

Transgene: Annual Results 2012 and Business Update

Solid operational performance in 2012, in preparation of key milestones in 2013 with the possible start of two phase 3 clinical trials for our most advanced products

Cash consumption in line with expectations and cash position of €92.9 million at end 2012

Strasbourg, France, March 21, 2013 - Transgene SA (Euronext Paris: FR0005175080) today announced the company's financial results for 2012 and provided a business update.

The year 2012 was marked by the publication of a number of clinical results, by the start of important clinical trials, by the strategic partnership concluded with the EORTC, a leading cancer research cooperative group, and by the start of activities in China.

"2012 was a year in which we substantially invested in clinical trials, key for the immediate future of Transgene" stated Philippe Archinard, Chairman and Chief Executive Officer of Transgene. He added: "We now have excellent visibility on our next milestones and by the end of 2013 we should have the necessary clinical results to be able to decide the start of phase 3 studies, the last development phase before registration, for TG4010 in lung cancer and Pexa-Vec (JX594/TG6006) in liver cancer. We await the attainment of these milestones with a great deal of enthusiasm".

The consolidated financial results for 2012 consisted mainly in a stable net loss of €43.2 million (to be compared with €43.6 million in 2011) and a cash consumption of €46.6 million (compared to €40.8 million in 2011).

As of 31 December 2012, the company had €92.9 million in cash. Transgene expects a cash consumption of around €50 million in 2013.

"2012 financial numbers are in line with our expectations" stated Stéphane Boissel, Executive Vice President and Chief Financial Officer of Transgene. He added: "At the end of 2012, Transgene had a cash runway of close to two years".

The company will host a conference call and webcast in English tomorrow, Friday, March 22nd, at 02:30pm CET. The dial-in numbers are:

+44(0)20 7136 2050 (UK)
+33(0)1 70 99 43 01 (FR)
+1646 254 3364 (US)

Confirmation Code: 7934677

The weblink for the webcast is:
<http://www.media-server.com/m/p/yp2gm6vc>

Key 2012 numbers:

Annual consolidated financial statements for 2012 can be summarized as follows:

- €13.1 million in revenue, compared with €14.4 million in 2011,
- €48.7 million in R&D expenses, compared with €53.0 million in 2011,
- €43.2 million in net loss, compared with €43.6 million in 2011, and
- €46.6 million in cash consumption, compared with €40.8 million in 2011.

As of December 31, 2012, Transgene had €92.9 million in cash.

The following table presents the income statement for 2011 and 2012:

In thousands of euros	12/31/2012	12/31/2011
Revenue from collaborative and licensing agreements	3,928	5,646
Government financing for research expenditures	9,133	8,800
Revenue	13,061	14,446
Research and development expenses	(48,679)	(53,048)
General and administrative expenses	(6,610)	(6,226)
Other income and (expenses), net	93	-
Net operating expense	(55,196)	(59,274)
Operating income	(42,135)	(44,828)
Interest income and (expenses), net	(594)	1,426
Income/ (loss) before tax	(42,729)	(43,402)
Income tax expense	-	-
Income from equity affiliates	(474)	(224)
Net income/ loss	(43,203)	(43,626)
Net Income per share (€)	(1.36)	(1.38)
Diluted earnings per share (€)	(1.36)	(1.38)

The financial statements for 2012 as well as the management discussion on those statements are attached to this press release (Appendixes A and B).

Key 2012 events and short term news-flow:

In 2012, Transgene presented or published scientific and clinical data for 4 out of its 5 most advanced products:

- **Pexa-Vec (liver, colorectal and renal cancers):**
Clinical data obtained in liver cancer were presented at ILCA¹ (Berlin, September 2012). They illustrate the safety of the intravenous injection of Pexa-Vec followed by Sorefanib, the standard of care in the indication. This opens new perspectives for the clinical development of the product. Promising survival benefit data were also published in early 2013 in Nature Medicine. In a small group of patients (30), those data showed a doubling in average overall survival for patients having received high, therapeutic, dose of Pexa-Vec compared to patients having received low, placebo-like, dose of the product.
- **TG4040 (hepatitis C):**
During the EASL² congress of 2012 (Barcelona, April 2012), additional data from the phase 2b HCVac study were presented. They showed a prolongation of benefits of TG4040 under treatment. Primary endpoint of the trial was met. Final data will be orally presented by Transgene during the EASL congress of 2013 (Amsterdam, April 2013). An update on the TG4040 development strategy will then be made.
- **TG4001 (cancer of the oropharynx):**
Phase 2b data showing significant superior efficacy of the therapeutic vaccine over placebo in HPV-related CIN 2/3 cervical neoplasia patients were communicated in May 2012. Detailed data were then presented by Roche³ in the context of the 28th international papillomavirus conference (Puerto Rico, December 2012). Those data are not sufficient to move the product in phase 3 in this indication. However, they represent a strong proof of concept for the product and enabled Transgene to enter into a strategic collaboration with EORTC, a leading cancer research cooperative group, for the conduct of a large phase 2b evaluating TG4001 in combination with radio-chemotherapy in HPV-related cancer of the oropharynx. This study will be initiated in 2013 and the first patient is expected to be randomized in early 2014.
- **TG1050 (hepatitis B):**
During the EASL congress of 2012 (Barcelona, April 2012), first pre-clinical data with TG1050 were presented. They allowed us to move the product into IND enabling studies. Additional data will be presented during the EASL congress of 2013. TG1050 should enter clinical trials in 2014. Transgene intends to enter into a collaborative partnership with TG1050 before the start of clinical trials.

In 2012, Transgene started important clinical trials for its two lead products, TG4010 (lung cancer) and Pexa-Vec (liver cancer).

¹ ILCA = International Liver Cancer Association.

² EASL = European Association for the Study of the Liver.

³ Roche had exclusive rights to TG4001 until February 2011 when rights were granted back to Transgene. Roche is sponsor of the still ongoing clinical data.

To date, around 70% of patients have been randomized in the phase 2b part of the phase 2b/3 trial with TG4010 in lung cancer. First data are expected in Q4 2013 and Novartis could exercise its option in late 2013 or early 2014.

To date, around 60% of patients in the TRAVERSE study (phase 2 b trial with Pexa-Vec in second line advanced liver cancer, or HCC) have been randomized. This study should give its first data by the end of 2013. With its partners, including Jennerex, Inc., Transgene has also started (i) a phase 2a clinical trial evaluating an intravenous injection-only protocol in liver cancer patients as well as (ii) a phase 1/2 evaluating Pexa-Vec in combination with chemotherapy in metastatic colorectal cancer. Data from the various ongoing clinical trials should enable the partners to decide on starting a phase 3 clinical trial by the end of 2013. A first patient in phase 3 could be randomized in early 2014.

About Transgene:

Transgene (NYSE-Euronext: TNG), a member of the Institut Mérieux Group, is a biopharmaceutical company. It creates, develops and manufactures targeted immunotherapeutics for the treatment of cancers and infectious diseases. Transgene's products are major technological breakthroughs. They use well tolerated viruses to indirectly or directly kill infected or cancerous cells. Its four most advanced products have generated proof of concept data in randomized clinical studies: in lung cancer (TG4010), liver cancer (Pexa-Vec), hepatitis C (TG4040) and HPV-related cervical lesions (TG4001). Transgene has concluded strategic agreements for the development of three of these products: an option agreement with Novartis for the development of TG4010, an in-licensing agreement with US-based Jennerex, Inc. to develop and market Pexa-Vec and a strategic collaboration with EORTC to develop TG4001 in cancer of the oropharynx. With 280 employees, it is based in Strasbourg, France, and has operations in Lyon, China and the USA. Additional information about Transgene is available at www.transgene.fr.

Disclaimer:

This press release contains forward-looking statements notably referring to the anticipated cash consumption for 2013. The Company's anticipated cash consumption for 2013 is based on currently anticipated costs for on-going and planned product development and testing, but may increase in the event of unanticipated expenses. For further information on the risks and uncertainties involved in the testing and development of Transgene's product candidates, see Transgene's Document de Référence on file with the French Autorité des marchés financiers on its website at <http://www.amffrance.org> and on Transgene's website at www.transgene.fr.

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Transgene can be followed on Twitter (@TransgeneSA) and LinkedIn.

APPENDIX: 2012 CONSOLIDATED FINANCIAL STATEMENTS

Consolidated 2012 financial statements were approved by the Board of Directors on March 20, 2013, and will be submitted for approval by the shareholders of the Company during its next annual general meeting, on June 19, 2013. Audit procedures have been performed and the auditors' report is dated March 21, 2013.

Appendix A: 2012 Financial Statements

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

ASSETS	12/31/2012	12/31/2011
<u>Current assets</u>		
Cash and cash equivalents	6,137	1,733
Other current financial assets	86,778	137,774
Cash, cash equivalents and other financial assets	92,915	139,507
Receivables	2,012	624
Inventories	1,107	1,093
Other current assets	2,340	2,560
Total current assets	98,374	143,784
<u>Non-current assets</u>		
Property, plant and equipment	24,805	25,507
Intangible assets	1,497	1,581
Financial assets	7,382	6,175
Equity consolidated affiliates	3,932	544
Other non-current assets	24,474	15,993
Total non-current assets	62,090	49,800
Total assets	160,464	193,584
<u>EQUITY AND LIABILITIES</u>		
<u>Current liabilities</u>		
Payables	9,587	10,840
Financial liabilities	961	955
Provisions for risk	2	3
Other current liabilities	8,853	9,319
Total current liabilities	19,402	21,117
<u>Non-current liabilities</u>		
Financial liabilities	38,006	27,374
Defined benefit obligations	3,226	2,794
Other non-current liabilities	252	883
Total non-current liabilities	41,484	31,051
Total liabilities	60,886	52,168
<u>Equity</u>		
Share capital	72,886	72,523
Share premiums	427,258	426,041
Retained earnings	(356,655)	(313,030)
Net loss for the year	(43,203)	(43,626)
Other comprehensive income	(709)	(492)
Total equity and reserves attributable to equity holders of the Company	99,578	141,416
Total equity and liabilities	160,464	193,584

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

	12/31/2012	12/31/2011
Revenue from collaborative and licensing agreements	3,928	5,646
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Operating income	(42,135)	(44,828)
Interest income and (expenses), net	(594)	1,426
Income/ (loss) before tax	(42,729)	(43,402)
Income tax expense	-	-
Income from equity affiliates	(474)	(224)
Net income/ loss	(43,203)	(43,626)
Net income per share (€)	(1.36)	(1.38)
Diluted earnings per share (€)	(1.36)	(1.38)

Consolidated statement of comprehensive income (IFRS)
(In thousands of euros)

	12/31/2012	12/31/2011
Net income/(loss)	(43,203)	(43,626)
Foreign exchange gains / (losses)	11	(1)
Reevaluation of hedging instruments	(227)	(270)
Other comprehensive income	(216)	(271)
Comprehensive income	(43,419)	(43,897)
Of which, Equity holders of the parent company	(43,419)	(43,897)
Of which, minority interests	-	-

Statement of cash flows (IFRS)
(In thousands of euros)

	12/31/2012	12/31/2011
Cash flows from operating activities		
Net Income	(43,203)	(43,626)
Elimination of financial result	594	(1,426)
Elimination of non-cash elements		
Income from equity affiliates	474	224
Changes in provisions	282	260
Depreciation and amortization of tangible and intangible assets	2,763	2,740
Payments in shares	856	1,441
Others	(1,233)	5
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow	(39,467)	(40,382)
Change in operating working capital		
Receivables	(1,620)	685
Inventories	(14)	(121)
Research tax credit	(8,418)	(7,786)
Other current assets	606	219
Payables	(1,283)	2,292
Prepaid income	(1,080)	(1,678)
Accrued Employee benefits expenses	459	39
Other current liabilities	(477)	714
Net cash generated from/(used in) operating activities	(51,294)	(46,018)
Cash flows from investing activities		
(Purchase) /disposal of property, plant and equipment	(1,379)	(3,302)
(Purchase)/ disposal of intangible assets	(566)	(548)
Other (purchases) /disposals	(2,631)	(1,668)
Net cash used in investing activities	(4,576)	(5,518)
Cash flows from financing activities		
Collected net financial result	194	1,856
Gross proceeds from issuance of share capital	725	254
Fees paid in relation to capital increase	-	-
Conditional subsidies	3,116	3,103
(Acquisition)/ disposal of current financial assets	50,582	41,143
Research tax credit financing	6,601	6,465
Repayment of finance lease liabilities	(955)	(930)
Net cash generated from /(used in) financing activities	60,263	51,891
Effect of change in exchange rates on cash and cash equivalents	11	(1)
Net increase (decrease) in cash and cash equivalents	4,404	354
cash and cash equivalents at beginning of period	1,733	1,379
Closing cash and cash equivalents	6,137	1,733
Investments in other financial assets	86,778	137,774
Cash, cash equivalents and other financial assets	92,915	139,507

Appendix B: Management Discussion on 2012 Financials

Revenue:

During 2012, revenue from collaborative and licensing agreements were composed principally of:

- Revenue from collaborative research and manufacturing activities for strategic partners (such as for Jennerex, Inc. in connection with Pexa-Vec (JX594/TG6006) in 2012 and 2011, and Roche, for TG4001, in 2011), amounting to €1.8 million in 2012 (€2.8 million in 2011),
- Milestone or upfront payments on products partnered-out (such as the option payment from Novartis in connection with TG4010), amounting to €1.4 million in 2012 (€2.1 million in 2011), and
- Royalties on sales of technologies or products out-licensed by Transgene, amounting to €0.7 million in 2012 (unchanged).

The \$10.0 million (€7.4 million) received from Novartis in March 2010 for the payment of the exclusive option for an exclusive license to TG4010, was spread over the expected duration period of the option. This period runs from signature date up to March 31, 2014. Revenue recognized on this option amounted to €1.4 million (€2.1 million in 2011). The balance (€1.2 million) will be recognized in revenue in 2013 and 2014.

For year ending December 31, 2012, government financing for research expenditures are composed of subsidies received or accrued and research tax credit for the year 2012.

Subsidies amounted to €0.7 million in 2012, compared with €1.0 million in 2011. In 2012, subsidies were related principally to the ADNA program (a program to develop biomarkers for new therapeutics), funded by French innovation agency OSEO. Transgene expects to cash in another €1.4 million in subsidies in relation to this program in the future (€3.0 million in revenue, as part of this amount was already cashed-in).

Research tax credit amounted to €8.4 million in 2012 (€7.8 million in 2011). Net eligible expenses amounted to €27.6 million in 2012 (€26.3 million in 2011). Variation in net eligible expenses between 2011 and 2012 (+5%) does not reflect the change in research and development expenses (-8%). This is mainly explained by a significant decrease, between 2011 and 2012, in non-eligible expenses such as milestone payments to Jennerex, Inc. (zero in 2012 compared to €6.9 million in 2011). Retreated of these milestone payments, research and development expenses increased by €2.6 million (6%) between 2011 and 2012, mostly due to an increase in external expenses on clinical trials.

Operating expenses:

R&D expenses amounted to €48.7 million in 2012, compared with €53.0 million in 2011, a decrease of 8%. This decrease was mainly due to the absence of milestone payment to Jennerex, Inc. in 2012.

The table below lists research and development expenses per nature of expense:

In millions of euros	12/31/2012	12/31/2011	Variation
Personnel costs	19.5	18.9	+3%
Share-based payments	0.7	1.1	-36%
Intellectual property expenses and license costs	1.6	9.2	-83%
External costs on clinical projects	11.7	8.6	+36%
External costs on other projects	3.2	3.9	-18%
Operating costs	9.2	8.6	+7%
Depreciation, amortization and provisions	2.8	2.7	+4%
Research and development expenses	48.7	53.0	-8%

R&D staff costs amounted to €19.5 million in 2012, compared to €18.9 million in 2011. This change (+3%) is explained by an increase in salaries (2% in average) as well as by an increase in headcount (247 FTE in 2012 vs. 242 in 2011).

External intellectual property and licensing costs amounted to €1.6 million in 2012, compared to €9.2 million in 2011. This significant decrease is mostly explained by the absence of payments made or due to Jennerex, Inc. in 2012 (€6.9 million in 2011 for clinical and production milestone achieved in 2011 with Pexa-Vec).

External expenses on clinical trials amounted to €11.7 million in 2012, compared to €8.6 million in 2011. This increase (+36%) is explained by clinical advancement in 2012 of our two most advanced products: start of patient recruitment in the phase 2b part of a large phase 2b/3 clinical trial with TG4010 in lung cancer (€6.1 million in 2012 vs. €3.1 million in 2011) and patients recruitment in the TRAVERSE phase 2b clinical trial and other clinical trials with Pexa-Vec (€2.7million in 2012 vs. €0.9 million in 2011).

External expenses on other projects, including research, pre-clinical and industrial projects, amounted to €3.2 million in 2012, to be compared with €3.9 million in 2011. This change is mostly explained by a decrease in outsourcing activities on industrial development projects, in particular for the development of novel manufacturing processes.

Internal/structure costs are expenses related to operating research and production facilities, including but not limited to cost of the finance lease, maintenance costs and supply of laboratory materials. These costs amounted to €9.2 million in 2012, compared to €8.6 million in 2011. This change is mostly explained by an increase in maintenance and qualification costs of our production unit. This evolution is mostly driven by regulatory requirements.

The table below lists the general and administrative expenses per nature of expense:

In millions of euros	31/12/2012	31/12/2011	Variation
Personnel costs	2.7	2.7	N/S
Share-based payments	0.2	0.4	N/S
Fees and administrative expenses	2.6	2.1	+24%
Other fixed costs	1.0	0.9	+11%
Depreciation, amortization and provisions	0.1	0.1	N/S
Fixed costs	6.6	6.2	+6%

G&A staff costs amounted to €2.7 million in 2012, unchanged, reflecting a stable headcount.

Advisory and management fees amounted to €2.6 million in 2012, compared with €2.1 million euros in 2011.

Interest income and (expenses), net:

Interest expenses, net of interest income, amounted to €0.6 million in 2012 (income of €1.4 million in 2011). Interest income on investments amounted to €0.5 million in 2012 (€1.9 million in 2011). This change is explained by a decrease in average invested amounts (€115 million in 2012 vs. €159 million in 2011), as well as by a decrease in monetary market rates (3-month Euribor average at 0.57% in 2012, compared to 1.39% in 2011).

Interest expenses were mostly related to the interest on lease financing of the main premises of Transgene (€0.4 million in 2012, unchanged).

Net loss:

Net loss amounted to €43.2 million in 2012, compared with €43.6 million in 2011. Net loss per share amounted to €1.36 in 2012 (€1.38 per share in 2011).

Investments:

Investment in tangible and intangible assets amounted to €2.0 million in 2012, compared with €3.8 million in 2011. Transgene also invested €3.8 million in Transgene Tasly (Tianjin) Biopharmaceuticals Co. Ltd, including €2.6 million in cash payment and €1.2 million in contribution in intellectual property rights related to TG3003 product for the Transgene Tasly (Tianjin) Biopharmaceuticals Co. Ltd area which is China, Hong Kong, Taiwan and Macao.

Borrowings and conditional subsidies:

In 2012, Transgene received €3.1 million in conditional subsidies from OSEO in relation to the ADNA program (see above). The Company expects to receive another €6.3 million in conditional loans up to the end of this program (2016).

Cash, cash equivalents and other financial assets:

Cash is invested primarily in short term mutual funds or in a cash pooling managed by the Institut Mérieux, its controlling shareholder. As of December 31, 2012, the Company had €92.9 million in cash, cash equivalents and other financial assets, compared with €139.5 million as of December 31, 2011.

Elements of cash flow:

Excluding the investment made in the equity capital of Transgene Tasly (Tianjin) Biopharmaceuticals Co. Ltd., cash consumption amounted to €44.0 million in 2012 (€39.6 million in 2011).

Including the €2.6 million investment made in the equity capital of Transgene Tasly (Tianjin) Biopharmaceuticals Co. Ltd., cash consumption of Transgene amounted to €46.6 million in 2012.

Post-closing events:

In March 2013, Jennerex, Inc. started a fundraising in the form of a rights issue to its shareholders, including Transgene. The contemplated fundraising is offered at a price per share which is below what Transgene has retained for its equity stake in Jennerex, Inc. in its balance sheet. Given its nature, i.e. a rights issue, Transgene considers that the contemplated fundraising does not reflect Jennerex' fair value, Inc. as of December 31, 2012. This transaction was not completed at the time Transgene's board of directors approved these financial statements.

Risk factors:

Risk factors are presented in Section 4 of the *Document de Référence*.