

Transgene reports full year results 2008:

- **A year of substantial pipeline developments**
- **Cash position of €86.7m to finance future growth**
- **New research and development facility at Illkirch**

Parc d'Innovation, Illkirch, France, March 10, 2009 – Transgene (Euronext Paris: FR0005175080) announces today its operational and financial performance for 2008, and outlook for 2009.

Key highlights include:

- ⇒ Phase IIb results for TG4010, for the treatment of advanced non small cell lung cancer, confirmed a statistically significant overall survival benefit of six months.
- ⇒ Additional interim results confirm good safety profile of TG4040, for the treatment of hepatitis C, and show coincident viral load decrease and increasing vaccine-specific immune responses.
- ⇒ TG4001/R3484, in partnership with Roche, for the treatment of precancerous cervical lesions caused by the HPV virus will soon enter a large international phase IIb trial, aimed at enhancing the product's profile.
- ⇒ TG1042, for the treatment of relapsed cutaneous B-cell lymphoma, met its primary end point in step one of its phase II clinical trial.
- ⇒ Anticipate the entry of TG4023, for the treatment of metastatic colorectal cancer and hepatocarcinoma, into phase I trial by the third quarter of 2009.
- ⇒ Investment in new site to regroup R&D, manufacturing and administrative services.

“2008 was marked by very encouraging clinical results across our product pipeline. The refocusing of our product portfolio coupled with our biomarker based development strategy is bearing the desired results. We announced promising phase IIb results for TG4010, making this Transgene's second product in line for a partnership deal. Encouraging data from the TG1042 phase II trial in CBCL has led us to widen the product's positioning to include indications in onco-dermatology where the incidence of disease is substantially greater. As a consequence, we are developing a new strategy to fully realise the product's potential. Solid progress has also been made in HCV (TG4040) that allows us to advance toward the initiation of a phase II trial,” declared Philippe Archinard, Chief Executive Officer of Transgene.

Key financial highlights include:

- ⇒ Total revenues for the year were €13.9m compared to €28m in 2007, which included €23m payments from Roche.
- ⇒ Transgene closed the year with a net loss of €18m compared to a net loss of €5.5m a year earlier.
- ⇒ Research and development expenditures were €32.3m compared to €28.8m in 2007, partly reflecting the increase in preparatory studies for commercial bio-manufacturing.
- ⇒ In 2008, net cash expenditure was €24.6m.

- ⇒ At the end of 2008, the company held cash and cash equivalents of €86.7m, which should enable it to finance over 3 years of operating expenses.
- ⇒ Transgene anticipates a cash burn of around €20m for 2009, due to the accelerated refunding of research tax credits, and the OSEO financing for the ADNA programme¹.

Outlook for 2009

“This year we should witness further acceleration in the development of our pipeline and growth of our company. We have started the year with €86.7m of cash that should cover our operating costs for the next three years. As in 2008, we should report strong news flow during the year. Our efforts are focused on signing a partnership deal for TG4010 whilst continuing development of our pipeline. We will be adding one new product to the clinical pipeline this year: TG4023, a novel approach to treat advanced liver cancers, is scheduled to enter phase I trials at the end of the third quarter 2009”, added Philippe Archinard.

“This is an exciting time for the company. Our long term commitment to invest in product development is generating the desired results and looking forward we are closer to becoming a leader in the field of cancer and infectious diseases immunotherapy”, concluded Philippe Archinard, Chief Executive Officer of Transgene.

Telephone Conference Call

A telephone conference call is organised for tomorrow, 11th March 2009, in English at 10am Paris time (9am London time). To participate in the conference please dial one of the following numbers ten minutes before the conference begins:

France: +33 (0)1 70 72 25 50
UK: +44 (0)20 7111 1258
Participant Passcode: 306805

A replay service of the call will be available for 14 days using the following dial in details:

France: +33 (0)1 71 23 02 48
UK: +44 (0)20 7806 1970
Passcode: 306805

2008 Financial Results

Comments on 2008 Financial Results

Revenues

€ million	2008	2007	Trend
Manufacturing contracts (excluding Roche)	0.9	1.0	- 10 %
R&D services for Roche	2.0	0.4	+ 400 %
AFM Contract	0.5	0.7	- 30 %
Revenues from licensees	1.0	0.7	+ 40 %
Research grants	3.9	0.5	+ 680 %
Research tax credit	5.6	1.7	+ 230 %
<i>Subtotal</i>	<u>13.9</u>	<u>5.0</u>	+ 178 %
Roche partnership payments		23.0	
<i>Total revenues</i>	13.9	28.0	- 50 %

In 2008 total revenues were €13.9m compared to €28m in 2007. The substantial decrease in revenues was a consequence of the payment in 2007 of €23m received from Roche as part of the TG4001/R3484 licensing agreement. Excluding this payment, revenues grew mainly due to an increase in research grants, research tax credits and research and development services to Roche.

Revenues from third party manufacturing services remained almost stable at €0.9m. As planned, R&D services for Roche (manufacturing of clinical batches and laboratory work) increased from €0.4m in 2007 to €2.0m in 2008.

Billings to the French Muscular Dystrophy Association (AFM) have declined by some 30% and reflect the decline in the workload on the preclinical Myodys programme. The AFM and Transgene mutually agreed to terminate, effective November 30, 2008, their research and development contract on the Myodys programme. Transgene's rights have been transferred to the AFM which is now in charge of the programme.

Research grants significantly progressed from €0.5m in 2007 to €3.9m in 2008 after the European Commission authorised OSEO, in October 2008, to finance the ADNA programme¹ (« Advanced Diagnostics for New Therapeutic Approaches »). Transgene accrued revenues of €3.2m from this programme in 2008 and could receive additional non-refundable grants of up to €5.4m over the remaining life of the project.

Research and development tax credits increased substantially to €5.6m in 2008 as a result of the 2008 French reform on research tax credits. Transgene has in 2009 applied for an accelerated refund of research tax credits covering the years 2005 to 2008 for a total amount of €9.5m.

Operating Expenses

Research and Development expenses amounted to €32.3m in 2008 compared to €28.8m in 2007. The increase was mainly due to:

- Increase in personnel costs of €2.4m due to the strengthening of existing teams;
- The cost of clinical trials decreased by €1.5m, largely due to lower expenses on the TG4010 Phase IIb trial; and
- Higher manufacturing process development costs as we prepare for commercial scale manufacturing and new clinical trials, toxicology studies and patents filing costs (+ €2.3m).

Administrative and general expenses declined to €52m in 2008 against €5.7m in 2007. This decline was mainly due to a reduction in the level of local taxes incurred.

Other Gains and Losses

Other gains totalled €1.6m in 2008 against other losses in 2007 amounting to € 0.9m. In 2007, the other losses mainly reflected a provision to cover the cost of leaving our rented office and laboratory premises in Strasbourg. In 2008, other gains mainly reflected:

- The non-cash profit relating to the cancellation of the long-term debt due the AFM following the termination of the research contract (+ €3m);
- The exceptional amortisation charge for certain proprietary real-estate fixed assets located in the Strasbourg premises (- €1.2m).

Interest Income

Interest income was €4.0m in 2008 compared to €1.9m in 2007 as a result of higher cash held over the year.

Net Loss

Transgene reported a net loss of €18.0m in 2008 compared to a net loss of €5.5m in 2007. Basic loss per ordinary share amounted to €0.81 in 2008 compared to €0.28 in 2007.

Liquidity and Capital Resources

As of 31 December 2008, Transgene held €86.7m in cash and cash equivalents compared to €111.3m a year earlier. Cash equivalents are invested in short-term EU-government treasury bonds funds.

In 2008, net cash expenditures were €24.6m compared to €5.5m in 2007, excluding the capital increase. The increase in net cash expenditures is a consequence of the payment in 2007 of €23m received from Roche as part of the TG4001/R3484 licensing agreement. However, this increase was partially offset in 2008 by a higher level of revenues stemming from grants (ADNA), R&D services for Roche and higher interest income. Transgene currently anticipates a cash burn for 2009 in the order of €20m excluding product out-licensing revenue, due to the accelerated refunding of research tax credits, and the OSEO financing for the ADNA programme¹.

In 2008 and 2007, investments in tangible and intangible assets amounted to €16.9m and € 2.6m, respectively. The 2008 investments related mainly to a new building of some 6,800 m² for mixed usage (laboratories and offices) which was commissioned late 2008. In December 2008, all Strasbourg personnel and R&D activities were moved to this new facility situated in Illkirch, a Strasbourg suburb where Transgene's clinical production site has been located since 1995. The building is fully financed by a € 15.5m finance lease over 15 years.

In 2008, Transgene received €0.8m in repayable advances relating to the publicly-funded ADNA programme¹. The company should receive further repayable advances of up to €9m over the remaining life of the program.

¹ Transgene expects to receive funding worth €18.4m over the life of the programme. This amount breaks down into €8.6m non refundable grants and €9.8m in advance repayables.

Product Pipeline Review

Products in Clinical Development

TG4010 (MVA-MUC1-IL2) for the treatment of advanced non-small cell lung cancer in combination with chemotherapy. Clinical benefit is confirmed.

- **Background:** Ongoing controlled phase IIb trial involving 148 patients suffering from NSCLC of all histological sub-types, expressing MUC1. The study is conducted in 27 centres located in France, Germany, Poland and Hungary. The primary endpoint of the phase IIb trial was to observe at least 40% of patients free of progression 6 months after randomization in the experimental arm. The primary end point was met with 44% of patients in the experimental arm showing progression free survival at 6 months against 35% in the control arm. Secondary endpoints were response rate, time to progression, overall survival, safety, immunological responses, biomarker analysis.

Transgene's biomarker programme, partly financed by an OSEO grant, identified a major sub-population of patients (patients with normal levels of activated Natural Killer cells at baseline) that particularly benefit from treatment with TG4010 in combination with chemotherapy versus chemotherapy alone. After 17 months of median follow-up, patients in this sub population recorded an increased statistical survival rate of some six months.

Following the publication of this promising clinical data at the European Society of Medical Oncology conference (poster on www.transgene.fr), in September 2008, Transgene announced that it would seek a pharmaceutical partner to guarantee the future clinical development and commercialization of the product.

- **Recent Developments and Timeline:** After 21 months of median follow-up, Transgene confirmed a statistically significant overall survival benefit of six months (17.1 months in the experimental arm versus 11.3 months in the control arm) for the sub-population of patients (latest press release, 17th February 2009, on www.transgene.fr). All other classical metrics for efficacy have also shown a significant benefit for those patients in the experimental arms versus the control arm.

Transgene plans to have meetings with the US Food and Drug Administration and the European Medicines Agency during the second quarter of 2009 to discuss preparation of a phase III programme in metastatic NSCLC.

The company continues to make progress in its discussions for potential partnership with pharmaceutical companies.

TG4040 (MVA-HCV) for the treatment of hepatitis C: Preparatory steps for phase II initiation.

- **Background:** A phase I trial, conducted in three clinical sites in France began in the 1st quarter 2007. 15 patients who had not received any previous treatment for their chronic infection were recruited (genotype 1 HCV). Patients received three weekly subcutaneous injections of TG4040 at escalating doses of 10⁶ pfu (3 patients), 10⁷ pfu (3 patients) and 10⁸ pfu (9 patients). The patients treated at the highest dose also received a boost injection of TG4040 at month six.

Preliminary results of the trial were reported in May 2008 (see press release, 19th May 2008, on www.transgene.fr) and showed that TG4040 had a favourable safety profile up to the highest dosage (prior to receiving boost) and that 6 of the 15 patients experienced a viral load reduction ranging from 0.5 to 1.4 log₁₀.

In March 2008 Transgene extended the ongoing clinical trial to include 27 new patients with more advanced stages of liver disease in order to potentially enlarge the target patient population, and also to assess shortened booster vaccination schedules (2 and 4 months instead of 6 months).

In parallel a phase I study is in progress in Canada, co-financed by the University of Montreal and supported by the Canadian Network for Vaccines and Immunotherapies, involving 24 patients who have relapsed after having received standard of care treatment (Ribavirin and Pegylated-Interferon Alpha).

- **Recent Developments and Timeline: Phase I France**

In the phase I trial conducted in France new additional interim results confirm the safety profile of TG4040 and demonstrate evidence of coincident viral load decrease and mounting vaccine-specific immune responses.

These results are very encouraging, and the preliminary immunological analysis supports the expected mechanism of action of TG4040 that aims at inducing an effective HCV-specific T cell base response capable of controlling viral replication.

Transgene will publish detailed clinical and immunological data at an international scientific meeting to be held at the end of April 2009.

The phase I trial extension is ongoing and results are expected in the third quarter 2009.

First interim results from the ongoing phase I Canadian clinical study found no cause for any safety concerns. Final results of this study are expected in the final quarter of 2009.

- **Preparing the Next Development Steps**

The primary objectives of the ongoing trials are to assess safety and determine best treatment modalities and doses in order to initiate, in late 2009/early 2010, a phase II trial that will involve TG4040 in combination with current standard of care (Pegylated-Interferon Alpha plus Ribavirin).

TG4001/R3484 (MVA-HPV-IL2) for the treatment of precancerous cervical lesions caused by the HPV virus: Phase IIb related activities on schedule

- **Background:** A phase IIa trial involving 21 patients affected with CIN 2/3 lesions caused by the HPV virus was completed in 2006 with encouraging data as to the vaccine's safety and efficacy. Based on these results Transgene signed a partnership agreement with Roche in April 2007. According to the terms of this agreement Roche will be responsible for the development and commercialisation of the vaccine worldwide (clinical results and partnership details available on www.transgene.fr).

- **Recent Developments and Timeline:** At the end of August 2008, Transgene and Roche announced the decision to launch a larger phase IIb trial. The intention is to enhance the product's profile by creating a stronger platform of clinical data prior to moving into phase III. The new placebo controlled trial is expected to enrol some 200 patients with HPV related CIN 2/3 lesions. (See press release dated 28th August 2008 on www.transgene.fr).

Roche is progressing with phase IIb trial related activities as planned.

TG1042 (Ad-IFN γ) for the treatment of relapsed cutaneous B-cell lymphoma (CBCL): Seeking a broader franchise in onco-dermatology.

- **Background:** Following encouraging results of a phase I/II clinical study, a phase II clinical trial for TG1042 in CBCBL was initiated with the first patients recruited in March 2007. In the first stage of this trial, 13 patients with relapsing CBCL were enrolled in France, Switzerland and the United States. CBCL, a malignant disease of the skin is a very rare illness. The primary objective of this non-controlled open label study was to evaluate efficacy of intra-lesional injections of TG1042 in patients with relapsing CBCL after standard radiotherapy treatments. The clinical objectives of the trial were regression and disappearance of lesions, tolerance of the treatment and quality of life.
- **Recent Developments and Timeline:** Transgene announced at the end of November 2008 that TG1042 had met its primary end point (at least 8 responders out of 13 included patients) in step 1 of its ongoing phase II trial. In fact the data showed that out of 12 patients evaluable for response, 10 patients presented an objective response. After a complete review of these results the Data and Safety Monitoring Board concluded that the efficacy and safety data of step one of the trial were encouraging, justifying continued clinical development. (See press release dated 21st November 2008 on www.transgene.fr)

Concurrent with these promising clinical results, the company decided to review a number of potential development strategies, including that of establishing a collaborative partnership. The aim is to optimize the products potential and widen the scope of possible indications for treatment to include more frequent dermatological malignancies.

Transgene expects to provide an update on the product's future development strategy during the second half of 2009.

Product to Enter Clinical Development in 2009

TG4023 (MVA-FCU1) for the treatment of metastatic colorectal cancer (mCRC) and hepatocarcinoma (HCC): A new product in the clinical pipeline.

- **Background and Target Market:** TG4023 is a new product from Transgene that may increase the efficacy of chemotherapy in solid tumors accessible to intra-tumoral injection. The chosen indications for the product include liver metastasis and HCC. TG4023 is a non-propagative vaccinia virus containing a sequence encoding the FCU1 gene. The FCU1 gene converts the prodrug 5-FC into 5-FU (a chemotherapy agent). TG4023 when injected intra-tumor aims to reduce the systemic toxicity of 5-FU while increasing its anti-tumor efficacy. The product adopts a unique approach that combines immunotherapy and targeted chemotherapy.

The target market for TG4023 is the treatment of cancerous lesions of the liver. The definition includes primary liver tumors (hepatocellular carcinomas) and liver metastasis of other cancers – mainly colorectal cancers (mCRC). There are over 500.000 new cases of hepatocarcinoma per year and around 1 million new cases of colorectal cancers per year, of which some 60 per cent develop liver metastasis (source: Globocan 2002).

The medical need to develop an effective product to treat cancers of the liver is high both in order to increase the cure rate and to prolong the survival of inoperable patients.

- **Future Development and Timeline:**

Preclinical studies provide very encouraging data to support future clinical development. *In vitro* and *in vivo* results, including biological and toxicological studies, suggest a favourable safety profile of TG4023.

We anticipate phase I entry towards the end of the third quarter 2009. Further details will be provided at the time of product entry into the clinical pipeline.

About Transgene

Transgene is a France-based biopharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases. The company has three compounds in phase II trials (TG4001/R3484, TG4010 and TG1042) and one compound in phase I studies (TG4040). Transgene has concluded a strategic partnership agreement with Roche for the development of its TG4001/R3484 therapeutic vaccine to treat HPV-mediated diseases. Transgene has bio-manufacturing capacities for viral-based vectors and technologies available for out-licensing. Additional information about Transgene is available on the Internet at www.transgene.fr.

Cautionary note regarding forward-looking statements

This press release contains forward-looking statements referring to the planned clinical testing and development of Transgene's therapeutic vaccine candidates, and the possible entry into new partnership agreements. However, clinical testing and successful product development depend on a variety of factors, including the timing and success of future patient enrolment and the risk of unanticipated adverse patient reactions. Results from future studies with more data may show less favorable outcomes than prior studies, and there is no certainty that product candidates will ever demonstrate adequate therapeutic efficacy or achieve regulatory approval or commercial use. Furthermore, the entry into new partnerships involves a process of negotiation with partner candidates, including with respect to financial, technical, commercial and legal matters, and there is no certainty that appropriate partnerships will be established or will be successful. 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.amf-france.org> and Transgene's website at www.transgene.fr.

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APPENDIX

Condensed Consolidated Balance Sheets

(IAS/IFRS)

(Amounts in thousands of euros)

	December 31,		December 31,	
	2008		2007	
ASSETS				
Fixed assets, net	22 312		6 182	
Intangible assets, net	1 564		1 669	
Financial assets, net	425		383	
Other non-current assets	0		3 957	
Total non-current assets	<u>24 301</u>		<u>12 191</u>	
Cash and cash equivalents	86 701		111 312	
Other current assets	15 645		4 811	
Total current assets	<u>102 346</u>		<u>116 123</u>	
Total assets	<u>126 647</u>		<u>128 314</u>	
LIABILITIES AND SHAREHOLDERS' EQUITY				
Shareholders' equity	94 223		110 936	
Liabilities, non current	17 056		5 996	
Liabilities, current	15 368		11 382	
Total liabilities and shareholders' equity	<u>126 647</u>		<u>128 314</u>	

Condensed Consolidated Statements of Operations

(IAS/IFRS)

(Amounts in thousands of euros except share and per share data)

	Six months ended		12 months ended	
	December 31,		December 31,	
	2008	2007	2008	2007
	€	€	€	€
Revenues				
Revenues from collaborative and licensing agreements	2 156	2 159	4 462	25 834
Grants and tax credit received for research	6 260	1 115	9 487	2 185
Total revenues	<u>8 416</u>	<u>3 274</u>	<u>13 949</u>	<u>28 019</u>
Operating expenses				
Research and development	(16 202)	(15 722)	(32 272)	(28 799)
General and administrative	(2 474)	(3 105)	(5 256)	(5 747)
Other operating gains and losses	2 211	7	1 625	(931)
Total operating expenses	<u>(16 465)</u>	<u>(18 820)</u>	<u>(35 903)</u>	<u>(35 477)</u>
Profit (loss) from operations	<u>(8 049)</u>	<u>(15 546)</u>	<u>(21 954)</u>	<u>(7 458)</u>
Interest and other income, net	1 768	1 563	3 954	1 937
Income tax	0	0	0	0
Net profit (loss)	<u>(6 281)</u>	<u>(13 983)</u>	<u>(18 000)</u>	<u>(5 521)</u>
Minority interests	0	0	0	0
Profit (loss) attributable to equity holders of the parent	<u>(6 281)</u>	<u>(13 983)</u>	<u>(18 000)</u>	<u>(5 521)</u>
Basic profit (loss) per ordinary share	(0,28)	(0,69)	(0,81)	(0,28)
Diluted profit (loss) per ordinary share	(0,28)	(0,69)	(0,81)	(0,28)