EDISON

Transgene

Q3 pipeline update

Multiple assets in the clinic as data readouts near

Pharma & biotech

Transgene's strategy is focused on combining its products with approved therapies with the aim of improving response rates in patients. The company now has nine ongoing clinical trials, which are expected to readout in the next 12-18 months, and data will inform Transgene's future strategy. In addition to numerous trial initiations, Transgene recently presented data on TG1050 in hepatitis B patients, launched its next generation oncolytic virus platform Invir.IO and signed a collaboration agreement with Randox. We value Transgene at €207m (€3.7/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	(23.1)	(0.43)	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.

All speed ahead on expansive pipeline

Multiple trial readouts over the next 12-18 months will inform Transgene's long-term strategy as the utility of its assets with other approved treatments (notably immune checkpoint inhibitors) becomes known. Recent trial initiations include a Phase I/IIa trial of TG6002 in recurrent glioblastoma, a Phase Ib/II trial of TG4001 in combination with avelumab for treatment of HPV-positive cancers and a Phase I/II trial of Pexa-Vec in combination with nivolumab for the treatment of liver cancer. Recent data comes from the presentation of Phase Ib data of TG1050 in hepatitis B patients, which was well tolerated and generated an immune response.

Preparing the next wave

Transgene recently launched Invir.IO, a next-generation oncolytic virus platform. Preclinical data has demonstrated the platform's ability to express anti-cancer therapeutics within tumours and promote cancer cell death. On the back of the launch of Invir.IO, Transgene announced a collaboration with Randox (no financial terms disclosed) to develop viruses for use in solid tumours, where it will look to express Randox's single domain antibodies.

Q3 financials: Cash through to end 2018

As of 30 September, short-term investments and cash was €40.0m; cash burn for the first nine months of 2017 was €16.2m (9M16: €16.3m). Transgene expects a total FY17 cash burn of c €30m, mainly as a result of significant increased clinical trial expenses in the fourth quarter. €10m of the EIB loan is eligible to be draw down in H217.

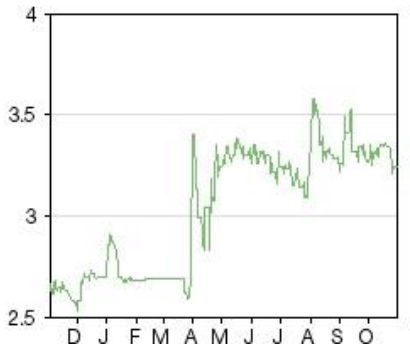
Valuation: €207m (€3.7/share)

Our valuation is based on a risk-adjusted NPV model. We have updated our valuation to include the recently initiated TG4001 and TG6002 trials, but this was offset by a reduction in net cash. We value Transgene at €207m (€3.7/share).

1 November 2017

Price	**€3.24**
Market cap	**€183m**
Gross cash and short-term investments (€m) as of 30 September	40.0
Shares in issue	56.4m
Free float	34%
Code	TNG
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(0.9)	4.9	20.9
Rel (local)	(3.4)	(1.7)	(0.3)
52-week high/low		€3.6	€2.5

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	Q118
TG4010 + nivolumab in 2nd line NSCLC	Q118
Pexa-Vec+ nivolumab data in 1st line HCC	H218

Analysts

Dr Daniel Wilkinson +44 (0)20 3077 5734

Juan Pedro Serrate +44 (0)20 3681 2534

healthcare@edisongroup.com

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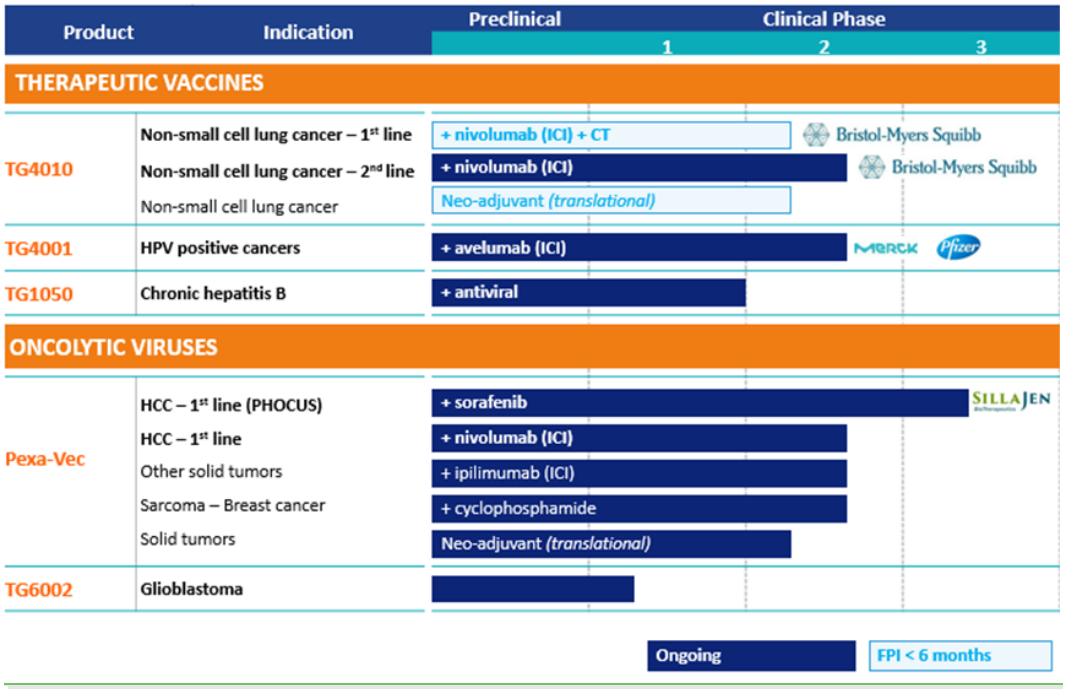
Pipeline update: Multiple data readouts in 2018

Transgene now has nine ongoing clinical trials, which are expected to readout in the next 12-18 months; readouts from these trials are set to inform the company's future strategy. As Exhibit 1 demonstrates, these cover a range of cancers and combinations. All trials have initiated except for two TG4010 trials in non-small cell lung cancer (NSCLC) (first-line in combination with chemotherapy plus nivolumab and separately as a neo-adjuvant monotherapy), which are expected to initiate within the next six months. We expect the following data readouts in 2018:

- Q118: Pexa-Vec + ipilimumab in solid tumours
- Q118: Initial data on TG4010 + nivolumab in second-line NSCLC
- H218: Pexa-Vec + nivolumab in first-line HCC
- H218: Initial data on Pexa-Vec + cyclophosphamide in advanced breast cancer
- 2018: Full data package on TG1050 at an international conference
- 2018: Safety data on TG6002

Exhibit 1: Transgene clinical pipeline



Source: Transgene

Current cash to the end of 2018 will enable these data readouts, while future financing and strategy will be influenced heavily by these aforementioned data packages. We note that in addition to the trials Transgene is undertaking, its partner SillaJen is expecting to shortly begin recruitment of a Phase I trial testing Pexa-Vec in combination with a PD-1 inhibitor (Regeneron: REGN2810) in metastatic or unresectable renal cell carcinoma. Meanwhile in an investigator-led Phase I/II trial, the National Cancer Institute (NCI) is testing Pexa-Vec in combination with CTLA-4 immune checkpoint inhibitor tremelimumab (AstraZeneca) and PD-L1 immune checkpoint inhibitor durvalumab (AstraZeneca) in refractory colorectal cancer patients.

Looking to the future, Transgene recently launched Invir.IO, a next-generation oncolytic virus platform. The most advanced research candidates are based on the company's Vaccinia virus strain. To date, it has demonstrated potential in various mouse models, including in the expression of key immune components and promotion of cancer cell death. On the back of the launch of

Invir.IO, Transgene announced a collaboration with Randox (no financial terms disclosed) to develop viruses for use in solid tumours, where it will look to vectorise Randox's single domain antibodies.

TG4010: Opportunities await in NSCLC non-responders

Lung cancer is one of the, if not the most diagnosed cancer globally. In 2012, 1.8m new cases were diagnosed worldwide (Globocan). Of lung cancer cases, between 85% and 90% are non-small cell (NSC), with annual sales in this subset indication of $11.5bn in 2016, and forecast to grow to $26.7bn in 2022 (EP Vantage). Despite the significant money invested into lung cancer treatment, mortality remains high, with 1.6m deaths worldwide in 2012 (19% of total cancer deaths). In England and Wales, the five-year survival of lung cancer patients is only 9.5% (Cancer Research UK).

Treatment paradigms continue to shift, noticeably over the last few years with the approval of immune checkpoint inhibitors (ICIs), a broad class of drugs that aim to enable a patient's immune system to detect and subsequently kill cancer cells. However, these treatments work only in a small subset of patients and the majority of patients see no or limited response. To improve the efficacy of the ICIs and address larger patient populations, combination therapies are being tested across multiple drug classes. TG4010 is a therapeutic vaccine that induces an immune response against tumour cells that express the MUC1 protein (IL-2 stimulates the immune response). In the Phase IIb TIME trial in NSCLC, TG4010 in combination with chemotherapy led to improvements in progression-free survival and overall survival. New immunology data are expected to be presented from the TIME trial at the Society for Immunotherapy of Cancer Meeting 2017 on 8-12 November. Transgene currently has three TG4010 trials on which it is focused:

- Patient enrolment is ongoing in the Phase II combination trial of TG4010 and Opdivo (nivolumab) for the treatment of second-line metastatic non-small cell lung cancer. Transgene is funding the trial and BMS is providing Opdivo, while UC Davis will conduct the trial under the supervision of Dr Karen Kelly. The multi-centre, single-arm, open-label study plans to enrol up to 33 patients with advanced NSCLC who have failed first-line therapy. It will measure response (primary endpoint) and survival for up to two years. So far, five patients have been recruited, as Dr Kelly mentioned at Transgene's R&D day on 22 June. Preliminary data are expected early in 2018.
- Transgene has received IND approval for a Phase II trial of TG4010 in combination with Opdivo and chemotherapy in first-line NSCLC patients that express low or undetectable levels of PD-L1. Transgene will sponsor the trial and BMS will provide Opdivo. The multi-centre, single-arm, open-label study will evaluate response and disease control along with safety and tolerability in up to 39 patients. It is expected to start enrolment in the coming months.
- TG4010 is to be tested in a Phase II trial as a neoadjuvant (first step to shrink a tumour before the main treatment like surgery). Little is known on the trial design at this point, but the first patient is expected to be enrolled in the next six months.

TG1050: AASLD Liver Meeting 2017

At the 2017 American Association for the Study of Liver Diseases (AASLD) Liver Meeting, Transgene presented initial data on the treatment of hepatitis B patients with TG1050. TG1050 is a therapeutic vaccine for the treatment of chronic hepatitis B that expresses three antigens of the hepatitis B virus (HBV). Patients treated to date received a single administration at either 10^9, 10^{10} or 10^{11} virus particles. Four patients were in each dose group with one of those receiving placebo and only immunogenicity data was available for presentation. Response against HBV antigens was measured at baseline and weeks two, four and 12 after administration of TG1050. Patients were determined as responders for an antigen if the response doubled or an increase of 500 and above

in spot forming cells (sfc) was observed. Nine of 10 patients eligible for evaluation had at least one antigen achieve a response, while four of 10 patients had a response in at least three antigens. Early safety data indicates that TG1050 is well tolerated as all adverse events presented to date were grade 1 or 2. While this earlier data highlights that TG1050 appears to have a positive safety profile and creates an immune response, we await the full data package next year, which will better inform the market on its potential, in particular TG1050's ability to reduce the presence of hepatitis B virus.

TG6002 and TG4001: Patients enter the clinic

The first recurrent glioblastoma patient has been treated in the Phase I/IIa trial of TG6002 in combination with 5-flucytosine (5-FC). The trial is an open label dose escalation study with an accelerated titration 3+3 design. Primary endpoints are defining the number of patients with dose limiting toxicities and assessment of tumour progression at six months. Secondary endpoints include, among others, selecting the recommended Phase IIa dose and overall survival. TG6002 has been designed by Transgene to induce both cancer cell death and allow the local production of the chemotherapy 5-FU. TG6002 causes the expression of the Fcu1 gene in cancer cells that it infects; this then leads to the local conversion of 5-FC (administrated in conjunction with TG6002) into the chemotherapeutic agent 5-FU. The Phase I/IIa trial is expected to enrol 78 patients with an estimated primary completion date in 2019. Initial safety data is anticipated in 2018.

Transgene has treated the first patient in its Phase Ib/II trial of TG4001 in combination with avelumab for the treatment of HPV positive cancers. The trial will be funded by Transgene while Pfizer and Merck will provide avelumab and co-design the Phase I and II cohorts of the study, which will be open-label and enrol up to 50 patients; primary endpoints will include dose limiting toxicities (in Phase I) and overall response rate (in Phase II). Details on the trial design, financial terms, IP rights or other aspects of the agreement have not been disclosed. Avelumab is approved in Merkel cell carcinoma and metastatic urothelial cell carcinoma in the US.

Pexa-Vec: Expected combination readouts in 2018

Pexa-Vec is in five ongoing Transgene initiated clinical trials, with three data readouts expected in 2018, notably two of which are individually with the immune checkpoint inhibitors nivolumab (first-line HCC) and ipilimumab (solid tumours). The three readouts expected are:

- An open-label, investigator-sponsored Phase I/II trial of Pexa-Vec in combination with ipilimumab (Yervoy) in up to 60 patients with solid tumours, which is ongoing at the Léon Bérard Cancer Centre. Endpoints include toxicities, response and survival. Initial data will be available by Q118.
- A Phase I/II trial testing Pexa-Vec in combination with nivolumab (Opdivo) for first-line treatment of advanced hepatocellular carcinoma patients, which has begun enrolling patients. The Phase I part will study the safety profile of the combination while in the Phase II part, antitumor efficacy will be monitored. Secondary endpoints include overall survival and disease control rate. A total of 30 patients are expected to be enrolled. Phase I data is expected in 2018.
- In April 2017, Transgene started the Phase II part of the METROmaJX trial. This Phase I/II study evaluates the combination of Pexa-Vec with metronomic cyclophosphamide (repetitive, low doses; shown to potentiate the activity of other immunotherapies) in patients with advanced soft tissue sarcoma and HER2 negative breast cancer and it will measure the maximum tolerated dose of the first cycle of the combination and antitumour activity. The trial is sponsored by the Bergonié Institute. The primary completion date is September 2018. In September, Transgene presented data at ESMO on the Phase I portion of the trial

demonstrating the combination was well tolerated and no dose-limiting toxicities were observed.

We note that Pexa-Vec (in combination with sorafenib) is in an ongoing Phase III study (PHOCUS) in first-line hepatocellular carcinoma conducted by its partner SillaJen. Initial overall survival data is expected in 2019. SillaJen has responsibility for conducting and funding the study and worldwide rights. Transgene retains development and commercialisation rights in Europe. In addition to PHOCUS, SillaJen expects to shortly begin recruitment of a Phase I trial testing Pexa-Vec in combination with a PD-1 inhibitor (Regeneron: REGN2810) in metastatic or unresectable renal cell carcinoma.

Financials

Transgene reported cash, cash equivalents and financial assets of €40.0m as of 30 September 2017. The company has access to a further €10m from the EIB loan that can be drawn down before the end of 2017. The EIB loan is for five years, with the interest repayable from 2019 and the capital in 2021. Operating revenue for the first nine months of 2017 was €4.9m (2016: €6.4m). This was mainly as a result of revenue from collaboration and licence agreements including the Servier collaboration. The company expects to have sufficient funds to conduct its pipeline development activities through 2017 and 2018 with a cash burn of €30m anticipated by the company in 2017 (company reported cash burn for FY16 was €30.6m). As of Q317, Transgene's cash burn was €16.2m, indicating a significant rise in cash burn is expected in Q417. We expected this to predominately be a result of increasing clinical trial activity. Our model predicts current cash reach until end 2018.

Valuation

Our rNPV valuation of Transgene is €207m or €3.7/share (vs €208m or €3.7/share). Our key inputs and assumptions are summarised in Exhibit 2 below. We have now added TG4001 and TG6002 to our valuation following the recent clinical trial initiations and we model that both are out-licensed following Phase I. We utilise oesophageal cancer as our model indication for TG4001. We additionally note that we expect a higher penetration and price for TG6002 than typical, as if successful in clinical development it would address a significant unmet need. We have additionally updated our net cash following Q3 results. For a more detailed overview of our valuation, please see our previously published outlook note, Building a strong immunotherapy portfolio.

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	108.8	1,062	40%	17.5%	44.7	0.79	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	91.5	1,429	40%	17.5%	36.6	0.65	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	144.9	518	50%	25.0%	68.2	1.21	c 66k annual EU incidence of liver cancer; 80% HCC; 25% peak penetration; €30k treatment price
TG1050 - HepB (EU + US)	Phase Ib	2025	229.5	2,054	15%	20.0%	23.0	0.41	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	34.2	198	15%	20.0%	1.2	0.02	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	54.1	240	15%	25.0%	4.2	0.07	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)							29.2	0.52	
Total							**207.2**	**3.67**	

Source: Edison Investment Research. Note: Peak sales represent the largest one-year sales that occur over the projected product lifespan. Spot rate $1.13/€.

Exhibit 3: Financial summary

€000s	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	9,949	10,311	8,253	8,618
Cost of Sales	0	0	0	0
Gross Profit	9,949	10,311	8,253	8,618
R&D expenses	(32,138)	(26,419)	(35,441)	(37,019)
G&A expenses	(5,798)	(6,236)	(6,423)	(6,616)
EBITDA	(25,671)	(20,397)	(32,026)	(33,607)
Operating Profit (before amort. and except)	(27,957)	(22,514)	(33,484)	(34,922)
Intangible Amortisation	(350)	(150)	(127)	(95)
Exceptionals (restructuring costs / discontinued operations)	(15,965)	(1,024)	0	0
Operating Profit	(44,272)	(23,688)	(33,611)	(35,017)
Other	0	0	0	0
Net Interest	(930)	(602)	(1,564)	(1,864)
Profit Before Tax (norm)	(28,887)	(23,116)	(35,048)	(36,786)
Profit Before Tax (IFRS)	(45,202)	(24,290)	(35,175)	(36,881)
Tax	0	0	0	0
Minority interest	(1,172)	(917)	0	0
Profit After Tax (norm)	(30,059)	(24,033)	(35,048)	(36,786)
Profit After Tax (IFRS)	(46,374)	(25,207)	(35,175)	(36,881)
Average Number of Shares Outstanding (m)	38.5	56.0	56.4	56.4
EPS - normalised (c)	(78.08)	(42.90)	(62.11)	(65.19)
EPS - IFRS (c)	(1.20)	(0.45)	(0.62)	(0.65)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	49,841	48,895	47,359	45,999
Intangible Assets	485	423	317	243
Tangible Assets	16,559	14,580	13,150	11,865
Other	32,797	33,892	33,892	33,892
Current Assets	51,028	74,055	57,030	27,539
Stocks	1,164	221	221	221
Debtors	1,784	2,385	452	472
Cash	31,650	56,207	41,115	11,603
Other	16,430	15,242	15,242	15,242
Current Liabilities	(26,725)	(19,919)	(20,613)	(18,815)
Creditors	(6,521)	(4,504)	(7,088)	(7,404)
Short term borrowings	0	0	0	0
Short term leases	(9,396)	(10,198)	(8,308)	(6,194)
Other	(10,808)	(5,217)	(5,217)	(5,217)
Long Term Liabilities	(47,597)	(56,528)	(65,892)	(65,286)
Long term borrowings	0	(10,000)	(20,000)	(20,000)
Long term leases	(44,401)	(42,803)	(42,167)	(41,561)
Other long term liabilities	(3,196)	(3,725)	(3,725)	(3,725)
Net Assets	26,547	46,503	17,884	(10,563)
CASH FLOW				
Operating Cash Flow	(46,082)	(34,187)	(28,799)	(34,893)
Net Interest	930	602	(1,890)	(2,114)
Tax	0	0	0	0
Capex	(1,527)	(47)	(49)	(51)
Acquisitions/disposals	0	0	0	0
Financing	477	45,080	0	0
Dividends	0	0	0	0
Other	12,975	4,561	6,282	8,151
Net Cash Flow	(33,227)	16,009	(24,456)	(28,906)
Opening net debt/(cash)	(13,744)	22,147	6,794	29,360
HP finance leases initiated	(2,646)	(427)	1,890	2,114
Other	(18)	(229)	0	0
Closing net debt/(cash)	22,147	6,794	29,360	56,152

Source: Transgene accounts, Edison Investment Research

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia