

# **Transgene Reports 2011 Half Year Results**

- Increase in clinical trial expenses
- Cash of €163.2 million at end of June 2011
- Rich news-flow ahead, with important clinical data from Q4 2011

**Strasbourg, France, September 6, 2011 – Transgene** (Euronext Paris: FR0005175080) announces today its financial results for the six-month period ended June 30, 2011. The 2011 half year results were approved by the Board of Directors on September 1, 2011. They will not be submitted for approval by the shareholders. The statutory auditors have performed a limited review of the accounts. The Interim Financial Report will be available on the Company's website on September 9, 2011.

## Financial Statements for the six-month period ending June 30, 2011:

The following table gives the key figures for the first half of 2011, in comparison with the first half of 2010:

	First H	First Half		
In million euros	2011	2010		
Revenue	8.1	7.3		
Operating income	(18.3)	(14.4)		
Net income (loss)	(17.7)	(14.5)		
Increase (decrease) in cash <sup>(1)</sup>	(17.1)	(14.6)		

<sup>(1)</sup> In the first half of 2010, the decrease in cash is corrected from (i) the option payment by Novartis re: TG4010 (7.4 million euros in March 2010) and (ii) the 152.1 million euros capital increase (May 2010).

Key highlights of the 2011 half year financial statements are as follows:

- Around 10% increase in revenue to 8.1 million euros, up from 7.3 million euros in the first six months of 2010, mostly explained by payments received from Roche for manufacturing work related to TG4001,
- Increase by approximately 25% in research and development expenses to 23.4 million euros versus 18.6 million euros in the first six months of 2010, principally due to an increase in clinical trials expenses,
- A net loss of 17.7 million euros compared to a net loss of 14.5 million euros in the first six months of 2010, mainly due to growth in research and development expenses, and notably expenses related to clinical trials,
- A net cash consumption of 17.1 million euros during the first six months of 2011, compared to 14.6 million euros in the first six months of 2010 (excluding the Novartis option payment re: TG4010 and the May 2010 capital increase).

As of June 30, 2011, the Company had 163.2 million euros in cash, cash equivalents and other financial assets. Transgene expects a cash consumption of approximately 40 million euros in 2011, with higher cash consumption in the second part of the year due to the start of large Phase IIb randomized clinical trials for the products TG4010 and JX594/TG6006.

### **Key Events since January 2011:**

In February, Roche terminated the 2007 license agreement for TG4001, with a full grant back of rights to the Company. In March, recruitment was completed for a large (200+ patients) Phase II trial testing TG4001 in patients with HPV related CIN 2/3 cervical lesions.

In March, the Company completed the recruitment for a 150-patient large Phase II trial ("HCVac study") of TG4040 in patients with type C chronic hepatitis ("HCV").

In April, the Company announced the creation of Platine Pharma services, a company offering immunomonitoring services to the biotechnology industry, as a joint-venture with Innate Pharma.

In May, the Company published important efficacy data from a randomized trial in liver cancer for JX594/TG6006, a product co-developed with US-based Jennerex, Inc.

In July, the Company entered into a licensing agreement with Vivalis for the development of a manufacturing process for its MVA products based on Vivalis' cell line.

#### <u>Update on the Portfolio of Product Candidates:</u>

Concerning the product candidate TG4010, dossiers to start the Phase IIb part of the large Phase IIb/III clinical trial in lung cancer ("NSCLC") were filed during spring and summer. First patient-in this 200-patient large trial is expected in December this year. Enrolment should last 12 months and first clinical data are expected in early 2013.

The development of the product candidate JX594/TG6006 is progressing according to plan. The recruitment of the first patient in the Phase IIb clinical study (120 patients) in second line treatment of advanced hepatocarcinoma (liver cancer) is expected during the present quarter. Enrolment in this trial should last 18 months and clinical data are expected in early 2013. A Phase I/II clinical study in metastatic colorectal cancer is also expected to start in the second half of 2011. Further clinical data from a randomized trial in liver cancer for JX594/TG6006 should be released during the upcoming AASLD meeting (*American Association for the Study of Liver Diseases* in San Francisco, November 3<sup>rd</sup> to 8<sup>th</sup>).

In addition, the Company should release the first efficacy data from the HCVac study (a Phase II clinical trial) with its HCV therapeutic vaccine TG4040 during the said AASLD meeting. Six-month efficacy data with TG4001, a therapeutic vaccine in CIN2/3 pre-cancerous lesions of the cervix, should be released in the first part of 2012.

"During the first half we successfully completed patient recruitment for the HCVac Phase II trial for TG4040 and finalized preparation for JX594/TG6006 and TG4010 to enter advanced clinical trials whilst maintaining a tight control over costs" said Philippe Archinard, Transgene's Chairman and Chief Executive Officer. He added: "Transgene has a solid balance sheet and our four lead products are now entering a period of key clinical milestones that should deliver material news-flow over the coming 18 months or so".

#### **DISCUSSIONS ON FINANCIALS FOR THE FIRST HALF OF 2011**

#### Revenue:

The following table summarizes the change in revenue in the first six months of 2011, in comparison to the same period in 2010:

	First six mo	First six months		
In million euros	2011	2010		
Revenue from collaborative and licensing agreements	3.8	3.0		
Government financing for research expenditures	4.3	4.3		
Revenue	8.1	7.3		

During the first half of 2011, revenue from collaborative and licensing agreements were composed principally of:

- Fees for manufacturing product batches for third parties (such as for Roche, in connection with TG4001), amounting to 2.4 million euros in the six-month period ended June 30, 2011, compared with 0.9 million euros in the same period in 2010,
- Milestone or upfront payments on products partnered-out (such as the option payment from Novartis in connection with TG4010), amounting to 1.2 million euros in the six-month period ended June 30, 2011, compared with 1.1 million euros in the same period in 2010), and
- Royalties on sales of technologies or products out-licensed by Transgene, amounting to 0.2 million euros in the six-month period ended June 30, 2011, compared with 1.1 million euros in the six-month period ended June 30, 2010.

The 10.0 million US dollars (7.4 million euros) received from Novartis in March 2010 for the payment of the exclusive option for license of TG4010, was spread over the expected duration period of the option. Revenue recognized on this option amounted 1.1 million euros in the sixmonth period ended June 30, 2011, and 3.9 million euros since the upfront payment was received. The balance, 3.5 million euros, will be recognized as revenue up until March 2013.

For the six-month period ended June 30, 2011, government financing for research expenditures were composed of subsidies received or accrued as well as research tax credit.

Subsidies amounted to 0.4 million euros in the six-month period ended June 30, 2011, compared to 0.5 million euros in the six-month period ended June 30, 2010. In the first half of 2011, subsidies were mostly related to the ADNA program. Transgene expects to cash-in around 3.8 million euros in subsidies and grants in relation to the ADNA program in the second half of 2011.

The research tax credit amounted to 3.9 million euros in the six-month period ended June 30, 2011, compared to 3.8 million euros in the six-month period ended June 30, 2010. The research tax credit for the first six months of 2011 was calculated as half of the research tax credit expected (as of June 30, 2011) for the full year 2011.

#### **Operating expenses:**

R&D expenses amounted to 23.4 million euros in the six-month period ended June 30, 2011, compared with 18.6 million euros in the six-month period ended June 30, 2010. This increase was due principally to the increase in expenses relating to clinical trials as well as to increased R&D payroll expenses following the 2010 staff additions.

The main R&D line items were:

- Staff costs, including payroll and other staff related expenses, amounting to 9.4 million euros in the six-month period ended June 30, 2011, compared to 8.6 million euros in the six-month period ended June 30, 2010,
- Expenses related to operating the research and production facilities, and other on-going expenses such as the cost of the finance lease, laboratory materials and intellectual property expenses, amounting to 5.6 million euros in the six-month period ended June 30, 2011, compared to 5.1 million euros in the six-month period ended June 30, 2010,
- External expenses in relation to clinical trials, amounting to 4.9 million euros in the sixmonth period ended June 30, 2011, compared to 2.3 million euros in the sixmonth period ended June 30, 2010,
- Other external expenses, including expenses on research and pre-clinical programs as well as expenses on industrial projects, amounting to 2.4 million euros in the six-month period ended June 30, 2011, compared to 2.0 million euros in the six-month period ended June 30, 2010.

General and administrative expenses amounted to 3.0 million euros in the six-month period ended June 30, 2011, compared to 3.3 million euros in the six-month period ended June 30, 2010. Principal G&A expenses were staff costs (1.2 million euros in the six-month period ended June 30, 2011, compared to 1.7 million euros in the six-month period ended June 30, 2010) as well as consulting and management fees (1.0 million euros in the six-month period ended June 30, 2011, unchanged).

#### Other expenses and income, net:

Other income, net, amounted to 0.1 million euros in the six-month period ended June 30, 2011, unchanged.

#### Interest income and (expenses), net:

Interest income, net of interest expenses, amounted to 0.6 million euros in the six-month period ended June 30, 2011, compared to 0.1 million euros in interest expenses, net of interest income in the six-month period ended June 30, 2010. Interest income on investments amounted to 0.9 million euros in the six-month period ended June 30, 2011, compared to 1.0 million euros in the six-month period ended June 30, 2010. The interest expenses were principally related to the interest on lease financing of the main premises of Transgene, which amounted to 0.1 million euros in the six-month period ended June 30, 2011, unchanged.

### Net loss:

Net loss amounted to 17.7 million euros in the six-month period ended June 30, 2011, compared to 14.5 million euros in the six-month period ended June 30, 2010. Net loss per share amounted to 0.56 euros in the six-month period ended June 30, 2011, compared to 0.61 euros in the six-month period ended June 30, 2010.

### **Investments:**

Investments in tangible and intangible assets (nets of disposals) amounted to 2.2 and 1.2 million euros in the six-month periods ended respectively June 30, 2011 and 2010. In 2011, Transgene also invested 0.4 million euros in the equity capital of Platine Pharma Services SAS.

#### **Borrowings and conditional subsidies:**

In the first six months of 2011, Transgene did not receive conditional loan under the ADNA program, which has public funding from OSEO.

In the first six months of 2011, the Company pre-financed its 2010 research credit amounting to 7.8 million euros through a bank loan maturing mid-2014, the expected repayment period by the French government for this claim.

### 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 June 30, 2011, the Company had 163.2 million euros in cash, cash equivalents and other financial assets, compared with 180.3 million euros as of December 31, 2010.

#### **Elements of cash-flow:**

The cash consumption amounted to 17.1 million euros in the first six months of 2011, compared with 14.6 million euros in the first six months of 2010 (excluding payment from Novartis for the option on TG4010 and capital increase dated May 2010).

Transgene expects a net cash consumption in the region of 40 million euros in 2011.

### **KEY NEWS-FLOW SINCE JANUARY 2011**

- February 2011: termination by Roche of the 2007 licensing agreement re: TG4001.
   Completion of recruitment in the 200-patient large clinical trial in HPV-induced CIN 2/3 with this product.
- March: completion of the recruitment of patients in the HCVac study, a Phase II clinical trial with TG4040 in type C viral hepatitis.
- April: communication of clinical data (activity) with JX594/TG6006 in hepatocarcinoma at the European Association for the Study of the Liver ("EASL") annual congress.
- April: communication of clinical data (mechanism of action) with JX594/TG6006 at the American Association of Cancer Research ("AACR") annual congress.
- April: collaboration with Inovio and ChronTech on a "prime-boost" Phase I clinical trial with TG4040 in type C viral hepatitis.
- May: creation of Platine Pharma Services SAS, a joint company with Innate Pharma delivering immune-monitoring services to pharma and biotech clients.
- May: communication of clinical data (efficacy in a randomized trial) with JX594/TG6006 in hepatocarcinoma at the American Society of Gene and Cellular Therapy ("ASGCT") annual congress.
- May: Transgene held its first R&D Day.
- July: license agreement with Vivalis for the development of a production process for MVAbased therapeutic vaccines in Vivalis cell line.
- August: publication of Phase 1 clinical data with TG4040 in HCV in journal Gastroenterology.
- August: publication of Phase 1 clinical data with JX594/TG6006 in hepatorcarcinoma in journal Nature.

#### **KEY EXPECTED NEWS-FLOW IN THE SHORT TERM**

- Interim data from the Phase I clinical trial with TG4023 in solid tumors (2011)
- First patient enrolled in the Phase IIb/III clinical trial of JX594/TG6006 in HCC (2011)
- First data from the Phase II clinical trial with TG4040 in HCV (HCVac) (2011)
- First patient enrolled in the Phase IIb/III clinical trial with TG4010 in NSCLC (2011)
- Interim data from the Phase IIb clinical trial with TG4001 in high-grade cervical dysplasia (CIN 2/3) caused by the human papilloma virus (« HPV ») (early 2012)

## **About Transgene:**

Transgene, a member of the Institut Mérieux Group, is a publicly traded French biopharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases, and has five compounds in clinical development: TG4010 and JX-594/TG6006 having completed initial Phase II trials, TG4001 in Phase IIb trial, TG4040 in Phase II trial and TG4023 in Phase I trial. Transgene has concluded strategic agreements for the development of two of its immunotherapy products: (i) an option agreement with Novartis for the development of TG4010 to treat various cancers, and (ii) an in-licensing agreement with US-based Jennerex Biotherapeutics, Inc., to develop and market JX-594/TG6006, an oncolytic product. Transgene has bio-manufacturing capacities for viral-based products. Additional information about Transgene is available on the internet at <a href="https://www.transgene.fr">www.transgene.fr</a>.

#### **Disclaimer:**

This press release contains forward-looking statements referring to the anticipated cash consumption for 2011. The Company's anticipated cash consumption for 2011 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 Trangene's Document de Référence on file with the French Autorité des marchés financiers on its website at <a href="http://www.amffrance.org">http://www.amffrance.org</a> and on Transgene's website at <a href="http://www.transgene.fr">www.transgene.fr</a>.

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## <u>Transgene SA</u> Consolidated balance sheet, IFRS

(in thousands of euros)

**ASSETS** 

30/06/2011

31/12/2010

A33E13	30/00/2011	31/12/2010
Current assets:		
Cash and cash equivalents	13,791	1,379
Other current financial assets	149,424	178,917
Cash, cash equivalent and other	163,215	180,296
financial assets:	·	
Receivables	261	1,162
Inventories	1,033	972
Other current assets	2,861	2,764
Total current assets	167,370	185,194
Non-current assets:	24.072	24.762
Property, plant and equipment	24,873	24,763
Intangible assets Financial assets	1,808 4,898	1,650 4,111
Equity consolidated affiliates	4,696 767	4,111
Other non-current assets	12,214	7,855
Total non-current assets	44,560	38,492
Total assets	211,930	223,686
EQUITY and LIABILITIES	30/06/2011	31/12/2010
Current liabilities:		
Payables	7,998	8,714
Financial liabilities	1,090	1,150
Provision for risks	2	2
Other current liabilities	7,553	8,773
Total current liabilities	16,643	18,639
Non-current liabilities:		
Financial liabilities	24,150	16,684
Defined benefit obligations	2,593	2,390
Other non-current liabilities	1,546	2,355
Total non-current liabilities	28,289	21,429
Total liabilities	44,932	40,068
Equity:	,	•
Share capital	72,523	72,460
Share premiums	425,320	424,408
Retained earnings	(313,029)	(278,810)
Net loss for the year	(17,670)	(34,219)
•		
Other comprehensive income	(146)	(221)
Minority interests	-	
Total Equity and Reserves Attributable to Equity Holders of the Company	166,998	183,618
Total equity and liabilities	211,930	223,686

## <u>Transgene SA</u> Income statement

(in thousands of euros, except for per share data)

	30/06/2011	30/06/2010
Revenue from collaborative and licensing agreements	3,744	3,022
Government financing for research expenditures	4,320	4,310
Revenue	8,064	7,332
Research and development expenses	(23,431)	(18,589)
General and administrative expenses	(2,983)	(3,267)
Other income and (expenses), net	41	156
Net operating expenses	(26,373)	(21,700)
Operating income	(18,309)	(14,368)
Interest income and (expenses), net	639	(94)
Income / (loss) before tax	(17,670)	(14,462)
Income tax expense	-	-
Net income / (loss)	(17,670)	(14,462)
Net income per share (€)	(0.56)	(0.61)
Diluted earnings per share (€)	(0.56)	(0.61)

# <u>Transgene SA</u> Comprehensive income

(in thousands of euros)

	30/06/2011	30/06/2010
Net income / (loss)	(17,670)	(14,462)
Foreign exchange gains or losses	(2)	1
Reevaluation of hedging instruments	77	(374)
Other comprehensive income	75	(373)
Comprehensive income	(17,595)	(14,835)
Of which, equity holders of the	parent (17,595)	(14,835)
Of which, minority in	terests -	-

# <u>Transgene SA</u> Consolidated cash flow statement, IFRS

(in thousands of euros)

	30/06/2011	30/06/2010
Cash flow from operating activities:		
Operating income	(18,309)	(14,367)
Elimination of non-cash elements:		
Changes in provisions	143	95
Depreciation and amortization of tangible and intangible assets	1,305	1,163
Payments in shares	720	512
Others	23	3
Net cash generated from / (used in) operating activities before change in	(16,118)	(12,594)
working capital and other operating cash flow:	(10,110)	(12,334)
Changes in operating working capital:		
Receivables	1, 017	363
Inventories	(61)	32
Other current asset	(3,953)	482
Payables	(405)	301
Prepaid income	(1,438)	5,832
Accrued employee benefits expense	(591)	(93)
Other current liabilities	-	12
Net cash generated from / (used in) operating activities before other	(21,549)	(5,665)
operating cash flow:	(21,545)	(3,003)
Other operating cash flows:		
Financial income	918	184
Financial expenses	(208)	(196)
Exchange gains and losses	50	23
Net cash generated from / (used in) operating activities:	(20,789)	(5,654)
Cash flow from investing activities:		
(Purchase) / disposal of property, plant and equipment	(1,709)	(613)
(Purchase) / disposal of intangible assets	(463)	(631)
Other (purchase) / disposal	(390)	11
Net cash generated from / (used in) investing activities:	(2,562)	(1,233)
Cash flow from financing activities:		
Gross proceeds from issuance of share capital	255	152,143
Fees paid in relation to capital increase	-	(3,645)
Conditional subsidies	13	-
(Acquisition)/disposal of current financial assets	29,493	(204,645)
Net incomes on research tac credit financing	6,465	-
Repayment of finance lease liabilities	(461)	(444)
Net cash generated from / (used in) financing activities:	35,765	(56,591)
Effect of changes in exchange rates on cash and cash equivalents	(2)	4
Net increase (decrease) in cash and cash equivalents:	12,412	(63,474)
Cash and cash equivalents at beginning of period	1,379	64,693
Cash and cash equivalents at end of period	13,791	1,219
Investment in other financial assets	149,424	204,645
Cash, cash equivalent and other financial assets:	163,215	205,864

# <u>Transgene SA</u> Statement of consolidated changes in equity

(in thousands of euros)

	Common	shares	<b>.</b>		Other		Closing
Movements	Number of shares	Share capital	Share premium	Retained earnings	comprehensive	Profit and loss	balance net worth
As at June 30, 2010	31,662,775	72,448	424,024	(278,810)	(373)	(14,462)	202,827
Payments in shares	-	-	525	-	-	-	525
Capital increase	5,425	12	(141)	-	-	-	(129)
Net loss for the period	-	-	-	-	-	(19,757)	(19,757)
Change in fair value of marketable securities available-for-sale	-	-	-	-	(2)	-	(2)
Cash flow hedging	-	-	-	-	154	-	154
As at December 31, 2010	31,668,200	72,460	424,408	(278,810)	(221)	(34,219)	183,618
Payments in shares	-	-	720	-	-	-	720
Issuance of shares	27,682	63	192	-	-	-	255
Net loss appropriation 2010	-	-	-	(34,219)	-	34,219	-
Net loss for the period	-	-	-	-	-	(17,670)	(17,670)
Change in fair value of marketable securities available-for-sale	-	-	-	-	(2)	-	(2)
Cash flow hedging	-	-	-	-	77	-	77
As at June 30, 2011	31,695,882	72,523	425,320	(313,029)	(146)	(17,670)	166,998