

Transgene Reports 2015 Financial Results and Provides Outlook for 2016

- **Solid financial position:**
 - **2015 year-end cash available of €31.7 million, plus up to €30 million in additional financing secured in January 2016**
- **Implementation of new development strategy underway:**
 - **Ambitious development plan with Transgene's immunotherapy product candidates in combination with immune checkpoint inhibitors**

Conference call and webcast (in English) March 9 at 2:30pm CET (1:30pm GMT/8:30am EST)

Strasbourg, France, March 8, 2016 – Transgene SA (Euronext: TNG) today announced its financial results for the fiscal year ended December 31, 2015 and provided an outlook for 2016.

Financial Year 2015 highlights:

- Net cash burn for 2015 decreased by 22.5% to €34.8 million, versus €44.9 million in 2014
- Cash available at year-end 2015 were €31.7 million compared to €65.9 million at year-end 2014
- R&D expenses of €32.1 million compared to €41.7 million in 2014
- Restructuring costs of €7.5 million in 2015
- Net loss of €46.4 million in 2015, including restructuring costs, compared to €48.6 million in 2014

The financial statements for 2015 as well as management's discussion and analysis are attached to this press release (Appendices A and B).

Key Operational Achievements 2015:

- TG4010 (Targeted active immunotherapy to treat MUC1-expressing solid tumors)
 - Data from TIME Phase 2b trial in non-small cell lung cancer (NSCLC) presented at the American Society of Clinical Oncology (ASCO) Annual Meeting and at the World Conference on Lung Cancer
 - Data from TIME trial published in *The Lancet Oncology*
 - New pre-clinical data presented at the American Association for Cancer Research (AACR) Annual Meeting of TG4010 in combination with immune checkpoint inhibitors (ICIs)
- Pexa-Vec (Oncolytic immunotherapy to treat solid tumors)
 - Agreement with FDA for Special Protocol Assessment (SPA) for Phase 3 trial (PHOCUS trial) in advanced hepatocellular carcinoma (HCC, liver cancer)
 - First patient treated in PHOCUS Phase 3

- TG1050 (For the treatment of chronic hepatitis B)
 - New pre-clinical data presented at The International Liver Congress™ 2015
 - Initiation of a first clinical trial in patients chronically infected by the hepatitis B virus.
- Corporate restructuring implemented to focus on research and development
- New phase in strategic development focusing on combination trials with ICIs and strengthening of translational research

Development Strategy and Financial Resources

Philippe Archinard, Chairman and Chief Executive Officer, stated: *“Our strategic priority is to develop our products in combination with ICIs and existing standard of care. The implementation of our ambitious development plan in combination with ICIs is well underway. In addition, the promising TG4010 data accumulated to date places us in a position to now consider a possible Conditional Marketing Approval¹ submission in Europe. We are currently evaluating the means by which such a project, including the associated phase 3 trial in first line NSCLC, could be implemented. We will provide an update when available.”* Philippe Archinard added: *“We are in an excellent position to carry out our plans and achieve the goal of becoming a leader in active immunotherapies in oncology and infectious diseases.”*

Following the completion of its restructuring plan, Transgene announced on the 7th January 2016, its strategy based on its unique and well-known strengths in the immune-engineering of viral vectors and on its expertise in pre-clinical and clinical development. Transgene’s strategy is to give priority to combination studies with other immunotherapy products, including ICIs.

Transgene is an active player in this new paradigm where it has key strengths. Combining active immunotherapeutics with ICIs has been widely validated by the scientific community and it offers Transgene the potential to further assess synergies in the treatment of certain cancers and infectious diseases, with the aim of improving treatment outcomes and the quality of life of patients.

Transgene is in ongoing discussions with clinical and biopharmaceutical partners to start at least five clinical studies in combination with ICIs for its two most advanced products. These studies should be initiated during the second half of 2016.

The main combination programs are:

- Combination of TG4010 with an ICI in the first- and second-line treatment of advanced non-small cell lung cancer (NSCLC) patients.
- Combination of Pexa-Vec with an ICI in the first-line treatment of advanced HCC, and as well as for the treatment of other solid tumors.

Transgene is also further strengthening its translational research capabilities through collaborations with academic institutions. Transgene expects to organize an R&D day in the second half of 2016 to showcase its capabilities and partnerships.

After the close of fiscal year 2015, Transgene announced that it had secured up to €30 million in new funding from two sources:

¹ CMA: conditional marketing approvals are granted to products that address unmet medical needs and whose availability would result in a significant public health benefit. Consideration for full marketing authorization is contingent upon the completion of a Phase III study.

- A loan of €20 million from the EIB (European Investment Bank) under the IDFF (Infectious Diseases Finance Facility) program.
- A commitment by its major shareholder, Institut Mérieux, to provide additional funding of approximately €10 million. Details of the financing will be provided at a later date.

With these new sources of funding and the impact of the restructuring plan, the Company should have sufficient funds for scheduled operating activities through 2017.

Jean-Philippe Del, Vice President, Finance, said: *“During 2015 we implemented a cost savings plan to complement the restructuring program and took the steps necessary to secure additional financing, which we were able to obtain early this year. With the new structure now in place, we are in a good position to effectively implement our ambitious development plans and advance the Company’s goals”.*

Operational Outlook - next 12 months:

The Company provided information on potential newsflow during the next 12 months:

- TG4010
 - Initiate Phase 1/2 trials in NSCLC
 - Combination study with nivolumab in second line stage IV patients, to be conducted in the US
 - Combination study with ICI and chemotherapy in first line stage IV patients, to be conducted in Europe
 - Neo-Adjuvant study in early stage patients to be conducted in Europe
- Pexa-Vec: Initiate Phase 1/2 trials
 - Combination study with nivolumab in first-line advanced HCC
 - Combination study with ipilimumab in advanced solid tumors
- TG1050: First safety readout from Phase 1 trial
- TG6002 (oncolytic viral immunotherapy for the treatment of solid tumors): First-in-humans trial initiation in Glioblastoma patients.

Financial outlook 2016:

The restructuring started in 2015 will produce significant savings in fixed costs beginning in 2016:

- From 2016, we expect a reduction in overall operating costs of more than €10 million compared to full year 2015.
- As previously announced, cost of restructuring plan estimated at around €7.5 million, with negative cash impact of approximately €6 million in 2016
- Manufacturing plant and associated assets recently sold for €3.5 million

Transgene stated that it expects cash burn for 2016 to be around €35 million, which includes the conduct of ongoing clinical trials, as well as the initiation of several new combination trials with its immunotherapy programs and ICIs. Projected cash burn includes extraordinary items such as the €6 million in restructuring costs and a milestone payment to SillaJen, Inc. of \$4 million for the first patient enrolled in Europe in the PHOCUS Phase 3 trial with Pexa-Vec in HCC.

Conference call and analyst meeting scheduled:

A conference call in English has been scheduled for **March 9th, 2016 at 02:30pm CET (08:30am EST)**. A replay of the call will be available on the Transgene website (www.transgene.fr) following the live event.

In addition, an analyst (SFAF) meeting, to be conducted in French, has been scheduled for March 9th, at 11:30am CET at Convention Center Etoile Saint-Honoré, 21-25 rue de Balzac, Paris 8.

Webcast link to English language conference call:

<http://edge.media-server.com/m/p/83u89cx8>

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 27
United Kingdom:	+44 (0)20 3427 1905
US:	+1 646 254 3362
Confirmation Code:	3348416

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

About Transgene

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biopharmaceutical company focused on discovering and developing 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. 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 forward-looking statements, which 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 further development plans for TG4010, or (iii) the Company will find partners for its immunotherapies products in a timely manner and on satisfactory terms and conditions, 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 manufacturing, 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, available on the AMF website (<http://www.amf-france.org>) or on Transgene's website (www.transgene.fr). Forward-looking statements speak only as of the date on which they are made and Transgene undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.

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APPENDICES: 2015 CONSOLIDATED FINANCIAL STATEMENTS

The 2015 consolidated financial statements were approved by the Board of Directors on March 7, 2016, and will be submitted for approval by the shareholders of the Company during the next annual general meeting on May 24, 2016. Audit procedures have been performed and the delivery of the auditors' report is ongoing.

Appendix A: 2015 Financial Statements

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

ASSETS	December 31, 2015	December 31, 2014
<u>Current assets:</u>		
Cash and cash equivalents	3,285	3,513
Other current financial assets	28,365	62,422
Cash, cash equivalents and other financial assets:	31,650	65,935
Trade receivables	1,784	1,540
Inventories	1,164	1,149
Other current assets	12,930	10,614
Assets held for sale	3,500	-
Total current assets	51,028	79,238
<u>Non-current assets:</u>		
Property, plant and equipment	16,559	23,641
Intangible assets	485	1,056
Non-current financial assets	4,050	3,852
Equity consolidated affiliates	1,148	2,320
Other non-current assets	27,599	30,846
Total non-current assets	49,841	61,715
Total assets	100,869	140,953
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LIABILITIES AND EQUITY	December 31, 2015	December 31, 2014
<u>Current liabilities:</u>		
Trade payables	6,521	8,296
Financial liabilities	9,396	8,992
Provision for risks and charges	7,038	127
Other current liabilities	3,770	4,148
Total current liabilities	26,725	21,563
<u>Non-current liabilities:</u>		
Financial liabilities	44,401	43,199
Employee benefits	3,196	4,352
Other non-current liabilities	-	-
Total non-current liabilities	47,597	47,551
Total liabilities	74,322	69,114
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<u>Equity:</u>		
Capital	88,196	88,156
Share premium	476,788	476,255
Retained earnings	(491,263)	(442,707)
Net loss for the period	(46,374)	(48,556)
Other comprehensive income	(800)	(1,309)
Total equity and reserves attributable to Company shareholders	26,547	71,839
Total liabilities and equity	100,869	140,953

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

	December 31, 2015	December 31, 2014
Revenue from collaborative and licensing agreements	1,465	1,837
Government financing for research expenditure	8,100	9,262
Revenue	9,565	11,099
Research and development expenses	(32,138)	(41,731)
General and administrative expenses	(5,798)	(7,578)
Other revenue and (expenses), net	(7,436)	(1,282)
Net operating expenses	(45,372)	(50,591)
Operating income / (loss)	(35,807)	(39,492)
Interest income/(expense), net	(930)	(801)
Income from equity consolidated affiliates	(1,172)	(823)
Income / (loss) before tax	(37,909)	(41,116)
Income tax expense	-	-
Net income / (loss) from continuing operations	(37,909)	(41,116)
Net income / (loss) from discontinued operations	(8,465)	(7,440)
Net income/(loss)	(46,374)	(48,556)
Net income per share (€)	(1.20)	(1.26)
Diluted earnings per share (€)	(1.20)	(1.26)

Comprehensive income (IFRS)
(in thousands of euros)

	December 31, 2015	December 31, 2014
Net income / (loss)	(46,374)	(48,556)
Foreign exchange gains / (losses)	28	18
Re-evaluation hedging instruments	115	(159)
Other comprehensive income re-classifiable into profit or loss	143	(141)
Actuarial gain / (losses) on provision for retirements	366	459
Other comprehensive income non re-classifiable into profit or loss	366	459
Other comprehensive	509	318
Comprehensive income (loss)	(45,865)	(48,238)
<i>Of which, equity holder of the parent:</i>	<i>(45,865)</i>	<i>(48,238)</i>
<i>Of which, minority interests:</i>	<i>-</i>	<i>-</i>

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

	December 31, 2015	December 31, 2014
Cash flow from operating activities:		
Net income	(46,374)	(48,556)
Elimination of financial elements	930	801
Elimination of non-cash items		
Income from equity consolidated affiliates	1,172	824
Changes in provisions	8,697	267
Depreciation and amortization of tangible and intangible assets	2,636	3,039
Payment in shares	462	721
Others	11	1,034
Net cash generated from / (used in) operating activities before change in working capital and other operating cash flow:	(32,466)	(41,870)
Change in operating working capital:		
Receivables	73	(977)
Inventories	(14)	(174)
Research tax credit	(8,532)	(8,702)
Other current assets	(2,150)	(61)
Trade payables	(1,685)	(899)
Prepaid income	461	(533)
Employee benefits	(841)	(1,036)
Other current liabilities	2	16
Net cash generated from / (used in) operating activities:	(45,152)	(54,236)
Cash flow from investing activities :		
(Acquisition) / disposal of property, plant and equipment	(1,527)	(2,463)
(Acquisition) / disposal of intangible assets	0	(139)
Other (Acquisitions) / disposals	3,843	3,134
Net cash generated from / (used in) investing activities:	2,316	532
Cash flow from financing activities		
Net cash interest	(165)	(4)
Gross proceeds from issuance of share capital	477	65,664
Fees paid in relation to capital increase	0	(2,929)
Conditional subsidies	923	955
(Acquisition) / disposal of other financial assets	34,176	(19,445)
Research tax credit financing	8,209	8,438
Repayment of finance lease liabilities	(1,040)	(618)
Net cash generated from / (used in) financing activities:	42,580	52,061
Effect of changes in exchange rates on cash and cash equivalents	28	18
Net increase/ (decrease) in cash and cash equivalents:	(228)	(1,625)
Cash and cash equivalents at beginning of period	3,513	5,138
Cash and cash equivalents at end of period:	3,285	3,513
Investments in other financial assets	28,365	62,422
Cash, cash equivalents and other financial assets:	31,650	65,935

Appendix B: Management Discussion of 2015 Financials

Revenue:

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

- research and development services for third parties (including Emergent Biosolutions, Inc. for a product candidate against tuberculosis) amounting to €0.8 million in 2015 (€1.0 million in 2014); and
- income related to commercial use of technologies or products provided under license by Transgene, amounting to €0.7 million in 2015 (€0.6 million in 2014).

At December 31, 2015, government financing for research expenditures consisted of grants received and receivable, as well as a research tax credit.

Research grants amounted to €0.2 million in 2015 (€0.6 million in 2014).

The research tax credit (CIR - crédit impôt recherche) amounted to €7.9 million in 2015 (€8.8 million in 2014). Related eligible expenses (net of grants received during the fiscal year) amounted to €25.8 million in 2015 and €29.8 million in 2014. This decrease in expenses was due to lower eligible research and development (R&D) expenses (€26.9 million in 2015 versus €31.2 million in 2014), including operating expenses, clinical trial expenses and outsourced R&D expenses.

Operating expenses:

R&D expenses amounted to €32.1 million in 2015, compared to €41.7 million in 2014, at constant perimeter. This decrease was due to (i) a reduction in payroll costs and operating expenses as a result of the restructuring plan initiated in 2015, and (ii) a decrease in external expenses for clinical and other projects.

The following table details R&D expenses by type:

In millions of euros	Dec. 31, 2015	Dec. 31, 2014	Change
Payroll costs	14.6	16.1	-9%
Share-based payments	0.3	0.5	-40%
Intellectual property expenses and licensing costs	1.5	1.3	+15%
External expenses for clinical projects	4.2	7.6	-45%
External expenses for other projects	4.4	7.6	-42%
Operating expenses	5.1	6.7	-24%
Depreciation and provisions	2.0	1.9	+5%
Research and development expenses	32.1	41.7	-23%

Employee costs allocated to R&D (salaries, employer contributions and related expenses) amounted to €14.6 million in 2015, compared to €16.1 million in 2014. This decrease was due to the cost savings measures implemented in 2015, including not filling job openings and not renewing temporary employment contracts, as a complement to the restructuring plan.

Intellectual property and licensing expenses amounted to €1.5 million in 2015 versus €1.3 million in 2014.

External expenses for clinical trials amounted to €4.2 million in 2015 versus €7.6 million in 2014. This significant decrease (-45%) was due to the following:

- the decrease in 2015 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 and in development costs for related companion diagnostic tests (€1.5 million in external expenses for this program in 2015 versus €4.8 million in 2014);
- 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 (no external expenses in 2015 versus €1.4 million in 2014);
- conversely, costs in 2015 related to the initiation of two new clinical trials - a Phase 3 trial with Pexa-Vec and a Phase 1 trial with TG1050 - of €1.7 million and €0.8 million, respectively.

Other external expenses, including expenses for research, pre-clinical and manufacturing projects, amounted to €4.4 million in 2015 versus €7.6 million in 2014. This decrease was due to lower expenses related to regulatory toxicology studies and sub-contracting manufacturing of TG1050 (€0.3 million in 2015 versus €1.5 million in 2014) and a decrease in expenses for the commercial production unit with Sanofi/Genzyme (€1.8 million in 2015 versus €2.6 million in 2014).

Operating expenses, including the cost of operating research laboratories, amounted to €5.1 million in 2015 versus €6.7 million in 2014.

General and administrative (G&A) expenses amounted to €5.8 million in 2015 versus €7.6 million in 2014.

The following table details G&A expenses by type:

In millions of euros	Dec. 31, 2015	Dec. 31, 2014	Change
Payroll costs	2.9	3.7	-22%
Share-based payments	0.1	0.2	-50%
Fees and administrative expenses	1.7	2.5	-32%
Other fixed costs	1.0	1.1	-9%
Depreciation and provisions	0.1	0.1	N/S
General and administrative expenses	5.8	7.6	-24%

Employee costs allocated to G&A amounted to €2.9 million in 2015 versus €3.7 million in 2014. This decrease was mainly due to a staff reduction in financial and administrative support functions.

Fees and administrative expenses amounted to €1.7 million in 2015 versus €2.5 million in 2014.

Other revenue and expenses, net

Other expenses, net amounted to €7.4 million in 2015 versus €1.4 million in 2014.

The decision in 2015 to restructure the Company resulted in a net restructuring charge of €7.5 million in 2015.

In 2014, the capital operations related to Platine Pharma Services SAS resulted in a net expense of €0.7 million, and the sale of shares in Jennerex, Inc. resulted in a net expense of €0.2 million.

Interest income (expense):

Net interest expense amounted to €0.9 million in 2015 versus €0.8 million in 2014.

Financial income (investment income) amounted to €0.5 million in 2015 versus €0.3 million in 2014.

Interest expense mainly consisted of bank interest on the financing of the research tax credit (€0.4 million), discount of the advances received by Bpifrance under the ADNA (Advanced Diagnostics for New Therapeutic Approaches) program (€0.6 million), interest on financing leases (€0.2 million) and a decrease in Transgene's estimated interest in Sillajen, Inc. subsequent to the disposal of Jennerex, Inc. shares (€0.3 million).

Net loss from continuing operations:

Net loss from continuing operations was €37.9 million in 2015, compared to €41.1 million in 2014, at constant perimeter.

Net loss from discontinued operations:

Net loss from discontinued manufacturing operations amounted to €8.5 million in 2015, compared to €7.4 million in 2014, at constant perimeter. Net loss consisted of:

- €0.5 million in revenue from manufacturing in 2015 (€0.6 million in 2014);
- €6.0 million in expenses in 2015 (€8.1 million in 2014);
- €2.9 million in loss from the evaluation of assets held for sale measured at fair value.

Total net loss:

Total net loss for 2015 was €46.4 million (€48.6 million in 2014). Net loss per share was €1.20 in 2015 (€1.26 in 2014).

Investments:

Investments in tangible and intangible assets (net of disposals) amounted to €1.4 million in 2015 (€2.3 million in 2014).

Repayable advances and loans:

In 2015, the Company refinanced its 2014 research tax credit of €8.9 million through a bank loan with Bpifrance, which matures in mid-2018, at which time the receivable is expected to be paid by the French government.

In 2015, Transgene also received €0.9 million (€0.8 million in 2014) in repayable advances for the ADNA program, which receives public funding from Bpifrance. Since the start of the ADNA program, the Company has received €14.3 million in repayable advances under this program. The Company may receive

up to €1.7 million in additional repayable advances over the remaining term of the ADNA program (until 2017).

Liquidity and capital resources:

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

At December 31, 2015, the Company's available cash amounted to €31.7 million versus €65.9 million at December 31, 2014.

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

Cash flow:

Excluding capital increases, the Company's net cash burn amounted to €34.8 million in 2015 versus €44.9 million in 2014.

Post-closing events:

In early January, the Company obtained a loan of €20 million from the EIB (European Investment Bank) under the IDFF (Infectious Diseases Finance Facility) program. This is a 5-year loan, without securities granted, and the principal and accumulated interest will be reimbursable only from the fourth year. The loan will be released in two tranches at the request of the Company and no security was granted by the Company

Transgene has also received a commitment by its major shareholder, the Institut Mérieux, to provide additional financing of around 10 million euros, confirming its support of the Company's strategy.

In early February 2016, Transgene announced the sale of the assets of its biomanufacturing unit, based in Illkirch-Graffenstaden, to ABL Europe SAS, a Contract Manufacturing Organization wholly-owned subsidiary of ABL, Inc. and member of the Institut Mérieux. This production assets was sold for a total amount of €3.5 million. ABL Europe has become a sub-lessee of Transgene's main building for the use of quality control laboratories. In parallel, both companies have signed a three-year agreement under which Transgene has secured the production of the necessary clinical lots for its clinical development plan. The sale by Transgene of its production asset was the last step of the company's reorganization decided in June 2015 which aimed to outsource the manufacturing of clinical lots and to focus on the company's core expertise, the immuno-engineering of viral vectors and clinical developments.