EDISON

TiGenix

FY14 results

Refocused and funded

Pharma & biotech

Tigenix's FY14 results show a company now completely refocused on the proprietary allogeneic eASC technology platform and pipeline where the commercial potential is much greater. The ADMIRE Phase III results in fistulising Crohn's disease in Q315 could lead to a possible EMA filing and a second, US Phase III; Lonza will produce the cells in the US. FY14 results show a reported loss of €11.4m, an operational cash outflow of €13.4m and year-end cash of €13.5m. A €25m non-dilutive funding was completed in Q115. The indicative value remains at €1.26 per share, but could rise to €1.82 per share if ADMIRE delivers significant Q3 data.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/13	0.9	(14.8)	(10.8)	0.0	N/A	N/A
12/14	0.8	(15.9)	(9.8)	0.0	N/A	N/A
12/15e	1.8	(17.3)	(10.0)	0.0	N/A	N/A
12/16e	2.1	(20.5)	(12.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments. Accounts restated on continuing basis 2013.

Focus on clinical-stage projects

The investment case for TiGenix has shifted to Cx601, with ADMIRE 24-week Phase III study data due in Q315 after 289 patients were recruited by 12 November. This trial is in perianal fistulising Crohn's disease, comparing a 120m dose of expanded adipose stem cells (eASC) against placebo over 24 weeks. A Special Protocol Assessment (SPA) request on a Phase III design was submitted to the FDA in late 2014; feedback is expected in Q315. TiGenix aims to start a 180-patient Phase III in H216 once US contract manufacturing with Lonza is established and an IND is in place. Cx611, the intravenous eASC product, is in development for early rheumatoid arthritis and severe sepsis. Results from the Phase I sepsis challenge trial are expected in H115. A Phase IIa study in study in severe sepsis and a Phase IIb study in early RA are expected to start by the end of 2015.

Funding continuing operations

In 2014, to focus on the eASC projects, ChondroCelect was licensed to Sobi and the manufacturing facility sold to PharmaCell. The accounts have been rebased on a continuing operations basis. TiGenix received €338k in royalties in H214 covering the four months from September 2014; management notes that the implied sales of €1.54m were an increase over 2014. The company had €13.5m of cash on 31 December. A €25m, 9% convertible was issued in early March 2015. Management has stated that the company is now financed through to at least mid-2016.

Valuation: €1.26/share with cash to Q315

If Cx601 shows statistically significant efficacy, EU sales could start in 2017. We have maintained our indicative valuation of €1.26 per share based on sales forecasts to 2025. A 2025 multiple of 20x has been included to reflect continuing Cx601 sales and the potential of Cx611. The indicative value could rise to €1.82 per share on Cx601 success.

20 April 2015

Price	**€0.68**
Market cap	**€109m**

Cash (€m) at 31 December 2014	13.5
Shares in issue	160.5m
Free float	72%
Code	TIG
Primary exchange	Euronext Brussels
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(3.3)	25.0	0.4
Rel (local)	(4.5)	11.2	(17.4)
52-week high/low		€0.82	€0.48

Business description

TiGenix produces cell therapeutics. Its lead Phase III development candidate, Cx601, treats perianal fistulas in Crohn's disease, with data due in Q315. Cx611 has completed a successful Phase IIa study in unresponsive rheumatoid arthritis. A knee repair product is licensed to Sobi. TiGenix is a Belgian-Spanish company. Grifols has a 21% equity stake.

Next events

Phase I sepsis data	Q215
Cx601 Phase III data	Q315
Interim results	15 September 2015

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FY14 overview

In 2014, TiGenix focused its cash and resources onto allogeneic, eASC products (see Exhibit 1). ChondroCelect, the EU-approved knee cartilage cell repair therapy, was out-licensed in Q214 so is now classed as discontinued operations. The restructuring decreased the loss from discontinued operations from €3.3m in FY13 to €1.6m in FY14. On a continuing basis, ChondroCelect now produces profitable royalties.

Exhibit 1: TiGenix portfolio

Product	Indication	Status	Notes
Cx601 (eASC)	Complex perianal fistulae in Crohn's disease; orphan drug status ADMIRE study	Phase III, data Q315. Single dose of 120m cells	Phase III with 289 patients across 51 centres in seven European countries and Israel. Patients have been treated with intralesional delivery of 120m cells after separate prior surgical clean-up. Endpoints of closure of any lesion over 2cm or clinical remission with superficial closure so no lesion over 2cm. Lesion size confirmed by MRI. A US-specific trial will be run once the first Phase III outcome is known. A US SPA could be agreed by mid-2015. Lonza has been selected as the US manufacturing partner. Technology transfer is expected by management to be completed in H116.
Cx611 (eASC)	Autoimmune and inflammatory diseases like rheumatoid arthritis	Phase IIb due to start Q415. Design still to be confirmed	Allogeneic eASC product. Intravenous delivery. Phase IIa tested three doses (1, 2, 4m cells/kg) given iv on days 1, 8 and 15. All patients had failed typically three biological and three DMARD therapies. Phase IIa data in a 53-patient (46 active, seven placebo) double-blind, randomised study show systemic delivery is safe (one withdrawal due to adverse events). After three months, 20% of patients showed ACR20 responses with 4% (two patients) reaching ACR70. The EULAR data showed good and moderate responses in 39% of treated patients (18) against zero on placebo. There was no dose response effect, so groups are pooled. The cultured adipose stem cells are found to die or become undetectable within a few days of administration, so the effect of the cells on the immune system must be longer term for the sustained effects seen in the study.
	Severe sepsis	Phase I	A small trial using a clinical model of induced sepsis in volunteers started in December 2014 with data due in H115. Management expects Phase II to start in Q415.
Cx621 (eASC)	Autoimmune diseases	Phase I	Allogeneic eASC product. Phase II data showed intralymphatic delivery method was safe and well tolerated. Method might be used in further trials of eASC in autoimmune disease. Project on hold to allow a focus on more advanced projects.
ChondroCelect (autologous)	Single cartilage knee defects	EU approved	Out-licensed to Sobi from 1 June 2014 for net royalties of 20% (22% in year one) plus cost reimbursement. Royalties received in H214 were €0.3m.

Source: Edison Investment Research, literature sources, TiGenix statements

Revised financial statements

The new accounting basis reports continuing operations. Royalties generated by Sobi in H214 were €0.34m. This represents four months of Sobi sales from September 2014. From June to August 2014, Sobi used biopsies from patient orders already taken by TiGenix. TiGenix sales for 2014 are included under net discontinued items. Sales volumes are reported to have increased during 2014. Going forward, we forecast €1.5m per year in cash royalties from ChondroCelect with minimal costs plus some minor grant income.

Accounts for FY14 also reported €5.9m of grant and "other" income. Of this, €5.5m was non-cash, some of which is due to recognition of theoretical income to reflect the ostensible additional value of soft loans. This notional income reduced the reported loss to -€11.4m; it does, whatever the number, reflect the benefits that TiGenix has gained from soft loans over the last few years. TiGenix has significant depreciation and amortisation of about €3.1m annually, about €2.5m of which may have been due to the Cellerix acquisition.

Reported R&D (which includes amortisation) rose to €11.4m, up from €9.8m, reflecting the costs of the Cx601 Phase III and the need to accelerate recruitment rates. General costs rose to €7.4m, up 27%, probably partly due to the costs of fund-raising. The senior team was strengthened by the appointment of a chief medical officer and a VP for medical affairs and product commercialisation. The future trial programme is ambitious and covers Crohn's, rheumatoid arthritis and sepsis.

There was an operating cash outflow of €13.37m, after cash revenues of €764k. This was offset by €3.5m from the plant sale to PharmaCell and €9.58m of net financial loans from Kreos. Interest paid was €960k and €0.26m of small loans was paid in full (€140k) or in part (€106k). This gave year-end cash of €13.5m on a net cash outflow of €2m.

Kreos loan and convertible bonds

The €10m gross loan from Kreos (announced on December 2013) will be repaid over 36 months starting in February 2015. The disclosed fixed annual interest rate is 12.5%. There were costs of €334k. In addition, 2m warrants at €0.75 were valued by TiGenix at €0.7m (fair value) as of 31 December 2014. Loan repayments are spread over three years starting in February 2015. The cash repayment in 2015 will be about €3.1m over 2015 rising to €3.3m the following year.

The €25m convertible bonds were selected as the best non-dilutive option ahead of the Cx601 Phase III data. They pay 9% cash interest (€2.25m per 12 months) paid semi-annually; the first payment is on 30 September 2015. The bonds are either redeemed at face value or converted to shares at €0.9414/share (26,556,192 shares implying a 17% increase in the current share capital), at any time before 6 March 2018. Alternatively, TiGenix can convert the bonds to equity on or after 27 March 2017 if the 20-day volume weighted average share over a 30-day period is at least 130% of the conversion price: €1.2238.

The interest charged to the P&L includes non-cash accounting adjustments, as the Kreos loan is accounted by the effective interest method (see the update note published on 28 January) and the convertible bonds are treated as loans using a non-convertible equivalent interest rate (15% assumed). The Edison net debt cash flow model excludes the Kreos or convertible loan principal repayments from the cash flow statement.

Sensitivities

The €25m loan allows TiGenix to complete the ADMIRE study and progress the development of other projects. The Cx601 data might be either: clearly positive, ambiguous, or negative. If the Cx601 Phase III data is positive, TiGenix has the option of partnering in Europe and whether it develops Cx601 in the US directly or with a partner. Direct sales in Europe will require additional cash to fund market launch preparations, have working capital for the launch phase and respond to regulatory enquiries. In the event of an ambiguous outcome, TiGenix may want to do additional Cx601 work and will need to fund a Cx611 study. In the event of a clearly negative Cx601 outcome, the value would rest on Cx611.

Valuation

The indicative value rests on Cx601. The EU clinical probability of 55% (45% US) used by Edison is cautious for a Phase III trial, but cell therapies are still a new area. The forecast runs to 2025 to capture Cx601 US sales. Cx611 is not forecast specifically, but the potential in autoimmune diseases is included in the 2025 multiple of 20x used in Exhibit 2.

Assuming Cx601 EU sales from 2016 (55% probability), plus US partner revenues from early 2021 at a 45% probability (20% post Phase III royalties assumed plus net eASC supply), the model indicates an unchanged indicative value on rDCF (at 12.5%) of €212m, or €1.26 per share including known dilution. Exhibit 2 shows the breakdown of the current valuation.

Exhibit 2: TiGenix value estimate

		Probability	Partnering	Royalty	2025 revenues (m)
Cx601	EU	55%	N/A	N/A	€68.03
CX601	US	45%	75%	33%	€21.28
ChondroCelect royalty (Sobi)	EU	50%	N/A	20%	€2.54
Cx611/621					N/A
Revenues					€91.85
CoG					(€3.96)
Operating Profit					€33.67
Interest					€7.63
Tax					(€12.30)
Profit					€28.70
NPV cash flow					€54.83
NPV multiple (at 20x)					€157.13
Indicative value					€211.97
Shares in issue					160.5
Warrants					7.62
Indicative value per share					€1.26

Source: Edison Investment Research. Note: The ChondroCelect risk adjustment relates only to new sales generated by Sobi outside current markets. Warrants include those for Kreos.

If the Phase III trial with Cx601 has a positive outcome, the probability of EU approval would rise to 80% with the US rising to 65% and partnering probability at 80%, Exhibit 3. A lower assumed multiple of 17x is used in this scenario as Cx611 might be a smaller part of the value mix in 2025.

Exhibit 3: Cx601 indicative value on statistically significant Phase III data

		Probability	Partnering	Royalty	2025 revenues(m)
Cx601	EU	80%	N/A	N/A	€99
CX601	US	65%	80%	33%	€33
ChondroCelect royalty	EU (Sobi)	50%	N/A	20%	€3
Cx611/621					N/A
NPV cash flow					€102
NPV multiple (at 17x)					€204
Indicative value					€306
Shares in issue					160.5
Warrants					7.62
Indicative value per share					€1.82

Source: Edison Investment Research

If the ADMIRE trial outcome is ambiguous, the indicative value would depend on the cash and debt level of the business plus development plans for Cx611. Loans at original value with interest rates and repayment terms are shown in Exhibit 4. Note that €8.3m of these are "soft" loans (from Madrid Network and the Spanish government) given to aid Cx601 development.

Exhibit 4: Main loans (at December 2014 face value) and bonds

Lender	Amount	Interest rate	Repayment	2015 cash payments
Madrid Network	€5.9m	1.46%	10 years from 2015	Payment of €450k
Spanish government	€2.9m	0%	To 2025	Payment of €225k
Other loans	€0.1m	Euribor three months + margin	To 2017	2015 repayment €40k
Kreos	€10.0m	12.5*	Three years from 2015	€1.1m interest, €3.2m capital
Convertible Bonds	€25.0m	9%	Might convert to equity in 2018	€1.125m interest
Total	€43.9m			

Source: TiGenix FY14 Annual Report. Note: *Flat rate interest; effective interest will be about 17%.

2015-16 forecasts

Forecasts for 2015 and 2016 are potentially fluid in view of the ADMIRE Q315 decision point. In Exhibit 5, the estimates assume a successful trial outcome with extra cost in 2016 due to a US Phase III study and work in sepsis and rheumatoid arthritis. A small additional financing of €10m is assumed in mid-2016; this is represented as a loan but might be equity or bonds. TiGenix might do partnering deals which could bring in cash and remove the launch cost requirements. Interest rate charges in the P&L include loan accounting items and are therefore higher than in the cash flow.

Exhibit 5: Financial summary

€000s	2013	2014	2015e	2016e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	883	764	1,800	2,050
Cost of sales	0	0	0	0
Gross profit	883	764	1,800	2,050
EBITDA	(12,407)	(14,513)	(14,600)	(16,950)
Operating profit (before amort and except)	(14,789)	(15,076)	(14,700)	(17,050)
Intangible amortisation	(3,008)	(2,550)	(2,600)	(2,600)
Other operating expenses	0	0	0	0
Share-based payments	(348)	(459)	(500)	(500)
Operating profit	(18,145)	(18,085)	(17,800)	(20,150)
Exceptional items	0	5,522	0	0
Fx and other	(352)	1,101	0	0
Net interest	(390)	250	(2,606)	(3,491)
Profit before tax (norm)	(14,827)	(15,927)	(17,306)	(20,541)
Profit before tax (FRS 3)	(15,179)	(12,313)	(20,406)	(23,641)
Tax	59	927	1,200	1,000
Profit after tax (norm)	(14,768)	(15,000)	(16,106)	(19,541)
Profit after tax (FRS 3)	(18,476)	(11,386)	(19,206)	(22,641)
Average number of shares outstanding (m)	115.0	153.2	160.5	160.5
EPS - normalised (c)	(10.8)	(9.8)	(10.0)	(12.2)
EPS - (IFRS) (c)	(13.1)	(7.4)	(12.0)	(14.1)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross margin (%)	100.0	100.0	100.0	100.0
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				
Non-current assets	38,863	36,808	34,463	32,118
Intangible assets	36,407	34,172	31,887	29,602
Tangible assets	879	601	541	481
Investments (inc assets for sale)	1,576	2,035	2,035	2,035
Current assets	18,045	17,113	21,284	8,357
Stocks	77	102	102	102
Debtors	1,583	1,734	1,734	1,734
Cash	15,565	13,471	18,570	5,643
Deferred charges and accrued income	820	1,805	878	878
Current liabilities	(5,877)	(8,483)	(7,589)	(7,692)
Creditors	(3,007)	(2,352)	(2,352)	(2,685)
Short-term borrowings	(343)	(2,256)	(1,904)	(1,673)
Other current liabilities	(2,527)	(3,875)	(3,333)	(3,333)
Long term liabilities	(8,378)	(10,681)	(31,219)	(38,438)
Long term borrowings (inc soft loans)	(8,263)	(10,652)	(31,190)	(38,409)
Other long term liabilities	(115)	(29)	(29)	(29)
Net assets	42,653	34,596	16,938	(5,655)
CASH FLOW				
Operating cash flow	(14,425)	(12,464)	(14,600)	(16,617)
Net interest	(43)	(903)	(2,078)	(2,808)
Tax	20	0	927	1,200
Capex	(35)	(40)	(40)	(40)
Purchase of intangibles	(323)	(315)	(315)	(315)
Acquisitions/disposals	12	3,494	0	0
Financing	17,694	(415)	0	0
Dividends	0	0	0	0
Other	(441)	4,247	1,018	(1,334)
Change in net cash	2,459	(6,396)	(15,088)	(19,914)
Opening net debt/(cash)	(4,500)	(6,959)	(563)	14,525
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(6,959)	(563)	14,525	34,439

Source: Edison Investment Research, TiGenix accounts. Note: €10m Kreos loan in 2014 and €25m convertible loan in 2015. A small illustrative additional loan of €10m is assumed in mid-2016 to provide working capital.

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