

# Transgene Reports 2014 Financial Results and Outlines Promising Clinical Pipeline

- Strong year ahead for clinical activity with Company's immunotherapies, including in combination with immune checkpoint inhibitors
  - Cash and cash equivalents at December 31, 2014 of €65.9 million

**Strasbourg, France, March 24, 2015** – Transgene SA (Euronext: TNG) today announced its financial results for the fiscal year ended December 31, 2014 and provided a business update.

Clinical highlights include:

- Two Phase 3 trials in preparation for TG4010 and Pexa-Vec
- Several Phase 2 trials planned in combination with immune checkpoint inhibitors (ICIs)
- TG1050 to enter Phase 1 trial in chronic hepatitis B

More details on these developments appear later in this release.

Financial highlights include:

- Cash, cash equivalents and other financial assets at year end 2014 totaling €65.9 million compared to €47.9 million at year end 2013
- Net cash burn for 2014 of €44.9 million versus €45.0 million in 2013
- Research and development (R&D) expenses of €49.8 million for 2014 compared to €50.1 million for 2013
- Results for 2014 were in line with expectations
- Cash burn guidance for 2015 expected to be around €45 million

The financial statements for 2014 as well as management's discussion and analysis are attached to this press release (Appendices A and B).

"2014 was a busy year for Transgene, with the presentation of important clinical data with TG4010 in non-small cell lung cancer and the advancement of our pipeline, including TG4010 and Pexa-Vec, progressing towards Phase 3 initiation, and TG1050, about to enter the clinic for the treatment of chronic hepatitis B" said Philippe Archinard, Chairman and Chief Executive Officer. "The year ahead will be pivotal for Transgene. Our partnering discussions remain a priority, and, while we have not yet been able to conclude a deal for TG4010, these efforts are ongoing. In addition, we remain focused on driving forward the development of our two most advanced programs – TG4010 and Pexa-Vec. Furthermore, we intend to initiate within one year clinical trials in combination with immune checkpoint inhibitors (ICIs), a promising area of immunotherapy treatment that we believe is highly complementary to our immunotherapy approach." Eric Quéméneur, Executive Vice President and Vice President, Research & Development, stated: "Our R&D efforts are focused on value generation – in the short term through supporting our clinical-stage product candidates and for the longer term by identifying and characterizing the next generation of Transgene immunotherapies. We are currently conducting an ambitious pre-clinical program to evaluate the combination of our product candidates with immune checkpoint inhibitors and to guide our clinical programs. We look forward to publishing these results and presenting them in April at the upcoming Annual Meeting of the American Association for Cancer Research (AACR). To achieve our goals, we are also collaborating with leading academic, medical and industry institutions to complement our internal team's strengths, an outreach effort that we have expanded in recent months."

# Update on key development programs

The Company provided the following update on its development programs.

**TG4010 MUC-1 targeted immunotherapy:** In September 2014, data from the Phase 2b part of the Phase 2b/3 TIME trial evaluating TG4010 in combination with chemotherapy versus placebo plus chemotherapy in the first-line treatment of advanced non-small cell lung cancer (NSCLC) patients were presented at the European Society of Medical Oncology (ESMO) 2014 Congress. The data presented showed promising and consistent results in progression-free survival and overall survival, particularly in patients with non-squamous histology.

Transgene is finalizing a global development plan which includes two key parts:

- The initiation of the Phase 3 part of the TIME trial for the first-line treatment of nonsquamous NSCLC patients, subject to a partnering event.
- The initiation of Phase 2 trials in combination with ICIs in both first- and second-line NSCLC patients within one year.

Transgene has already produced promising pre-clinical results evaluating TG4010 in combination with several ICIs. Some of these data will be presented at the upcoming Annual Meeting of the American Association for Cancer Research (AACR) in April.

**Pexa-Vec oncolytic immunotherapy:** Transgene and its partners SillaJen, Inc. and Lee's Pharmaceutical are preparing to initiate a global Phase 3 trial in the first-line treatment of advanced liver cancer, and this trial is now planned to start in the fourth quarter of 2015. Transgene is also independently initiating exploratory trials in various cancers, including in combination with an ICI, which are planned to be initiated within one year.

**TG1050** adenovirus-based immunotherapy: This immunotherapeutic is being developed for the treatment of chronic hepatitis B. The Company expects to enroll the first patient in a first-in-humans clinical trial in mid-2015.

**TG4001:** Transgene has made the decision to not move forward with the previously announced study in oropharyngeal (oral cavity) cancer caused by human papilloma virus (HPV), which was to be conducted with the EORTC (European Organization for Research and Treatment of Cancer), a European cancer cooperative group. Instead, the Company has made the decision to focus further development efforts on evaluating TG4001 in combination with ICIs in advanced HPV-induced cancer. The Company is interacting with both academic and industry partners with the goal of initiating such a trial as soon as possible.

**Earlier stage pipeline:** The Company also has a rich pipeline of earlier stage programs. This includes TG3003, a pre-clinical stage monoclonal antibody against an important cancer target, CD115, the CSF1 receptor. Data with TG3003 are to be presented at the upcoming AACR Annual Meeting in April. TG6002, an oncolytic immunotherapy being developed for the treatment of solid tumors, is also in pre-clinical testing. The Company also has a research program to develop an active immunotherapeutic to treat tuberculosis (TB), including drug-resistant TB, and several potential product candidates have been generated and are currently being evaluated to determine the best one to advance into further development.

# Potential newsflow next 12 months

# TG4010

- Partnership
- Initiation of the Phase 3 part of the TIME trial with a partner
- Presentation of clinical and pre-clinical data at upcoming medical and scientific conferences, including the AACR Annual Meeting
- Initiation of Phase 2 trials in combination with ICIs

# Pexa-Vec

- Initiation of Phase 3 trial in first-line hepatocellular carcinoma
- Initiation of two clinical trials in various indications, including combination trial with an ICI

# TG1050

- Enrollment of first patient in Ph1/1b trial for the treatment of chronic hepatitis B
- Presentation of pre-clinical data at upcoming medical and scientific conferences, including the International Liver Congress<sup>™</sup> (EASL)

# Pipeline

- Continued advancement of pre-clinical candidates such as TG6002 towards the clinic
- Presentation of pre-clinical data at upcoming scientific conferences, including the AACR Annual Meeting

# Conference call and analyst meeting scheduled

A conference call in English has been scheduled for Wednesday, March 25, 2015 at 2 PM CET/9 AM EST. A replay of the call will be available on the Transgene website (<u>www.transgene.fr</u>) following the live event.

In addition, an analyst (SFAF) meeting, to be conducted in French, has been scheduled for Wednesday, March 25, 2015 at 11:30 AM CET at Maison des Arts & Métiers (Salon Liancourt), 9bis, Avenue d'Iéna, Paris.

### Webcast link to English language conference call:

### http://edge.media-server.com/m/p/s2grgv7n

#### Webcast access on mobile devices - QR code:

For access to the live and on demand webcast from any IOS apple or Android mobile devices:



#### Participant telephone numbers:

France:	+33(0)1 76 77 22 25
United Kingdom:	+44(0)20 3427 1910
US:	+1 646 254 3367

Confirmation Code: 7377606

Participants will need to provide the above code when dialing into the call.

#### **About Transgene**

Transgene (Euronext: TNG), part of Institut Mérieux, 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 viral vector technology 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.

#### Disclaimer

This press release contains certain forward-looking statements about the Company's financial situation, including statements about cash burn and statements about the future development of its product candidates. 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 and 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 and its Actualisation, which are available on the AMF website (http://www.amffrance.org) or on Transgene's website (www.transgene.fr).

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## **APPENDICES: 2014 CONSOLIDATED FINANCIAL STATEMENTS**

The 2014 consolidated financial statements were approved by the Board of Directors on March 24, 2015, and will be submitted for approval by the shareholders of the Company during the next annual general meeting on June 11, 2015. Audit procedures have been performed and the delivery of the auditors' report is ongoing.

# Appendix A: 2014 Financial Statements

# Consolidated balance sheet (IFRS)

(in thousands of euros)

ASSETS	December 31,	December 31,
	2014	2013
Current assets:	2 542	5 400
Cash and cash equivalents	3,513	5,138
Other current financial assets	62,422	42,724
Cash, cash equivalents and other current financial assets:	65,935	47,862
Receivables	1,540	1,896
Inventories	1,149	975
Other current assets	10,614	10,616
Total current assets	79,238	61,349
Non-current assets:		
Property, plant and equipment	23,641	23,988
Intangible assets	1,056	1,329
Financial assets	3,852	9,937
Equity consolidated affiliates	2,320	3,841
Other non-current assets	30,846	25,406
Total non-current assets	61,715	64,501
Total assets	140,953	125,850
LIABILITIES and EQUITY	December 31,	December 31,
Current liabilities:	2014	2013
Payables	8,296	9,364
Financial liabilities	8,992	8,830
Provisions for risks	127	103
Other current liabilities	4,148	5,699
Total current liabilities	•	-
	21,563	23,996
Non-current liabilities:	12 100	40 700
Financial liabilities	43,199	40,788
		4,444
Defined benefit obligations	4,352	
Other non-current liabilities	-	-
Other non-current liabilities Total non-current liabilities	47,551	45,232
Other non-current liabilities Total non-current liabilities Total liabilities	-	- 45,232 69,228
Other non-current liabilities Total non-current liabilities Total liabilities Equity:	- 47,551 69,114	69,228
Other non-current liabilities Total non-current liabilities Total liabilities Equity: Share capital	- 47,551 69,114 88,156	<b>69,228</b> 72,933
Other non-current liabilities Total non-current liabilities Total liabilities Equity: Share capital Share premiums	- 47,551 69,114 88,156 476,255	<b>69,228</b> 72,933
Other non-current liabilities Total non-current liabilities Total liabilities Equity: Share capital	- 47,551 69,114 88,156	<b>69,228</b> 72,933 428,023
Other non-current liabilities Total non-current liabilities Total liabilities Equity: Share capital Share premiums	- 47,551 69,114 88,156 476,255	<b>69,228</b> 72,933 428,023 (399,849)
Other non-current liabilities Total non-current liabilities Equity: Share capital Share premiums Retained earnings	- 47,551 69,114 88,156 476,255 (442,707)	<b>69,228</b> 72,933
Other non-current liabilities Total non-current liabilities Total liabilities Equity: Share capital Share premiums Retained earnings Net loss	- 47,551 69,114 88,156 476,255 (442,707) (48,556)	<b>69,228</b> 72,933 428,023 (399,849) (42,858)

# **Consolidated income statement (IFRS)** (In thousands of euros, except per share data)

	December 31, 2014	December 31, 2013
Revenue from collaborative and licensing agreements	2,490	3,849
Government financing for research expenditures	9,262	11,886
Revenue	11,752	15,735
Research and development expenses	(49,824)	(50,063)
General and administrative expenses	(7,578)	(6,769)
Other revenue and (expenses), net	(1,282)	(101)
Net operating expenses	(58,684)	(56,933)
Operating income / (loss)	(46,932)	(41,198)
Interest income and (expense), net	(801)	(730)
Income / (loss) before tax	(47,733)	(41,928)
Income tax expense	-	-
Income from equity consolidated affiliates	(823)	(930)
Net income/ (loss)	(48,556)	(42,858)
Net income per share (€)	(1.26)	(1.34)
Diluted earnings per share (€)	(1.26)	(1.34)

# Consolidated statement of comprehensive income (IFRS)

(In thousands of euros)

	December 31, 2014	December 31, 2013
Net income / (loss)	(48,556)	(42,858)
Foreign exchange gains / (losses)	18	(16)
Re-evaluation hedging instruments	(159)	217
Actuarial gains and losses on provision for retirements benefits	459	247
Other comprehensive income	318	448
Comprehensive income	(48,238)	(42,410)
Of which, equity holder of the parent	(48,238)	(42,410)
Of which, minority interests	-	-

# Statement of cash flows (IFRS)

(In thousands of euros)

	December 31, 2014	December 31, 2013
Cash flow from operating activities:		
Net income	(48,556)	(42,858)
Elimination of financial elements	801	731
Elimination of non-cash items:		
Income from equity consolidated affiliates	824	930
Changes in provisions	267	97
Depreciation and amortization of tangible and intangible assets	3,039	2,911
Payments in shares	721	742
Others	1,034	191
Net cash generated from / (used in) operating activities before change in working capital and other operating cash flow:	(41,870)	(37,256)
Change in operating working capital requirements:		
Receivables	(977)	188
Inventories	(174)	133
Research tax credits	(8,702)	(9,073)
Other current assets	(61)	(614)
Payables	(899)	(156)
Prepaid income	(533)	(3,126)
Accrued employee benefits expense	(1,036)	(111)
Other current liabilities	16	(170)
Net cash generated from /(used in) operating activities:	(54,236)	(50,185)
Cash flow from investing activities :		
(Acquisition) / disposal of property, plant and equipment	(2,463)	(1,962)
(Acquisition) / disposal of intangible assets	(139)	(222)
(Acquisition) / disposal of financial assets	3,134	(2,446)
Net cash generated from / (used in) investing activities:	532	(4,630)
Cash flow from financing activities		
Net cash interest	(4)	244
Gross proceeds from issuance of share capital	65,664	70
Fees paid in relation to capital increase	(2,929)	-
Conditional subsidies	955	2,929
(Acquisition) / disposal of other financial assets	(19,445)	43,931
Tax credits financing	8,438	7,418
Repayment of finance lease liabilities	(618)	(760)
Net cash generated from /(used in) financing activities:	52,061	53,832
Effect of changes in exchange rates on cash and cash equivalents	18	(16)
Net increase (decrease) in cash and cash equivalents:	(1,625)	(999)
Cash and cash equivalents at beginning of period	5,138	6,137
Cash and cash equivalents at end of period:	3,513	5,138
Investments in other financial assets	62,422	42,724

# Appendix B: Management Discussion of 2014 Financials

During the periods under review, revenues from collaborative and licensing agreements mainly included the following:

- manufacturing or research services for third parties (including for, Jennerex, Inc. for Pexa-Vec, and for Emergent Biosolutions, Inc. for a product candidate against tuberculosis) amounting to €1.7 million in 2014 (€2.2 million in 2013);
- "upfront payment" or "milestone" income for products under development, amounting to €0.2 million in 2014 (€1.0 million in 2013); and
- income related to commercial use of technologies or products provided under license by Transgene, amounting to €0.6 million in 2014 (same as in 2013).

At December 31, 2014, government financing for research expenditures corresponded to grants received and receivable, as well as a research tax credit. Research grants amounted to  $\notin 0.6$  million in 2014 ( $\notin 3.1$  million in 2013). In 2014, grants were provided mainly by the ADNA (Advanced Diagnostics for New Therapeutic Approaches) program funded by Bpifrance. Transgene could collect receive up to  $\notin 0.8$  million in additional funding over the remainder of the program, i.e. until 2016.

The research tax credit (CIR - crédit impôt recherche) totaled €8.8 million in 2014 (€8.9 million in 2013). Eligible expenses (net of grants received during the fiscal year) amounted to €29.3 million in 2014 and €29.6 million in 2013. In 2014, lower eligible expenses were offset by lower public financing of research expenditures. The decrease in eligible R&D expenses between 2013 and 2014 (€30.7 million in 2014 versus €33.1 million in 2013) is due to the decrease in clinical trial expenses (use of companies such as CRO – contract research organization) and the outsourcing of eligible research (€7.3 million in 2014 versus €9.8 million in 2013), which was partly offset by an increase in employee costs and operating expenses eligible for the CIR (€22.2 million in 2014 versus €21.9 million in 2013). This reduction leads to an increase in the basis of expenses eligible for the calculation of the tax credit.

### **Operating expenses:**

R&D expenses amounted to €49.8 million in 2014, stable compared to 2013 (€50.1 million).

The following table details R&D expenses by type:

In millions of Euros	Dec. 31, 2014	Dec. 31, 2013	Change
Payroll costs	19.8	19.4	+2%
Share-based payments	0.5	0.6	-17%
Intellectual property expenses and licensing costs	1.3	1.7	-24%
External expenses for clinical projects	7.6	12.5	-39%
External expenses for other projects	7.6	3.9	+95%
Operating expenses	10.1	9.3	+9%
Depreciation and provisions	2.9	2.7	+7%
Research and development expenses	49.8	50.1	-0.5%

Employee costs allocated to R&D (salaries, employer contributions and related expenses) amounted to €19.8 million in 2014, compared to €19.4 million in 2013. The Company's R&D workforce decreased slightly in 2014 (243 full-time equivalents in 2014 versus 246 in 2013).

Expenses for intellectual property and licensing amounted to €1.3 million in 2014 versus €1.7 million in 2013.

External expenses for clinical trials amounted to €7.6 million in 2014 versus €12.5 million in 2013. This significant decrease (-39%) was due to the following:

- the decrease , in 2014, in the number of patients treated in the Phase 2b part of the Phase 2b/3 TIME trial with TG4010 in lung cancer following the completion of this part of the study (€4.8 million in external expenses for this product in 2014 versus €8.1 million in 2013);
- the completion, in 2014, of the TRAVERSE study, a Phase 2b clinical trial with Pexa-Vec for the second-line treatment of advanced liver cancer, which was still recruiting patients in 2013 (€1.4 million in external expenses for this product in 2014 versus €3.4 million in 2013);
- conversely, the costs for preparing the Phase 3 part of the Phase 2b/3 TIME trial with TG4010 in lung cancer amounted to €1.1 million in 2014.

Other external expenses, including expenses for research, pre-clinical and manufacturing projects, amounted to  $\notin$ 7.6 million in 2014 versus  $\notin$ 3.9 million in 2013. This sharp increase (95%) was mainly due to the decision taken at the beginning of the year to launch the construction of a commercial batch production unit in collaboration with Sanofi/Genzyme ( $\notin$ 2.6 million in external expenses in 2014 versus  $\notin$ 0.2 million in 2013), and the initiation of regulatory toxicology studies (preclinical studies) with various product candidates ( $\notin$ 1.1 million in external expenses in 2014 versus  $\notin$ 0.1 million in 2013).

Operating expenses, including the cost of operating research laboratories and Transgene's manufacturing facility, amounted to  $\leq 10.1$  million in 2014 versus  $\leq 9.3$  million in 2013. This increase stems from the following: the use of raw materials and consumables ( $\leq 4.9$  million in 2014 versus  $\leq 4.6$  million in 2013); and the implementation of a program for IT hosting and backup amounting to  $\leq 0.4$  million in 2014 versus  $\leq 0.2$  million in 2013.

General and administrative expenses amounted to €7.6 million in 2014 versus €6.8 million in 2013.

In millions of Euros	Dec. 31, 2014	Dec. 31, 2013	Change
Payroll costs	3.7	3.2	+16%
Share-based payments	0.2	0.2	N/S
Fees and administrative expenses	2.5	2.3	+9%
Other fixed costs	1.1	0.9	+22%
Depreciation and provisions	0.1	0.2	-50%
General and administrative expenses	7.6	6.8	+12%

The following table details general and administrative expenses by type:

Employee costs amounted to  $\notin 3.7$  million in 2014 versus  $\notin 3.2$  million in 2013. This increase is mainly due to an increase in the number of senior employees in the Company's U.S. subsidiary. The number of employees working in administrative functions decreased slightly between 2013 and 2014 (23 full-time equivalents in 2014 versus 27 in 2013).

Fees and administrative expenses amounted to €2.5 million in 2014 versus €2.3 million in 2013.

### Other revenue and expenses, net

Other expenses, net amounted to €1.3 million in 2014 versus €0.1 million in 2013.

In July 2014, the U.S. Company ABL, Inc. acquired a majority interest in Platine Pharma Services SAS. Prior to the transaction, a part of the losses of Platine were re-absorbed through a capital reduction. The transaction was followed by a free transfer to ABL of shares held by Transgene and the two other main shareholders, Innate Pharma and Indicia. These transactions resulted in a loss of €0.7 million in 2014.

The sale of shares in Jennerex, Inc. in April 2014 also generated a net expense of  $\notin 0.2$  million in 2014, corresponding to the difference between the actual amount received and the estimate of the receivable, versus the value of the shares on the balance sheet.

### Financial income (expense):

A net financial expense of €0.8 million was recognized in 2014 versus €0.7 million in 2013.

Financial income (investment income) amounted to €0.3 million in 2014 versus €0.7 million in 2013.

The main financial expenses consisted of bank interest on the financing of the research tax credit ( $\notin 0.4$  million), the discounting of the advances received by Bpifrance under the ADNA program ( $\notin 0.6$  million), and interest on the property finance lease ( $\notin 0.2$  million).

### Net loss:

Net loss for 2014 was €48.6 million (€42.9 million in 2013). Net loss per share was €1.26 in 2014 (€1.34 in 2013).

## Investments:

Investments in tangible and intangible assets (net of disposals) amounted to  $\in 2.3$  million in 2014 ( $\notin 2.1$  million in 2013).

## Repayable advances and loans:

In 2014, the Company used its 2013 research tax credit of €8.9 million. To this effect, it took out a bank loan with Bpifrance that matures in mid-2017, at which time the receivable is expected to be paid by the French government.

In 2014, Transgene also received €0.8 million (versus €2.9 million in 2013) in repayable advances for the ADNA program, which receives public funding from Bpifrance. Since the start of the ADNA program, the Company has received €13.4 million in repayable advances under this program. The Company may receive up to €2.6 million in additional repayable advances over the remaining term of the ADNA program, i.e., until 2016.

# Liquidity and capital resources:

On March 25, 2014, the Company announced that a total of €65.5 million was raised via a capital increase in two steps:

- a capital increase with preferential subscription rights, launched on February 28, 2014, which raised gross proceeds of €45.5 million; and
- a private placement completed on March 24, 2014, which raised €20 million.

The Company's cash is invested in short-term money-market mutual funds or placed, under market conditions, in a cash pool arranged by the majority shareholder of Transgene, Institut Mérieux.

At December 31, 2014, the Company's available cash amounted to €65.9 million versus €47.9 million at December 31, 2013.

At the date of this Registration Document, the Company had no bank debt subject to covenants.

# Cash flow:

Excluding the issuance of shares, the Company's net cash consumption amounted to €44.9 million in 2014 versus €45.0 million in 2013.

### Post-closing events:

None

# <u>Risk factors:</u>

Risk factors are presented in Section 1.5 of the Document de Référence.