transgene

2025 Half-Year Results and Business Update

PRESS RELEASE

Transgene's Individualized Neoantigen Therapeutic Cancer Vaccine TG4050 Delivers Positive Randomized Phase I Data – Randomization to be Completed in Phase II Part in Q4 2025

Positive Phase I data with TG4050 in operable Head and Neck Squamous Cell Carcinoma (HNSCC)

- 100% disease-free survival after 2 years of follow-up — data presented in a rapid oral presentation at ASCO (June 2025)
- Transgene to report additional immunological data at a scientific conference in Q4 2025

Ongoing Phase II part with TG4050 in operable HNSCC

- Patient screening completed, completion of randomization expected in Q4 2025
- First immunogenicity data expected in H2 2026, and efficacy data expected in Q4 2027

Preparing new Phase I trial in an additional indication

Business funded until the end of December 2026

Conference call scheduled today at 6 p.m. CET (in English). See details below.

Strasbourg, France, September 16, 2025, 5:45 pm CET — **Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer,** today announces its **financial results for the six-month period ended June 30, 2025**, and provides an update on the *myvac*® platform, its lead asset TG4050, and upcoming plans.

Dr. Alessandro Riva, MD, Chairman and CEO of Transgene, commented: *"We are extremely proud that all patients treated with TG4050 in our Phase I trial remained disease-free after a median follow-up of 30 months. These results, selected for oral presentation at ASCO 2025, represent a pivotal milestone for Transgene and underscore the potential of our viral vector-based individualized therapeutic cancer vaccine platform. The durable clinical benefit and robust immune responses we have observed, together with the strong enthusiasm from clinicians, reinforce our vision to deliver transformative therapies to people living with operable head and neck cancer. TG4050 continues to progress through Phase II and we look forward to sharing first data from his trial in 2026. We will also present further immunological data from our Phase I study later this year."*

TG4050: Individualized Neoantigen Therapeutic Cancer Vaccine (INTV)

ASCO 2025: TG4050, the first candidate from Transgene's *myvac*® platform, achieves all Phase I endpoints, with 100% disease-free survival (DFS) after more than 2-years

Transgene presented positive data from the randomized Phase I part of the ongoing multicenter Phase I/II trial (NCT04183166) in an oral presentation at the **American Society of Clinical Oncology** (**ASCO 2025**) Annual Meeting (see press release). **TG4050** was administered as a single agent in the adjuvant treatment of HPV-negative operable head and neck squamous cell carcinoma (HNSCC).

- All patients who received TG4050 remained **disease-free for at least two years** (median follow-up: 30 months), providing strong **clinical proof of principle**. TG4050 also induced **durable and specific T cell responses persisting 24 months after the start of treatment**.

➔ In addition, the **results** successfully **met all trial endpoints (**including safety and feasibility). **Additional immunological data from Phase I patients will be presented at an upcoming congress in Q4 2025. These data will provide further insight into the phenotyping of patients' immune responses against selected epitopes. In addition, Transgene expects to communicate on the 3-year follow-up of Phase I patients in H1 2026.**

Based on the positive Phase I data presented at ASCO and further immunological data (that will be communicated in Q4 2025), Transgene is currently evaluating the most efficient regulatory pathway to **accelerate the development** of TG4050 and bring it to patients with operable HNSCC as quickly as possible.

Ongoing Phase II part: critical milestones in 2026 and 2027

Initial patient screening has been completed in the randomized Phase II part of the Phase I/II clinical trial with TG4050 (see press release).

Randomization of all patients in the Phase II part is expected to be completed by the end of 2025.

First immunogenicity data and preliminary efficacy data from the Phase II part of the trial are expected in H2 2026 and Q4 2027, respectively.

Expanding the *myvac*® potential in 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 with the development plan in HNSCC, Transgene is setting up a **new Phase I trial** in a second indication **in an early treatment setting**, with the aim to initiate it as soon as all conditions are met.

Other viral vector-based assets

BT-001 (oncolytic virus – intratumoral administration): Updated data on Phase I/II trial to be presented at ESMO 2025

Transgene and BioInvent will present a poster on updated data from the ongoing Phase I trial (NCT04725331) evaluating BT-001, an armed oncolytic virus expressing an anti-CTLA4 monoclonal antibody, in combination with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab)[1], at **the European Society for Medical Oncology** Annual Meeting (ESMO 2025 — see press release). The abstract will be available on the ESMO website on October 13, 2025, at 0:05 am CEST.

In previously reported data (ESMO 2024), BT-001 was well tolerated with limited adverse events and no dose-limiting toxicities. BT-001 in monotherapy was shown to shrink injected lesions in patients with advanced solid tumors.
In combination with pembrolizumab, BT-001 showed promising efficacy data with partial responses in patients with relapsed and refractory advanced melanoma and leiomyosarcoma.

Transgene and BioInvent are pursuing clinical development opportunities with clinicians for BT-001 administered intratumorally.

TG4001 (HPV16 therapeutic vaccine)

Transgene presented a poster (available here) on randomized Phase II data of TG4001 in combination with avelumab in a cervical cancer subgroup at the 2025 ASCO conference.

Transgene is currently evaluating potential partnership opportunities to determine the best path forward for the program.

TG6050 (oncolytic virus — intravenous administration)

The Phase I dose-escalation *Delivir* trial (NCT05788926), evaluating TG6050 administered by intravenous infusion, has enrolled 22 patients with advanced non-small cell lung cancer who have failed standard therapeutic options.

TG6050 has demonstrated good tolerability as monotherapy, with no new safety signals identified. However, the analysis of preliminary efficacy and translational data did not demonstrate a clear efficacy signal in the context of intravenous administration in this indication. Patient recruitment of the Phase I trial is completed, and the Company is evaluating the best way forward for this candidate.

Governance: Simone Steiner joined Transgene as Chief Technical Officer and Emmanuelle Quilès as independent Board member

In April 2025, **Simone Steiner joined Transgene as Chief Technical Officer** (CTO), and member of the executive team (see press release). Her track record in the field of CAR-T cell and TCR engineered T cell therapies will be key in **optimizing the manufacturing of *myvac*®-based immunotherapies** with a focus on scalability, productivity and efficiency.

In addition, on July 9, 2025, the Board of Directors appointed a new **independent director**, **Emmanuelle Quilès**. Emmanuelle brings 25 years of experience in strategic leadership roles across the global pharmaceutical industry (Johnson & Johnson, Wyeth, Pfizer and her own biotech start-up Harmonium). She succeeds Philippe Archinard, who has retired from the Board (see press release).

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

Key financial elements

The Board of Directors of Transgene met on September 16, 2025, and closed the financial statements for the six-month period ended June 30, 2025. The Statutory Auditors have conducted a limited review of the interim consolidated financial statements.

The half-year financial report is available on Transgene's website.

Key elements of the income statement

(in thousands of euros)	**June 30, 2025**	**June 30, 2024**
Operating income	**4,579**	**3,357**
Research and development expenses	(17,910)	(15,423)
General and administrative expenses	(3,783)	(4,558)
Other expenses	54	129
Operating expenses	**(21,639)**	**(19,852)**
Operating income/(loss)	**(17,060)**	**(16,495)**
Financial income/(loss)	(2,235)	10
Net income/(loss)	**(19,295)**	**(16,485)**

Operating income amounted to €4.6 million for the first six months of 2025 compared to €3.4 million for the same period in 2024.

- The Research Tax Credit for the first half of 2025, amounted to €4.4 million versus €3.2 million for the same period in 2024.
- Revenue from research and development collaborations amounted to €96,000 in the first half of 2025, compared to €23,000 in the first half of 2024.

As of June 30, 2025, Transgene had €16.8 million in cash, compared to €16.7 million as of December 31, 2024.

Transgene's **cash burn**[2] amounted to €18.8 million in the first half of 2025 compared with €20.4 million for the same period in 2024.

Business funded until the end of 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. The Company has drawn down €28.8 million from this facility as of June 30, 2025.

With this credit facility and the commitment of TSGH (Institut Mérieux) to support the company, Transgene is now able to fund its business until the end of December 2026, enabling the Company to reach important development milestones and deliver significant news flow on its lead asset TG4050.

[2] *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.*

A conference call **in English** is scheduled today, **September 16, 2025, at 6:00 p.m. CET (12:00 p.m. ET)**.

Webcast link to English language conference call:

https://edge.media-server.com/mmc/p/ebm8ddzc

Please log in to the following link to obtain your personal telephone IDs.

https://register-conf.media-server.com/register/BI22b157713fbc4d06bd6d51b6107f1351

A replay of the call will be available on the Transgene website (www.transgene.com) following the live event.

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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. 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 portfolio also includes other viral-vector-based immunotherapies: 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. 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 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: www.transgene.com
Follow us on social media: X (formerly Twitter): @TransgeneSA — LinkedIn: @Transgene — Bluesky: @Transgene

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.