

Acarix

Preparing for commercialisation

Following the successful SEK140m IPO in December 2016, Acarix is commercialising its novel CE-marked CADScor System in Germany. CADScor is used as a frontline test by doctors to help assess a patient's risk of coronary artery disease (CAD) by "listening" to the blood flow in the coronary arteries. This can enable CAD to be ruled out, so avoiding expensive further testing. Full EU reimbursement may start in 2019. US marketing will probably require a US clinical study, with sales from 2021 possible. The unchanged indicative value remains at SEK728m, equal to SEK31.62/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/15	-	(15.4)	(1.1)	0.0	N/A	N/A
12/16	-	(26.8)	(1.8)	0.0	N/A	N/A
12/17e	3.0	(51.4)	(2.1)	0.0	N/A	N/A
12/18e	3.8	(49.5)	(2.0)	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.

Noisy business – ruling out atherosclerosis

The Acarix test uses a highly sensitive microphone linked to a minimalist self-contained processing module to record the patient's heart sounds. Sophisticated algorithms then identify the patients who probably require no further clinical testing. CADScor will sell for over €3,000. A disposable, single-use patch has a price of at least €30 per unit. [Researchers](#) claim that 35% of US primary care tests are not needed and harmful. US healthcare providers could save over \$500m a year if low-risk patients could be quickly and accurately tested, reassured and sent home.

FY16 funding and IPO gives resources to start sales

Acarix raised SEK176.7m in 2016 including SEK140m in the December IPO. Operational expenses were SEK26.79m plus SEK12.20m of capitalised development work. There was a SEK24.25m non-cash financial charge in Q316 that we treat as an exceptional item. The December 2016 IPO issued 7.96m shares at SEK17.60 each. Year-end cash was SEK145.9m, above our December 2016 forecast of SEK125.1m. The potential additional cash need in 2018 has been lowered from SEK50m to SEK26.3m.

Valuation: Indicative value of SEK728m

Management plans direct sales starting this year. Initial customers are likely to be patients with private insurance in Germany plus some Scandinavian sales to specialists. Full German reimbursement is assumed from 2019. A US *de novo* 510(k) application might be filed in 2020, allowing US launch and reimbursement from 2021. The US has over 3.8 million tests for coronary artery disease per year ordered by primary care physicians. In Edison's view, Acarix could achieve profitability from 2022. Financial estimates have been updated following publication of the FY16 annual report. Using a discounted cash flow model, a 12.5% discount rate and a terminal valuation based on a 1% growth rate, we calculate an unchanged indicative value of about SEK728m. This equates to SEK31.62/share.

FY16 report and update

Healthcare equipment
& services

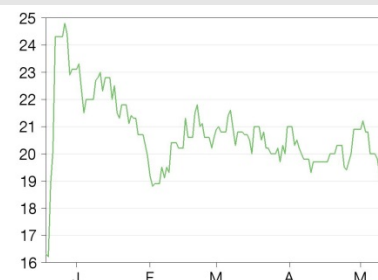
15 May 2017

Price **SEK19.70**
Market cap **SEK454m**

Net cash (SEKm) at 31 December 2016 145.9
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 (6.2) (12.4) N/A
Rel (local) (5.0) (17.6) N/A
52-week high/low SEK24.8 SEK16.2

Business description

Acarix, a Swedish company with Danish origins, has developed the CE-marked CADScor to enable about half of the patients to be ruled out from further, expensive testing. Full EU sales may start from 2019. US sales might start from 2021.

Next events

H1 results Q317

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Funded for launch in 2017

Following its 19 December 2016, IPO Acarix is funded and preparing for commercial launch in Germany in 2017 of its CADScor system. CADScor is a doctor's office acoustic test device and software algorithm, designed to be used by doctors to help assess patients' risk of coronary artery disease (CAD). This could enable about half of the patients to be ruled out from further, expensive testing. Using CADScor, about half of these people might be sent home, saving money. Acarix AB is a Swedish company (Malmö). It was founded in Denmark as Acarix A/S and has an operational office just north of Copenhagen.

The business case rests on achieving a good penetration rate of primary care providers with the CADScor device sold for over €3,000 (Europe) and \$5,000 (US). A disposable, single-use sticky patch priced at over €30 (Europe) or US\$75 (US) is required to run the test. A substantial installed base of devices, if achieved over time, could generate significant sales revenues at high margin with low marketing cost.

The US market alone is estimated by independent researchers to be at least 3.8 million tests per year. As a simple to use, primary care device, CADScor offers a quick and relatively cheap alternative to more complex and much more expensive testing.

Acarix plans to sell the test from 2017 in Germany and Scandinavia, although full government reimbursement is not likely before 2019. Distributors will be appointed for other European countries. In the US, further trials may be required and Edison expects that a *de novo* 510(k) or PMA application will be needed for FDA approval. Our model assumes US sales from 2021.

The device: CADScor

Every year, many patients at low and intermediate risk of CAD visit their doctor complaining of non-specific chest pains. CADScor, Exhibit 1, 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: The CADScor acoustic device on the base station



Source: Acarix. Note: CADScor is a registered trademark of Acarix.

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. Consequently, 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.

Simple patient data are entered into the CADScor device before the test. Otherwise, there are no external inputs. Calculation of the test result, the CAD-score, is done 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. CADScor test data from trials are discussed below.

Patients with diagnosed angina (chest pain caused by poor blood supply to the heart) would not be tested by CADScor, but would be referred for further tests.

Dan-NICAD – current clinical data

The Dan-NICAD study (the latest data available) is not yet published. Exhibit 2 shows the limited preliminary data that Acarix has made available showing the cited negative predictive value (NPV) of 97.1%. The trial analysis used three datasets. For more explanation and terminology, please see the published note of [21 December 2016](#).

- Firstly, the study itself recruited 1,676 patients, of whom 1,437 were available for analysis. About 10% (144 assumed) of those are stated by Acarix to have had coronary artery disease (CAD), as identified by coronary angiography, a gold standard test using x-ray scanning.
- In addition, the trial analysis included a historic negative control cohort of 754 patients, of whom 606 were included in the dataset. These individuals were selected from the 1,156-patient [DanRisk](#) study ([Diederichsen 2012](#)) and confirmed to be clear of CAD.
- The 228 patients from an earlier study, AC003, were also included; there were 63 CAD cases.

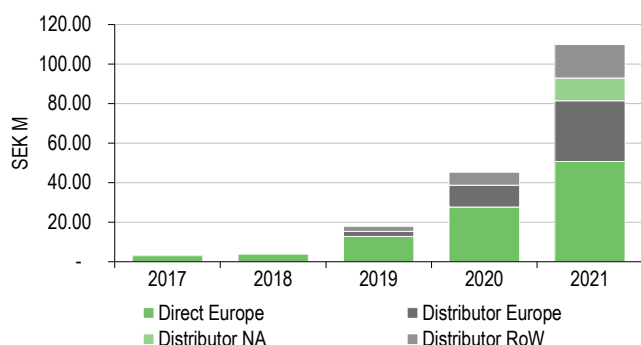
This gives 2,271 patients, of whom 207 are believed to have CAD: about 9%. Note that exact numbers have not been provided by Acarix.

Exhibit 2: Dan-NICAD results using algorithm V3					
		Angiography result		Total CADScor result	
		+ve (CAD)	-ve (no or intermediate CAD)		
CAD-score	+ve	176	1032	1208	PPV 14.6%
	-ve	31	1032	1063	NPV 97.1%
Actual result on CTA		207	2,064	2271	
		Sensitivity 85.0%	Specificity 50%		
Accuracy 75% (measured separately and not shown)					
Source: Edison Investment Research based on Acarix data					

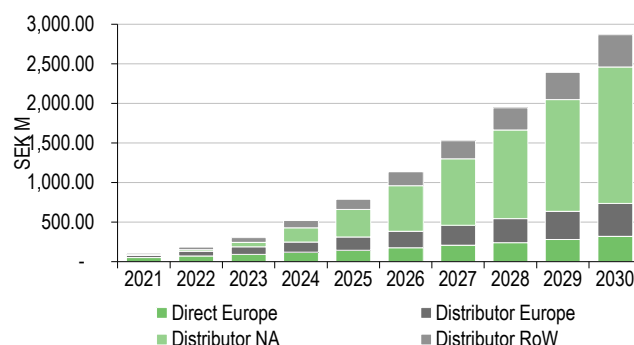
Sales forecast – early years' growth mainly in Europe

The sales of units are particularly important in the first few years of any market, but as the installed base of systems grows, the consumable patch use rate becomes the key growth driver factor. Exhibit 3 shows the forecast market development up to 2021 before probability adjustment. This period is dominated by Europe, with German full reimbursement assumed from 2019.

Exhibit 4 shows the non-risk-adjusted forecast from 2021 to 2030. This indicates Acarix 2030 sales of about \$270m/€260m (SEK2.5bn) before risk adjustment. This is a significant market for a diagnostic product. The probability-adjusted sales forecast is \$72m/€69m (SEK677m). From 2031 onwards, a long-term growth rate of 1% is assumed as the market may then have matured and competitors could have entered as the patents will have expired. In the terminal year of 2030, Edison forecasts 4,500 units sold globally and disposable patch sales of 4.2 million units.

Exhibit 3: Forecast overall sales by market to 2021 before probability adjustment (SEK)


Source: Edison Investment Research forecast

Exhibit 4: Forecast overall sales by market 2021-30 before probability adjustment (SEK)


Source: Edison Investment Research forecast

Discounted cash flow valuation

Our assumptions on valuation remain unchanged from our 21 December 2016 note. There are two elements to the valuation, Exhibit 5.

Firstly, the discounted value of cash flows between 2017 and 2030 is estimated using a 12.5% discount rate. A Swedish corporation tax rate of 22% is used. Tax losses to mid-2016 have been stated by management to be worth DKK40m (SEK578m). Because of the long period of marketing investment required to commercialise the product, the estimated value of cash flows to 2030 is relatively low at about SEK90m.

Secondly, as a diagnostic product established as the brand leader in its market, the company should have a continuing value. With lower marketing costs, due to the distributor strategy, and no further part investments, the profitability could be very high since most revenues could come from high-value consumables requiring a low level of marketing support. The terminal value in 2030 of SEK3.3bn discounted to 2017 gives a terminal value of SEK639m. Note that investment in and cash flows from new products are not estimated.

Exhibit 5: Acarix valuation

		SEKm	€m
Discounted value of cash flows	12.50% discount rate	89.5	9.2
Terminal value 2030	1% long-term growth rate	638.6	65.3
Indicative value (January 2017)		728.2	74.5
Value per share	23.0m shares in issue	SEK31.62	€3.24

Source: Edison Investment Research

At close of 2016, Acarix had 23m shares in issue. The combined indicative value is SEK728m, implying a fair value of SEK31.62/share. The IPO price was SEK17.60/share.

FY16 financials

2016 was dominated by the IPO process, which completed in December 2016. Acarix now has the cash to invest in marketing and to consider and plan US trials. Any future funding need from 2018 depends on a successful launch in Germany and on the company's cost base. Edison forecasts profitability from 2022 if full European reimbursement is gained and a US approval is obtained. Financial forecasts to 2018 in Swedish kronor are shown in Exhibit 6. These have been updated

with 2016 reported figures. Any other changes to the last forecast issued are minor adjustments due to the use of the reported rather than forecast opening SEK balances.

Operational costs

Operationally, Acarix was in a commercialisation phase during 2016 while completing a further clinical evaluation (the Dan-NICAD study) of the CADScor System: With no revenues, the operating loss (EBITDA) was SEK26.8m (2015: loss of SEK15.4m). Due to a restructuring of the capital structure involving a convertible loan in Q316, there were non-cash financial charges totalling SEK24.3m (Note 9 to the accounts); we have treated these as an exceptional item to calculate the normalised result. This gave a reported loss of SEK48.2m (2015: loss of SEK12.4m). Note that this excludes capitalised development costs.

Cash flow

Since August 2015, Acarix has capitalised its development costs. These will be amortised against sales revenues from 2017 onwards. Capitalisation gave a cash flow charge of SEK12.2m, an increase in expenditure from SEK6.5m in 2015. Capitalised development assets in December 2016 rose to SEK18.2m and are included in SEK23.1m of fixed assets.

In 2016, operational net cash outflow was SEK9.1m (including a tax credit of SEK3m), compared with an outflow of SEK8.6m during 2015. Within this, changes in working capital increased cash flow by SEK14.7m (vs SEK1m); Note 18 to the accounts shows that SEK11.1m was accrued in personnel-related expenses, a significant amount for a small company and including SEK9.3m of management bonuses (Note 8). In addition, SEK2.3m in accrued IPO liabilities and other items were outstanding at year end. Accounts payable (Note 17) rose from SEK2.3m to SEK4.4m in 2016. Acarix did not report any product stock (inventory) in 2016; management informs us that stocks will feature from 2017 onwards as the company is now in its commercialisation phase;

Total funds raised during 2016 were SEK176.7m gross, SEK165.7m net. The total cash use was SEK21.2m including capitalised development expenses and after working capital gains. This gave a net increase in cash and cash equivalents of SEK144.4m, giving year-end cash of SEK145.9m with 2015 year-end cash of SEK2.1m and after negative exchange rate adjustments of SEK0.6m.

Future costs and cash flows

Limited direct product sales into the German market are expected in 2017 with sales progression in 2018. Our forecast anticipates a rise in cash expenditure (burn rate) in 2017 to around SEK64m. This is a reported operational cost base of SEK51m and assumes in addition that SEK13m of the 2016 working capital gains are unwound giving a SEK 64m outflow. An unchanged tax credit of SEK2.8m is assumed to offset this. We then expect SEK23m of development to be capitalised plus some capital expenditure of SEK1m, SEK24m total. Combined, these indicate a cash outflow of about SEK85m in 2017.

The cash outflow in 2018 is harder to predict since it depends on any US clinical trial costs and the level of private sales achieved. However, Acarix may need further funding in 2018. A nominal SEK26.5m interest-free loan is included by Edison for 2018 as a result. This is lower than previously expected (SEK50m) but more may still be needed. However, funding could come from a variety of sources.

Exhibit 6: Financial summary

SEK000s	2015	2016	2017e	2018e
Year end 31 Dec	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	-	-	3,023	3,847
Cost of Sales	-	-	(983)	(1,038)
Gross Profit	-	-	2,040	2,809
EBITDA	(15,248)	(26,790)	(51,800)	(49,563)
Operating Profit (before GW and except)	(15,377)	(26,790)	(51,957)	(49,721)
Intangible Amortisation	-	-	-	-
Exceptionals	-	-	-	-
Operating Profit	(15,377)	(26,790)	(51,957)	(49,721)
Convertible loan and warrants	-	(24,250)	-	-
Net Interest	(23)	(15)	526	197
Profit Before Tax (norm)	(15,400)	(26,805)	(51,431)	(49,523)
Profit Before Tax (FRS 3)	(15,400)	(51,055)	(51,431)	(49,523)
Tax	3,007	2,815	2,815	2,815
Profit After Tax (norm)	(12,393)	(23,975)	(48,616)	(46,708)
Profit After Tax (FRS 3)	(12,393)	(48,240)	(48,616)	(46,708)
Average Number of Shares Outstanding (m)	11	13	23	23
EPS - normalised (ore)	(114)	(183)	(211)	(203)
EPS - FRS 3	(114)	(368)	(211)	(203)
Dividend per share (ore)	-	-	-	-
Gross Margin (%)	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	8,670	23,123	47,215	71,306
Intangible Assets	5,971	18,179	42,271	66,362
Tangible Assets	-	-	-	-
Acquired rights	2,699	4,944	3,760	3,760
Current Assets	6,912	150,163	66,326	22,095
Stocks	-	-	-	-
Debtors	1,771	1,488	2,893	5,260
Cash	2,121	145,895	60,618	14,020
Other	3,020	2,780	2,815	2,815
Current Liabilities	(3,443)	(17,770)	(17,433)	(17,433)
Creditors	(2,315)	(4,404)	(4,404)	(4,404)
Short term borrowings	-	-	-	-
Short term leases	-	-	-	-
Other	(1,128)	(13,365)	(13,029)	(13,029)
Long Term Liabilities	-	-	-	(26,300)
Long term borrowings	-	-	-	(26,300)
Long term leases	-	-	-	-
Other long term liabilities	-	-	-	-
Net Assets	12,139	155,516	96,107	49,668
CASH FLOW				
Operating Cash Flow	(13,570)	(12,042)	(64,527)	(51,818)
Net Interest	(4)	(15)	526	197
Tax	4,943	3,001	2,815	2,815
Capex	(6,520)	(12,201)	(24,092)	(24,092)
Acquisitions/disposals	-	-	-	-
Financing	8,840	176,698	-	26,300
Dividends	-	-	-	-
Other	(273)	(11,666)	-	-
Net Cash Flow	(6,584)	143,774	(85,277)	(46,598)
Opening net debt/(cash)	(8,705)	(2,121)	(145,895)	(60,618)
HP finance leases initiated	-	-	-	-
Other	-	-	-	(26,300)
Closing net debt/(cash)	(2,121)	(145,895)	(60,618)	12,280

Source: Acarix reports, Edison Investment Research forecasts

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