transgene

2023 Full-year results and business update

PRESS RELEASE

Transgene anticipates significant progress from immunotherapy pipeline in 2024 and extends financial visibility until Q4 2025

- *Lead program TG4050 to deliver data in 2024.*
- *Advancements in other clinical programs and Research and Innovation (R&I) activity to deliver news flow and fuel growth in Transgene's portfolio over the next 24 months.*
- *New leadership team focused on successfully delivering TG4050 and portfolio products to patients.*
- *Extended financial visibility secured until Q4 2025 through a revised credit facility provided by the major shareholder Institut Mérieux.*

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

Strasbourg, France, March 27, 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 publishes its financial results for 2023, and provides an update on its product pipeline and upcoming plans.

"During 2023 Transgene continued to make significant progress, delivering compelling data that confirm the value of our approach to treating cancer using our novel immunotherapies" commented **Dr. Alessandro Riva, MD, Chairman and CEO of Transgene**.

"At the upcoming AACR conference in April 2024, we will be presenting additional data from the randomized Phase I study in adjuvant head and neck cancer for our lead therapeutic cancer vaccine, TG4050. Together with our partner NEC we are expanding the Phase I trial in a randomized Phase I/II to further strengthen the initial data in a larger patient population and set the foundation for a registrational development strategy."

"In the second half of 2024 we anticipate the first topline data from our fully enrolled randomized Phase II trial evaluating our shared antigens cancer vaccine TG4001 in HPV-positive anogenital cancers."

"Together with expected Phase I data from our oncolytic virus programs BT-001 and TG6050 this promises to be a key year for Transgene, with further important milestones in 2025 that we believe will enhance the value of our platform. Backed by our extended financial visibility and our strong management team we are confident in our ability to achieve our ambitious goals of delivering transformative therapies for cancer patients. I look forward to sharing updates on our continued progress."

Key events and upcoming milestones

Neoantigen therapeutic cancer vaccine (TG4050)

Additional data from the randomized Phase I trial in adjuvant head and neck cancer to be presented in H1 2024 The trial will be expanded in a randomized Phase I/II trial in the same indication. The Phase II part will start in Q2 2024.

In 2023, highly promising TG4050 data were presented at AACR and ASCO 2023 (see poster here). These data show that this **individualized neoantigen cancer vaccine** can induce strong immune responses, which are expected to result in longer remission periods for patients.

The initial data from the randomized Phase I trial in the adjuvant treatment of head and neck cancer (NCT04183166) **presented at ASCO showed that all evaluable patients treated with TG4050 developed a robust and specific immune response against multiple cancer neoantigens and remained disease-free**. These data suggest that TG4050 can boost the immune system of patients despite a challenging tumor microenvironment at the time of tumor resection.

Transgene and its partner NEC plan to report updated data at AACR (poster presentation on April-10, 2024) **and the additional data on the 24-month median follow up of patients in H2 2024.**

The randomized Phase I trial will be expanded to a randomized Phase I/II trial in the adjuvant setting of head and neck cancer. The Phase II part is expected to start enrolling patients in Q2 2024 within the framework of an extended collaboration between Transgene and NEC.

TG4050 has potential applicability across a range of solid tumors where the medical need is still significant despite the existing therapeutic option including immunotherapies. As a consequence, Transgene is performing preliminary work on a potential new Phase I trial in another undisclosed indication.

Shared antigens cancer vaccine (TG4001)

Transgene has completed the enrollment of 86 patients in the ongoing randomized Phase II trial evaluating TG4001 in HPV-positive anogenital cancers (NCT03260023)**. Transgene confirms that top line readouts are expected** in H2 2024.

In 2023, immunological response data from TG4001 were presented in a poster at ASCO, confirming that **TG4001 can induce *de novo* immune responses against HPV16 antigens** E6 and E7 in patients with advanced HPV16-positive anogenital cancers. Patients with a complete objective response showed strong vaccine-induced immunoreactivity.

Promising results from the previous Phase I/II trial evaluating TG4001 in combination with an immune checkpoint inhibitor were published in the September 2023 issue of the European Journal of Cancer (https://doi.org/10.1016/j.ejca.2023.112981). This study showed that TG4001 in combination with avelumab is safe and demonstrated antitumor activity in heavily pretreated HPV16-positive cancer patients. It also served as the basis for the ongoing randomized Phase II trial.

Oncolytic Viruses

In 2023, clinical data presented at AACR confirmed the mechanism of action and the safety of our Invir.IO® based oncolytic viruses, which offer a key competitive advantage with the ability to be administered intravenously. **These findings support the potential of Invir.IO®-based oncolytic viruses to have multiple treatment applications in a broad range of solid tumors, via intravenous, locoregional and intratumoral administration.**

TG6050: Initial Phase I data expected in H2 2024, from this novel Invir.IO® candidate administered intravenously

A first patient was dosed with TG6050, a novel oncolytic virus from Transgene's Invir.IO® platform, in 2023. This innovative candidate has been designed to express human IL-12, a cytokine known to trigger a potent antitumor immune response, and an anti-CTLA4 antibody. The Phase I Delivir trial (NCT05788926) is evaluating TG6050 in patients with advanced non-small cell lung cancer who have failed standard therapeutic options. **Initial data from the trial is expected in H2 2024.**

BT-001: Positive single agent data — Part B of the Phase I trial (combination with pembrolizumab) to deliver initial data in H2 2024

Transgene and its partner BioInvent have communicated positive data from Part A (monotherapy) of the ongoing Phase I trial in May 2023 (NCT04725331)**.** Out of 18 patients who received escalating intratumoral doses of BT-001, two showed a decrease of injected lesion size of 50% or more, and eleven had a stabilization of the injected lesion. No safety concerns were reported.

Part B of the Phase I trial in combination with pembrolizumab (KEYTRUDA®) started in October 2023. KEYTRUDA® is provided by MSD (Merck & Co). Initial data from this part of the trial are expected in H2 2024.

As announced on May 5, 2023, AstraZeneca terminated its oncolytic virus research and development collaboration with Transgene following a strategic review of its pipeline.

All clinical assets are expected to deliver important data in 2024

In 2024, Transgene expects to communicate progress and significant results and readout on all of its clinical stage assets.

TG4050	Randomized Phase I trial (head and neck): - *Poster presentation* - *Additional data*	 *April 10, 2024 (AACR)* *H2 2024*
	Randomized Phase II to start (head and neck)	H1 2024
	Preliminary work to launch additional Phase I trial	2024
TG4001	Randomized Phase II: topline results	H2 2024
TG6050	Initial data from Phase I trial	H2 2024
BT-001	Initial data from combination part of Phase I	H2 2024

New leadership structure appointed to accelerate the development of Transgene's innovative immunotherapy portfolio

On May 5, 2023, Transgene announced its **Board of Directors' decision to appoint Dr. Alessandro Riva, MD, as the Company's Chairman and CEO.** Alessandro Riva, who started as new CEO on June 1, 2023, has been the Chairman of Board of Directors since May 2022. Dr. Riva has an outstanding track record in the pharmaceutical and biotechnology industry, including responsibility for securing the approval of personalized oncology treatments in the US and in Europe, in particular CAR-T cell therapies.

Transgene's Management Committee is comprised of the following members:

- Alessandro Riva, Chairman & Chief Executive Officer (CEO);
- Éric Quéméneur, Chief Scientific Officer (CSO);
- Christophe Ancel, Chief Pharmaceutical Operations Officer & Qualified Pharmacist;
- Maud Brandely-Talbot, Chief Medical and Regulatory Officer (CMO);
- Lucie Larguier, Chief Financial Officer (CFO) (as of March 2024);
- James Wentworth, Chief Business Officer (CBO);
- John Felitti, General Counsel, Corporate Secretary;
- Christelle Schwoerer, Chief Human Resources Officer (as of April, 2024).

In addition, on May 5, 2023, the Combined General Meeting **appointed Carol Stuckley, MBA, as an independent Director of the Company**. Carol Stuckley brings more than 35 years of experience as a strategic and international financial executive, with proven success leading finance teams and creating shareholder value for healthcare companies.

In March 2023, Transgene appointed **Dr. John C. Bell and Dr. Pedro Romero, key opinion leaders in cancer immunotherapy, as scientific advisors**. John C. Bell is Senior Scientist, Cancer Therapeutics Program at Ottawa Hospital Research Institute and Director, Canadian Oncolytic Virus Consortium and is an internationally renowned expert in the use of oncolytic viruses. Pedro Romero is an honorary professor at the University of Lausanne, focusing on tumor immunology and cancer immunotherapy, particularly on the biology and dynamics of cytolytic CD8 T lymphocyte (CTL) responses. He has also been Editor-in-Chief of the Journal for ImmunoTherapy of Cancer.

Key financials for 2023

- **Operating revenue of €7.9 million in 2023**, compared to €10.3 million in 2022. R&D services for third parties amounted to €1.2 million in 2023 (€3.1 million in 2022), mainly due to the collaboration with AstraZeneca (terminated in May 2023).
  Research tax credit amounted to €6.4 million in 2023 (€6.8 million in 2022).
- **Net operating expenses of €37.9 million in 2023,** compared to €40.2 million in 2022. R&D expenses were €29.6 million in 2023 (€32.2 million in 2022). General and administrative expenses amounted to €7.0 million in 2023 (€7.9 million in 2022).
- **Financial income of €7.7 million in 2023**, compared to a financial loss of €2.9 million in 2022.
- **Net loss of €22.3 million in 2023,** compared to a net loss of €32.8 million in 2022. During the reporting period, the Company reached an agreement for the sale of its remaining shares held in Tasly BioPharmaceuticals for a total amount of US$15.3 million (€14 million). The transaction was closed in July 2023 upon receipt of the funds.**Net cash burn of €24.0 million in 2023,** compared to €22.8 million in 2022 (excluding capital increase and Institut Mérieux credit facility). **Cash available at year-end 2023: €15.7 million**, compared to €26.8 million at the end of 2022.
- **Transgene has a financial visibility until Q4 2025.**

Financial visibility extended until Q4 2025

The Company has signed an amendment to the current account advance agreement with Institut Mérieux (TSGH) raising the available amount from €36 million to a new maximum of €66 million. **This credit facility extends Transgene's financial visibility until Q4 2025, enabling the Company to deliver significant news flow on its portfolio in the next 24 months.**
The credit facility will be available until the end of 2025 and Transgene will be able to draw on and repay the facility at its discretion. In September 2023, Transgene had signed an initial facility for a maximum of €36 million (24-month term).

The financial statements for 2023 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, 2024, under the chairmanship of Dr. Alessandro Riva and closed the 2023 financial statements. Audit procedures have been performed by the statutory auditors and the auditor's reports is in the process of being issued.

The Company's universal registration document, which includes the annual financial report, will be available early April 2024 on Transgene's website, www.transgene.fr.

A conference call **in English** is scheduled today on **March 27, 2024, 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/66eebfa3

Please log in to the following link to obtain your personal telephone IDs.
https://register.vevent.com/register/BI1e9b40a25efe464fa60306adcf6632d5

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. 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: 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 2023

CONSOLIDATED BALANCE SHEET, IFRS

(in € thousands)

Assets	December 31,2023	December 31,2022
CURRENT ASSETS		
Cash and cash equivalents	15,666	4,403
Other current financial assets	-	22,423
Cash, cash equivalents and other current financial assets	**15,666**	**26,826**
Trade receivables	778	2,789
Other current assets	1,540	2,546
Assets available for sale	-	14,345
Total current assets	**17,984**	**46,506**
NON-CURRENT ASSETS		
Property, plant and equipment	12,314	11,177
Intangible assets	80	77
Non-current financial assets	1,347	1,673
Other non-current assets	13,492	7,003
Total non-current assets	**27,233**	**19,930**
TOTAL ASSETS	**45,217**	**66,436**

Liabilities and equity	December 31,2023	December 31,2022
CURRENT LIABILITIES		
Trade payables	4,545	6,965
Current financial liabilities	1,332	1,192
Provisions for risks and expenses	494	23
Other current liabilities	3,671	4,602
Total current liabilities	**10,042**	**12,782**
NON-CURRENT LIABILITIES		
Non-current financial liabilities	15,963	12,327
Employee benefits	3,345	3,282
Provisions for risks and expenses	255	-
Other non-current liabilities	-	204
Total non-current liabilities	**19,563**	**15,813**
Total liabilities	**29,605**	**28,595**
EQUITY		
Share capital	50,426	50,102
Share premiums and reserves	71,588	71,621
Retained earnings	(83,432)	(50,628)
Profit/(loss) for the period	(22,328)	(32,804)
Other comprehensive income/(loss)	(642)	(450)
Total equity attributable to the Company's shareholders	**15,612**	**37,841**
TOTAL LIABILITIES AND EQUITY	**45,217**	**66,436**

Consolidated income statement, IFRS

(in € thousands, except for per-share data)

	December 31,2023	December 31,2022
Revenue from collaborative and licensing agreements	1,184	3,126
Government financing for research expenditure	6,450	6,876
Other revenue	266	342
Operating revenue	**7,900**	**10,344**
Research and development expenses	(29,588)	(32,168)
General and administrative expenses	(6,987)	(7,912)
Other expenses	(1,372)	(168)
Operating expenses	**(37,947)**	**(40,248)**
Operating income/(loss)	**(30,047)**	**(29,904)**
Financial income/(loss)	7,719	(2,900)
Income/(loss) before tax	**(22,328)**	**(32,804)**
Income tax expense	-	-
NET INCOME/(LOSS)	**(22,328)**	**(32,804)**
Basic earnings per share (€)	(0.22)	(0.33)
Diluted earnings per share (€)	(0.22)	(0.33)

Cash Flow statement, IFRS

(in € thousands)

	December 31,2023	December 31,2022
Cash flow from operating activities		
Net income/(loss)	(22,328)	(32,804)
Cancellation of financial income/(loss)	(7,719)	2,900
Elimination of non-cash items		
Provisions	506	191
Depreciation and amortization	1,572	1,686
Share-based payments	290	2,675
Others	73	(41)
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow	**(27,606)**	**(25,393)**
Change in operating working capital requirements		
Current receivables and prepaid expenses	2,722	7,301
Research tax credit (RTC)	(6,489)	(198)
Other current assets	303	226
Trade payables	(2,466)	(750)
Prepaid revenue	(944)	(804)
Other current liabilities	(191)	(685)
Net cash used in operating activities	**(34,671)**	**(20,303)**
Cash flows from investing activities		
(Acquisitions)/disposals of property, plant and equipment	(2,667)	(1,497)
(Acquisitions)/disposals of intangible assets	(79)	(38)
(Acquisitions)/disposals of non-consolidated equity securities	14,345	-
Disposals of other financial assets	22,641	21,500
Other (acquisitions)/disposals	332	307
Net cash used in investing activities	**34,572**	**20,272**
Cash flow from financing activities		
Net financial income/(loss) proceeds	(298)	(646)
Gross proceeds from the issuance of shares	-	-
Share issue costs	-	-
Conditional subsidies	-	455
Current account advance	12,859	-
Net amounts received for financing of tax credits	-	(5)
Financial leases and change in lease obligations	(1,192)	(1,281)
Net cash generated from/(used in) financing activities	**11,369**	**(1,477)**
Exchange rate differences on cash and cash equivalents	(7)	-
Net increase/(decrease) in cash and cash equivalents	**11,263**	**(1,508)**
Cash and cash equivalents at beginning of period	4,403	5,911
Cash and cash equivalents at end of period	**15,666**	**4,403**
Investments in other current financial assets	-	22,423
Cash, cash equivalent and other current financial assets	**15,666**	**26,826**

Appendix B: Management Discussion of 2023 Financials

Operating revenue

Revenue from collaboration and licensing agreements represented €1.2 million in 2023 versus €3.1 million in 2022. It came mainly from the collaboration with AstraZeneca. In the first half of 2023, AstraZeneca informed Transgene of its decision to end the collaboration following a strategic review.

Public funding for research expenses accounted for €6.4 million in 2023 (versus €6.9 million in 2022), mainly due to research tax credit.

Other revenue

Other revenue amounted to €0.3 million in 2023 as in 2022.

Operating expenses

Research and development (R&D) expenses

R&D expenses amounted to €29.6 million in 2023 versus €32.2 million in 2022.

The following table details R&D expenses by type:

(in € millions)	**Dec. 31, 2023**	**Dec. 31, 2022**
Payroll costs	11.6	12.2
Share-based payments	0.6	1.4
Intellectual property expenses and licensing costs	0.7	1.1
External expenses for clinical projects	6.6	6.2
External expenses for other projects	2.6	4.3
Operating expenses	6.0	5.4
Depreciation, amortization and provisions	1.5	1.6
RESEARCH AND DEVELOPMENT EXPENSES	**29.6**	**32.2**

General and administrative (G&A) expenses

General and administrative (G&A) expenses stood at €7.0 million in 2023 (€7.9 million in 2022).

The following table details G&A expenses by type:

(in € millions)	**Dec. 31, 2023**	**Dec. 31, 2022**
Payroll costs	3.4	3.3
Share-based payments	(0.3)	1.3
Fees and administrative expenses	2.6	2.3
Other general and administrative expenses	1.2	0.9
Depreciation, amortization and provisions	0.1	0.1
GENERAL AND ADMINISTRATIVE EXPENSES	**7.0**	**7.9**

Share-based payments generated a revenue of €0.3 million in 2023, compared to an expense of €1.3 million in 2022. This change is due to departures that occurred in 2023 and to the end of several significant free shares plans in 2022.

Financial income

Financial income stood at €7.1 million in 2023 compared to a net loss of €2.9 million in 2022.

The valuation of ADNA conditional advances as of December 31, 2023, generated a financial revenue of €8.1 million, compared to €2.2 million in 2022.

Net income (loss)

The net loss was €22.3 million in 2023, compared with a net loss of €32.8 million in 2022.
The net loss was €0.22 per share in 2023, compared with a net loss per share of €0.33 in 2022.

Investments

Investments in tangible and intangible assets amounted €3.7 million in 2023 (€2.2 million in 2022).

Liquidity and capital resources

As of December 31, 2023, the Company had €15.7 million in cash available, compared with €26.8 million as of December 31, 2022.

In addition, Transgene signed in September 2023 a current account advance agreement with Institut Mérieux for €36 million. Transgene used €12.9 million as of the end of 2023.
An amendment has been signed to extend this advance from €36 million to €66 million. This credit facility extends Transgene's financial visibility until Q4 2025.

Cash burn

The Company's net cash burn amounted to €24 million in 2023, versus €22.8 million in 2022, excluding capital increase and current account advance from Institut Mérieux.

Post-closing events

An amendment to the current account service agreement with Institut Mérieux has been signed on to increase the amount of initial advance signed in September 2023 from €36 million to €66 million. This credit facility extends Transgene's financial visibility until Q4 2025.