EDISON

Transgene

Q316 results update

Business update and Q316 results

Pharma & biotech

During Q316 Transgene announced a collaboration agreement with Pfizer and Merck to develop TG4001 in combination with avelumab in a Phase I/II trial, the recruitment of the first patient in the multiple-dose cohort of Phase I/Ib of TG4001 in HBV patients and preclinical data from its vaccinia technology platform. The company plans to raise €48.1m (gross) through a rights issue that will fund operations to the end of 2018. Cash and equivalents at end Q316 amount to €25.4m. We value Transgene at €161.5m or €4.2/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	11.1	(38.9)	(1.03)	0.0	N/A	N/A
12/15	9.6	(28.9)	(0.78)	0.0	N/A	N/A
12/16e	6.1	(27.2)	(0.71)	0.0	N/A	N/A
12/17e	7.8	(31.5)	(0.82)	0.0	N/A	N/A

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

Rights issue to fund strategy into first readouts

Transgene announced a rights issue for a planned gross amount of €48.1m. The subscription period will end on 4 November. The company will use funds to continue with its strategy of combining key pipeline assets with immune checkpoint inhibitors. In total, seven clinical trials are due to start before end 2017, with the first readouts expected in H217. With cash and equivalents of €25.4m at end Q316, the company guides FY16 cash burn at €35m.

Deal with Pfizer and Merck on combination trial

Transgene has entered into a collaboration with Pfizer and Merck KGaA to evaluate TG4001 in combination with immune checkpoint inhibitor (ICI) avelumab for second-line human papilloma virus (HPV) positive head and neck squamous cell carcinoma (HNSCC). The study is slated to start in H117; Pfizer and Merck will provide avelumab and will co-design the Phase I/II clinical trial with Transgene. The company will cover most expenses. Additional details were not disclosed.

Additional newsflow

During the quarter, Transgene announced the inclusion of the first patient in the multiple-dose cohort of the Phase I/Ib study of TG1050 (HBV vaccine). This trial evaluates the safety, tolerability and antiviral activity of TG1050 in patients with chronic Hepatitis B infection who are being treated with standard-of-care antiviral therapy. The first data readout is expected in H217. Additionally, preclinical data from its vaccinia technology platform were presented at the 10th International Meeting on Replicating Oncolytic Virus in Vancouver, Canada.

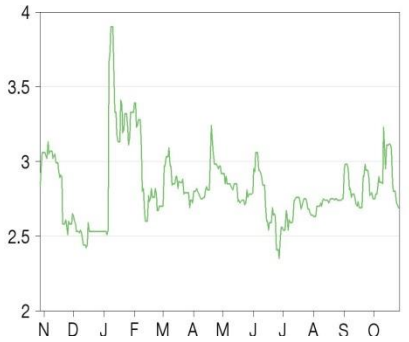
Valuation: Updating NPV to €161.5m or €4.2/share

We are updating the cash position to €25.4m, but introduce no further changes to our DCF valuation, which moves to €4.2/share (from €4.40/share). We await the results of the rights issue before updating our model.

28 October 2016

Price	**€2.68**
Market cap	**€103m**
Net cash and ST investments (€m) at 30 September 2016	25.4
Shares in issue	38.5m
Free float	43%
Code	TNG
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(1.2)	2.1	(2.6)
Rel (local)	(3.5)	0.2	3.0
52-week high/low	€3.80		€2.35

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 (in Phase III for HCC) and TG4010 (Phase IIb complete for NSCLC).

Next events

TG4010 +Opdivo NSCLC (second-line) trial start	H216
Pexa-Vec +Yervoy Solid Tumours trial start	H216

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Rights issue and deal execution reinforces strategy

The company's strategy involves developing its pipeline assets in combination with other products, predominantly immune checkpoint inhibitors (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 this type of study. 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 to combine ICIs with cancer vaccines or oncolytic viruses. As an example, Bavarian Nordic's prostate cancer vaccine ProstVac is undergoing a Phase II trial in combination with Bristol-Myers Squibb's ipilimumab. Oncolytic virus therapy Imlygic (talimogene laherparepvec, Amgen) is being tested in combination with ipilimumab in a Phase II trial in advanced melanoma.

To fund operations for the next two years, Transgene announced a subscription rights issue to existing shareholders. As a result of the capital increase, approximately 18.5m new shares will be issued at €2.60/share, raising c €48.1m gross. Institut Mérieux, Transgene's key shareholder, has committed to subscribing up to 75% of the total number of the new shares. The subscription period to exercise rights and subscribe for new shares starts on 27 October and ends on 4 November 2016.

Exhibit 1: Transgene Clinical pipeline

Compound	Combination Compound	Indication	Phase	Collaborators	Trial start date	Data Readout
TG4010	Opdivo (Nivolumab) (BMY) anti-PD-1	Second-line NSCLC	II	UC Davis Medical Centre (US)	H216	2017
TG4010	Unspecified ICI	First-line NSCLC	II	N/A	H117	N/A
TG4010	N/A	Neoadjuvant NSCLC	Translational	N/A	2017	N/A
Pexa-Vec	Sorafenib	First-line HCC	III	Conducted by partner SillaJen	Ongoing	2019
Pexa-Vec	Yervoy (Ipilimumab) (BMY) anti CTLA-4	Solid Tumours	II	Centre Leon Berard	H216	2017
Pexa-Vec	Opdivo (Nivolumab) (BMY) anti-PD-1	First-line HCC	II	N/A	H117	N/A
TG4001	Avelumab (Pfizer/Merck) anti-PD-L1	HPV positive head and neck cancer	II	Prof Christopher Le Tourneau, Institut Curie, principal investigator	H117	N/A
TG1050	Standard of care antiviral	Chronic hepatitis B	I/Ib	N/A	Ongoing	H217
TG6002	N/A	Glioblastoma	I	Assistance Publique Hôpitaux, Paris (PI Pr Delattre), support from French National Cancer Institute	H117	N/A

Source: Edison Research Investment, Transgene

Collaboration agreement with Pfizer and Merck

Transgene has announced a collaboration agreement with Pfizer and Merck to combine TG4001 and avelumab, a fully human monoclonal antibody that inhibits programmed cell death ligand 1 (PD-L1) in a Phase I/II study in second-line HPV-positive HNSCC. The trial will be funded by Transgene and will start in H117. 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; endpoints will include response rate and duration of response. Further details on the trial design, financial terms, IP rights or other aspects of the agreement have not been disclosed.

TG4001 is a therapeutic vaccine based on a modified vaccinia virus Ankara (MVA) vector engineered to express HPV 16 antigens E6 and E7 with adjuvant interleukin-2 (IL-2). Clinical data from 206 female patients with CIN2/3 Intraepithelial Cervical Neoplasia showed a 38% (20/52) clearance rate in HPV 16 mono-infected patients compared with 9% for placebo (2/23) (p value = 0.009) with a favourable safety profile.

According to ClinicalTrials.gov, avelumab is being tested in 19 clinical trials, eight of which are in combination with other products in various oncology indications. In particular, avelumab is expected to start a small Phase I trial in patients with locally advanced HNSCC in combination with radiotherapy and cetuximab in Q416. Two multi-tumour Phase I trials include cohorts with HNSCC patients and are currently recruiting patients. An additional Phase II trial is recruiting patients with nasopharyngeal cancer, a form of HNSCC. There are no data available from these studies and first readouts could occur in mid-2018, according to ClinicalTrials.gov timelines.

Data from a pivotal Phase II study published in Lancet Oncology in second-line metastatic Merkel cell carcinoma (MCC) showed an overall response rate of 31.8% (n=88, irrespective of PD-L1 status), with Grade 1 or 2 treatment-related adverse events (AEs) in 62 patients (70.5%). Grade 3 treatment-related AEs were reported in four patients (5%). There were no Grade 4 treatment-related AEs or deaths. Merck plans to apply for approval in MCC in the US and Europe by end 2016.

Head and neck cancer is a heterogeneous group of cancers in the oral cavity, oropharynx, larynx, nasal cavity and salivary glands that affect 500,000 people annually worldwide. Over 90% of cases are squamous cell carcinomas (HNSCC). Annual incidences of oropharyngeal squamous cell cancers have risen to 6.2 per 100,000 men and 1.4 per 100,000 women in the US and 73% of these tumours are HPV positive (data from 2004-08 period). The current treatments are surgery, chemotherapy and/or radiation, aggressive and with significant toxicities.

Additional newsflow

During the quarter Transgene announced that the first patient had been dosed in the multiple dose cohort of an ongoing Phase I/Ib trial of TG1050 with standard of care in HBV patients. TG1050 is a therapeutic vaccine for the treatment of chronic Hepatitis B that expresses three antigens of the Hepatitis B virus. This announcement comes after the Safety Review Committee recommended its continuation. The Phase I/Ib trial is an international, randomised, double-blind, placebo-controlled safety and dose-finding study evaluating single and multiple doses of TG1050 in patients who are currently being treated for chronic HBV infection with standard-of-care antiviral therapy (n=48). Secondary objectives include the antiviral activity of and immune responses to TG1050. Data are expected in H217. There are currently limited treatments for HBV. The cure rate from nucleotide analogues such as tenofovir (Viread) and entecavir (Baraclude) or pegylated interferon-α is only 3-5%, so that patients normally need long-term antiviral therapy to control their infection. Around 240 million people have chronic HBV infection, according to the World Health Organization (WHO). Transgene will look to partner TG1050 once it has proof-of-concept data from this study.

Furthermore, preclinical work was presented at the 10th International Meeting on Replicating Oncolytic Virus Therapeutics held in Vancouver, Canada on 1-4 October 2016. The company presented a new technique to improve the cytotoxic power of vaccinia vectors based on intracellular fragments that overcome cancer cell resistance. This work underscores Transgene's vaccinia platform capabilities for the design of the next generation of preclinical candidates. These data build on previously published experiments in April 2016 at the American Association for Cancer Research (AACR) meeting in New Orleans. At AACR, Transgene reported data from several oncolytic virus constructs, which showed they could express anti-PD-1 fragments and accumulate in tumours, with a similar anti-tumour effect as a combination of anti-PD-1 antibody and oncolytic virus and better than any of the single products in a preclinical model.

Financials and valuation: Cash updated, NPV of €161.5m

We are updating our valuation, with reported cash of €25.4m at end September 2016, which results in an NPV of €161.5m or €4.2/share (from €169.5m or €4.40/share). We will update our valuation with the new shares and total cash raised once the subscription period for the rights issue closes on

4 November. We are currently not introducing any changes to our assumptions until we receive more information on the clinical data for both the ongoing trials and the upcoming combination studies.

Transgene reported that operating revenue for the first nine months of 2016 (9M16) was down to €6.4m from €7.5m in the same period in 2015 (9M15), which was mainly due to a reduction in the eligible research and development expenses that decreased from €6.4m in 9M15 to €4.4m in 9M16. Cash and cash equivalents, including available-for-sale financial assets, stood at €25.4m as of 30 September 2016 (€31.7m as of 31 December 2015). Cash does not include the recently announced share capital increase, by which the company aims to raise a gross €48.1m.

Cash burn for the first nine months of 2016 was €16.3m (excluding the EIB loan), approximately half of which was burnt in Q3 (€8.1m). Removing €4.2m net cash outflows linked to the restructuring plan, cash burn stood at €12.1m for the first nine months of 2016. Transgene expects to burn €35m by year end as it ramps up its clinical programme. In Q416 a reduction in tax credits received and milestone payments paid, in addition to the clinical programme, will contribute to this increased burn.

Exhibit 2: Financial summary

€'000s	2013	2014	2015	2016e	2017e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	15,735	11,099	9,565	6,086	7,835
Cost of Sales	0	0	0	0	0
Gross Profit	15,735	11,099	9,565	6,086	7,835
R&D expenses	(50,063)	(41,731)	(32,138)	(27,465)	(32,958)
G&A expenses	(6,769)	(7,578)	(5,798)	(4,339)	(4,469)
EBITDA	(38,287)	(35,453)	(25,671)	(23,943)	(27,858)
Operating Profit (before GW and except)	(40,813)	(38,127)	(27,957)	(25,584)	(29,488)
Intangible Amortisation	(385)	(365)	(350)	(135)	(105)
Exceptionals (restructuring costs / discontinued operations)	0	(8,440)	(15,965)	0	0
Operating Profit	(41,198)	(46,932)	(44,272)	(25,719)	(29,592)
Other	0	0	0	0	0
Net Interest	(730)	(801)	(930)	(1,579)	(2,034)
Profit Before Tax (norm)	(41,543)	(38,928)	(28,887)	(27,163)	(31,522)
Profit Before Tax (IFRS)	(41,928)	(47,733)	(45,202)	(27,298)	(31,627)
Tax	0	0	0	0	0
Minority interest	(930)	(823)	(1,172)	0	0
Profit After Tax (norm)	(42,473)	(39,751)	(30,059)	(27,163)	(31,522)
Profit After Tax (IFRS)	(42,858)	(48,556)	(46,374)	(27,298)	(31,627)
Average Number of Shares Outstanding (m)	31.9	38.5	38.5	38.5	38.5
EPS - normalised (c)	(1.33)	(103.25)	(78.08)	(70.55)	(81.87)
EPS - IFRS (c)	(1.34)	(126.12)	(120.45)	(70.90)	(82.15)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	64,501	61,715	49,841	49,440	49,135
Intangible Assets	1,329	1,056	485	350	245
Tangible Assets	23,988	23,641	16,559	16,293	16,093
Other	39,184	37,018	32,797	32,797	32,797
Current Assets	61,349	79,238	51,028	42,772	28,237
Stocks	975	1,149	1,164	1,164	1,164
Debtors	1,896	1,540	1,784	1,784	429
Cash	47,862	65,935	31,650	26,894	13,713
Other	10,616	10,614	16,430	12,930	12,930
Current Liabilities	(23,996)	(21,563)	(26,725)	(19,697)	(20,796)
Creditors	(9,364)	(8,296)	(6,521)	(5,493)	(6,592)
Short term borrowings	0	0	0	0	0
Short term leases	(8,830)	(8,992)	(9,396)	(9,396)	(9,396)
Other	(5,802)	(4,275)	(10,808)	(4,808)	(4,808)
Long Term Liabilities	(45,232)	(47,551)	(47,597)	(66,953)	(76,316)
Long term borrowings	0	0	0	(20,000)	(30,000)
Long term leases	(40,788)	(43,199)	(44,401)	(43,757)	(43,120)
Other long term liabilities	(4,444)	(4,352)	(3,196)	(3,196)	(3,196)
Net Assets	56,622	71,839	26,547	5,561	(19,740)
CASH FLOW					
Operating Cash Flow	(50,186)	(55,037)	(46,082)	(30,495)	(24,915)
Net Interest	244	801	930	(1,579)	(2,034)
Tax	0	0	0	0	0
Capex	(2,184)	(2,602)	(1,527)	(1,374)	(1,429)
Acquisitions/disposals	0	0	0	3,500	0
Financing	70	62,735	477	0	0
Dividends	0	0	0	0	0
Other	7,902	12,527	12,975	5,836	5,836
Net Cash Flow	(44,154)	18,424	(33,227)	(24,113)	(22,542)
Opening net debt/(cash)	(53,948)	1,756	(13,744)	22,147	46,260
HP finance leases initiated	(11,411)	(3,191)	(2,646)	0	0
Other	(139)	267	(18)	(0)	0
Closing net debt/(cash)	1,756	(13,744)	22,147	46,260	68,802

Source: Transgene, Edison Investment Research

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