TRANSGENE: First Half 2009 Results

Substantial progress in clinical developments
R&D investments maintained
Cash position of €81.6m

Parc d'Innovation, Illkirch, France, September 2, 2009 – Transgene (Euronext Paris: FR0005175080) announces results for the first half of 2009.

Highlights of the first half of 2009 include:

- **TG4010 (MVA-MUC1-IL2**): **targeted immunotherapy for the treatment of non-small cell lung cancer (NSCLC).** Long-term data presented at AACR and ASCO during the first half of 2009 confirm positive efficacy results on a major sub-population of patients. In June 2009, the FDA gave its green light to proceed to phase III trial on this sub-population of patients.

- **TG4040 (MVA-HCV): active immunotherapy for the treatment of chronic hepatitis C.** Focus on controlled phase II trial preparation following presentation of most recent data at EASL.

- **Inauguration of new R&D facility and Transgene's headquarters in the Parc d'Innovation d'Illkirch**, next to Strasbourg, inaugurated on June 24, 2009.

- **Cash burn of €5.1m** for the first half of 2009 following accelerated refund of research tax credits and receipt of ADNA grants.

- **Cash position of €81.6m** as of June 30, 2009.

"This first half of 2009 was very positive for Transgene. We have made significant progress across our clinical pipeline and are now progressing towards the next phases as planned. Discussions in view of a development partnership for TG4010 are on-going. Our cash burn which benefited from significant cash receipts in the first half should reach approximately € 22m for the whole year 2009, excluding potential partnership revenues" Philippe Archinard, Chief Executive Officer of Transgene, commented.

Financial Results:

First Half Revenues

€ million	2009	2008	Per cent change 2009 / 2008
Third Party Manufacturing Contracts	2.6	1.3	+ 100 %
R&D services for Roche	0.3	0.4	- 25%
AFM Contract	-	0.3	- 100 %
Revenues from Licenses	0.2	0.3	- 33 %
Research Grants	0.7	0.3	+ 133 %
Research Tax Credits	1.8	2.9	- 38 %
Total	5.6	5.5	+ 2 %

…/…

In the first half of 2009 total revenues were €5.6m compared to €5.5m in the same period of 2008.

Revenues from third party manufacturing services amounted to €2.6m in the first half of 2009, with the majority related to the IAVI[1] manufacturing contract.

Billing of R&D services for Roche amounted to €0.3m in the first half of 2009 compared to €0.4m in the first half of 2008.

Due to the termination of the contract in November 2008, billings to the French Muscular Dystrophy Association (AFM) were nil in the first half of 2009 compared to €0.3m in the same period of last year.

Revenues from technology licenses were stable at €0.2m.

Research grants increased to €0.7m in the first half of 2009 from €0.3m in the first half of 2008. The grants mainly related to the ADNA programme.

The research tax credit decreased to €1.8m in the first of 2009 compared to €2.9m in the same period of last year. Net credit-eligible expenses were lower as they were partly offset by significant cash receipts related to the ADNA project (€ 5.2m).

Research and development expenses

Research and development expenses were maintained at €15.9m in the first half of 2009 compared to €16.1m in the same period of 2008. The decrease in clinical trial expenses, due to the completion of the TG4010 Phase IIb trial, was offset by higher expenses in the area of industrial manufacturing processes. Two-thirds of R&D expenses related to products in clinical development, the remaining third to products at the pre-clinical stage.

General and administrative costs

General and administrative costs were €3.3m in the first half of 2009 compared to €2.8m in the first half of last year, mainly due to higher personnel costs.

Other gains and losses

Other gains amounted to €0.1m in the first half of 2009 compared to other losses of €0.6m in the same period of last year. In the first half of 2008, there was an exceptional amortisation charge of €0.6m for certain proprietary real-estate fixed assets located in the Strasbourg premises.

Interest income and expenses

Interest income decreased significantly from €2.3m in the first half of 2008 to €0.4m in the first half of 2009 due to the decrease of money market interest rates.

Interest expenses increased from nil in the first half of 2008 to €0.3m in the first half of 2009 due to the financial lease expenses of the new premises in Illkirch.

Net result

Transgene reported a net loss of €13.5m in the first half of 2009 compared to a net loss of €11.7m in the first half of 2008.

Loss per ordinary share amounted to €0.61 in the first half of 2009 compared to a loss per ordinary share of €0.53 in the first half of 2008.

[1] International AIDS Vaccine Initiative

Liquidity and Capital Resources:

As of June 30, 2009, cash and cash equivalents totalled €81.6m. Net cash expenditures totalled €5.1m in the first half of 2009 compared to €12.4m in the same period of last year. In the first half of 2009, Transgene received cash in the amount of €5.2m relating to the ADNA project and €9.5m relating to the accelerated refund of research tax credits covering the years 2005 to 2008.

Transgene currently anticipates a cash burn for 2009 of approximately €22m, excluding potential partnership revenues.

Note: the first half 2009 financial report is accessible on Transgene's internet website (www.transgene.fr). It includes the condensed financial statements, the first half activity report, the statutory auditors report and the declaration of the people responsible for the report.

Clinical development update :

- **TG4010 (MVA-MUC1-IL2**): **Targeted immunotherapy for the treatment of non-small cell lung cancer (NSCLC).**

  Additional clinical data (24 months median follow-up) presented at ASCO on the 31st May 2009 confirmed a 6 month increase in median survival (17.1 months in the experimental arm versus 11.3 months in the control arm) on a major sub-population of patients treated with TG4010 and chemotherapy versus chemotherapy alone. Transgene's biomarker programme identified that patients with normal levels of activated natural killer (NK) cells at baseline (some 75 per cent of the patients in the trial) not only survived significantly longer in the experimental arm, but that other metrics such as response rate, progression free survival at 6 months, and time to progression also showed improvement. For further details please see the ASCO poster on www.transgene.fr.

  The results of the controlled phase IIb clinical study of TG4010 in combination with chemotherapy were reviewed by the US Food and Drug Administration (FDA) in May 2009. As per the minutes of the meeting, the FDA agreed with Transgene's proposal to proceed as planned to a phase III clinical study of TG4010 in combination with first line chemotherapy in patients with advanced NSCLC and with normal level of activated NK cells before treatment (please see press release dated 9th June 2009 on www.transgene.fr).

  Transgene is seeking a pharmaceutical partner to further develop and commercialize the product.

- **TG4001/R3484 (MVA-HPV-IL2): Targeted immunotherapy for the treatment of HPV-induced cervical diseases.**

  In the framework of Transgene's partnership agreement with Roche, Roche plans to enrol the first patient this month in a randomized, double blind, placebo-controlled and multicenter phase 2b study of TG4001/R3484 in 200 patients affected with cervical intraepithelial neoplasia (CIN), grade 2 or 3 lesions, resulting from infection with the human papilloma virus (HPV).

  The primary objective is histologic resolution at month 6, whilst secondary objectives are: viral clearance, immunological response, safety and tolerability.

  The study is expected to last some two and a half years and preliminary data are expected by the first quarter of 2011.

- **TG4040 (MVA-HCV): Active immunotherapy for the treatment of chronic hepatitis C.**

  Additional interim results from Transgene's France-based phase I clinical study of TG4040 in treatment-naïve patients chronically infected with the hepatitis C virus (HCV) were announced on 27th April 2009 (see press release on www.transgene.fr) after an oral presentation at the EASL (European Association for the Study of Liver Disease).

  The decrease in viral load and increase in immune response of patients treated with TG4040 is encouraging and supports the expected mechanism of action of the product, which aims at inducing an effective HCV-specific T cell-based immune response with the control in viral replication. The data also confirms the very good safety profile of the product

We are actively preparing the next clinical steps for TG4040 and anticipate launching a large proof of concept controlled phase II clinical trial that aims to demonstrate synergy of the product in combination with standard of care (pegylated interferon-alpha plus ribavirin). We expect to begin the phase II trial in the first quarter of 2010.

Interim results of the ongoing Canadian trial, announced on 11th March 2009 (see 2008 Annual Results press release on www.transgene.fr), showed a good safety profile and we continue to expect virology and immunology results by the end of 2009.

- **TG1042 (Ad-IFNg): Antigen-independent immunotherapy for the local/regional treatment of cutaneous lymphomas and other solid tumors. Scope of possible franchise being analysed and new development strategy to be decided with a future partner.**

  After positive phase II step I clinical trial results of TG1042 in patients affected with cutaneous B-cell lymphoma, Transgene decided to temporarily halt sole clinical development of the product. The encouraging data (see press release November 21, 2008 on www.transgene.fr), and favourable recommendation from the independent DSMB (Data Safety Monitoring Board), coupled with the disease's rarity has led the company to review the development strategy of the product with the aim of maximising the product's potential.

  To this end, we are conducting an in-depth analysis covering TG1042's potential medical positioning in onco-dermatological indications. We are also assessing, more generally, the overall potential of our adenoviral platform where clinical results (TG1024 / Ad-IL2) have been promising across other oncology indications.

  We anticipate providing the market with a business development update during the second half of 2009.

- **TG4023 (MVA-FCU1): Immunotherapy and targeted chemotherapy for the treatment of various cancers. Clinical protocol for a phase I clinical trial is approved by the French regulatory agency AFSSAPS and study is due to start shortly.**

  As reported in our press release of 11th March 2009 (www.transgene.fr), Transgene is bringing to clinical trials a new oncology product candidate that offers a unique approach by combining immunotherapy and targeted chemotherapy.

  The target market is for the treatment of cancerous lesions of the liver resulting from primary liver tumors (hepatocellular carcinomas or HCC) and metastasis in the liver of other cancers, mainly colorectal cancer (mCRC).

About Transgene

Transgene is a France-based biopharmaceutical company dedicated to the development of 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 immunotherapeutic product to treat HPV-mediated diseases. Transgene has bio-manufacturing capacities for viral-based vectors. 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, anticipated cash consumption and the possible establishment of new partnership relationships. 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. The Company's anticipated cash consumption for 2009 is based on currently anticipated costs for on-going and planned product development and testing, but may increase in the event of unanticipated expenses. Finally, the entry into new partnerships involves a process of selection of and 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 Trangene'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 .

For further information please contact:

Transgene
Philippe Archinard, CEO
+33 (0)3 88279122

Philippe Poncet, CFO
+33 (0)3 88279102

Elisabetta Castelli, Director IR
+33 (0)1 44085505

Capital MS&L
Mary Clark, Director
+44 (0)20 7307 5336

Anna Mitchell, Account Director
+44 (0)20 7307 5346

Condensed Consolidated Balance Sheets

(IAS/IFRS) (Amounts in thousands of euros)	June 30, 2009 (unaudited)	December 31, 2008 (audited)
ASSETS		
Fixed assets, net	23 413	22 312
Intangible assets, net	1 441	1 564
Financial assets, net	421	425
Other non-current assets	1 825	0
Total non-current assets	27 100	24 301
Cash and cash equivalents	81 638	86 701
Other current assets	3 177	15 645
Total current assets	84 815	102 346
Total assets	111 915	126 647
LIABILITIES AND SHAREHOLDERS' EQUITY		
Shareholders' equity	81 603	94 223
Liabilities, non current	18 915	17 056
Liabilities, current	11 397	15 368
Total liabilities and shareholders' equity	111 915	126 647

Condensed Consolidated Statements of Operations

(IAS/IFRS) (Amounts in thousands of euros except per share data)	Six months ended June 30, 2009 € (unaudited)	 2008 € (audited)
Revenues		
Revenues from collaborative and licensing agreements	3 119	2 306
Grants and tax credit received for research	2 509	3 227
Total revenues	**5 628**	**5 533**
Operating expenses		
Research and development	(15 932)	(16 070)
General and administrative	(3 298)	(2 782)
Other operating gains and losses	52	(586)
Total operating expenses	**(19 178)**	**(19 438)**
Profit (loss) from operations	**(13 550)**	**(13 905)**
Interest and other income, net	16	2 186
Income tax	0	0
Net profit (loss)	**(13 534)**	**(11 719)**
Minority interests	0	0
Profit (loss) attributable to equity holders of the parent	**(13 534)**	**(11 719)**
Basic profit (loss) per ordinary share	(0.61)	(0.53)
Diluted profit (loss) per ordinary share	(0.61)	(0.53)

Comprehensive income

	Six months ended June 30, 2009 € (unaudited)	 2008 € (audited)
Net profit (loss)	(13 534)	(11 719)
Change in conversion reserves	-	(4)
Change in fair market value of hedging instruments	(25)	-
Total of gains and losses in shareholder's equity	**(25)**	**(4)**
Comprehensive income	**(13 559)**	**(11 723)**
Attributable to equity holders of the parent	(13 559)	(11 723)
Minority interests	-	-

Condensed Consolidated Cash Flow Statement

(Amounts in thousands of Euros)	Six months ended June 30,	
(IAS/IFRS)	**2009**	**2008**
	€	**€**
	(unaudited)	(audited)
Cash flow from operating activities		
Operating loss	(13 550)	(13 905)
Adjustments for:		
Change in provisions	93	110
Depreciation and amortization	1 077	1 216
Amortization of stock option and bonus share cost	829	585
Other	15	(38)
Cash flow	**(11 536)**	**(12 032)**
Change in operating working capital	7 713	(1 777)
Net interest income	101	2 224
Net cash used in operating activities	**(3 722)**	**(11 585)**
Cash flow from investing activities	(2 575)	(768)
Cash flow from financing activities	1 234	(63)
Effect of changes in exchange rates on cash	-	(2)
Net increase (decrease) in cash and cash equivalents	**(5 063)**	**(12 418)**
Cash and cash equivalents at 1 January	86 701	111 312
Cash and cash equivalents at 30 June	81 638	98 894