

Transgene Provides Business and Financial Update for Q3 2025

Comprehensive immunogenicity data of individualized neoantigen therapeutic vaccine (**INTV**) TG4050, from the randomized Phase I study in operable Head and Neck Squamous Cell Carcinoma (HNSCC) patients, to be presented at SITC 2025

New TG4050 data further validate its mechanism of action and potential to reduce risk of relapse presented at ASCO 2025

First immunogenicity data in the ongoing Phase II trial in operable HNSCC expected in H2 2026

Strasbourg, France, November 4, 2025, 5:50 p.m. CET – **Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer**, today provides a **business update on its lead asset TG4050 developed from its myvac® platform, upcoming plans, and its financial position** as of September 30, 2025.

TG4050 – INTV: New Data presented at SITC supports TG4050's potential role in preventing cancer relapse

Transgene and its partner NEC¹ will jointly present a poster on **additional immunological data profiling the neoantigen-specific T-cell response after treatment with TG4050 in head and neck cancer** at the **Society for Immunotherapy of Cancer (SITC) Annual Meeting**.

Comprehensive immunogenicity data confirm the ability of TG4050 monotherapy to **induce neoantigen-specific cytotoxic CD8+ T-cell responses capable of targeting and eliminating tumor cells** – see [press release](#). These CD8+ T cells target multiple neoantigens encoded in the vaccine, have tissue resident cytosignature, and are still detectable up to two years after the start of TG4050 treatment. Overall, these data support the TG4050 mechanism of action that resulted in the reduction of risk of relapse observed in the randomized Phase I study.

¹ NEC Corporation (NEC; TSE: 6701), a leader in IT, network and AI technologies

These data have been generated from the randomized Phase I part of the ongoing Phase I/II trial evaluating TG4050 as a single agent in the adjuvant treatment of HPV-negative HNSCC, in patients that are in complete response following surgery and adjuvant (chemo-)radiotherapy.

These results follow the positive randomized Phase I data presented in a rapid oral presentation at the American Society of Clinical Oncology (ASCO Annual Meeting – see [press release](#)).

The SITC **abstract** is available both on the [SITC](#) and [Transgene](#) websites. The **poster presentation** will take place on **November 8** at the Conference and will be available on Transgene's website following the presentation.

Transgene will host a webcast (in English) to discuss the SITC data on November 14, 2025, from 10:00 a.m. to 11:00 a.m. ET (16:00 to 17:00 CET). The webcast and the replay will be available [here](#) and on [Transgene's](#) website.

Transgene expects to complete the randomization of patients with operable HNSCC in the Phase II part of the trial by early 2026. First immunogenicity data from this Phase II part are expected to be available in H2 2026. The first efficacy data (2-year disease-free survival, DFS) will become available as soon as all patients are evaluable for two-year DFS with either an event (relapse or death) or 2-year follow-up whichever occurs first.

Transgene is currently evaluating the most efficient regulatory pathway to **accelerate the development** of its **lead asset, TG4050**, with the goal of bringing it to patients with operable HNSCC as quickly as possible.

myvac® platform: Potential to reduce the risk of relapse across multiple operable solid tumors

Transgene's INTV platform, *myvac*®, could be applied across a range of solid tumors where in many cases a **significant unmet medical need remains**. In parallel, Transgene is initiating start-up activities for a potential **new Phase I trial in a second indication in an early treatment setting**, with the aim of initiating once all conditions are met.

BT-001 (oncolytic virus - intratumoral administration): Updated Phase I/II data presented at ESMO 2025 demonstrated positive antitumoral activity

Transgene and BioInvent presented a poster **on updated clinical results showing the positive antitumoral activity of BT-001 in patients with advanced refractory tumors** at the 2025 European Society for Medical Oncology (ESMO) Annual Meeting – see [press release](#).

These updated data from the Phase I trial ([NCT04725331](#)) evaluating **BT-001 in combination with MSD's** (Merck & Co., Inc., Rahway, NJ, USA) **anti-PD-1 therapy, KEYTRUDA®** (pembrolizumab)² showed positive local, abscopal and sustained antitumoral activity in injected and non-injected lesions. Immune-mediated tumor shrinkage is consistent with the mechanistic hypothesis that BT-001, in combination with pembrolizumab, turns “cold” tumors into immunologically active ones.

The poster is available on [Transgene's](#) website.

Transgene and BioInvent are exploring clinical development opportunities for intratumoral administration of BT-001 in collaboration with clinicians.

² KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

Key financial elements

In millions of euros

	Q3	
	2025	2024
Research Tax Credit	5.8	4.8
Revenue from collaborative and licensing agreements	0.1	-
Other income	0.3	0.2
Operating income	6.1³	5.0

During the third quarter of 2025, the Research Tax Credit increased to €5.8 million compared to €4.8 million for the same period in 2024, reflecting the progress of the ongoing Phase II part of the clinical trial evaluating TG4050 in head and neck cancer, with sustained patient enrollment and related expenses, including the manufacturing of individualized batches.

As of September 30, 2025, Transgene had €12.8 million in cash, compared to €16.7 million as of December 31, 2024.

Over the first nine months of 2025, Transgene's net cash burn⁴ was €28.8 million (including the prefinancing of the 2024 Research Tax Credit for €5.2 million in June 2025) compared to €31.3 million for the same period in 2024.

Business funded until the end of December 2026

In March 2025, the Company signed a new amendment to the current account advance agreement with its major shareholder TSGH (Institut Mérieux), which increased the total amount of the facility by €15 million to €48 million. As of September 30, 2025, the Company has drawn down €35.5 million from this facility.

With this credit facility and the support of TSGH (Institut Mérieux), Transgene is able to fund its business until the end of December 2026, enabling the Company to deliver significant news flow on its myvac[®] platform over the next 12 months.

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³ The key financial statements are presented in millions of euros which may lead to apparent differences in rounding that are not factual

⁴ Cash burn corresponds to the sum of net cash flows from operating, investing and financing activities, excluding proceeds from share issuances and excluding current account advance/other financial asset disposals related to the parent company. It does not include the effects of exchange rate fluctuations

About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. The Company's clinical-stage programs consist of a portfolio of viral vector-based immunotherapeutics. TG4050, the first individualized therapeutic vaccine based on the *myvac*® platform is the Company's lead asset, with demonstrated proof of principle in patients in the adjuvant treatment of head and neck cancers. The Company has other viral vector-based assets, including BT-001, an oncolytic virus based on the Invir.IO® viral backbone, which is in clinical development. The Company also conducts innovative discovery and preclinical work, aimed at developing novel viral vector-based modalities.

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 through advanced Artificial Intelligence technologies.

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: www.transgene.com

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Disclaimer

This press release contains forward-looking statements, which are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results, regulatory authorities' agreement with development phases, and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product manufacturing, development and commercialization, and marketing approval by government regulatory authorities. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Universal Registration Document, available on the AMF website (<http://www.amf-france.org>) or on Transgene's website (www.transgene.com). Forward-looking statements speak only as of the date on which they are made, and Transgene undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.