on screen; no external software is used. A CAD-score of 20 or less identifies a patient as probably not requiring further investigation for CAD.

In the validation Dan-NICAD study published online in 2017 (Winther et al., 2018), 9% of patients had proven CAD. The positive predictive value (PPV)[1] (probability of a positive result being correct) was 15%, but the NPV (probability that a negative result showed that the patient had no CAD) was 96%. On this basis, 50% of patients with chest pains can be excluded from further invasive testing as they had a CAD score of 20 or less. This means that medical systems can save significant time and cost, and run more efficiently focused on patients with greater need. Winther et al. concluded:

[1] PPV: the number of true positives as a percentage of all positive test results but in a specific population. In populations with low number of true positives, as with CAD in the general population, the PPV is low as there are many false positives unless test specificity is very high. in the general population, the PPV is low as there are many false positives unless test specificity is very high. NPV: the probability that a negative test is correct in the tested population and that the patient does not, in this case, have coronary artery disease.

'Sound-based detection of CAD enables risk stratification superior to clinical risk scores. With a negative predictive value of 96%, this new acoustic rule-out system could potentially supplement clinical assessment to guide decisions on the need for further diagnostic investigation.'

This has been confirmed in real-life medical practice by feedback from users in Germany. For example, a group of private clinics run by Dr Katarina Varga has ordered a second system. She commented:

'We have used the CADScor system for more than 100 patients in the last three months and are very impressed with the system's high accuracy, which helps us determine the right treatment and pathway for our patients. With a second system in place for our other clinic, we will be able to help even more patients and shorten the waiting time for many concerned over their health. The waiting time to see a cardiologist is typically three to six months and with the help from CADScor system, we know in less than 10 minutes if the patient really needs to see the specialist.'

In 2018, Knuuti et al. (2018) published a meta-study of clinical trials on common diagnostic methods for CAD (not including CADScor). The cheapest and most widely used is stress testing where a patient runs on a treadmill (or cycles) while their heart is monitored: stress electrocardiogram (ECG). Stress ECG testing was found to have 'very limited diagnostic power'.

Ladapo et al. (2014) using US data 1993–2010 found that 45 in every 10,000 primary care or hospital outpatient visits resulted in a cardiac over stress test: that is 3.8 million referrals (out of 863 million primary care visits of all types).[2] These referrals were of patients who had no prior diagnosis of CAD, the target market for CADScor.

Of these 3.8 million US referrals, about 1.1 million patients had chest pain and 2.7 million had other symptoms. They could also be split into 1.3 million low risk and 2.5 million high risk on the basis of clinical symptoms.[3] Ladapo concluded that: 'At least 34.6% [of the cardiac tests ordered] were probably inappropriate, with associated annual costs… of $501m'. Referrals were for either a stress ECG test, a stress echocardiogram or stress myocardial perfusion imaging. The most 'popular' functional test was stress imaging with 87% use. This is also the most expensive (over $600) but gives direct heart perfusion images. If positive, patients may be referred for CT scanning and invasive tests.

As with all medical advances, changes in fundamental clinical practice take time to disseminate and payment systems lag behind. Ultimately, however, such advances are reflected in clinical guidelines and the techniques and equipment needed become standard practice. Once that happens, the leading companies have a solid income stream.

Further studies

The Dan-NICAD II study (NCT03481712) is enrolling 2,000 patients with suspected stable CAD to add data and evaluate the test in patients aged 30–39. The trial has primary data due in Q1 2020.

The Seismo study with 200 patients (NCT03656354) explores the use of CADScor for the early diagnosis of heart failure. Seismo is being run to develop and validate an algorithm based on seismocardiography recordings to detect heart failure using CADScor. Seismocardiography measures vibrations in the chest wall caused by heart function and blood flow. It is an active research area with several groups looking at developing wearable devices, although there are no

[2] US National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS) from 1993–2010. This survey provides a systematic evidence base for the number of US consultations by healthy individuals for cardiovascular disease.

[3] Low risk defined as not a smoker, having no chest pain and no diagnosis for hypertension, dyslipidemia, diabetes or obesity. Note that CAD was not diagnosed by CTA so this is not a medically defined group.

commercial products. It could lead, possibly, to a positive test for CAD, which if it had high accuracy with high PPV would be very valuable. The trial is due to complete in mid-2019.

Strategic outlook

Detail on individual markets is in Exhibit 2. This also updates the probability of success assumptions and launch dates as used in the revised valuation.

Exhibit 2: National market characteristics and adjusted assumptions

Market	Reimbursement	Probability and market assumptions
Germany, Austria and Scandinavia	Acarix has direct sales in these markets. The price is within the typical capital budget of a German primary healthcare provider. There seems to have been some discounting over Q3 and Q4. In Germany, test reimbursement is mostly from the government-run insurance schemes (there are 158 such schemes). There are now proposed rule changes with a more centralised system. About 10% of Germans prefer to use private insurance from a variety of providers. Private providers operate their own coding and reimbursement scheme and are often early adopters of new technologies since these innovations make their health insurance products more attractive to customers. Each insurer makes its own decision about reimbursement and it can be a slow process. Acarix has directly applied for public reimbursement to the Federal Joint Committee (G-BA)) and should expect an initial response after eight weeks (end April/May 2019). This response will determine when reimbursement is possible. Our assumption is that more evidence will be needed and that reimbursement will be granted in 2020. Reimbursement was formerly expected in late 2019.	The German market can be difficult to enter due to its complexity and tight cash budgets. Hospitals also like to run complex procedures to gain fees. Reimbursement is not guaranteed. However, it is Acarix's major European market and private medical insurers and clinics are willing to adopt new technology before government reimbursement is guaranteed as it gives them a market edge with private patients. For these reasons a low level of sales was initially projected, and seen, over 2017 and 2018. This low sales level is now forecast to continue over 2019 and 2020 with increasing levels of instrument sales as private clinics and insurers become aware of the product. Patch sales should also rise as the installed base slowly increases and as patches bundled with an instrument sale (Edison estimates 120/unit) are used up. Edison formerly used a 50% probability of achieving the forecast sales targets. This has increased to 55% as the filing for reimbursement has been filed. No probability adjustment is made to 2019 and 2020 forecasts.
Other European territories	Acarix has started discussions with national health assessment bodies; for example, a submission was made in December 2018 to the UK Medical Technologies Evaluation Programme (MTEP) run by the National Institute for Health and Care Clinical Excellence (NICE). Reimbursement in the UK will be determined by local clinical groups. They tend be very budget driven, irrespective of national recommendations. Other European countries have similar systems although they differ in detail and they note any UK findings.	Because of the higher barriers in the other European markets, Edison has used a 40% probability of achieving the forecast sales targets (unchanged). Edison assumes that a list price for the product is the same as Germany but there are 40% distributor discounts. We are unaware of any distributor agreements to date. The level of discount reflects the investment required by distributors and the probably smaller individual national markets. Adoption is likely to be slow unless there is strong national KOL support.
US	FDA approval may require a pre-market approval (PMA) process. This is scientifically and clinically rigorous and we expect it will require a US clinical study; although by H220 there will be two Danish-led clinical studies that may suffice, marketing studies might still be advised to gain KOL support. An assumption was previously made that a US trial might start in 2019. This is now assumed from H220. An alternative is the *de novo* 510(k) route, which requires less clinical proof and is much faster. However, *de novo* is open only to tests that are low risk. In this case, as CAD is being ruled out, we assume that PMA is more likely. Once FDA approval has been obtained, Acarix will need to obtain reimbursement for the test. Part of this will be to gain inclusion in guidelines issued by the two medical cardiology associations in the US (American Heart Association and American College of Cardiology). Medicare covers Americans over 65 years old, so the higher-risk group for coronary artery disease. Medicare sets its own reimbursement rate once a Current Procedural Terminology (CPT) code has been obtained for the test. CPT codes are issued by the American Medical Association.	Edison assumes that Acarix can overcome these hurdles and that a price per unit of $5,000 is achievable with a 40% distributor discount. The price for the consumable patch is set at $75 before distributor discount with an average use rate of 150 per year; this is above the European level, but the US tends to adopt new technology more enthusiastically. Edison assumes that Acarix will sell up 2,000 units per year in the US with 5% growth once the market is mature. Sales are not now expected before 2023 (formerly 2021). Because of the higher regulatory and reimbursement hurdles to overcome in the US market, Edison uses a 30% (unchanged) probability of success in achieving the forecast sales level. Nonetheless, due to the size of the US market, this forms a major part of the valuation. Medicare is not obliged to reimburse a procedure even if it has a CPT code. Private health insurers and health maintenance organisations usually refuse to cover investigational tests. It will be crucial to gain their support as they could use the CADScor test as a gatekeeper test before funding to more expensive hospital testing.
Canada	Canada is a major market in its own right. It has its own regulatory system: Health Canada. CADScor was approved by Health Canada in July 2016. Acarix has not disclosed any commercialisation plan.	For simplicity, Canada is recognised in the Edison model as being 7% of the US forecast. This is slightly less than the US on a pro rata population basis, but Canada is a more price-sensitive market.
Rest of world including China	Pre-IPO, there was an investment by Puhua Jingxin, a joint healthcare fund in China between Puhua Healthcare and major pharmaceutical company Zhejiang Jingxin Pharmaceuticals. No details have been disclosed. This could be a good route into the Chinese market with a strong and committed partner. Edison remains cautious about forecasting significant Chinese sales until the regulatory and commercial strategy becomes clearer.	The rest of world sales are modelled by assuming they are 15% of the European and North American sales combined. The probability of achieving these forecasts in rest of world is set at 35% (unchanged), since the regulatory barriers are lower than in the US but the commercial challenges are varied. Although prices on imported medical products are often high, getting widespread uptake can be a problem.

Source: Edison Investment Research

We expect Acarix to focus on building the German, Austrian and Scandinavian markets for the next few years, possibly adding the UK and maybe France. Other European countries could be direct sales or through distributors, as modelled. Acarix is a small business to undertake European-wide marketing based on one novel product. In the US, it would make sense to get an FDA view and then enter a deal with a good marketing partner; management has not disclosed any US strategy.

Revised valuation

Pushing back short-term cash flows has reduced the immediate cash flow value. The longer-term terminal value is also reduced, but this is due to the use of updated exchange rates. The indicated current value is SEK369m as of 1 January 2019, formerly SEK448m, at a discount rate of 12.5%. The value per share is indicated at SEK16 before the required further capital raising.

Exhibit 3: Acarix valuation

		2019		Previous (SEK)
		SEK	€	
Cash flow		29,187	2,444	86,876
Terminal value	1.0%	339,322	31,981	360,864
Current value (as at 1 January 2019)		368,509	34,732	447,740
Shares			23m	
Indicative value		16.00	1.51	19.46

Source: Edison Investment Research

FY18 sales and financials

Acarix sold 19 units in 2018 with a further three sold on a long-term trial basis and so not included in revenues, Exhibit 4. Germany was reported as 12, Sweden two (plus the three units on sale or return), Denmark three and Austria two. The relatively small quarterly numbers mean that a consistent pattern is hard to discern. Revenues varied by quarter but discounts can be discerned: for example, Q4 unit sales were SEK13k, whereas one would have expected SEK120k.

Overall in 2018, 2,120 patches were sold. Most of these were probably bundled with CADScor units at the point of sale. There were some repeat orders, notably in Q3. A critical value for projecting future sales is the average level of patch use per installed machine. This is hard to assess on the sales data so far when tests are not reimbursed and doctors are still evaluating the use of the system. Edison has used a long-term assumed value of 10–12 per month per system.

Cost of goods overall (including patches) varied by quarter but averaged 31%, giving a 69% gross margin. With scale economies and more patches in the mix, this should significantly improve.

Exhibit 4: Sales by quarter FY18

	2018				2018 total
	Q1	Q2	Q3	Q4	
CADScor Units	4	4	7	4	19
Units on trial	0	0	0	3	3
CADScor sales	SEK75	SEK117	SEK133	SEK13	SEK338
Patch units	420	380	680	640	2,120
Patch sales	SEK155	SEK118	SEK218	SEK195	SEK686
Total revenues	SEK230	SEK235	SEK351	SEK208	SEK1,024
CoG	SEK72	SEK44	SEK125	SEK76	SEK318
Gross profit	SEK158	SEK191	SEK226	SEK132	SEK708

Source: Edison Investment Research based on Acarix Quarterly reports

Cash at year end was SEK65m. At the current burn rate, and assuming no significant US trial costs in 2019 and 2020, there is sufficient cash until about mid-2020, implying that a further funding will be required. This could be used to gain capital to invest in the US market. This clearly also depends

on sales in 2019 and 2020. For 2019, we have adjusted the forecast to 30 units and 5,400 patches (as there should be patch re-ordering from the 31 installed units) giving revenues of SEK2.6m, formerly SEK3.8m. This will be reviewed as quarterly sales data is reported. Financial forecasts are in Exhibit 5.

Exhibit 5: Financial summary

SEK000s	2017	2018	2019e	2020e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	638	1,024	2,623	4,105
Cost of Sales	(208)	(316)	(577)	(874)
Gross Profit	430	708	2,046	3,232
EBITDA	(29,499)	(41,028)	(41,959)	(43,273)
Operating Profit (before amort. and except.)	(30,743)	(42,523)	(43,454)	(44,768)
Intangible Amortisation	(1,261)	(1,430)	(1,430)	(1,430)
Exceptionals	-	-	-	-
Operating Profit	(32,004)	(43,953)	(44,884)	(46,198)
Other	-	-	-	1
Net Interest	7	273	120	20
Profit Before Tax (norm)	(30,736)	(42,250)	(43,334)	(44,747)
Profit Before Tax (FRS 3)	(30,736)	(42,250)	(43,334)	(44,747)
Tax	960	-	-	-
Profit After Tax (norm)	(29,776)	(42,250)	(43,334)	(44,747)
Profit After Tax (FRS 3)	(29,776)	(42,250)	(43,334)	(44,747)
Average Number of Shares Outstanding (m)	23.0	23.0	23.0	23.0
EPS - normalised (ore)	(129.31)	(183.48)	(188.18)	(194.32)
EPS - FRS 3 (ore)	(129.31)	(183.48)	(188.18)	(194.32)
Dividend per share (ore)	0.0	0.0	0.0	0.0
Gross Margin (%)	67.4	69.1	78.0	78.7
EBITDA Margin (%)	(4,624)	(4,007)	(1,600)	(1,054)
Operating Margin (before GW and except.) (%)	(4,819)	(4,153)	(1,657)	(1,091)
BALANCE SHEET				
Fixed Assets	25,191	23,696	22,201	20,706
Intangible Assets	20,351	18,921	17,491	16,060
Tangible Assets	0	0	0	1
Acquired rights	4,840	4,775	4,710	4,645
Current Assets	108,865	71,501	29,662	(13,588)
Stocks	1,945	2,625	2,625	2,625
Debtors	2,468	3,857	3,857	3,857
Cash	103,457	65,019	23,180	(20,070)
Other	995	0	0	0
Current Liabilities	(5,118)	(7,321)	(7,321)	(7,320)
Creditors	(1,464)	(2,504)	(2,504)	(2,504)
Short term borrowings	0	0	0	0
Short term leases	0	0	0	0
Other	(3,653)	(4,816)	(4,816)	(4,815)
Long Term Liabilities	0	0	0	0
Long term borrowings	0	0	0	0
Long term leases	0	0	0	0
Other long term liabilities	0	0	0	0
Net Assets	128,939	87,876	44,542	(202)
CASH FLOW				
Operating Cash Flow	(41,506)	(39,586)	(41,959)	(43,271)
Net Interest	7	273	120	20
Tax	960	977	0	0
Capex	(2,984)	0	0	1
Acquisitions/disposals	0	0	0	0
Financing	1,203	0	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(42,320)	(38,336)	(41,839)	(43,250)
Opening net debt/(cash)	(145,895)	(103,457)	(65,019)	(23,181)
HP finance leases initiated	-	-	-	-
Other	(118)	(102)	-	-
Closing net debt/(cash)	(103,457)	(65,019)	(23,181)	20,070

Source: Acarix Reports, Edison Investment Research forecasts

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