transgene

2024 Full-year results and business update

PRESS RELEASE

Transgene Achieves Key Milestones in 2024, Including Clinical Proof of Principle for Individualized Cancer Vaccine – Strong Outlook for 2025

- *Clinical proof of principle obtained in Phase I adjuvant head and neck cancer trial with individualized cancer vaccine TG4050 – Further data on 24-month follow-up for all patients of the Phase I part expected in Q2 2025*

- *Randomization in Phase II part of the Phase I/II trial evaluating TG4050 in head and neck cancer patients due to be completed in Q4 2025*

- *New trial with individualized cancer vaccine planned to start in Q4 2025 in a second indication*

- *Business funded until the end of April 2026*

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

Strasbourg, France, March 27, 2025, 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 publishes its **financial results for 2024**, and provides an **update on its product pipeline** and **outlook for 2025**.

"By demonstrating clinical proof of principle for TG4050, Transgene's first individualized therapeutic cancer vaccine derived from the myvac® *platform, we achieved a significant milestone in 2024. The highly encouraging early results from the Phase I part of our Phase I/II trial of TG4050 presented at SITC 2024 have enabled the initiation of the ongoing Phase II part of the study. Enrollment is progressing well, reflecting strong support from both patients and clinicians for this novel candidate. We are confident that this Phase II trial will allow us to further confirm our promising initial data. We are monitoring innovation in the adjuvant setting of operable head and neck cancer and assessing the potential next steps to further accelerate our program."*

"In 2025, we will continue to expand the potential of myvac®*. Our goal is to launch at least one new clinical trial in a second indication by year-end and continue optimizing our design and manufacturing processes. This innovative platform leverages the power of the MVA vector, the latest innovations in AI-powered neoantigen prediction and our strong bioengineering environment to design to design a tailored therapy for each patient and allows us to take advantage of the current momentum in individualized cancer vaccines."*

"Driven by these technology advancements and supported by an innovation-driven team, we remain committed to executing our growth strategy. We are confident that our focus on viral vector-based

immunotherapies will enable us to deliver transformative benefits to a broad spectrum of cancer patients," commented **Dr. Alessandro Riva, MD, Chairman and CEO of Transgene**.

Key events and upcoming milestones

Individualized neoantigen therapeutic cancer vaccine (TG4050)

Significant progress has been made with Transgene's *myvac*® individualized cancer vaccine program in 2024:

- ✓ **Proof of principle data from Phase I part of the Phase I/II trial of TG4050 in the adjuvant setting of head and neck cancer. All TG4050-treated patients remained disease-free after median follow-up of 24.1 months (compared to three relapses in the control arm);**
- ✓ **Phase II part of study launched in June 2024 based on these promising early data.**

Positive data from Phase I part:

Transgene and NEC presented **promising data from the ongoing randomized Phase I part of the Phase I/II trial** (NCT04183166) of the neoantigen individualized therapeutic cancer vaccine, TG4050, at AACR 2024 and at SITC 2024 (see poster here).

In the Phase I part of the trial, **all patients who received TG4050 after successful completion of adjuvant standard of care, remained disease-free and had not relapsed after a median follow-up of 24.1 months**, comparing favorably to the observational arm which showed three out of 16 patients had relapsed (data cut-off: end of September 2024).
Transgene and Institut Curie also presented compelling **immunogenicity data** in patients, showing the induction of **specific immune responses** against selected personalized antigen targets. Additionally, immune responses were shown to be sustained over a 7-month period.

In this trial, primary objectives were safety and tolerability. Feasibility and disease-free survival (DFS) were secondary objectives. Exploratory objectives included immunogenicity and assessment of tumor biomarkers (TMB, PD-L1).
These data provide robust clinical proof of principle for Transgene's lead asset in the adjuvant head and neck cancer setting, a patient population at risk of relapse.

Progress into Phase II part:

Based on the promising Phase I data, the randomized trial has **progressed, with the Phase II part having started patient enrollment in June 2024,** in collaboration with NEC.
Patient enrollment is progressing at a good pace and completion of randomization is expected in Q4 2025. In this trial, the primary objective is 24-month DFS (disease-free survival).

Upcoming news flow for TG4050 and the *myvac*® platform:

Transgene's objective for TG4050 is to extend DFS and reduce the risk of relapse. The Company will present **24-month DFS for all patients in the Phase I** part of the Phase I/II trial in Q2 2025. In locally advanced, resectable head and neck cancers, 25% of patients are expected to relapse within 24 months after successful completion of surgery and adjuvant chemoradiotherapy (*Cooper JS et al. NEJM, 2004; DY Lee et al. Head Neck,* 2020).

These updated clinical data combined with innovation in the adjuvant treatment of operable head and neck cancer will be instrumental in determining TG4050's optimal development path towards registration in this indication.

The *myvac*® individualized cancer vaccine platform is applicable across a range of solid tumors where a significant unmet medical need remains, despite current and future treatment options, including immunotherapies.

Consequently, Transgene is starting initial preparations for a **new Phase I trial** in a second undisclosed indication, **with the aim to initiate the trial in Q4 2025**.

Other viral vector-based assets

Shared antigens cancer vaccine (TG4001)

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 of patients showed a positive efficacy trend in favor of the TG4001 containing regimen in cervical cancer patients.

Transgene is currently evaluating the full clinical and translational study results to determine the best way forward for this program. **Clinical data from this trial will be presented at a scientific congress in Q2 2025.**

BT-001 (oncolytic virus — intratumoral administration)

The Phase I/IIa trial (NCT04725331) is ongoing and the last patient in the Phase I part was enrolled in August 2024. In Part A of the trial, patients are given BT-001 as monotherapy, while in Part B, patients are given BT-001 in combination with pembrolizumab. In this part, KEYTRUDA® (pembrolizumab) is provided by MSD (Merck & Co). KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Preliminary data were presented at ESMO 2024 (see press release here). The data indicated that BT-001 replicated in the tumor without being detectable in blood. As monotherapy and in combination with pembrolizumab, BT-001 was shown to be well tolerated. BT-001 also showed first signs of efficacy with clinical response in two out of six refractory patients, when given in combination with pembrolizumab, with shrinkage of injected and non-injected lesions. Treatment with BT-001 converted “cold” tumors into “hot” ones, and induced T-cell infiltration, as well as PD(L)-1 expression in the tumor microenvironment. Transgene and partner BioInvent are currently analyzing the second cohort of Part B of the Phase I to define the strategy for further development. Updated data is expected to be presented in H2 2025.

TG6050 (oncolytic virus — intravenous administration)

The Phase I *Delivir* trial, evaluating TG6050 in patients with advanced non-small cell lung cancer who have failed standard therapeutic options, has completed enrollment.

Initial data from the Phase I trial are expected to be reported in Q2 2025. Transgene will complete the analysis of these data to determine the best way forward for this candidate.

In July 2024, Transgene published preclinical data in the *Journal for ImmunoTherapy of Cancer* (JITC) (see article here), where the paper on TG6050 won the *JITC Best Oncolytic and Local Immunotherapy Paper Award*. The study demonstrated that TG6050 induces tumor regression in several “hot” and “cold” mouse tumor models. This antitumor activity was amplified when TG6050 was combined with an immune checkpoint inhibitor.

Transgene's new leadership structure focused on accelerating the development of its innovative immunotherapy portfolio

To drive its ambitious strategic plan centered on the individualized cancer vaccine platform *myvac®*, Transgene has gathered an expert leadership team.

Transgene's Management Committee comprises the following members:

- Alessandro Riva, Chairman & Chief Executive Officer (CEO);
- Christophe Ancel, Chief Quality Officer & Qualified Pharmacist;
- Maurizio Ceppi, Chief Scientific Officer (CSO) (as of September 2024);
- Emmanuelle Dochy, Chief Medical Officer (CMO) (as of September 2024);
- John Felitti, General Counsel & Corporate Secretary;
- Lucie Larguier, Chief Financial Officer (CFO) (as of March 2024);
- Christelle Schwoerer, Chief Human Resources Officer (as of April 2024);
- Simone Steiner, Chief Technical Officer (CTO) (as of April 2025);
- James Wentworth, Chief Business Officer (CBO) (as of January 2024).

Key elements of the 2024 income statement

- **Operating revenue was €6.4 million in 2024** compared to €7.9 million in 2023. Operating revenue was mostly comprised of the Research Tax Credit (**€6.0 million in 2024** and €6.4 million in 2023). The reduction in total operating revenue reflects the discontinuation of the AstraZeneca collaboration in 2023.
- **Net operating expenses stood at €42.0 million in 2024,** compared to €37.9 million in 2023, reflecting intense activity on all clinical-stage candidates, including the preparation and launch of the Phase II part of the trial evaluating TG4050 in head and neck cancer. This activity is reflected in **R&D expenses,** at **€34.3** million in 2024 versus €29.6 million in 2023. **General and administrative expenses** amounted to **€7.8** million in 2024 (€7.0 million in 2023).
- **In 2024, the operating loss was €35.7 million**, compared to a loss of €30.0 million in 2023.
- **Net loss was €34.0 million in 2024,** compared to a net loss of €22.3 million in 2023.
- **The net cash burn was €27.7 million in 2024,** compared to €24.0 million in 2023.
- **Cash available at year-end 2024 stood at €16.7 million**, compared to €15.7 million at the end of 2023.

Business funded until the end of April 2026

The Company has signed a new amendment to the current account advance agreement with TSGH (Institut Mérieux), which increases the total amount of the facility by €15 million to €48 million. The Company has drawn down €22.5 million from this facility as of today.
With this credit facility and the support of TSGH (Institut Mérieux), the Company is now **able to fund its business until the end of April 2026**.

In July 2024, TSGH subscribed to Transgene a €33 million capital increase and requested the reimbursement of an equivalent amount from the current account advance. This reimbursement was carried out by way of set-off against the payment of the subscription price of the capital increase by TSGH.

The financial statements for 2024 as well as management's discussion and analysis are attached to this press release (*appendices A and B*).

*The **Board of Directors of Transgene met on March 27, 2025**, under the chairmanship of Dr. Alessandro Riva and closed the **2024 financial statements**. Audit procedures have been performed by the statutory auditors and the auditor's reports are in the process of being issued.*

*The Company's universal registration document (URD), which includes the **annual financial report**, will be available early April 2025 on Transgene's website, www.transgene.fr.*

A conference call **in English** is scheduled **today** on **March 27, 2025, at 6:00 p.m. CET (1:00 p.m. ET)**.

Webcast link to English language conference call:
https://edge.media-server.com/mmc/p/w9y84tms

Please log in to the following link to obtain your personal telephone IDs:
https://register.vevent.com/register/BI913c7946a95044e58cbf4b40ff8155b9

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

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.fr
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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.fr). 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.

Appendix A: Financial statements 2024

CONSOLIDATED BALANCE SHEET, IFRS

(in € thousands)

Assets	December 31,2024	December 31,2023
CURRENT ASSETS		
Cash and cash equivalents	16,670	15,666
Other current financial assets	-	-
Cash, cash equivalents and other current financial assets	**16,670**	**15,666**
Trade receivables	1,186	778
Other current assets	2,812	1,540
Assets available for sale	-	-
Total current assets	**20,668**	**17,984**
NON-CURRENT ASSETS		
Property, plant and equipment	14,293	12,314
Intangible assets	62	80
Non-current financial assets	931	1,347
Other non-current assets	6,220	13,492
Total non-current assets	**21,506**	**27,233**
TOTAL ASSETS	**42,174**	**45,217**

Liabilities and equity	December 31,2024	December 31,2023
CURRENT LIABILITIES		
Trade payables	9,500	4,545
Current financial liabilities	181	1,332
Provisions for risks and expenses	726	494
Other current liabilities	3,577	3,671
Total current liabilities	**13,984**	**10,042**
NON-CURRENT LIABILITIES		
Non-current financial liabilities	10,215	15,963
Employee benefits	2,771	3,345
Provisions for risks and expenses	-	255
Other non-current liabilities	-	-
Total non-current liabilities	**12,986**	**19,563**
Total liabilities	**26,970**	**29,605**
EQUITY		
Share capital	66,147	50,426
Share premiums and reserves	89,234	71,588
Retained earnings	(105,760)	(83,432)
Profit/(loss) for the period	(33,971)	(22,328)
Other comprehensive income/(loss)	(446)	(642)
Total equity attributable to the Company's shareholders	**15,204**	**15,612**
TOTAL LIABILITIES AND EQUITY	**42,174**	**45,217**

Consolidated income statement, IFRS
(in € thousands, except for per-share data)

	December 31,2024	December 31,2023
Government funding for research expenditure	6,046	6,450
Revenue from collaborative and licensing agreements	35	1,184
Other revenue	272	266
Operating revenue	**6,353**	**7,900**
Research and development expenses	(34,278)	(29,588)
General and administrative expenses	(7,761)	(6,987)
Other expenses	28	(1,372)
Operating expenses	**(42,011)**	**(37,947)**
Operating income/(loss)	**(35,658)**	**(30,047)**
Financial income/(loss)	1,687	7,719
Income/(loss) before tax	**(33,971)**	**(22,328)**
Income tax expense	-	-
NET INCOME/(LOSS)	**(33,971)**	**(22,328)**
Basic earnings per share (€)	(0.29)	(0.22)
Diluted earnings per share (€)	(0.29)	(0.22)

Cash Flow statement, IFRS

(in € thousands)

	December 31, 2024	December 31, 2023
Cash flow from operating activities		
Net income/(loss)	(33,971)	(22,328)
Cancellation of financial income/(loss)	(1,687)	(7,719)
Elimination of non-cash items		
Provisions	(492)	506
Depreciation and amortization	1,281	1,572
Share-based payments	568	290
Others	-	73
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow	**(34,301)**	**(27,606)**
Change in operating working capital requirements		
Current receivables and prepaid expenses	(543)	2,722
Research tax credit (RTC)	7,188	(6,489)
Other current assets	(685)	303
Trade payables	4,911	(2,466)
Prepaid revenue	(23)	(944)
Other current liabilities	(95)	(191)
Net cash used in operating activities	**(23,548)**	**(34,671)**
Cash flows from investing activities		
(Acquisitions)/disposals of property, plant and equipment	(3,066)	(2,667)
(Acquisitions)/disposals of intangible assets	(9)	(79)
(Acquisitions)/disposals of non-consolidated equity securities	-	14,345
Disposals of other financial assets	-	22,641
Other (acquisitions)/disposals	(131)	332
Net cash used in investing activities	**(3,206)**	**34,572**
Cash flow from financing activities		
Net financial income/(loss) proceeds	(293)	(298)
Gross proceeds from the issuance of shares	-	-
Share issue costs	(158)	-
Conditional subsidies	-	-
Current account advance	36,150	12,859
Repayment of current account advance	(7,500)	-
Financial leases and change in lease obligations	(1,240)	(1,192)
Net cash generated from/(used in) financing activities	**26,959**	**11,369**
Exchange rate differences on cash and cash equivalents	799	(7)
Net increase/(decrease) in cash and cash equivalents	**1,004**	**11,263**
Cash and cash equivalents at beginning of period	15,666	4,403
Cash and cash equivalents at end of period	**16,670**	**15,666**
Investments in other current financial assets	-	-
Cash, cash equivalent and other current financial assets	**16,670**	**15,666**

Appendix B: Management Discussion of 2024 Financials

Operating revenue

Operating revenue was €6.4 million in 2024 compared to €7.9 million in 2023 and was mostly comprised of the Research Tax Credit (€6.0 million in 2024 and €6.4 million in 2023). Revenue from collaborative and licensing agreements stood at €0.03 million, down from €1.2 million in 2023 due to the discontinuation of the AstraZeneca collaboration in 2023.
Other revenue amounted to 0.3 million in 2024 (as in 2023).

Operating expenses

Research and development (R&D) expenses

R&D expenses amounted to €34.2 million in 2024 versus €29.6 million in 2023, reflecting an acceleration of external expenses with clinical trials active on all candidates of the portfolio, the preparation and launch of the Phase II part of the head and neck cancer trial of TG4050 and the work related to the optimization of the manufacturing of our individualized cancer vaccine.

The following table details R&D expenses by type:

(in € millions)	**Dec. 31, 2024**	**Dec. 31, 2023**
Payroll costs	12.2	11.6
Share-based payments	0.3	0.6
Intellectual property expenses and licensing costs	1.2	0.7
External expenses for clinical projects	8.7	6.6
External expenses for other projects	3.8	2.6
Operating expenses	6.8	6.0
Depreciation, amortization and provisions	1.2	1.5
RESEARCH AND DEVELOPMENT EXPENSES	**34.2**	**29.6**

General and administrative (G&A) expenses

General and administrative (G&A) expenses stood at €7.8 million in 2024 (€7.0 million in 2023).

The following table details G&A expenses by type:

(in € millions)	**Dec. 31, 2024**	**Dec. 31, 2023**
Payroll costs	3.8	3.4
Share-based payments	0.3	(0.3)
Fees and administrative expenses	2.3	2.6
Other general and administrative expenses	1.4	1.2
Depreciation, amortization and provisions	0	0.1
GENERAL AND ADMINISTRATIVE EXPENSES	**7.8**	**7.0**

Share-based payments generated an expense of €0.3 million in 2024, compared to a revenue of €0.3 million in 2023. This change is due to departures that occurred in 2023.

Financial income/(loss)

Financial income stood at €1.7 million in 2024 compared to €7.7 million in 2023. This is explained by the discounting of the ADNA debt generated a financial revenue of €1.4 million, compared to €8.1 million in 2023.

Net income/(loss)

The net loss was €34.0 million in 2024, compared with a net loss of €22.3 million in 2023.
The net loss was €0.29 per share in 2024, compared with a net loss per share of €0.22 in 2023.

Liquidity and capital resources

As of December 31, 2024, the Company had €16.7 million in cash available, compared with €15.7 million as of December 31, 2023.

In September 2023, Transgene signed a current account advance agreement with TSGH (Institut Mérieux) for €36 million. An amendment was signed on March 27, 2024, to increase the amount of the current account advance by €30 million to €66 million. On July 30, 2024, TSGH subscribed to a capital increase in Transgene for an amount of €33 million and requested repayment of the current account advance for the same amount. This repayment was made by offsetting it against the payment of the subscription price for the capital increase by TSGH, reducing the capacity of the current account facility by this amount to €33 million.
At December 31, 2024, the Company had drawn down €8.5 million from the current account advance and recognized €0.2 million in interest.
On March 27, 2025, a second amendment was signed to increase the amount of the current account advance by €15 million to €48 million. The term of this agreement, initially scheduled for 24 months, has been extended to April 30, 2026. As of the date hereof, €22 490 859 is drawn down and outstanding under this facility.
With this credit facility and the support of TSGH (Institut Mérieux), Transgene's business is funded until the end of April 2026.

The Company has the capacity to use this financing according to its cash requirements.

Net cash burn

The Company's net cash burn amounted to €27.7 million in 2024, versus €24.0 million in 2023.