EDISON

Transgene

FY17 results

2018: A year of clinical data

Pharma & biotech

We anticipate nine of Transgene's ongoing clinical trials to read out data later this year. This will be the first major test of the company's strategy for combining its products with approved therapies. In our view, data packages from two trials testing the combination of TG4010 and Opdivo in advanced first- and second-line NSCLC will be key inflection points. Cash as of FY17 results will be sufficient to fund operations into 2019. We value Transgene at €236m (€3.8/share) vs €207m (€3.7/share) previously.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (€)	Yield (%)
12/16	10.3	(23.1)	(0.43)	0.0	N/A	N/A
12/17	8.1	(35.0)	(0.52)	0.0	N/A	N/A
12/18e	7.2	(36.8)	(0.51)	0.0	N/A	N/A
12/19e	7.9	(34.0)	(0.55)	0.0	N/A	N/A

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

Multiple combination data expected in 2018

With 10 trials ongoing and a further two expected to initiate in the near term, multiple readouts, particularly in the second half of 2018, could provide various inflection points. We note the vast majority of these trials are testing Transgene's compounds in combination with approved therapies, particularly immune checkpoint inhibitors (ICI). ICIs continue to generate significant commercial success; however, their suitability is limited to a small portion of patients. Combination with other therapies may improve the number of patients who can be successfully treated. In our view, ICI combination data later this year with TG4010 in NSCLC, TG4001 in HPV-positive head and neck cancer, and Pexa-Vec in HCC is of particular interest.

Invir.IO: Investing in the future of oncolytic viruses

At the end of 2017, Transgene announced the launch of its Invir.IO technology platform. The technology is based around high capacity vaccinia viruses, which are engineered to express a range of anti-cancer drugs like ICIs, enzymes and cytokines. At the end of 2017, Transgene signed two partnership deals with BioInvent and Randox based on the Invir.IO technology, and it anticipates having its first wholly owned internal product candidate in the clinic in 2019.

FY17 results: Cash reach into 2019

Transgene reported a net loss for 2017 of €32.3m, compared with €24.2m in 2016. This was driven predominately by an increase in R&D expenditure to €30.4m (2016: €26.4m) and a reduction in revenue to €8.1m (2016: €10.3m). We forecast that current gross cash of €41.4m will be sufficient to fund operations into 2019.

Valuation: €236m (€3.8/share)

Our valuation is based on a risk-adjusted NPV model of TG4010, TG4001, TG1050, Pexa-Vec and TG6002. We have rolled forward our model, updated for current exchange rates and full-year results. We value Transgene at €236m.

23 March 2018

Price	**€3.04**
Market cap	**€189m**
Gross cash and short-term investments (€m) as of 31 December	41.4
Shares in issue	62.1m
Free float	38%
Code	TNG
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(0.5)	13.7	15.4
Rel (local)	2.0	17.4	9.9
52-week high/low		€3.58	€2.48

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, TG4010 and TG4001.

Next events

Pexa-Vec + ipilimumab data solid tumours	H218
TG4010 + nivolumab in second-line NSCLC	H218
Pexa-Vec+ nivolumab data in first-line HCC	H218

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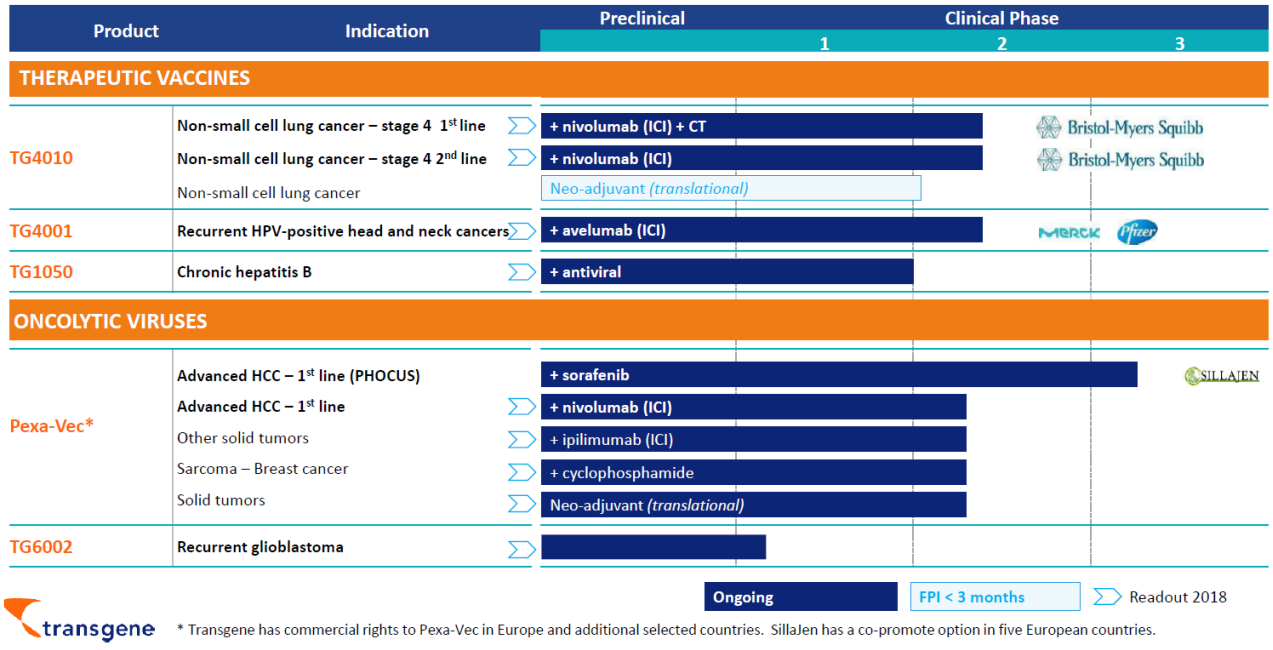
2018 a pivotal year as multiple readouts expected

Transgene now has 11 ongoing clinical trials, with nine of them expected to read out in 2018. Readouts from these trials are set to inform the company's future strategy. In our view, combination trials with approved ICIs hold significant commercial and clinical potential. To date, ICIs have generated blockbuster sales; however, the effectiveness of them is currently limited to a small minority of patients. Companies are now looking to test ICIs in combination with other treatments in order to broaden the therapeutic window of these drugs. Transgene's current strategy aims to leverage on this clinical need and it anticipates that data readouts later this year will further inform whether its product candidates are able to improve on the effectiveness of ICIs. Transgene's rationale is that the tumour microenvironment may be dampening the response of its therapeutic vaccines and oncolytic viruses. By utilising ICIs to inhibit this tumour generated immune dampening ('releasing the brakes' of the immune system), Transgene hopes that its product candidates could generate an improved response to a patient's cancer. We note that Transgene currently has no clinical data to indicate that its products will be successful in combination with ICIs. Current cash runway into 2019 will enable these data readouts, while future financing and strategy will be influenced heavily by these aforementioned data packages.

For a more detailed look at the pipeline and the expected upcoming data packages, please see our previously published report: Multiple assets in the clinic as data readouts near.

Exhibit 1: Transgene pipeline



Source: Transgene

NSCLC treatment landscape continues to shift rapidly

In January, Transgene dosed the first patient in a Phase II combination trial of TG4010, Opdivo (nivolumab – Bristol Myers Squib) and chemotherapy. Transgene's combination trial is a single arm EU/US study and is anticipated to enrol 39 patients (without EGFR mutations or ALK rearrangements) who express low or undetectable levels of PD-L1. The primary end point is objective response rate; Bristol Myers Squib is supplying Opdivo and initial data are forecast for 2019. Treatment of first-line NSCLC remains a significant market opportunity, particularly in combination with ICIs. While Keytruda (Merck) and Opdivo (Bristol Myers Squib) are currently

leaders in PD-1/PD-L1-treated NSCLC, the industry as a whole continues to invest heavily in the space, particularly in combination treatments. The start of 2018 has seen some significant first-line Phase III data readouts from PD-1/PD-L1 inhibitors used in combination. In January, Merck announced Keytruda (KEYNOTE-189) in combination with chemotherapy significantly improved overall survival (OS) and progression-free survival (PFS) in first-line metastatic non-squamous NSCLC patients, when compared with chemotherapy alone. In February, Bristol Myers Squib announced that the combination of Opdivo (Checkmate-227) and Yervoy demonstrated superior PFS to that of chemotherapy alone in first-line NSCLC patients with high tumour burden. Most recently in March, Roche announced Tecentriq plus chemotherapy improved PFS in first line patients with advanced squamous NSCLC (IMpower131), when compared with chemotherapy alone. Recent deal flow has also highlighted that pharmaceutical companies are willing to invest significantly to partner synergistic assets. Of recent note, on the back of positive Phase I/II combination data in PD-L1 negative NSCLC patients, Bristol Myers Squib announced a joint development and commercialisation partnership worth over $3.6bn with Nektar Therapeutics for its immuno-oncology asset, NKTR-214. Patients with low or undetectable levels of PD-1/PD-L1 remain the majority of NSCLC patients and any ability to treat these is significant.

Chinese partner moves asset into the clinic

Transgene continues to progress products with partners; recently, at the start of 2018, it announced that the first patient had been dosed in China in a Phase I trial of T101 for the treatment of chronic hepatitis B virus infection. T101 is a viral vector that expresses the same suite of HBV antigens as the already-in-development TG1050. While TG1050 is in clinical development in Europe and North America, T101 is being developed in China through a joint venture (50:50) with Tasly Pharmaceuticals. The trial is a randomised, double blind, placebo controlled study, which is expected to enrol up to 36 patients who are on antiviral therapy. While the primary end point is to validate the tolerability of T101, key secondary end points include studying how the drug acts (in comparison to TG1050) in a Chinese population with different characteristics to that of an EU and US population. Initial data are expected at the start of 2019; at this time, we anticipate safety and efficacy comparable with that of TG1050.

Invir.IO: Viralytics acquisition highlights potential

In 2017, Transgene announced the launch of its Invir.IO technology platform. The technology aims to utilise the oncolytic activity of oncolytic viruses in combination with the ability to express anti-cancer compounds. The technology is based around high capacity vaccinia viruses, which are engineered to express a range of anti-cancer drugs like ICIs, enzymes, ligands, chemokines and cytokines. At the end of 2017, Transgene signed two partnership deals with BioInvent and Randox based on the Invir.IO technology. The partnership with Randox (no financial terms disclosed) aims to develop multifunctional viruses for use in solid tumours, where it will look to vectorise Randox's single domain antibodies. The BioInvent deal will look to vectorise BioInvent's anti-CTLA-4 antibodies for use in cancers. R&D costs, in addition to revenues and royalties from any candidates produced, will be shared 50:50. Transgene currently has 10 wholly owned preclinical candidates based on its Invir.IO platform and it anticipates the first product candidate will enter the clinic in 2019.

We note recent M&A action in the sector: Merck announced the proposed acquisition of Australian oncolytic immunotherapy company, Viralytics. The deal values Viralytics at approximately A$502m (US$394m) and is predominately focused on CAVATAK, an oncolytic virus (Coxsackievirus Type A21) that is believed to preferentially infect and kill cancer cells. CAVATAK is in multiple Phase I and II trials, including in combination with Merck's Keytruda.

Financials

Transgene reported cash, cash equivalents and financial assets of €41.4m as of 31 December 2017 (compared to €56.2m as of 31 December 2016). This includes the gross €14.4m raised in an accelerated book build in November 2017.

Revenue in 2017 was €8.1m (2016: €10.3m). In core, this was driven by government financing in the form of research grants and tax credits, which were €5.4m (2016: €6.4m) and less then €0.1m (2016: €0.1m), respectively.

R&D expenses in 2017 were €30.4m, an increase on 2016 expenditure of €26.4m, driven by the initiation of multiple trials in 2017. We forecast 2018 R&D will increase slightly to €31.2m as the clinical trials mature. The majority of R&D expenditure continues to be driven by payroll costs as R&D staff costs are accounted for in the R&D expenditure; these were €11.1m versus €10.8m in 2016. Of note, intellectual property costs increased substantially to €4.8m from €1.1m in the previous period, mainly as a result of a €3.8m milestone payment to SillaJen. This was triggered on the first European patient being enrolled in the Phase 3 Pexa-Vec trial (PHOCUS). External expenses for clinical projects remained flat at €7.0m (2016: €7.0m).

G&A costs decreased to €5.7m in 2017 from €6.2m in 2016. This was driven in core by a reduction in payroll costs, which were reported at €3.0m for the period (2016: €3.8m) offset slightly by increases in share based payments, admin fees and other fixed costs. We note interest on the EIB loan (€10m) that was drawn down in June 2016 is not repayable until 2019 with the capital repayable in 2021.

Net loss for 2017 was €32.3m, compared with €24.2m in 2016. We forecast net loss to remain relatively stable over 2018 and 2019 at €31.5m and €34.1m, respectively.

In 2017, Transgene's cash burn was €28.1m in 2017 versus €30.6m in 2016 excluding capital increases and EIB loan; the company anticipates its cash burn in 2018 to be comparable with that of 2017. Our model predicts a current cash reach until mid-2019, which will incorporate multiple trial readouts later this year.

Valuation: €236m (€3.8/share)

We value Transgene at €236m vs €207m (€3.7/share) previously. Our valuation is based on a risk-adjusted NPV model of TG4010, TG4001, TG1050, Pexa-Vec and TG6002. We have rolled forward our model, updated for current exchange rates and full-year results. Our operational and product assumptions remain unchanged (Exhibit 2).

Exhibit 2: Transgene valuation model and key assumptions

Product	Status	Market launch	NPV (€m)	Peak sales (€m)	Probability of success	Royalty estimate	rNPV (€m)	rNPV/ share (€)	Key assumptions
TG4010 – NSCLC (EU)	Phase I/II	2025	120.6	1,062	40%	17.5%	52.6	0.85	c 313k annual EU-28 incidence of lung cancer; 85% NSCLC; 75% MUC1 +ve; 66% normal NK cells; 20% peak penetration; €30k treatment price; €30m upfront on Phase IIb completion.
TG4010 – NSCLC (US)	Phase I/II	2025	89.2	1,429	40%	17.5%	35.7	0.57	c 222k annual US incidence of lung cancer; 85% NSCLC; 75% MUC1 +ve; 66% normal NK cells; 20% peak penetration; $50k treatment price
Pexa-Vec – HCC (EU)	Phase III	2020	159.3	518	50%	25.0%	78.0	1.26	c 66k annual EU incidence of liver cancer; 80% HCC; 25% peak penetration; €30k treatment price
TG1050 – HepB (EU + US)	Phase Ib	2025	246.5	2,054	15%	20.0%	27.5	0.44	c 5.4m chronic hep B prevalence in EU + US; 66% diagnosis rate; 33% require treatment; 5% peak penetration; €35k treatment price
TG4001 – Oesophageal cancer (EU + US)	Phase Ib/II	2026	38.8	198	15%	20.0%	3.9	0.06	c 42k annual incidence of oesophageal cancer in EU5 + US; 70% with HPV; 75% fail; 25% peak penetration; 20% peak royalty rate; €35k treatment price
TG6002 – Glioblastoma (EU + US)	Phase I/IIa	2026	59.9	240	15%	25.0%	7.0	0.11	c 36k annual incidence of brain/CNS cancer in EU5 + US; 30% are glioblastoma, 85% will be recurrent, 50% peak penetration, 25% peak royalty rate, €50k treatment price
Net cash (30 September 2017)							31.1	0.50	
Total							235.7	3.80	

Source: Edison Investment Research. Note: Peak sales represent the largest one-year sales that occur over the projected product lifespan. Spot rate $1.23/€.

Exhibit 3: Financial summary

€000s	2015	2016	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	9,949	10,311	8,144	7,170	7,887
Cost of Sales	0	0	0	0	0
Gross Profit	9,949	10,311	8,144	7,170	7,887
R&D expenses	(32,138)	(26,419)	(30,359)	(31,175)	(34,292)
G&A expenses	(5,798)	(6,236)	(5,674)	(5,844)	(6,020)
EBITDA	(25,671)	(20,397)	(26,352)	(28,413)	(31,093)
Operating Profit (before amort. and except).	(27,957)	(22,514)	(28,043)	(29,774)	(32,363)
Intangible Amortisation	(350)	(150)	0	(75)	(62)
Exceptionals (restructuring costs / discontinued operations)	(15,965)	(1,024)	0	0	0
Operating Profit	(44,272)	(23,688)	(28,043)	(29,849)	(32,425)
Other	0	0	0	0	0
Net Interest	(930)	(602)	(2,287)	(1,619)	(1,649)
Profit Before Tax (norm)	(28,887)	(23,116)	(35,048)	(36,786)	(34,012)
Profit Before Tax (IFRS)	(45,202)	(24,290)	(30,330)	(31,467)	(34,074)
Tax	0	0	0	0	0
Minority interest	(1,172)	(917)	(1,944)	0	0
Profit After Tax (norm)	(30,059)	(24,033)	(32,274)	(31,392)	(34,012)
Profit After Tax (IFRS)	(46,374)	(25,207)	(32,274)	(31,467)	(34,074)
Average Number of Shares Outstanding (m)	38.5	56.0	62.1	62.1	62.1
EPS - normalised (c)	(0.78)	(0.43)	(0.52)	(0.51)	(0.55)
EPS - IFRS (c)	(1.20)	(0.45)	(0.52)	(0.51)	(0.55)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	49,841	48,895	42,137	41,186	40,363
Intangible Assets	485	423	250	206	176
Tangible Assets	16,559	14,580	13,604	12,697	11,904
Other	32,797	33,892	28,283	28,283	28,283
Current Assets	51,028	74,055	58,736	34,790	7,301
Stocks	1,164	221	270	270	270
Debtors	1,784	2,385	2,564	393	432
Cash	31,650	56,207	41,405	19,630	(7,899)
Other	16,430	15,242	14,497	14,497	14,497
Current Liabilities	(26,725)	(19,919)	(16,866)	(18,373)	(17,215)
Creditors	(6,521)	(4,504)	(2,868)	(6,235)	(6,858)
Short term borrowings	0	0	0	0	0
Short term leases	(9,396)	(10,198)	(10,283)	(8,423)	(6,641)
Other	(10,808)	(5,217)	(3,715)	(3,715)	(3,715)
Long Term Liabilities	(47,597)	(56,528)	(55,918)	(55,174)	(54,461)
Long term borrowings	0	0	0	0	0
Long term leases	(44,401)	(52,803)	(51,717)	(50,973)	(50,260)
Other long term liabilities	(3,196)	(3,725)	(4,201)	(4,201)	(4,201)
Net Assets	26,547	46,503	28,089	2,429	(24,012)
CASH FLOW					
Operating Cash Flow	(46,082)	(34,187)	(37,657)	(24,045)	(31,696)
Net Interest	930	602	2,287	(1,860)	(1,782)
Tax	0	0	0	0	0
Capex	(1,527)	(47)	(462)	(485)	(508)
Acquisitions/disposals	0	0	0	0	0
Financing	477	45,080	13,272	0	0
Dividends	0	0	0	0	0
Other	12,975	4,561	8,935	5,358	7,170
Net Cash Flow	(33,227)	16,009	(13,625)	(21,031)	(26,815)
Opening net debt/(cash)	(13,744)	22,147	6,794	20,595	39,766
HP finance leases initiated	(2,646)	(427)	(120)	1,860	1,782
Other	(18)	(229)	(56)	0	0
Closing net debt/(cash)	22,147	6,794	20,595	39,766	64,800

Source: Transgene, Edison Investment Research

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