

## Transgene Reports Financial Results for First Six Months of 2014 and Provides Update on TG4010

- **€96.2 million in cash and cash equivalents as of June 30, 2014**
  - **Updated TG4010 data show an improvement in overall survival consistent with improvement in progression-free survival as previously reported**
  - **Updated TIME trial results in advanced non-small cell lung cancer to be presented at ESMO 2014 Congress**
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**Strasbourg, France, September 8, 2014** – Transgene (Euronext Paris: TNG) today announced its financial results<sup>1</sup> for the six-month period ended June 30, 2014 and provided an update on one of its lead development programs, TG4010 MUC-1 targeted cancer immunotherapy.

Key highlights of the Interim Financial Report are as follows:

- Stable operating revenue and expenses, with €6.3 million in revenue and €26.0 million in R&D expenses for the six-month period.
- Net loss (€25.1 million) and cash burn (€14.8 million) in line with budget, with no deviation expected in cash burn guidance for the full year 2014 (€50-55 million).
- Solid cash position: €96.2 million as of June 30, 2014.

The Company also reported that updated data, although still maturing, for overall survival (OS), a secondary endpoint in the TG4010 TIME trial, show an improvement in line with that observed with the progression-free survival (PFS) data from the study, as reported earlier this year. The TIME Phase 2b/3 clinical trial is evaluating TG4010 in combination with chemotherapy in patients with advanced non-small cell lung cancer. Updated<sup>2</sup> results will be presented at the European Society of Medical Oncology (ESMO) 2014 Congress in Madrid, September 26-30, 2014.

*“We will continue to make significant investment in our clinical pipeline as we prepare to initiate Phase 3 trials with our two lead programs, TG4010 and Pexa-Vec, and enter a third program, TG1050, into the clinic by the end of this year”* said Stéphane Boissel, Executive Vice President and Chief Financial Officer. *“With our successful fundraising earlier this year and ongoing careful cost control, we have the near-term resources to implement our development strategy.”*

*“The first part of 2014 was a busy and exciting time for us with promising data results from the TIME trial with TG4010”* said Philippe Archinard, Chairman and Chief Executive Officer. *“Recent interaction with regulatory authorities has encouraged us to move forward with the preparations of the Phase 3 of TG4010, while we are actively seeking a development and commercialization partner for this promising cancer immunotherapy candidate.”*

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<sup>1</sup> Unaudited and not subject to approval by the Board of Directors.

<sup>2</sup> ESMO Congress rules prohibit detailed quantitative data disclosure in advance of presentation.

He continued: *“While advancing and partnering TG4010 is a high priority, our other programs also continue to make good progress. Pexa-Vec oncolytic immunotherapy is advancing in development, with several studies slated to start in 2014-2015. TG1050 for the treatment of chronic hepatitis B is slated to enter the clinic by the end of this year, and our oncolytic immunotherapy candidate TG6002 is planned to enter the clinic next year, depending on the outcome of pre-clinical tests currently underway.”*

#### **Summary of the Interim Financial Report:**

Revenue for the six-month period ending June 30, 2014 amounted to €6.3 million, compared to €6.7 million for the same period in 2013. Government financing for research expenditures still accounted for the majority of revenue, with €5.0 million as of June 30, 2014 (€5.3 million as of June 30, 2013).

Research and development expenses amounted to €26.0 million for the first six months of 2014, compared to €25.5 million for the first six months of 2013. This increase was driven mostly by pre-clinical expenses with TG1050, an immunotherapy product for the treatment of hepatitis B expected to enter the clinic by year end 2014, as well as by expenses related to the construction by Sanofi of a commercial manufacturing site co-financed by the Company.

General and administrative expenses amounted to €3.9 million for the first six months of 2014, compared to €3.3 million for the same period in 2013. This increase was mostly due to the increase in G&A headcount at the US affiliate of the Company over the two periods.

Net loss amounted to €25.1 million for the first half of 2014, compared to €23.2 million for the same period in 2013. Net loss per share was €0.65 for the first six months of 2014 compared to €0.73 for the same period in 2013.

Cash burn for the first six months of 2014, excluding the capital increases completed in the first quarter of 2014 (€62.6 million in net proceeds), was €14.8 million, which included cash burn of €12.5 million in the first quarter and €2.3 million in the second quarter of 2014. Cash burn for the second quarter was low compared to the previous quarter mainly due to the receipt of pre-financing of the 2013 research tax credit (€8.0 million), as well as SillaJen’s partial payment for the sale by the Company of its shares in Jennerex, Inc. (€2.3 million) and the receipt of some government financing for research expenditure (€1.1 million).

As of June 30, 2014, the Company had cash, cash equivalents, available-for-sale financial assets and other financial assets of €96.2 million, compared to €47.9 million as of December 31, 2013.

The Company confirmed its previous guidance for cash burn: Excluding the capital increase completed in the first quarter of 2014, Transgene expects to spend € 50-55 million to fund its operations for the full year 2014.

#### **Major News First Six Months of 2014:**

- Promising results announced with TG4010 from Phase 2b part of TIME trial in advanced non-small cell lung cancer
- Novartis informs Transgene of decision to not exercise its option on TG4010 following exclusivity period
- Clinical development plan for Pexa-Vec confirmed with global partners SillaJen and Lee’s Pharmaceutical following closing of acquisition of Jennerex, Inc. by SillaJen

- Sanofi and Transgene launch construction phase of new state-of-the-art bioproduction platform
- Rights issue and private placement successfully completed, raising €65.5 million (€62.6 million in net proceeds).

### **Expected Key Newsflow:**

#### **TG4010**

- Present results of Phase 2b part of TIME trial at ESMO 2014 Congress
- Initiate Phase 3 trial in non-small cell lung cancer
- Secure development and commercialization partnership

#### **Pexa-Vec**

- Initiate Phase 3 trial in first-line hepatocellular carcinoma (liver cancer)
- Initiate additional clinical trials in various indications

#### **R&D pipeline:**

- TG1050: Initiate first-in-humans study in chronic hepatitis B
- Continue to advance pre-clinical candidates, including oncolytic immunotherapy TG6002 and monoclonal antibody TG3003

### **About TG4010:**

TG4010, a novel MUC1 targeting immunotherapy, is in development for the treatment of metastatic NSCLC in combination with first-line chemotherapy. TG4010 is a recombinant vaccinia virus of the Ankara strain (MVA) expressing the coding sequences of the MUC1 antigen and of the cytokine, Interleukin-2 (IL2). In healthy cells, the MUC1 protein is normally found on the surface of epithelial cells in many types of tissue and works to protect these cells. In tumor cells, several modifications of MUC1 can occur: over expression, hypo-glycosylation and changes in cellular localization. These changes transform the MUC1 protein into a highly immunogenic tumor associated antigen (TAA) and make it an attractive target for cancer immunotherapy. Thus, the strategy is to induce MUC1 antigen expression in a non-tumor environment, i.e., where the immune system is fully functional, in order to induce both innate and MUC1 specific adaptive immunity. In addition to NSCLC, the MUC1 TAA is expressed in many other solid tumor types, such as lung, breast, colorectal, kidney and prostate cancers.

### **About Transgene:**

Transgene (NYSE-Euronext: TNG), a member of the Institut Mérieux Group, is a publicly traded French biopharmaceutical company focused on discovering, developing and manufacturing targeted immunotherapies for the treatment of cancer and infectious diseases. Transgene's programs utilize well-tolerated viruses with the goal of indirectly or directly killing infected or cancerous cells. The Company's two lead clinical-stage programs are: TG4010 for non-small cell lung cancer and Pexa-Vec for liver cancer. The Company has several other programs in clinical and pre-clinical development that are based on its core viral vector technology. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as satellite offices in China and the U.S. Additional information about Transgene is available at [www.transgene.fr](http://www.transgene.fr).

**Disclaimer:**

*This press release contains forward-looking statements about the Company's financial position and development programs, including TG4010. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. There can be no guarantee that (i) the results of the Phase 2b part of the TIME trial will be predictive of future results with TG4010, (ii) regulatory authorities will agree with the Company's plans for the Phase 3 part of the trial, or (iii) that the Company will find a development and commercialization partner for TG4010 in a timely manner, if at all. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product development and commercialization, and marketing approval by government regulatory authorities. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Document de Référence, which is available on the AMF website (<http://www.amf-france.org>) or on Transgene's website ([www.transgene.fr](http://www.transgene.fr)).*

*The work related to TG4010 is a contribution to ADNA (Advanced Diagnostics for New Therapeutic Approaches), a program dedicated to personalized medicine, coordinated by Institut Mérieux and supported and partially funded by the French public agency, BPI.*

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**Consolidated interim balance sheet, IFRS**  
(in thousands of euros)

<b>ASSETS</b>	<b>June 30, 2014</b>	<b>December 31, 2013</b>
<u>Current assets:</u>		
Cash and cash equivalents	8,348	5,138
Other current financial assets	87,818	42,724
<b>Cash, cash equivalents and other current financial assets:</b>	<b>96,166</b>	<b>47,862</b>
Receivables	1,206	1,896
Inventories	1,176	975
Other current assets	18,439	10,616
<b>Total current assets</b>	<b>116,987</b>	<b>61,349</b>
<u>Non-current assets:</u>		
Property, plant and equipment	23,520	23,988
Intangible assets	1,224	1,329
Financial assets	4,502	9,937
Equity consolidated affiliates	3,086	3,841
Other non-current assets	27,105	25,406
<b>Total non-current assets</b>	<b>59,437</b>	<b>64,501</b>
<b>Total assets</b>	<b>176,424</b>	<b>125,850</b>
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<b>LIABILITIES and EQUITY</b>	<b>June 30, 2014</b>	<b>December 31, 2013</b>
<u>Current liabilities:</u>		
Payables	12,854	9,364
Financial liabilities	16,796	8,830
Provisions for risks	182	103
Other current liabilities	4,844	5,699
<b>Total current liabilities</b>	<b>34,676</b>	<b>23,996</b>
<u>Non-current liabilities:</u>		
Financial liabilities	42,583	40,788
Defined benefit obligations	4,681	4,444
Other non-current liabilities	-	-
<b>Total non-current liabilities</b>	<b>47,264</b>	<b>45,232</b>
<b>Total liabilities</b>	<b>81,940</b>	<b>69,228</b>
<u>Equity:</u>		
Share capital	87,965	72,933
Share premiums	476,083	428,023
Retained earnings	(442,707)	(399,849)
Net loss for the period	(25,113)	(42,858)
Other comprehensive income	(1,744)	(1,627)
<b>Total equity and reserves attributable to equity holders of the Company</b>	<b>94,484</b>	<b>56,622</b>
<b>Total liabilities and equity</b>	<b>176,424</b>	<b>125,850</b>

**Consolidated interim income statement, IFRS**  
(in thousands of euros, except per share data)

	June 30, 2014	June 30, 2013
Revenue from collaborative and licensing agreements	1,291	1,401
Government financing for research expenditures	4,988	5,313
<b>Revenue</b>	<b>6,279</b>	<b>6,714</b>
Research and development expenses	(26,024)	(25,458)
General and administrative expenses	(3,850)	(3,265)
Other revenue and expenses, net	(197)	(226)
<b>Net operating expenses</b>	<b>(30,071)</b>	<b>(28,949)</b>
<b>Operating income / (loss)</b>	<b>(23,792)</b>	<b>(22,235)</b>
<b>Interest income and (expense), net</b>	<b>(566)</b>	<b>(805)</b>
<b>Income / (loss) before tax</b>	<b>(24,358)</b>	<b>(23,040)</b>
Income tax expense	-	-
Income from equity consolidated affiliates	(755)	(126)
<b>Net income/ (loss)</b>	<b>(25,113)</b>	<b>(23,166)</b>
Net income per share (€)	(0.65)	(0.73)
Diluted earnings per share (€)	(0.65)	(0.73)

**Comprehensive income (IFRS)**  
(in thousands of euros)

	June 30, 2014	June 30, 2013
<b>Net income / (loss)</b>	<b>(25,113)</b>	<b>(23,166)</b>
Foreign exchange gains / (losses)	(1)	3
Re-evaluation hedging instruments	(116)	168
<b>Other comprehensive income</b>	<b>(117)</b>	<b>171</b>
<b>Comprehensive income</b>	<b>(25,230)</b>	<b>(22,995)</b>
Of which, equity holder of the parent	<b>(25,230)</b>	<b>(22,995)</b>
Of which, minority interests	-	-

**Consolidated interim cash flow statement, IFRS**  
(in thousands of euros)

	June 30, 2014	June 30, 2013
<b>Cash flow from operating activities:</b>		
Net income	(25,113)	(23,166)
Elimination of financial elements	566	1,121
<b>Elimination of non-cash items:</b>		
Income from equity consolidated affiliates	755	126
Changes in provisions	252	184
Depreciation and amortization of tangible and intangible assets	1,499	1,386
Payments in shares	360	371
Others	2	182
<b>Net cash generated from / (used in) operating activities before change in working capital and other operating cash flow:</b>	<b>(21,679)</b>	<b>(19,796)</b>
<b>Change in operating working capital requirements:</b>		
Receivables	60	1,280
Inventories	(201)	210
Research tax credits	(4,959)	(3,688)
Other current assets	324	616
Payables	3,489	831
Prepaid income	(439)	(2,316)
Accrued employee benefits expense	(423)	(564)
Other current liabilities	7	(180)
<b>Net cash generated from / (used in) operating activities:</b>	<b>(23,821)</b>	<b>(23,607)</b>
<b>Cash flow from investing activities :</b>		
(Acquisition) / disposal of property, plant and equipment	(831)	(1,122)
(Acquisition) / disposal of intangible assets	(97)	(126)
Other (Acquisitions) / disposals	2,553	(2,442)
<b>Net cash generated from / (used in) investing activities:</b>	<b>1,625</b>	<b>(3,690)</b>
<b>Cash flow from financing activities</b>		
Net cash interest	-	(394)
Gross proceeds from issuance of share capital	65,654	-
Fees paid in relation to capital increase	(2,922)	-
Conditional subsidies	775	-
(Acquisitions) / disposal of other financial assets	(45,813)	22,678
Research tax credit financing	7,967	7,418
Repayment of finance lease liabilities	(254)	(301)
<b>Net cash generated from / (used in) financing activities:</b>	<b>25,407</b>	<b>29,401</b>
Effect of changes in exchange rates on cash and cash equivalents	(1)	3
<b>Net increase (decrease) in cash and cash equivalents:</b>	<b>3,210</b>	<b>2,107</b>
Cash and cash equivalents at beginning of period	5,138	6,137
<b>Cash and cash equivalents at end of period:</b>	<b>8,348</b>	<b>8,244</b>
Investments in other financial assets	87,818	63,800
<b>Cash, cash equivalents and other financial assets:</b>	<b>96,166</b>	<b>72,044</b>