

Transgene

Combination trials start, FY16 results

Company update

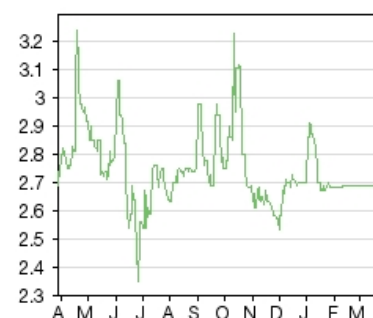
Pharma & biotech

24 March 2017

Price €2.62
Market cap €148m

Cash and ST investments (€m) at end December 2016	56.2
Shares in issue at end December 2016	56.4m
Free float	34%
Code	TNG
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(3.0)	(2.2)	(4.1)
Rel (local)	(5.4)	(6.3)	(15.6)
52-week high/low	€3.2	€2.3	

Business description

Transgene is a French drug discovery and development company focused on the treatment of cancer and infectious diseases with immunotherapies. The lead products are Pexa-Vec and TG4010.

Next events

Pexa-Vec + Opdivo in HCC trial start	Q217
TG6002 glioblastoma trial start	Q217
TG1050 Phase I data	H217
TG4001 + avelumab trial start	H217
First results from ICI combination trials	Q417
TG4010 +ICI in first-line NSCLC trial start	Q417

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Transgene has announced the initiation of two clinical trials of its main assets in combination with immune checkpoint inhibitors (ICIs). A Phase I trial of oncolytic virus Pexa-Vec in combination with Yervoy in solid tumours has started. Additionally, a Phase II study of the therapeutic vaccine TG4010 with Opdivo in second-line advanced lung cancer has started at UC Davis in collaboration with Bristol-Myers Squibb; initial results from both trials are expected later this year. Cash and equivalents at end 2016 amount to €56.2m. Our updated valuation is €204m or €3.6/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	9.9	(28.9)	(0.78)	0.0	N/A	N/A
12/16	10.3	(22.8)	(0.42)	0.0	N/A	N/A
12/17e	8.3	(35.0)	(0.62)	0.0	N/A	N/A
12/18e	8.6	(36.8)	(0.65)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Pexa-Vec plus Yervoy to boost the immune response

An open-label, investigator-sponsored [Phase I trial](#) of Pexa-Vec in combination with Yervoy (ipilimumab) in up to 60 patients with solid tumours has dosed the first patient at the Léon Bérard Cancer Centre. Endpoints include toxicities, response and survival. Initial data will be available later this year. This strategy is in line with the interest from industry in this approach, according to the increasing number of [clinical trials](#) of oncolytic viruses with ICIs. Moreover, Transgene is expanding further on this strategy by producing a new generation of ICI-expressing oncolytic immunotherapies that have shown a durable [anti-tumour effect](#) in preclinical models.

TG4010 plus Opdivo accelerate and release the brake

Transgene has also started a [Phase II clinical trial](#) of TG4010 in combination with Opdivo (nivolumab) in collaboration with Bristol-Myers Squibb (BMS) and the University of California, Davis Medical Center. Transgene will fund the trial and BMS will provide Opdivo while UC Davis will conduct the trial. It is an open-label study that plans to enrol up to 33 patients with advanced non-small cell lung cancer (NSCLC) who have failed first-line therapy. It will measure response and survival for up to two years. Preliminary data are expected later in 2017. As with oncolytic viruses, [combination trials](#) of cancer vaccines with ICIs have gained traction recently. In H117 the company plans to initiate another study of TG4010 in combination with an undisclosed ICI in first-line NSCLC patients that express low or undetectable levels of PD-L1.

Valuation: rNPV of €204m

We update our valuation to €204m (from €161.5m), which uses a 12.5% discount rate. The increased valuation is a result of rolling forward our model in time and updating cash. The increased rNPV falls to €3.6/share (from €4.2/share) owing to the higher share count (56.4m from 38.5m) following the November 2016 €46.4m (gross proceeds) rights issue at €2.60/share.

Data expected across the pipeline in 2017

The company's strategy involves developing its pipeline assets in combination with other products, predominantly ICIs. The combination of ICIs with other products, especially other immunotherapeutics, is becoming increasingly popular in the oncology space, as demonstrated by the number of studies currently underway in this area. At August 2016 there were 734 ongoing combination trials with 47 ICIs, according to [Beacon Intelligence](#). In particular, there is increasing interest from the industry in combining ICIs with cancer vaccines or oncolytic viruses. Transgene currently has five product candidates that are in or being prepared for clinical trials (11 in total; six underway, five about to start or being prepared for) and we expect a number of them to read out or initiate by year end. Key news includes:

- TG4010 (Phase II): results by year end in combination with nivolumab in NSCLC (second-line), in partnership with BMJ.
- TG4001 (Phase II): dosing of the first patient in combination with avelumab in-HPV positive cancers (in partnership with Merck & Pfizer).
- TG1050 (Phase I): first results in combination with antiviral treatment in chronic Hepatitis B in H217.
- Pexa-Vec (Phase I): first data in combination with ipilimumab in solid tumours by year end.
- Pexa-Vec (Phase II): dosing of the first hepatocellular carcinoma patients (first-line) in combination with nivolumab by Q217.
- TG6002 (Phase I): dosing of the first glioblastoma patient by Q217.

Given Transgene's forecast cash reach to end 2018, we expect these trials to be key short-term drivers to the value of Transgene and data from these trials will be crucial in the search for future partnerships.

Financials and valuation

We have updated our forecasts to reflect the recent results. Transgene reported R&D expenses of €26.4m in FY16 vs €32.1 in FY15. This decrease was mainly due to the continuation of the restructuring activities initiated in 2015, which resulted in a reduction of the workforce. This was close to our 2016 estimate of €27.5m. Transgene will have seven clinical trials active at different points during the 2017-18 period, hence we expect an uptick in R&D expenses to €35.4m in 2017, which includes a delayed \$4m milestone payment to SillaJen on initiation of the Phase III PHOCUS study in Europe. This is an increase with respect to our previous 2017 forecast of €33.0. G&A expenses were €6.2m in FY16, vs €5.8m in FY15, above our estimate of €4.3m. We expect G&A costs to remain broadly stable, hence we have increased G&A costs to €6.4m in 2017 and €6.6m in 2018 from the higher than expected 2016 base.

Cash burn for FY16 was €30.6m. Excluding c €5m net cash outflows linked to the restructuring plan, cash burn reduced to €27.6m, which was in line with our €26m forecast. Transgene's end-2016 gross cash and equivalents position was €56.2m vs €31.7m in FY15. The increase largely reflects the net proceeds of €45m from the rights issue at €2.60 per share, which completed in November 2016, and from the first tranche of €10m from the €20m loan from the European Investment Bank (EIB). In line with our forecasts, Transgene expects to burn €30m in 2017.

We update our valuation to €204m or €3.6 per share (vs €161.5m or €4.2/share), with a 12.5% discount rate. The increased valuation is a result of rolling forward our model and updating cash. Additionally, we have updated the number of shares, from 38.5m to 56.4m to reflect the recent capital increase, resulting in a decrease in our per share valuation.

Exhibit 1: Financial summary

	€'000s	2014	2015	2016	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		11,099	9,949	10,311	8,253	8,618
Cost of Sales		0	0	0	0	0
Gross Profit		11,099	9,949	10,311	8,253	8,618
R&D expenses		(41,731)	(32,138)	(26,419)	(35,441)	(37,019)
G&A expenses		(7,578)	(5,798)	(6,236)	(6,423)	(6,616)
EBITDA		(35,171)	(25,671)	(20,077)	(32,026)	(33,607)
Operating Profit (before GW and except)		(37,845)	(27,957)	(22,194)	(33,484)	(34,922)
Intangible Amortisation		(365)	(350)	(150)	(127)	(95)
Exceptionals (restructuring costs/discontinued operations)		(8,722)	(15,965)	(1,344)	0	0
Operating Profit		(46,932)	(44,272)	(23,688)	(33,611)	(35,017)
Other		0	0	0	0	0
Net Interest		(801)	(930)	(602)	(1,564)	(1,864)
Profit Before Tax (norm)		(38,646)	(28,887)	(22,796)	(35,048)	(36,786)
Profit Before Tax (IFRS)		(47,733)	(45,202)	(24,290)	(35,175)	(36,881)
Tax		0	0	0	0	0
Minority interest		(823)	(1,172)	(917)	0	0
Profit After Tax (norm)		(39,469)	(30,059)	(23,713)	(35,048)	(36,786)
Profit After Tax (IFRS)		(48,556)	(46,374)	(25,207)	(35,175)	(36,881)
Average Number of Shares Outstanding (m)		38.5	38.5	56.0	56.4	56.4
EPS - normalised (c)		(102.52)	(78.08)	(42.33)	(62.11)	(65.19)
EPS - IFRS (c)		(126.12)	(120.45)	(45.00)	(62.33)	(65.36)
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		61,715	49,841	48,895	47,359	45,999
Intangible Assets		1,056	485	423	317	243
Tangible Assets		23,641	16,559	14,580	13,150	11,865
Other		37,018	32,797	33,892	33,892	33,892
Current Assets		79,238	51,028	74,055	57,030	27,539
Stocks		1,149	1,164	221	221	221
Debtors		1,540	1,784	2,385	452	472
Cash		65,935	31,650	56,207	41,115	11,603
Other		10,614	16,430	15,242	15,242	15,242
Current Liabilities		(21,563)	(26,725)	(19,919)	(20,613)	(18,815)
Creditors		(8,296)	(6,521)	(4,504)	(7,088)	(7,404)
Short term borrowings		0	0	0	0	0
Short term leases		(8,992)	(9,396)	(10,198)	(8,308)	(6,194)
Other		(4,275)	(10,808)	(5,217)	(5,217)	(5,217)
Long Term Liabilities		(47,551)	(47,597)	(56,528)	(65,892)	(65,286)
Long term borrowings		0	0	(10,000)	(20,000)	(20,000)
Long term leases		(43,199)	(44,401)	(42,803)	(42,167)	(41,561)
Other long term liabilities		(4,352)	(3,196)	(3,725)	(3,725)	(3,725)
Net Assets		71,839	26,547	46,503	17,884	(10,563)
CASH FLOW						
Operating Cash Flow		(55,037)	(46,082)	(34,187)	(28,799)	(34,893)
Net Interest		801	930	602	(1,890)	(2,114)
Tax		0	0	0	0	0
Capex		(2,602)	(1,527)	(47)	(49)	(51)
Acquisitions/disposals		0	0	0	0	0
Financing		62,735	477	45,080	0	0
Dividends		0	0	0	0	0
Other		12,527	12,975	4,561	6,282	8,151
Net Cash Flow		18,424	(33,227)	16,009	(24,456)	(28,906)
Opening net debt/(cash)		1,756	(13,744)	22,147	6,794	29,360
HP finance leases initiated		(3,191)	(2,646)	(427)	1,890	2,114
Other		267	(18)	(229)	0	0
Closing net debt/(cash)		(13,744)	22,147	6,794	29,360	56,152

Source: Transgene, Edison Investment Research

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