PRESS RELEASE

Transgene Reports Business, Pipeline and Financial Update for Q3 2024

TG4050: Promising Phase I data to be presented at SITC 2024 providing clinical proof of principle in adjuvant head and neck cancer setting

Financial visibility confirmed into Q4 2025

Strasbourg, France, November 7, 2024, 5:45 p.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, today provides its business update and financial position for the quarter ending September 30, 2024.

Key events and upcoming milestones

TG4050: Neoantigen therapeutic cancer vaccine

Transgene and NEC will present promising new data from the ongoing randomized Phase I trial of the neoantigen individualized therapeutic cancer vaccine, TG4050 at SITC 2024 on November 9, 2024 (see press release here). These data provide robust clinical proof of principle for Transgene's lead candidate in the adjuvant head and neck cancer setting, a patient population at high risk of relapse.

Compelling 24.1-month median follow-up data presented showed that all 16 patients treated with TG4050 after completion of adjuvant standard of care remain disease-free and have not relapsed, comparing favorably to the observational arm which saw 3 out of 16 patients relapse. All patients treated with TG4050 developed specific immune responses against the selected personalized antigen targets, demonstrating the strong immunogenicity of the cancer vaccine, with both *de novo* and amplified responses. Additionally, immune responses are sustained over a 7-month period, covering the induction and boost periods.

In Q2 2024, Transgene started enrolling patients in the Phase II part of the expanded randomized Phase I/II trial investigating TG4050 in the adjuvant treatment of head and neck cancer (NCT04183166). Patient enrollment continues to progress at a good pace.

TG4050 is the only individualized neoantigen cancer vaccine currently being developed in a randomized trial in the adjuvant treatment of head and neck cancer.

TG4050 has potential applicability across a range of solid tumors where there remains a significant unmet medical need, despite the existing therapeutic options, including immunotherapies. As a result, Transgene is conducting preliminary work on a potential new Phase I trial in a further undisclosed indication.

TG4001 – Shared antigen cancer vaccine

In October 2024, Transgene announced that its randomized Phase II study evaluating TG4001 in combination with avelumab versus avelumab alone in patients with recurrent or metastatic HPV16-positive cervical and anogenital tumors did not meet its primary objective (improvement in progression-free survival).

However, analysis of a pre-planned subgroup showed a positive efficacy trend in favor of the TG4001 containing regimen in cervical cancer patients, which requires further confirmation through additional analyses, including by PD-L1 status. These patients account for approximately half of the patients enrolled in the study. Transgene is currently evaluating the full study results in detail to determine the best way forward for this program and will communicate further once this is completed.

Oncolytic Viruses

BT-001 (intratumoral administration):

In September 2024, Transgene and its partner BioInvent presented preliminary Phase I/IIa data (NCT04725331) at ESMO (see press release here) showing that **BT-001 induced tumor regression in patients unresponsive to prior anti PD(L)-1 treatment**, both as monotherapy and in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab).

BT-001 replicated in the tumor and expressed the encoded GM-CSF and anti-CTLA-4 transgenes. Notably, BT-001 in combination with pembrolizumab showed first signs of efficacy in 2 out of 6 patients, with shrinkage of injected and non-injected lesions. In a reported case study, BT-001 treatment was able to modulate the tumor microenvironment, converting "cold tumors" into "hot tumors", and inducing T cell infiltration.

Transgene and BioInvent are finalizing the second cohort in the part B of the Phase I/IIa trial, to inform on the further development strategy.

TG6050 (intravenous administration):

The Phase I *Delivir* trial (NCT05788926), evaluating TG6050 in patients with advanced non-small cell lung cancer who have failed standard therapeutic options, completed the first two dose levels. Dose-limiting toxicity was observed in one patient in the third cohort and additional patients are being enrolled according to the protocol to complete this trial. Initial data are now expected in H1 2025.

Preclinical data, recently published in the *Journal for ImmunoTherapy of Cancer* (JITC), were awarded with the *JITC Best Oncolytic and Local Immunotherapy Paper Award*. The article on TG6050 demonstrates that it induces tumor regression in numerous "hot" and "cold" murine tumor models investigated in these studies. This antitumoral activity was further amplified when TG6050 was combined with an immune checkpoint inhibitor (article available here).

Operating revenue and income

In millions of euros	**2024 First Nine Months**	**2023 First Nine Months**
Research Tax Credit	4.8	4.8
Revenue from collaborative and licensing agreements	-	1.2
Other income	0.2	0.2
Operating revenue and income	**5.0**	**6.2**

During the first nine months of 2024, operating revenue was mostly comprised of the Research Tax Credit (€4.8 million for the period in 2023 and 2024). The reduction in total operating revenue reflects the discontinuation of the AstraZeneca collaboration in 2023.

Cash, cash equivalents and other financial assets

Cash, cash equivalents and other financial assets stood at €14.0 million as of September 30, 2024, compared to €15.7 million as of December 31, 2023.

In the first nine months of 2024, Transgene's cash burn amounted to €31.3 million compared to a cash burn of €13.8 million in the same period of 2023. The difference is explained by the July 2023 sale of Transgene's remaining shares held in Tasly BioPharmaceuticals for a total amount of US$15.3 million (€14.3 million).

At of the end of July 2024, Transgene announced the conversion into shares of €33 million debt drawn down from the current account advance granted by the Company's major shareholder TSGH (Institut Merieux), in accordance with the terms of an agreement signed for the first time in 2023. As a result, the share capital of Transgene held by TSGH increased from 59.7% to 69.1% of the outstanding shares. In carrying out this transaction, Transgene has strengthened its balance sheet, reduced its debt levels and its debt burden as a result of lower interest payments.

As of September 30, 2024, Transgene had the capacity to draw down €23.5 million from the current account advance provided by TSGH.

Transgene confirms financial visibility into Q4 2025, enabling the Company to deliver news flow on its portfolio progress over the next 12 months.

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About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing cancer cells. The Company's clinical-stage programs consist of a portfolio of therapeutic vaccines and oncolytic viruses: TG4050, the first individualized therapeutic vaccine based on the *myvac*® platform, TG4001 for the treatment of HPV-positive cancers, as well as BT-001 and TG6050, two oncolytic viruses based on the Invir.IO® viral backbone. With Transgene's *myvac*® platform, therapeutic vaccination enters the field of precision medicine with a novel immunotherapy that is fully tailored to each individual. The *myvac*® approach allows the generation of a virus-based immunotherapy that encodes patient-specific mutations identified and selected by Artificial Intelligence capabilities provided by its partner NEC.
With its proprietary platform Invir.IO®, Transgene is building on its viral vector engineering expertise to design a new generation of multifunctional oncolytic viruses.
Additional information about Transgene is available at: http://www.transgene.fr
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