2020 Half-year results and business update

Positive clinical results for TG4001 and TG6002 and financial visibility secured until 2022

- *TG4001: Very promising results from Phase 1b/2 trial in HPV-positive cancers*
- *TG6002: Initial translational results confirm the value of intravenous administration*
- *Preclinical and clinical projects progressing despite the Covid-19 pandemic*
- *€33.2 million of cash at the end of June 2020 was followed by the receipt of €19 million due to the partial sale of the stake in Tasly BioPharmaceuticals in August 2020, providing financial visibility until 2022*
- *Succession of the Chairman and Chief Executive Officer planned at the end of 2020*

Conference call scheduled today at 6:00 p.m. CET (in English). See details below.

Strasbourg, France, September 16, 2020, 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 the six-month period ended June 30, 2020, and provides an update on progress of its portfolio.

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, commented:

"I would like to thank the teams at Transgene for their remarkable job in advancing all our clinical and preclinical projects in an environment that has been severely disrupted by the Covid-19 pandemic.

During the period we delivered positive Phase 1b/2 results with TG4001, which have given us the confidence to progress the clinical development of this therapeutic vaccine against HPV-induced cancers. We intend to provide more detail on these positive Phase 1b/2 study results in the coming months.

Our oncolytic virus TG6002 showed positive initial data in a Phase 1 trial, indicating that it induces the production of a chemotherapy agent in the tumor. These promising results confirm the safety of TG6002 when given intravenously and are highly supportive of the new generations of oncolytic viruses that we are developing based on our exciting Invir.IO™ platform.

Patient inclusion continues in line with expectations in the first trials of the individualized immunotherapy TG4050, which has been generated from our myvac® *platform. The* myvac® *platform and the launch of these trials earlier this year exemplify our technological leadership in individualized immunotherapies. The data which were presented at the AACR congress in June highlighted the power of NEC's artificial intelligence and the integration of the first block chain solution into the* myvac® *production process. In parallel, we successfully produced the first clinical batches of TG4050.*

The collaboration with AstraZeneca continues with the delivery of new oncolytic viruses.

Finally, by selling part of approximately 40% of the stake in Tasly BioPharmaceuticals for $22.2 million, Transgene has the cash resources to fund its activities until 2022."

Promising initial data for TG4001

The analysis of the efficacy data from the Phase 1b/2 trial combining TG4001 with avelumab in HPV16-positive recurrent and/or metastatic malignancies showed a **promising clinical activity in the overall study population (34 evaluable patients).**

In addition, Transgene identified a selection criterion corresponding to patients showing particularly encouraging clinical activity. For more than 50% of these patients, the disease had not progressed at 12 weeks, compared to an expected median progression-free survival (PFS) of 8 weeks for this population with current treatment regimens or with immune checkpoint inhibitors in monotherapy. Responses are durable in most of the responder patients. Transgene is currently completing translational analyses. Patient follow-up is still ongoing. Complete data will be presented at an upcoming scientific conference.

Transgene intends to pursue the development of TG4001 and is actively working on the preparation of a confirmatory clinical study.

Advanced technological leadership with the *myvac*® platform

Transgene is developing the therapeutic vaccine TG4050, together with NEC. This individualized cancer vaccine is based on the *myvac*® platform and integrates NEC's artificial intelligence capabilities.

The first Phase 1 clinical trials assessing TG4050 in patients with ovarian and head and neck cancers started in January 2020 in Europe and in the United States. NEC is financing 50% of these studies.

The Company has set up an in-house production unit dedicated to the manufacturing of the individualized clinical batches of TG4050 needed for each patient. This unit is operational and complies with good manufacturing practice (GMP) norms. The manufacturing process and unit have been validated and the first clinical batches have been produced.

The *myvac*® platform is being actively promoted as it exemplifies Transgene's technological leadership in individualized immunotherapies.

- ✓ Data validating the vaccine design principle and underlining the accuracy of the artificial intelligence used to personalize TG4050 were presented at the AACR congress (June 2020).
- ✓ Transgene has implemented the first block chain solution dedicated to the traceability of personalized treatment in clinical trials. This cloud-based solution monitors and orchestrates all of the processes related to the design and manufacturing of Transgene's individualized therapeutic vaccine TG4050.
- ✓ Other innovative approaches were integrated into the *myvac*® approach and will be detailed in the coming months.

The initial translational data of TG6002 highlight the potential of the Invir.IO™ platform

Initial data from the Phase 1 trial confirm the good tolerability of TG6002 in humans and demonstrate that this *Vaccinia Virus*, which is the viral backbone on which the Invir.IO™ platform is based, can reach the tumor and replicate within these cancer cells when administered intravenously.

BT-001 is the first oncolytic virus from the Invir.IO™ platform. A first-in-human trial is being prepared; the trial protocol has been filed in France and in Belgium. Promising preclinical results for BT-001 were presented at the AACR annual congress (June 2020).

The collaboration with AstraZeneca continues with the development of new innovative oncolytic viruses. AstraZeneca can exercise an option to further develop each of these novel drug candidates.

Summary of key ongoing clinical trials

TG4001
+ Bavencio®
(avelumab)
Phase 1b/2

Targets: HPV16 E6 and E7 oncoproteins

Advanced HPV-positive cancers including oropharyngeal head and neck cancer – 2nd line

- ✓ Clinical collaboration with Merck KGaA and Pfizer, for the supply of avelumab
- ✓ Very promising results; patient follow-up is ongoing
- ➲ **Detailed results will be presented at an upcoming scientific conference**
- ➲ **Transgene intends to launch a larger, controlled, confirmatory trial**

myvac®

TG4050
Phase 1

Targets: tumor neoantigens

- ✓ Data demonstrating the high accuracy of AI-based neoantigen prediction technology used to design TG4050 were presented at AACR

Ovarian cancer – after surgery and first-line chemotherapy

- ✓ Trial authorized in the United States and in France
- ✓ First patient enrolled in January 2020 – inclusions progressing in line with forecast
- ➲ **First scientific communication in 2021**

TG4050
Phase 1

HPV-negative head and neck cancer – after surgery and adjuvant therapy

- ✓ Trial authorized in the United Kingdom and in France
- ✓ First patient enrolled in January 2020 – inclusions progressing in line with forecast
- ➲ **First scientific communication in 2021**

TG6002
Phase 1/2a

Payload: FCU1 for the local production of a 5-FU chemotherapy

Gastro-intestinal cancer (colorectal cancer for Phase 2) – Intravenous (IV) administration

- ✓ Multicenter trial ongoing in Belgium, France and Spain
- ✓ **First findings confirm that 5-FU is produced in the tumor**
- ➲ **Dose escalation is ongoing in the Phase 1 part, testing additional dose levels**

TG6002
Phase 1/2a

Colorectal cancer with liver metastasis – Intrahepatic artery (IHA) administration

- ✓ Multicenter trial authorized in the United Kingdom
- ✓ First patient treated in February 2020; enrollment resuming in September 2020 after pausing due to Covid-19
- ➲ **First observations in 2021**

Invir.IO™
BT-001
Phase 1/2

Payload: anti-CTLA4 antibody and GM-CSF cytokine

Solid tumors

- ✓ Collaboration with BioInvent
- ✓ First clinical trial applications submitted (France and Belgium)
- ✓ Presentation of very encouraging preclinical results at AACR 2020
- ➲ **Approval from health authorities expected before the end of 2020**

Key Financials

The Board of Directors of Transgene met on September 16, 2020 and approved the financial statements for the six-month period ended June 30, 2020. 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, https://www.transgene.fr.

Key elements of the income statement

(in thousands of euros)	**June 30, 2020**	**June 30, 2019**
Operating revenues	**5,731**	**4,909**
Research and development expenses	(13,831)	(14,668)
General and administrative expenses	(3,297)	(3,572)
Other expenses	-	(141)
Operating expenses	**(17,128)**	**(18,381)**
Operating income/(loss)	**(11,397)**	**(13,472)**
Financial income/(loss)	**9,183**	**(1,870)**
Net income/(loss)	**(2,214)**	**(15,342)**

Operating revenues amounted to €5.7 million for the first six months of 2020 compared to €4.9 million for the same period in 2019.

- In 2019, the Company entered into a collaboration agreement with AstraZeneca with exclusive licensing options to co-develop oncolytic immunotherapies derived from the Invir.IO™ platform. As a result, in the first half of 2019 Transgene received €8.9 million (US$10 million) in fees for access to its platform. This initial payment is recognized as revenue based on the stage of completion of the related activities. Over the period, the income recognized under this collaboration agreement was €2.2 million (€0.7 million in the first half of 2019). Of this amount €1.8 million reflects recognition of the initial payment for work done during the period and €0.4 million for the achievement of certain preclinical milestones.
- The research tax credit amounted to €2.9 million for the first half of 2020, compared to €3.1 million for the first half of 2019.

Research and Development (R&D) expenses amounted to €13.8 million in the first half of 2020 compared to €14.7 million for the same period in 2019. External expenses for clinical projects decreased to €3.0 million from €4.7 million in the first half of 2019. This decrease is mainly due to a reduction in subcontracted clinical batch production expenses in the first half of 2020 compared to the same period in 2019.

General and administrative expenses amounted to €3.3 million for the first half of 2020 compared to €3.6 million for the same period in 2019.

Net interest income amounted to a gain of €9.2 million in the first half of 2020 compared to an expense of €1.9 million for the same period in 2019. This change is mainly due to the increase in the fair value of Tasly Biopharmaceuticals shares: in July 2020, the sale of the shares was carried out at a higher price than the acquisition price in July 2018. This sale price was applied to all the shares held.

As a consequence, the **net comprehensive loss** amounted to €2.2 million for the first half of 2020 compared to a loss of €15.3 million for the same period in 2019.

As of June 30, 2020, the Company's **cash, cash equivalents and other financial assets** amounted to €33.2 million versus €43.3 million as of December 31, 2019.
Transgene's cash burn amounted to €10.1 million in the first half of 2020, compared with €4.1 million for the same period in 2019.

Transgene intends to reimburse the €10 million bank loan from the European Investment Bank in advance of its June 2021 maturity.

The Company confirms its financial visibility until 2022.

Partial sale of the stake in Tasly BioPharmaceuticals

On August 4, 2020, Transgene announced the receipt of $22.2 million (€19 million) following the sale to a Chinese investment fund of part of its minority stake in Tasly BioPharmaceuticals. This transaction involved the sale of 10.3 million shares of Tasly BioPharmaceuticals (38% of the shares held by Transgene).
Following this share sale, Transgene holds 17.1 million shares in Tasly BioPharmaceuticals, equivalent to 1.58% of the Chinese company's capital. Transgene's remaining shareholding in Tasly BioPharmaceuticals is valued at approximately $36.9 million based on the price of the current share sale.
At the end of August 2020, Tasly BioPharmaceuticals filed its IPO documentation with the Science and Technology Innovation Board (STIB) of the Shanghai Stock Exchange.

Succession of the Chairman and Chief Executive Officer planned at the end of 2020

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, has informed the Board of Directors of his intention to leave his position at the end of 2020 to take up new responsibilities within Institut Mérieux. The Board has acknowledged his decision and proposes that his successor be Hedi Ben Brahim, who has been a Board member of Transgene since May 2019. This decision will be approved at the Board meeting scheduled on December 3, 2020. Philippe Archinard will remain a Board Member of Transgene thereafter.

A conference call **in English** is scheduled today, on September 16th, 2020, at 6:00 p.m. CET.

Webcast link to English language conference call:
https://channel.royalcast.com/webcast/transgene/20200916_1/

Participant telephone numbers:
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Confirmation code: Transgene

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

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About Transgene
Transgene (Euronext: TNG) is a publicly traded French 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 two therapeutic vaccines (TG4001 for the treatment of HPV-positive cancers, and TG4050, the first individualized therapeutic vaccine based on the *myvac*® platform) as well as two oncolytic viruses (TG6002 for the treatment of solid tumors, and BT-001, the first oncolytic virus based on the Invir.IO™ platform).
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. Transgene has an ongoing Invir.IO™ collaboration with AstraZeneca.
Additional information about Transgene is available at: www.transgene.fr.
Follow us on Twitter: @TransgeneSA

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: Interim financial statements 2020

Consolidated balance sheet, IFRS

(in € thousands)

Assets	June 30, 2020	Dec.31, 2019
CURRENT ASSETS		
Cash and cash equivalents	7,174	1,343
Other current financial assets	26,027	42,028
Cash, cash equivalents and other current financial assets	**33,201**	**43,371**
Trade receivables	1,122	2,324
Other current assets	3,299	3,943
Assets available for sale	19,771	-
Total current assets	**57,393**	**49,638**
NON-CURRENT ASSETS		
Property, plant and equipment	13,683	13,283
Intangible assets	141	147
Financial fixed assets	34,541	42,931
Investments in associates	-	-
Other non-current assets	4,010	9,478
Total non-current assets	**52,375**	**65,839**
Total ASSETS	**109,768**	**115,477**

Liabilities and equity	June 30, 2020	Dec.31, 2019
CURRENT LIABILITIES		
Trade payables	5,120	7,092
Financial liabilities	11,615	2,037
Provisions for risks and charges	568	898
Other current liabilities	6,289	8,619
Total current liabilities	**23,592**	**18,646**
NON-CURRENT LIABILITIES		
Financial liabilities	17,344	26,703
Employee benefits	4,503	4,427
Other non-current liabilities	15	4
Total non-current liabilities	**21,862**	**31,134**
Total liabilities	**45,454**	**49,780**
EQUITY		
Share capital	41,921	83,265
Share premiums and reserves	39,962	39,738
Retained earnings	(14,327)	(37,444)
Profit/(loss) for the period	(2,214)	(18,804)
Other comprehensive income	(1,028)	(1,058)
Total equity attributable to Company shareholders	**64,314**	**65,697**
TOTAL LIABILITIES AND EQUITY	**109,768**	**115,477**

Consolidated income statement, IFRS

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

	June 30, 2020	June 30, 2019
Revenue from collaborative and licensing agreements	2,255	1,463
Public funding for research expenses	2,975	3,132
Other income	501	314
Operating income	**5,731**	**4,909**
Research and development expenses	(13,831)	(14,668)
General and administrative expenses	(3,297)	(3,572)
Other expenses	-	(141)
Operating expenses	**(17,128)**	**(18,381)**
Operating income/(loss)	**(11,397)**	**(13,472)**
Financial income/(loss)	9,183	(1,870)
Share of profit/(loss) of associates	-	-
Income/(loss) before tax	**(2,214)**	**(15,342)**
Income tax expense	-	-
NET INCOME/(LOSS)	**(2,214)**	**(15,342)**
Basic loss per share *(€)*	(0.03)	(0.25)
Diluted loss per share *(€)*	(0.03)	(0.25)

Cash Flow statement, IFRS

(in € thousands)

	June 30, 2020	June 30, 2019
Cash flow from operating activities		
Net income/(loss)	(2,214)	(15,342)
Cancellation of financial income	(9,183)	1,870
Elimination of non-cash items		
Income of associates	-	-
Provisions	828	70
Depreciation and amortization	869	(72)
Share-based payments	828	290
Others	(1,070)	51
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow	**(9,942)**	**(13,133)**
Change in operating working capital requirements		
Current receivables and prepaid expenses	738	(673)
Inventories and work in progress	-	25
Research tax credit	(2,967)	(3,110)
Other current assets	734	2
Trade payables	(1,966)	939
Prepaid income	(1,768)	8,059
Other current liabilities	(549)	419
Net cash used in operating activities	**(15,720)**	**(7,472)**
Cash flows from investing activities		
(Acquisitions)/disposals of property, plant and equipment	(520)	(210)
(Acquisitions)/disposals of intangible assets	(16)	(24)
Other (acquisitions)/disposals	321	1,106
Net cash used in investing activities	**(215)**	**872**
Cash flow from financing activities		
Net financial income/(loss) proceeds	(194)	(205)
Conditional subsidies	655	-
(Acquisition)/disposal of other financial assets	16,000	13,934
Net amounts received for financing of tax credits	6,288	5,500
Bank borrowing	(971)	(2,250)
Financial leases and change in lease obligations	(7)	(556)
Net cash generated from/(used in) financing activities	**21,771**	**16,423**
Exchange rate differences on cash and cash equivalents	(5)	1
Net increase/(decrease) in cash and cash equivalents	**5,831**	**9,824**
Cash and cash equivalents at beginning of period	1,343	1,885
Cash and cash equivalents at end of period	**7,174**	**11,709**
Investments in other current financial assets	26,027	1,081
Cash, cash equivalents and other current financial assets	**33,201**	**12,790**