

Transgene Extends its *myvac*® Platform, Further Establishing its Position as a Key Player in the Rapidly Emerging Individualized Cancer Immunotherapy Field

***myvac*® – Expanding potential across solid tumors through viral vector, AI driven neoantigen selection, and scalable cell-line manufacturing**

TG4050 – First Individualized Neoantigen Therapeutic Vaccine (INTV) from the *myvac*® platform advancing in resected HNSCC¹

- Randomized Phase 1 data published in *Nature Communications*; Sustained 100% disease-free survival (DFS) after more than 3 years of follow-up, showing durable clinical outcomes and potential to prevent cancer recurrence
- Randomized Phase 2 recruitment completed, trial is ongoing with topline results expected in Q1 2028
- Preparing for potential pivotal trial in HNSCC with cell-line manufacturing

TG4070 – Second novel *myvac*®-based INTV in early-stage NSCLC², with potential to be applied across multiple early-stage solid tumor types

- Leverages Transgene's proprietary AI driven neoantigen selection (SNIPER™) and cell-line manufacturing
- All clinical sites open for randomized Phase 1 trial

Positive preclinical data from TG-MVA™, a new generation of prophylactic vaccine against mpox and smallpox based on MVA vector

Business funded until early 2028

Strasbourg, France, September 24, 2026, 5:45 pm CET — **Transgene (Euronext Paris: TNG), a biotech company developing *myvac*®, an individualized neoantigen therapeutic vaccines (INTV) platform designed to prevent cancer recurrence and a portfolio of virus-based candidates**, today publishes its financial results for the six months ended June 30, 2026, and provides an update on the progress of its pipeline and its upcoming plans.

¹ HNSCC: Head and Neck Squamous Cell Carcinoma

² NSCLC: Non-Small Cell Lung Cancer

“Since the beginning of the year, Transgene has delivered tangible progress and important results with the publication of the TG4050 Phase 1 data, the completion of enrolment in the Phase 2 trial in the same indication and the initiation of the Phase 1 trial of TG4070, the second INTV from our myvac® platform introducing our proprietary AI-driven neoantigen selection and scalable cell-line manufacturing capabilities.” commented **Alessandro Riva, MD, Chairman and Chief Executive Officer of Transgene.**

“These milestones strengthen the foundation of the continued advancement of our myvac® platform, which will be key in our strategy to be Phase 3-ready in 2028, when we will obtain the topline results of the ongoing Phase 2 trial of TG4050 in resected head and neck cancer. At the same time, we are advancing our second INTV, TG4070, through Phase 1 development for non-small cell lung cancer.

“In parallel, we continue to leverage our expertise in MVA to develop TG-MVA™, a prophylactic vaccine against mpox and smallpox designed to address the growing global needs in biosecurity, pandemic preparedness and vaccine supply resilience. Supported by our financial visibility through early 2028, we are very well positioned to execute on our strategy and deliver the next wave of clinical and operational milestones for patients, partners and shareholders.”

TG4050: Data continue to support potential role in preventing cancer recurrence in HNSCC

Phase 1 part: Robust clinical proof of principle, with 100% DFS sustained after more than 3 years of follow-up – now published in leading peer-reviewed journal *Nature Communications*

At the end of August 2026, the comprehensive and compelling clinical and translational results from the Phase 1 part of Transgene’s randomized Phase 1/2 trial ([NCT04183166](#)) evaluating TG4050 in resected HNSCC ([see press release](#)) were published in *Nature Communications*. The peer-reviewed publication confirmed the positive clinical and translational findings, TG4050’s favorable safety profile and the persistence of durable neoantigen-specific CD8+ T-cell responses one year after the end of treatment.

Latest follow-up data, announced alongside the publication, demonstrate sustained 100% DFS in patients treated with TG4050 after more than 3 years of follow-up (41 months median follow-up), whereas 3 of 16 patients in the control arm have relapsed.

Phase 2 part: patient randomization completed

In April 2026, Transgene announced the completion of patient randomization in the Phase 2 part of the Phase 1/2 trial for the adjuvant treatment of HNSCC ([see press release](#)).

The primary objective of the Phase 1/2 trial is to compare TG4050’s efficacy as a single agent versus watchful waiting in patients with resected locoregionally advanced HPV-negative head and neck cancer, with 2-year DFS as the primary endpoint.

The emergence of immune checkpoint inhibitor (ICI)-based perioperative treatment marks an important advance in the HNSCC treatment landscape. However, a significant unmet medical need remains, with approximately 35% of patients still experiencing disease recurrence within two years. TG4050 is designed to further improve outcomes in this population by inducing durable, patient-specific anti-tumor immune responses with the potential to reduce the risk of relapse.

Transgene expects to communicate topline results from TG4050’s Phase 1/2 trial by the end of Q1 2028. First immunological data are expected to be available in H2 2026, with the goal of presenting them at a scientific conference in H1 2027.

Preparing future clinical development and potential pivotal clinical trial in HNSCC

In April 2026, **Transgene and NEC Bio B.V. announced the signing of a license agreement** to advance the clinical development of TG4050 in head and neck cancer ([see press release](#)).

Under this agreement, Transgene secures access to NEC's AI-based neoantigen prediction platform, to support TG4050's further clinical development, commercialization and potential partnering. Transgene has paid a technology access fee of €2.5 million in Transgene shares as well as €1.0 million of the additional €2.5 million cash payment, the remainder of which will be paid out in several instalments through early 2028. Additional development and milestone payments will be paid to NEC based upon progress of the clinical development of TG4050 in head and neck cancer. NEC retains full ownership and operational control of its AI platform and will support Transgene in conducting further clinical activity.

In parallel, **Transgene is optimizing its manufacturing processes and capabilities** to prepare for a potential pivotal clinical trial in HNSCC, including a transition of TG4050 to cell-line based manufacturing.

TG4070: Combining cutting-edge proprietary AI and scalable manufacturing to further expand the potential of the *myvac*® platform across multiple solid tumor indications

Initiation of a randomized Phase 1 trial for TG4070 in NSCLC

In June 2026, Transgene announced the initiation of a **randomized** Phase 1 trial evaluating TG4070, a novel INTV **fully designed and developed in-house** ([see press release](#)). Transgene's second INTV candidate, **TG4070, reflects the important strategic expansion of the *myvac*® platform**. Like TG4050, it leverages Transgene's clinically validated MVA viral vector, ensuring technological consistency of the *myvac*® platform.

Patient screening is underway in this multicenter trial. The study is evaluating TG4070 in combination with nivolumab in patients with resected NSCLC following neoadjuvant nivolumab plus chemotherapy ([EUCT 2025-520946-31-00](#)). The combination is designed to leverage the complementary potential of individualized vaccination and immune checkpoint inhibition to enhance and sustain patient-specific anti-tumor immune responses. Prof. Nicolas Girard, MD, PhD (Institut Curie) is the Principal Investigator. A replay of Transgene's KOL event to discuss this new indication and the associated clinical trial is available [here](#).

SNIPER™: Proprietary AI-based tool enabling high-precision neoantigen selection

Transgene has developed its proprietary in-house, AI-driven bioinformatics tool, SNIPER™, to support the development of TG4070 and future *myvac*®-derived candidates. Integrating multiple computational models, SNIPER™ is designed to identify and prioritize highly immunogenic neoantigens for each individual patient through a proprietary scoring framework.

In addition, **VacDesignR®**, fully integrated into the *myvac*® platform, is Transgene's patented in-house computational design engine that optimizes genetic constructs for MVA vectors, significantly improving production reliability and vector quality.

Cell-line optimized manufacturing to support large scale production for *myvac*® candidates

TG4070 is manufactured using a **scalable and transposable cell-line based process** designed to support broader deployment of INTV candidates while ensuring reliable vaccine supply. This optimized process enables more **efficient and automated production, improved lead times and**

scalability. These manufacturing advances broaden the potential application of the myvac® platform across additional indications and larger patient populations.

Together, these proprietary capabilities provide Transgene with an integrated in-house technology suite spanning neoantigen selection, vaccine design and scalable manufacturing to support INTV development from candidate design through clinical development.

Transgene extends its pipeline with TG-MVA™, a prophylactic vaccine candidate against mpox and smallpox

Leveraging the investment already made in the MVA cell-line platform used for myvac®, Transgene is applying its deep **viral-vector engineering** expertise to *Orthopoxvirus*-related diseases, including **mpox** and **smallpox**.

TG-MVA™ is a next generation vaccine candidate based on a non-replicating MVA backbone and an **innovative cell line-based manufacturing process**. It is designed to address key manufacturing and supply challenges, with the potential to diversify and expand vaccine availability to address public health needs and preparedness for future epidemics or bioterrorism threats.

On June 25, 2026, Transgene presented new preclinical data at the World Congress on Infectious Diseases (WCID) 2026, demonstrating the potential of TG-MVA™ to provide robust protection against monkeypox virus (MPXV) (see presentation [here](#)).

Based on these positive results and ongoing discussions with Health Authorities and other key stakeholders on the next development steps, Transgene is preparing to advance TG-MVA™ into clinical development to address future vaccine supply needs.

BT-001 oncolytic virus for intratumoral administration

The results obtained to date support the continued clinical development of BT-001 in solid tumors with the aim of improving responses to immunotherapy.

A Phase 1 clinical trial sponsored by an independent investigator at Copenhagen University Hospital has been approved by the Danish health authorities. Transgene and the University of Copenhagen are collaborating with the OV-PRIME-R trial to evaluate the combination of Transgene's armed oncolytic virus BT-001 with an anti-PD1 in patients with localized rectal cancer with proficient mismatch repair status. Patient screening is expected to start in the coming months.

Governance: Anne Stehlin joins Transgene as Chief Quality Officer; Katell Bidet Huang appointed Interim Chief Scientific Officer

Anne Stehlin, PharmD, recently joined Transgene as Chief Quality Officer and Responsible Pharmacist. Reporting to Chairman and CEO Alessandro Riva, she is a member of the Executive Committee.

Dr. Stehlin is a pharmaceutical executive with extensive experience in quality and manufacturing operations. Prior to joining Transgene, she held senior global quality leadership roles at Lonza, a leading biopharmaceutical CDMO. Before that, she served as Head of Global Quality Management and a member of the extended management team at Basilea Pharmaceutica.

Earlier in her career, she held multiple leadership roles at Novartis across technical operations and product quality, eventually serving as Global Head of Product Quality Lifecycle Management.

Dr. Stehlin holds a PharmD degree from the University of Strasbourg.

Katell Bidet Huang, PhD, head of Translational Medicine at Transgene, has been appointed Interim Chief Scientific Officer (CSO), succeeding Maurizio Ceppi who has left the Company. In this role, she joins Transgene's Executive Committee and will ensure continuity of the Company's scientific activities and maintain momentum across its research and development programs. She will serve in this position until a permanent Chief Scientific Officer is appointed.

Key Financial Elements & Financial Visibility

<i>(in thousands of euros)</i>	June 30, 2026	June 30, 2025
Operating income	2,993	4,579
Research and development expenses	(15,425)	(17,910)
General and administrative expenses	(4,122)	(3,783)
Other expenses	(186)	54
Operating expenses	(19,733)	(21,639)
Operating income/(loss)	(16,740)	(17,060)
Financial income/(loss)	1,071	(2,235)
Net income/(loss)	(15,669)	(19,295)

Operating income amounted to €3.0 million for the first six months of 2026 compared to €4.6 million for the same period in 2025. It mainly consisted of the Research Tax Credit, amounting to €2.5 million, compared with €4.4 million for the same period in 2025.

As of June 30, 2026, Transgene had €92.8 million in cash, cash equivalents and other current financial assets, compared to €111.9 million as of December 31, 2025.

Transgene's **cash burn**³ amounted to €20.3 million in the first half of 2026 compared with €18.8 million for the same period in 2025.

Under current plans, **the company has sufficient cash to ensure financial visibility until early 2028.**

The half-year financial report is available on [Transgene](#) website.

The Board of Directors of Transgene met on September 24, 2026, and closed the financial statements for the six-month period ended June 30, 2026. The Statutory Auditors have conducted a limited review of the interim consolidated financial statements.

³ 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.

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About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing virus-based targeted immunotherapies and vaccines. The Company's clinical-stage programs consist of a portfolio of viral vector-based immunotherapeutics. Transgene's *myvac*® platform is designed to develop individualized neoantigen therapeutic vaccines (INTVs), with potential across multiple solid tumor types.

TG4050, the first INTV based on the *myvac*® platform is the Company's lead asset, with demonstrated clinical proof of principle in the adjuvant treatment of head and neck cancer. TG4070, the second *myvac*®-based INTV introduces Transgene's proprietary AI-driven neoantigen selection and scalable cell-line manufacturing capabilities and is in Phase 1 clinical development in combination with nivolumab in the adjuvant treatment of non-small cell lung cancer (NSCLC). The Company's other viral vector-based assets include BT-001, an oncolytic virus based on the Invir.IO® viral backbone, which is in clinical development. Transgene 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 an immunotherapy tailored to each individual patient. The *myvac*® approach enables the generation of virus-based immunotherapies encoding patient-specific neoantigens. Transgene has further expanded the platform's capabilities with its own proprietary AI-driven neoantigen selection and scalable cell-line manufacturing.

Leveraging its MVA and cell-line manufacturing expertise, Transgene is developing TG-MVA™, a next-generation prophylactic vaccine candidate against mpox and smallpox designed to address key manufacturing and supply challenges.

With its proprietary Invir.IO® platform, 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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