

CHAIRMAN'S MESSAGE 2 **OVERVIEW OF TRANSGENE AND ITS** ANNUAL FINANCIAL STATEMENTS **BUSINESS** 5 AT DECEMBER 31, 2015 75 6 1.1 Selected financial data Consolidated financial statements and notes 76 Presentation of the Company and recent Statutory Auditors' report on the consolidated 1.2 7 financial statements 112 developments 10 1.3 Description of activities 4.3 Company financial statements and notes 113 1.4 Analysis and discussion on the year's activities 15 Statutory Auditors' report on the annual financial statements 134 1.5 Risk factors 27 4.5 Pro forma financial information 136 CORPORATE GOVERNANCE 37 INFORMATION ABOUT THE 2.1 Administrative and management bodies 38 COMPANY AND ITS CAPITAL 137 Compensation and benefits to senior Share capital 138 executives and Board members 45 141 5.2 Principal shareholders Report by the Chairman on corporate governance and internal controls, and report 5.3 Articles of incorporation and statutes 143 by the Statutory Auditors on the Chairman's History and information on the Company 52 report during the period 147 5.5 Information on investments in affiliates 148 Special report of the Statutory Auditors on regulated agreements and commitments 149 INFORMATION REGARDING **Employees** 152 THE COMPANY'S SOCIAL, **ENVIRONMENTAL AND SOCIETAL** RESPONSIBILITY 61 3.1 Note on methodology 62 ADDITIONAL INFORMATION 153 3.2 Employee information 64 154 6.1 Persons responsible 68 3.3 Environmental information 6.2 Persons responsible for auditing the financial Societal information: societal commitments to 155 statements promote sustainable development 71 Third party information, statements by experts 73 Independent third-party report and declarations of interest 157 6.4 Documents available to the public 158 6.5 Cross-reference tables 159 Glossary 6.6 162 Appendix: management report for the period

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# REFERENCE DOCUMENT 2 0 1 5

**Transgene** is a biopharmaceutical company that designs and develops immunotherapy products to fight cancer and infectious diseases.

These products use viral vectors to directly or indirectly destroy diseased cells.

Transgene has three lead products in clinical development: TG4010 for non-small cell lung cancer, Pexa-Vec for liver cancer and TG1050 for chronic hepatitis B. The Company also has several other programs based on its viral vector technology in research or in pre-clinical or clinical development.

Transgene is based in Illkirch-Graffenstaden (near Strasbourg) and has operations in Lyon, China and the United States.

Listed on the stock exchange (Euronext: TNG), Transgene is part of Institut Mérieux.



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Pursuant to Article 28 of European Commission Regulation No. 809/2004/EC, this *Document de référence* includes the 2013 consolidated financial statements and related audit report as found on pages 83 to 112 of the 2013 *Document de référence* filed with the AMF on April 17, 2014 under number D.14-0381, as well as the 2014 consolidated financial statements and related audit report as found on pages 77 to 136 of the 2015 *Document de référence* filed with the AMF on April 28, 2015 under number D.15-0423.



This Document de référence was filed with the Autorité des marchés financiers on April 28, 2016, in accordance with Article 212-13 of the General Regulation of the Autorité des marchés financiers. This Document de référence can be used in connection with an offering of securities if accompanied by a Note d'opération approved by the Autorité des marchés financiers. This document was prepared by the issuer and its signees are responsible for its content.

# CHAIRMAN'S

# **MESSAGE**

# PHILIPPE ARCHINARD



Dear shareholders,

2015 marked a turning point in Transgene's strategy, in which we refocused the Company on our core business of developing immunotherapy drug candidates for treating cancer and infectious diseases.

Our goal is to make headway in our pre-clinical and clinical development, while leveraging R&D efforts, which will be the building blocks of our future product portfolio. We also decided to withdraw from industrial development activities and the in-house manufacturing of our products. This led us to sell our production assets to a subsidiary of the Institut Mérieux specialized in bio-manufacturing. A redundancy plan (plan de sauvegarde de l'emploi) accompanied this sale and our headcount was reduced by close to half.

The Company now has a more streamlined base, enabling it to be more agile and reactive. We can free up more resources to work on our ambitious clinical development program. With research capabilities that are at the cutting-edge of virus engineering technology, Transgene can also capitalize on its various proprietary platforms to continue designing innovative products in the promising field of immunotherapy. In addition, Transgene is more open given its collaborations with both academic and private players across the globe. Our expertise will gain visibility in the major scientific events and medical conferences and in leading scientific journals.



The Company is more agile and reactive and can now concentrate on the target of conducting its clinical development program, Transgene can also capitalize on its various proprietary platforms to continue designing innovative products in the promising field of immunotherapy.

During the past year, our clinical programs produced positive results. At the end of 2014, we released promising data on phase 2b of TG4010, especially on progression-free survival and the overall survival of lung cancer patients with non-squamous histology, representing the vast majority of patients with this disease. In 2015, this data was spotlighted at annual conferences on lung cancer, such as at the renowned American Society of Clinical Oncology (ASCO) annual conference in June and at the 16th World Conference of the International Association for the Study of Lung Cancer (IASLC) in September. The data was also published in the prestigious medical journal The Lancet Oncology at the end of the year. With this promising data, we can now turn our sights on the possibility of filing for conditional market approval and its related phase 3 study. We are forging ahead with preparations to launch this study, while actively seeking a partner. We are also actively working on the preparation of phase 2 trials with TG4010 in combination with new treatments using immune checkpoint inhibitors (or blockers).

The oncolytic immunotherapy Pexa-Vec has entered phase 3 as a first-line treatment for liver cancer. Our partner, SillaJen, Inc., has assumed operating responsibility for this phase. Under an amended collaboration and licensing agreement with SillaJen, Transgene will independently develop clinical oncology studies of this product in combination with immune checkpoint inhibitors.

These studies combining our active immunotherapy products with checkpoint inhibitors represent a highly-promising new therapeutic model. The scientific community has overwhelmingly approved this type of approach. Transgene is looking to make advances in the evaluation of synergies against certain cancers and infectious diseases, with the aim of improving patient treatment and quality of life.

As a closing point, TG1050, an immunotherapy based on an adenovirus vector developed at Transgene, has moved into phase 1/1b for the treatment of chronic hepatitis B. The safety and tolerability results on this international study are expected in 2016. These results will also help provide clinical proof of the concept of this promising immunotherapy.

Today, Transgene is armed with a strategy drawing on both its solid and recognized know-how in immuno-engineering of viral vectors and its expertise in pre-clinical and clinical development. With the help of its main shareholder, Transgene was able to secure access to new funds in early 2016. It is now firmly on track to carry out its development plans and reach its goal of becoming a leader in active immunotherapies for cancer and infectious diseases.

Thank you for your interest in our Company and your confidence.

PHILIPPE ARCHINARD
Chairman and Chief Executive Officer



# OVERVIEW OF TRANSGENE AND ITS BUSINESS

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# □ 1.1 SELECTED FINANCIAL DATA

(in € thousands, except for shares and per share data) (Consolidated financial statements, IAS/IFRS)	12/31/2015 IAS/IFRS	12/31/2014 IAS/IFRS	12/31/2013 IAS/IFRS
INCOME STATEMENT DATA			
Operating income	9,565	11,099	15,735
Research and development expenses	(32,138)	(41,731)	(50,063)
General and administrative expenses	(5,798)	(7,578)	(6,769)
Other revenue and expenses	(7,436)	(1,282)	(101)
Net operational expenses	(45,372)	(50,591)	(56,933)
Operating income (loss)	(35,807)	(39,492)	(41,198)
Finance cost	(930)	(801)	(730)
Share of income from equity affiliates	(1,172)	(823)	(930)
Loss before tax	(37,909)	(41,116)	(42,858)
Tax on profits	-	-	-
Net income from continuing operations	(37,909)	(41,116)	(42,858)
Net income from discontinued operations	(8,465)	(7,440)	
Net loss	(46,374)	(48,556)	(42,858)
Diluted loss per share	(1.20)	(1.26)	(1.34)
Average number of shares outstanding	38,545,397	38,527,968	31,874,858
Cash, cash equivalents and other current financial assets	31,650	65,935	47,862
Total assets	100,869	140,953	125,850
Equity	26,547	71,839	56,622
Net cash flow generated by/(used in) operations	(45,152)	(54,236)	(50,185)

# 1.2 PRESENTATION OF THE COMPANY AND RECENT DEVELOPMENTS

# 1.2.1 Overview of operations

Transgene was founded in 1979 to apply emerging techniques in genetic engineering in the context of contract research for industrial groups in the fields of molecular and cellular biology, virology, immunology and protein chemistry. In the 1990s, the Company changed its business model to become a biopharmaceutical company that designs and develops its own products in the field of oncology and infectious diseases, up to the stage of advanced clinical trials, seeking out partnerships for the subsequent phases and marketing.

The Company was listed on the Paris and NASDAQ stock exchanges in 1998. It voluntarily delisted from NASDAQ in September 2005.

The Company's activities are focused on human health and, in particular, the research and development of immunotherapy products, including therapeutic vaccines and oncolytic viruses in the field of cancer and infectious diseases.

In September 2010, the Company rounded out its own portfolio of oncolytic viruses by acquiring from the US company Jennerex, Inc. certain rights for the development and commercialization of Pexa-Vec, an oncolytic virus being developed for the treatment of solid tumors. In March 2014, Jennerex, Inc., which specializes in the development of this type of product, was acquired by SillaJen, Inc., to which all contractual rights and obligations of Jennerex, Inc. have been transferred (see Section 1.4.2).

In June 2015, the Company announced plans to conduct a strategic restructuring and implement a redundancy plan (plan de sauvegarde de l'emploi), making half of its employees redundant. The restructuring focused primarily on outsourcing the manufacturing of its clinical batches and the related pharmaceutical development activities. The redundancy plan became effective at the end of 2015. The outsourcing of the manufacturing formally began on February 1, 2016, when the real estate assets and equipment were sold to the company ABL Europe, wholly-owned by ABL, Inc., a subsidiary of IMEurope, and itself a subsidiary of Institut Mérieux. Transgene secured the manufacturing of the required clinical batches for its clinical development by signing an exclusivity agreement with ABL Europe on February 1, 2016. Having also secured its capacity to manufacture its products on a commercial scale through a partnership with Sanofi Genzyme, the Company can now focus on its core competency, research and clinical development.

Today, the Company is fully engaged in the design of immunotherapy products and their development in combination with today's standard treatments, as well as up-and-coming treatments such as immune checkpoint inhibitors. The Company intends to maximize partnership opportunities at all stages of the development of its products, in recognition of the fact that the pursuit of late-stage development within the Company is dependent on its capacity to generate new agreements with other products or for its know-how.

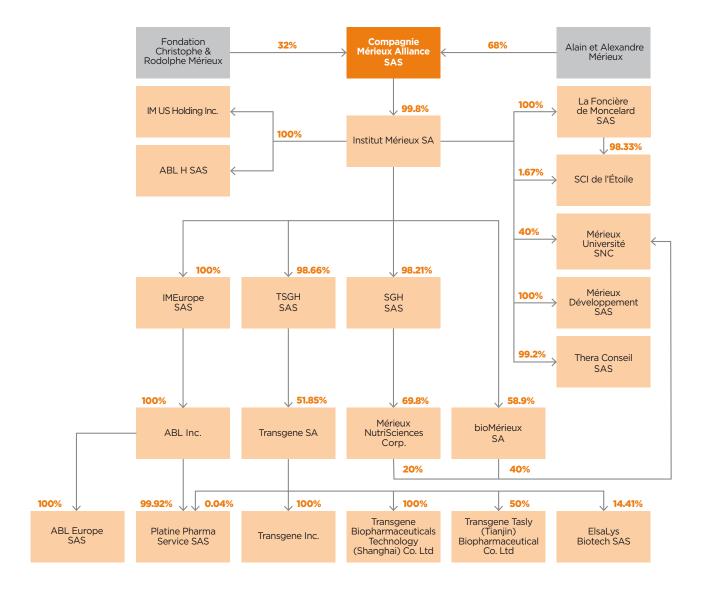
# 1.2.2 Organizational chart

# 1.2.2.1 Ownership by Institut Mérieux

Transgene is 51.85% owned by TSGH, a financial holding company, which in turn is 98.66% owned by Institut Mérieux (formerly Mérieux Alliance), itself 99.8% owned by Compagnie Mérieux Alliance, which is 68% owned by the Mérieux family and 32% owned by Fondation Christophe and Rodolphe Mérieux. Philippe Archinard, Chairman and CEO of Transgene,

is also the Chief Executive Officer of TSGH, in which he holds a 1.34% stake and a director at bioMérieux SA (a subsidiary of Institut Mérieux).

Within this group, Mérieux NutriSciences has a services business in food security and health, bioMérieux in clinical diagnostics and Transgene in immunotherapy research and development.



Presentation of the Company and recent developments

# 1.2.2.2 Subsidiaries and investments

#### Transgene, Inc.

The Company has a subsidiary in the United States, Transgene, Inc., based in Cambridge, Massachusetts, in which it holds 100% of its capital and voting rights. This subsidiary represents Transgene SA before various organizations, regulatory authorities and study centers for its clinical trials in the United States. In this context, it comes under the operational control of Transgene SA, charges its costs to Transgene SA and has no significant assets. Philippe Archinard, Chairman & Chief Executive Officer of Transgene and Jean-Philippe Del, Vice President, Finance, are directors of Transgene Inc.

# Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd.

Transgene also has a Chinese subsidiary, Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd., based in Shanghai, in which it holds 100% of the capital and voting rights. This company was established in 2012 to accommodate academic research collaborations conducted by Transgene in Chinese territory. In this context, it comes under the operational control of Transgene SA and has no significant assets. Philippe Archinard and Xia Meng, Chief Executive Officer of Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd., are directors of this company. Jean-Philippe Del is its supervisor.

The Company also holds equity interests in Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. (50% of the capital) and ElsaLys Biotech SAS (14.41% of the capital).

## Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.

Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. is a Chinese corporation created in 2010 to develop and ultimately sell biotechnology products, including Transgene products, in China. This company is jointly owned with Tasly Pharmaceutical Group, which is based in Tianjin, China. Philippe Archinard and Thibault du Fayet are directors of Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. Jean-Philippe Del is its supervisor.

#### **ElsaLys Biotech SAS**

On May 17, 2013, Transgene acquired a stake of around 37% in the capital of ElsaLys Biotech SAS. ElsaLys Biotech SAS was founded by former Transgene managers, alongside the Sofimac Partners investment fund, to develop monoclonal antibodies, a field of research still at a very early stage that Transgene did not wish to pursue at the moment, given its commitment to the development of viral vectors. On December 31, 2015, Transgene's equity interest in ElsaLys Biotech fell to 14.41% subsequent to the capital increases reserved for the Sofimac-Partners fund, IMEurope and CA Innovation. Transgene is represented on the Board of Directors by Éric Quéméneur.

# 1.2.3 Property, plant and equipment

The Company has a main site and a secondary site.

The main site is the registered headquarters located in the Illkirch innovation park, in the suburbs of Strasbourg, with one building and a vacant lot of land:

 the building, built in 2008, with an area of approximately 6,800 m², houses the registered headquarters and the clinical R&D activities. It is held under a finance lease that was still in effect as of the date of this *Document de* référence; and  the vacant lot, with a surface area of around 9,000 m², is adjacent to the main building; it was acquired in December 2014 through the exercise of a five-year option which was about to lapse. This acquisition gives the Company the possibility of extending its premises on a single site of adjacent lots.

The secondary site consists of around 300  $\mathrm{m^2}$ , housing laboratories and offices within the Lyon Gerland Center for Infectious Diseases. This site is leased.

# 1.3 DESCRIPTION OF ACTIVITIES

# 1.3.1 Principal markets and competitors

At the date of this *Document de référence*, none of Transgene's products had yet reached the marketing stage.

# **1.3.1.1** Oncology

#### **Cancer Treatment**

Accounting for one out of seven deaths, cancer is one of the leading causes of death in the world. It causes more deaths than Aids, tuberculosis and malaria combined. According to the estimates of the International Agency for Research on Cancer, 14.1 million new cancer cases and 8.2 million deaths worldwide were reported in 2012 (around 22,000 deaths per day). Out of this total, 2.9 million of these deaths occurred in developed countries and 5.3 million in developing countries. By 2030, new cancer cases are expected to reach 21.7 million with cancer deaths increasing to 13 million, simply due to the growth and the aging of population (source: American Cancer Society's Global Cancer Facts and Figures, 3rd edition).

Surgery and radiotherapy are currently considered the best treatments available for most cancers. However patients' chances of surviving drop when the cancer metastasizes and spreads. Chemotherapy and hormone therapy are the main treatments for metastatic cancer. Nevertheless, except in the case of certain less common types of cancer such as acute childhood leukemia, Hodgkin's disease and testicular cancer, few patients are cured by these treatments and improving their chances of survival remains challenging. New anticancer treatments called targeted therapies have emerged in recent years and several of them are already on the market. These therapies use agents that can specifically target and attack cancer cells without seriously harming healthy cells. Immunotherapy is another new field in cancer treatment. Immunotherapy uses the patients' immune system by either activating it against the cancer cells or by giving it additional protection such as proteins produced in bio-molecular engineering. Transgene's cancer treatment programs mainly seek to stimulate the immune system to induce tumor rejection or to destroy cancer cells by special viruses called oncolytics.

The global anti-cancer treatment market was valued at USD 72.8 billion in 2014 and is expected to grow to USD 153.1 billion by 2020, assuming an annual average growth rate of 11.2% (source: EvaluatePharma).

# 1.3.1.1.1 Non-small cell lung cancer

According to the statistics and estimates of GLOBOCAN 2012, lung cancer is the most common cancer in the world, with 1.8 million new cases diagnosed every year and close to 1.6 million deaths. It is the deadliest cancer in the world. Non-small cell lung cancer (NSCLC) accounts for approximately 85% of all lung cancers. More than 448,000 cases of lung cancer have been diagnosed and more than 388,000 deaths have been reported in Europe. The American Cancer Association estimated that lung cancer would be the deadliest cancer in 2015, accounting for 27% of cancer-related deaths. In the United States, it is estimated that in 2015 there were more than 221,000 new cases of lung cancer and more than 158,000 related deaths. Lung cancer survival rates are among the worst (the five year survival rate in the United States is 21% for NSCLC), underscoring the unmet medical need.

In a majority of patients, cancer is already at an advanced stage (IIIb/IV) when it is diagnosed. Traditional treatments such as surgery, chemotherapy and radiotherapy have little success in curing these patients, although they may extend life expectancy and relieve certain symptoms. Patients with specific genetic characteristics could respond to targeted therapies belonging to the class of epidermal growth factor receptor (EGFR) blockers, such as erlotinib (Tarceva®), afatinib (Gilotrif®), and gefitinib (Iressa®). These therapies block the EGFR signal controlling the tumor's cell growth. Bevacizumab (Avastin®) is a monoclonal antibody that targets the vascular endothelial growth factor receptor (VEGFR), a protein that stimulates angiogenesis (growth of blood vessels). By preventing tumor vascularization, Avastin deprives it of the nutrients circulated in blood. Ramucirumab (Cyramza®) is another example of an antibody targeting VEGFR in the treatment of NSCLC.

Immunotherapies could provide significant benefits to lung cancer patients, especially those for which other treatments prove ineffective. In 2015, two new immunotherapies, nivolumab (Opdivo®) and pembrolizumab (Keytruda®), received marketing authorization as post-chemotherapy second-line treatments for NSCLC. Nivolumab has been approved for treating squamous and non-squamous NSCLC and pembrolizumab has been approved for treating positive PD-L1 NSCLC. These two authorizations were significant events in cancer treatments in 2015.

#### 1.3.1.1.2 Liver cancer

More than 780,000 new cases of liver cancer were diagnosed and more than 745,000 related-deaths were reported worldwide in 2012 (source: GLOBOCAN 2012), with 63,000 new cases and 62,000 deaths in Europe. According to the American Cancer Society, more than 35,000 liver cancer cases will have been diagnosed and 24,000 deaths from this disease reported in the United States in 2015. Hepatocellular carcinomas (HCC) account for more than 80% of liver cancers.

At the early stages of the disease, liver cancer is operable if the patient's liver is sufficiently healthy. A liver transplant is another option. In the case of approximately 85% of all HCC, i.e., some 450,000 cases worldwide, neither surgery nor transplant is possible. For non-operable tumors, other localized therapies may be used such as ablation (destruction of the tumor) or embolization (blocking the tumor's blood vessels). Very few treatments are available to treat advanced stage HCC. Sorafenib (Nexavar\*) is the only medicine on the market authorized to treat the disease in non-operable patients or those who are not candidates for other loco-regional therapies. There is a crucial need to develop new treatment options given the very low five-year survival rate and the limited number of treatments available, especially for patients diagnosed at an advanced stage of the disease.

# 1.3.1.1.3 Cancers caused by the Human Papilloma Virus (HPV)

The human papilloma virus (HPV) has been identified as the main cause of cervical cancer and precancerous uterine lesions. It is also related to other carcinomas, including a subclass of head and neck cancers, especially oropharyngeal and laryngeal cancers. The current treatment options for patients with this type of cancer are radio-chemotherapy or surgical resection with or without adjuvant radiotherapy, dependent on the tumor's size, the expected functional loss associated with resection, and the patient's wishes. More efficient treatments need to be developed to treat these diseases.

# 1.3.1.2 Infectious diseases

# Chronic Hepatitis B Virus (HBV) Infection

Hepatitis B (HBV) is a virus that infects the liver and can lead to death. HBV can cause chronic infection or disease of the liver. If left untreated, it can lead to cirrhosis or deadly liver cancers. Recent estimates have indicated that the number of patients treated for chronic hepatitis B totals approximately 200,000 in the United States, Germany, France, Italy, Spain and the United Kingdom with approximately 100,000 patients in Japan. The total frequency of treated chronic hepatitis B cases across these seven principal markets is expected to reach 450,000 patients by 2020 (source: *ECDC-Incidence of Hepatitis B, Decision Resources:* expert opinions). The Chinese market is currently estimated at 500,000 patients. These figures are set to rise with the increase in the number of patients diagnosed and treated.

Several anti-viral treatments for chronic hepatitis B are currently on the market, including tenofovir (Viread\*) from Gilead and entecavir (Baraclude) by Bristol-Myers-Squibb (BMS), which were mainly designed to prevent the virus from spreading. Nevertheless, these treatments only cure approximately 3% of patients (source: EASL HBV guidelines) and need to be taken over long periods of time (average of fifteen years in developed countries) or even for the rest of the patients' lives. Therefore, the current challenge is the development of new therapeutic approaches, with a cure rate higher than today's.

# 1.3.1.3 Competition

The Company competes in a competitive environment in which many of the other companies have more substantial financial and human resources than it does. These competitors could roll out technologies similar to the Company's viral platforms or develop and market therapies for the same indications as the Company.

For example, Bavarian Nordic AS, Oncothyreon, Oxford BioMedica, NovaRX and Oncolytics Biotech are all aiming to develop viral immunotherapies. In the field of NSCLC, the lead indication for TG4010, companies such as Bristol-Myers-Squibb (BMS) and Merck have received market authorizations for their immunotherapies. Companies such as Roche and Astra Zeneca are moving ahead with the development of their own immunotherapies to combat this disease.

In liver cancer, the lead indication for Pexa-Vec, certain immunotherapies are currently at the clinical trial stage, including BMS's immunotherapy product, nivolumab.

For the treatment of chronic hepatitis B (indication for TG1050), the standard treatment is a class of antivirals, the nucleosides. One of the treatments, entecavir, is now available as a generic medication and the other treatment, tenofovir (Viread\*), is commercialized by Gilead. Other products at varying stages of development exist, including the Abivax, Gilead and Arrowhead Research programs.

Even though there is currently no effective treatment to cure cancer, there are other recognized methods of treatment which may be able to extend the chances of survival, such as chemotherapy. The outlook for patients has improved over recent years with targeted therapeutic approaches, monoclonal antibodies, small chemical molecules and even immunotherapies. These medications are therefore competing products. However, despite the advances made in cancer treatments, innovative therapies still need to be developed to extend patients' lives and improve their quality of life.

# 1.3.2 Research and development

All of the Company's activities relate to the research and development of innovative therapies. These activities are described in detail in Section 1.4.1.1.

# The technology platform: vectors and gene transfer

Genes are segments of deoxyribonucleic acid (DNA) present in each cell that provide the information required to produce proteins. The production of proteins starts in the cell's nucleus when the gene is copied. The process that results in the cells producing a gene is called "gene expression".

The development of gene transfer methods that are safe, reliable and adaptable is a key element in the development of effective therapies. A therapeutic gene must be included in a delivery system (or "vector") that, associated with the gene, transports it into the patient's cells. Gene transfer therapies are currently divided into two distinct approaches:

- the in vivo (inside the body) approach consists of directly administering to the patient a pharmaceutical compound containing the therapeutic gene and a "vector" responsible for conveying the gene to the patient's target cells, either for gene therapy purposes or to induce an immune response. Transgene products fall into this category;
- cellular, or ex vivo (outside the body), therapy consists of removing cells from a patient, cultivating them in appropriate laboratory conditions and using a vector to introduce the functional gene in the cells, then re-implanting the modified cells into the patient. At present, Transgene does not develop cellular therapy products. It does, however, have all the required know-how and may contemplate developments in this field at some point in the future.

Transgene's research in molecular biology techniques for gene transfer has led to the development of various vector technologies. Efforts are now focused on the poxvirus family for *in vivo* administration: MVA (Modified Vaccinia Ankara virus) and oncolytic VV (Vaccinia Virus), as well as adenoviruses.

To be effective, a vector must be able to:

- transport the gene of interest;
- transfer the gene to a sufficient number of target cells; and
- allow gene expression to produce the therapeutic protein over a sufficiently long period to ensure the success of the treatment or stimulation of the immune system.

This type of vector must also be safe. The gene delivery approach most widely used until now is based on gene transfer by viral vectors in which modified viruses of various types are used to transfer the genetic material into the patients' cells.

Transgene's research programs on vector technology aim to provide vectors with features that will optimize their performance and safety through:

- the search for potential interactions by combining different vectors, for more effective vaccination protocols;
- the insertion of the gene of interest in the most appropriate genome site;
- the generation of viral vectors able to multiply selectively in the tumors, thereby locally increasing the therapeutic protein level delivered by the gene; and
- the evaluation of combinations of Transgene's immunotherapy products and anti-cancer vaccines with conventional treatments and with new categories of immunotherapy products known as "immune checkpoint inhibitors (or blockers)".

Poxviruses are a family of viruses that includes the vaccinia virus broadly used in smallpox vaccinations. Vaccinia vectors administered *in vivo* have demonstrated a significant ability to induce an immune response against certain types of passenger antigens. This feature may provide a specific advantage for cancer treatment.

# Vaccine immunotherapy

Transgene has developed a new generation of poxviral vectors based on a strain of MVA that does not propagate in the cells of humans or other mammals and is therefore incapable of causing an infection in humans. This strain is thus particularly safe, as demonstrated by its intensive use as a human smallpox vaccine. The MVA vector was tested in phase 2 clinical trials of anti-cancer (TG4010, TG4001) and anti-infective (TG40404)

# Oncolytic immunotherapy (virotherapy)

Transgene was a pioneer in the development of replicative viruses with, in particular, a vaccinia virus that carries a gene of the rabies virus able to orally vaccinate (distribution of vaccine-impregnated bait) wild animals, in particular foxes, to prevent rabies, sold by Mérial, one of the world leaders in animal health. Replicative viruses are highly effective, but often at the price of

significant side effects. Transgene's oncolytic vector program intends to solve this difficulty by developing new generations of vaccinia viruses lacking certain genes, to increase tolerance while maintaining effectiveness.

Oncolytic immunotherapy is a new class of anti-cancer treatments. Unlike products using MVA, oncolytic products replicate in cancerous cells, leading to the destruction of these cells, and do not replicate in healthy cells. This mechanism is

unlike that of conventional treatments such as chemotherapy, tyrosine kinase inhibitors, antibodies and radiotherapy, and therefore these oncolytic products could be used in combination with these other treatments or alone in the treatment of resistant cancers.

Furthermore, these viruses could, for example, be armed with suicide genes such as FCU1, thereby improving their efficacy, or be modified to improve their specificity.

# 1.3.3 Investments

The main investments in tangible and intangible assets made by the Company during the past two years are as follows:

2015	Thousands of euros	Principal Investments
		Maintenance and laboratory equipment.
Tangible	1,527	None of these investments exceeded €0.5 million.
Intangible	-	-
2014	Thousands of euros	Principal Investments
		Land adjacent to the main building (€0.6 million)
		Maintenance equipment or upgrade of
		the pilot production unit, laboratory equipment.
		None of these investments exceeded
Tangible	2,463	€0 5 million.
Intangible	139	Licenses and software

The projected budget for tangible and intangible investments in 2016 amounts to around €0.2 million. This budget includes current operating capital investments and improvement of equipment and facilities.

Investments in financial assets made over the last three years consisted of investments in capital increases of companies:

- Jennerex, Inc. (€1.9 million in 2013);
- Platine Pharma Services SAS (€0.3 million in 2013);
- ElsaLys Biotech SAS (€0.5 million in 2013);
- Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd. (€0.5 million in 2013).

# 1.3.4 Competitive advantages

# The MVA vector technology platform

The MVA platform is one of Transgene's technology platforms and is designed to allow a maximum number of gene transfer applications. It makes available delivery techniques for differentiated genes, suited to distinct clinical situations, specifically in the field of cancer.

This technology platform has the following potential advantages:

- safety: MVA is a Modified Vaccinia virus obtained from a viral strain unable to propagate in human cells;
- easy administration: Transgene's technology is mainly focused on the development of ready-to-use products in ampules or vials, for direct administration to the patient; and
- manufacturing efficiency: production processes that allow for the application of practical cell culture and purification methods, ready for the production of commercial batches, have been developed.

# Integrated skills from research to development

Transgene relies on its three decades of recognized scientific expertise. The Company has been working since 1992 in the field of gene transfer therapy and immunotherapy and has gained extensive know-how in its key development areas: virology, the conduct of clinical trials and regulatory matters.

# An extensive portfolio of patents

Transgene has applied for patents and will continue to do so to protect its products, vector technologies and related processes and other technologies. As of the date of this *Document de référence* Transgene owns over 170 patents both in Europe and the United States. In addition to its patent portfolio, Transgene has licenses for third-party patents and the use of third-party processes and technologies.

# 1.4 ANALYSIS AND DISCUSSION ON THE YEAR'S ACTIVITIES

# 1.4.1 Principal activities

## 1.4.1.1 Nature of the business

Transgene is a biopharmaceutical company that designs and develops immunotherapy products to treat cancer and infectious diseases.

Transgene's competitive advantages include proprietary products in pre-clinical and clinical development, an extensive IP portfolio, a diversified technology platform for viral vectors, and integrated skills in research and development.

As of the date of this *Document de référence*, Transgene has three products in clinical development: two immunotherapy products for cancer treatment and an anti-infective immunotherapy product for chronic hepatitis B. The Company also has other product candidates that are expected to advance into clinical development in the near future.

# Transgene's activity is highly regulated

Research and development, preclinical tests, clinical trials, facilities and equipment, and the manufacture and marketing of

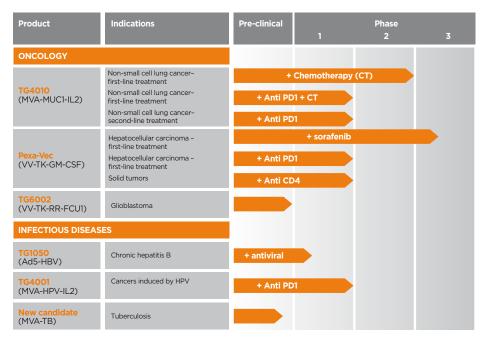
therapeutic products are subject to very thorough regulations devised by numerous governmental authorities in France, Europe, the United States and other countries. The European Medicines Agency (EMA), the French Agence nationale de sécurité du médicament et des produits de santé (ANSM), the US Food and Drug Administration (FDA) and other regulators require compliance with strict conditions for the manufacturing, development and marketing of products such as those developed by Transgene, especially at the pre-clinical and clinical stages.

The information required for the authorization of a clinical trial or marketing is standard for all medications and must meet quality, safety and efficacy requirements.

In the European Union, there is a "centralized" procedure for obtaining marketing authorizations for biotechnology products, thereby avoiding a separate submission to each Member State. In the United States and the European Union, the average time required to obtain this authorization is approximately one year from the date the request is submitted.

# 1.4.1.1.1 Principal products

The following table summarizes the status of Transgene's product portfolio as of the date of this Document de référence:





#### TG4010: immunotherapy for treating cancer

## Description and mechanism of action

TG4010 is an immunotherapy product targeting the mucine-1 protein (MUC1) and is currently being developed to treat NSCLC (non-small cell lung cancer). TG4010 is a therapeutic vaccine consisting of a vector, the Modified Vaccine Ankara (MVA) virus, which expresses the MUC1 antigen and interleukin-2, a cytokine that stimulates the immune system.

The MUC1 antigen is normally expressed in a large number of healthy cells in the human body. However, MUC1 is expressed in an abnormal biochemical form in cancerous cells, thereby making it a TAA (tumor associated antigen), making it a prime target for immunotherapy.

TG4010's purpose is to potentiate (or strengthen) the body's immune system to create a more powerful response against the cells carrying the TAA MUC1 and help destroy them. The coding sequence for the cytokine interleukin 2 (IL2) is added into the MVA genome for its immunostimulation capacity. In addition to lung cancer, the TAA MUC1 is expressed in other types of solid tumors such as breast, kidney cancer, prostate and colorectal cancers.

The MUC1 gene was obtained under license from Imperial Cancer Technology Ltd., the technology transfer unit of the Imperial Cancer Research Fund. This license is global and exclusively for the use of the MUC1 gene in applications for the transfer of genes using viral vectors.

# Lead therapeutic indication: metastatic non-small cell lung cancer (NSCLC) in combination with chemotherapy

Phase 2 clinical trials were conducted in patients with NSCLC and prostate cancer in Europe and the United States. The Company has made treating lung cancer its focus over the past few years. Developments in other indications are planned, should trials underway produce positive results.

#### Key clinical results

The high level of tolerability of to the product in combination with chemotherapy was confirmed during phase 1 and phase 2 trials: the main side effects related to TG4010 were classic post-vaccination reactions (reactions at the injection site and fatigue).

In 2014 and 2015, Transgene announced the positive results from the phase 2b part of the TIME study, a randomized and controlled phase 2 b/3 test to evaluate the targeted immunotherapy TG4010, compared with a placebo, in combination with first-line chemotherapy in patients with metastatic NSCLC. The primary objective of the phase 2b part of the TIME study was to validate the positive results obtained in an earlier study, TG4010.09, which were published in the clinical journal *Lancet Oncology* in October 2011. It was also to confirm the validity of the biomarker

known as "TrPAL", which was identified in the TG4010.09 study. TrPAL represents a sub-population of lymphocytic cells, which correspond for the most part to natural killer or activated NK cells (CD16+CD56+CD69+). They are critical to the innate response and are recognized as having a pivotal role in modulating the adaptive response. The safety and efficacy of the combination of TG4010 and standard chemotherapy was also evaluated. The TIME study results were published in the December 2015 edition of the journal *Lancet Oncology*. They were first unveiled at renowned global medical conferences on lung cancer, in June 2015 at the American Society of Clinical Oncology (ASCO), the leading annual conference in this field and in September 2015 at the 16th World Conference of the International Association for the Study of Lung Cancer (IASLC).

The analysis of these results shows that in 75% of patients with the lowest TrPAL values having received TG4010 in combination with chemotherapy, there was clinically meaningful improvement in progression-free survival and overall survival. This improvement is measured by a significant reduction in the risk of progression or death in patients in this group having received a combination of TG4010 and chemotherapy, compared with the placebo group. The positive effect of the addition of TG4010 was even more noticeable in the subgroup of patients with non-squamous histology (88% of the patients in the study). Conversely, in the 25% of patients with the highest level of TrPAL, no improvement in progression-free survival was shown in patients having received the combination therapy compared to the equivalent placebo group.

These results are consistent with the previously obtained results. They support the activity of TG4010 in this indication and the effectiveness of the TrPAL biomarker. Backed with these highly positive results, the study could build on this development in phase 3.

#### Next stages of development

Based on the these phase 2b TIME results, the Company is currently evaluating the means by which a possible Conditional Marketing Approval submission in Europe, including the associated phase 3 study, could be implemented.

Over the next 12 months, the Company also plans to launch an ambitious program of phase 2 trials with TG4010 in combination with immune checkpoint inhibitors. These new therapeutic approaches provide a highly promising outlook for treating certain types of cancer. Immunotherapy approaches are highly compatible with and potentially synergistic with approaches using immune checkpoint inhibitors.

## Marketing outlook

The Company has not set a possible date for commercial launch, given the uncertainty surrounding the date when the phase 3 trial will be initiated.

# Pexa-Vec oncolytic immunotherapy: liver cancer and other solid tumors

#### Description and mechanism of action

In September 2010, Transgene acquired the development and marketing rights for Europe, the CIS and the Middle East for Pexa-Vec, an oncolytic virus derived from the poxvirus strain (the vaccinia virus family), from Jennerex, Inc. (see Section 1.4.2).

The poxvirus strain from which Pexa-Vec is derived allows replication of the virus in cancerous cells. The safety profile and cancer cell selectivity were strengthened by the removal of the thymidine kinase (TK) gene, thus making it dependent on the constant high-level expression of the TK gene in cancer cells. To increase its efficacy even further, Pexa-Vec was also modified to express the GM-CSF gene, an addition that aims to increase cell lysis caused by the product. Pexa-Vec "attacks" tumors through three mechanisms of action: cell lysis via the selective replication of the virus in tumor cells, blocking of tumor vascularization and stimulation of the immune response against the tumor (active immunotherapy).

## Lead therapeutic indication

Most cancers carry the mutations and genetic alterations which Pexa-Vec needs to be active.

Phase 1 and 2 clinical trials in different types of tumors showed that, when injected into tumors or administered by infusion, Pexa-Vec is well tolerated by patients and has a biological activity. Pexa-Vec has a favorable safety profile with predictable and generally mild side effects such as flu-like symptoms that disappear in two or three days. The lead indication in the current development plan for the product is liver cancer (hepatocellular carcinoma, or HCC).

## Key clinical results as a first-line treatment in advanced liver cancer

Phase 2 study results (published in the journal *Nature Medicine* in February 2013) of patients with advanced liver cancer revealed that patients receiving the high dose had a statistically significant clinical improvement in terms of overall survival compared to the Group receiving the low dose. The risk of death in patients receiving the high dose of Pexa-Vec dropped sharply compared to the patients in the control group receiving the low dose (1/10th of the high dose). Median overall survival was respectively 14.1 months in the high dose group and 6.7 months in the low dose group.

2015 marked the launch of a phase 3 clinical study (PHOCUS) evaluating Pexa-Vec in combination with sorafenib in the first-line treatment of patients with advanced hepatocellular carcinoma (HCC). This global study is being conducted in Europe, Asia and North America and is expected to enroll approximately 600 patients. Patients will be randomized into two groups to receive Pexa-Vec immediately followed by sorafenib, or sorafenib only. Sorafenib (Nexavar®) is currently the only product approved for first-line treatment of advanced HCC.

Pexa-Vec was in-licensed in 2010 from Jennerex, Inc. as part of the development and commercialisation agreement, which was amended in 2015 (See Section 1.4.2 Material Contracts).

#### Next stages of development

In addition to the phase 3 study, a study evaluating Pexa-Vec in combination with cyclophosphamide administered in small doses ("metronomic"), in solid tumors, including breast cancer and soft-tissue sarcomas, is ongoing. This study is part of a program funded by INCa (the French National Cancer Institute) and is sponsored by the Institut Bergonié (Bordeaux, France). Cyclophosphamide administered continuously in small doses is used in combination with immunotherapy treatments to potentiate their activity. Moreover, a study using Pexa-Vec in solid tumors before surgical intervention (neo-adjuvant indication) has begun in the UK (Leeds University, principal investigator Professor Melcher). This study's objective is to better document Pexa-Vec's mechanism of action in the actual tumor environment.

The Company is also setting up studies based on the rationale of synergized efficacy in the combination of immunotherapy classes. This type of combinatorial approach is considered very promising in the field of oncology. The following studies will evaluate Pexa-Vec in combination with ICIs (immune checkpoint inhibitors) and are expected to begin by year-end:

- study of the combination of Pexa-Vec + ICI in first-line treatment of advanced liver cancer; and
- study of the combination of Pexa-Vec + ICI in solid tumors.

#### Marketing outlook

An initial application could be filed for marketing approval of Pexa-Vec in 2019-2020 as a first-line treatment in advanced liver cancer as indicated in the product's current development plan.

## TG4001: cancers caused by the Human Papilloma Virus (HPV)

# $Description\ and\ mechanism\ of\ action$

TG4001 immunotherapy is composed of a vector, the MVA vaccine virus expressing both antigens of the human papilloma virus (HPV) of the 16 type (HPV16) and interleukin-2 (cytokine also present in TG4010).

# OVERVIEW OF TRANSGENE AND ITS BUSINESS Analysis and discussion on the year's activities

#### Lead therapeutic indication

After initial development of this product in pre-cancerous lesions of the cervix (cervical intraepithelial neoplasia CIN2/3), the Company shifted the focus of its development to patients with cancers caused by the human papilloma virus (HPV) in combination with immune checkpoint inhibitors.

In previous studies, TG4001 showed a good safety profile, with mild reactions at the injection site as the most common side effects associated with the therapeutic vaccine. No serious side effect associated with the vaccine was observed. More specifically, in the last phase 2b study in patients with CIN2/3, this data was obtained with only three injections of TG4001 in monotherapy. Therefore, this provides solid proof of the activity of the immunotherapy product in a pathology caused by HPV and, in this respect, these results are extremely encouraging for TG4001 and the entire MVA platform.

#### Next stages of development

The Company intends to launch a study next year with TG4001 in combination with an immune checkpoint inhibitor, in cancers induced by HPV.

#### Marketing outlook

Transgene is not currently able to provide information on the timing to file for marketing approval for this product.

#### TG1050: Chronic hepatitis B

# Description and mechanism of action

TG1050 is an immunotherapy based on the human adenovirus serotype 5. This virus is non-replicative, meaning that it cannot proliferate in the patient's body. It expresses several antigens of the hepatitis B virus (HBV): the DNA polymerase enzyme, responsible for replication of the virus, the surface protein located outside the virus that allows HBV to enter the cells that it infects and finally the HBV capsid protein, i.e., the protein comprising the structure that surrounds the viral genome Once produced in the body via the adenovirus vector, these HBV proteins will activate the patient's immune system and induce HBV-specific T lymphocytes that can recognize infected cells and eliminate them.

#### Therapeutic vaccination

TG1050 is for treatment of chronic hepatitis B.

Despite the introduction over the last ten years of new effective drugs, nucleoside analogues (NAs) and pegylated interferon alpha (PEF-IFN), to treat chronic hepatitis B, these treatments only rarely succeed in eliminating the infection, i.e., the disappearance of the HBV surface antigen (HBsAg) at the same time as a measurable antibody response against the same antigen, or seroconversion against HBsAg.

In combination with standard treatment, TG1050 could increase the level of seroconversion against HBsAg, compared with current standard treatments alone, thus providing a new option for curing this disease.

#### Key results

Based on the data proving the pre-clinical concept (key findings were published in the scientific journal Gut), the Company moved ahead with a phase 1/1b study of TG1050 in patient with chronic hepatitis B.

# Next stages of development

Transgene has begun a first clinical trial with patients treated with anti-virotherapy. Initial results on tolerability are expected in mid-2016.

#### Marketing outlook

Transgene is not currently able to provide information on the timing to file for marketing approval for this product.

# 1.4.1.1.2 Other products

Transgene is making a major investment in its next generation of products. Its main research interests are oncolytic viruses for cancer (TG6002) and immunotherapeutic products for infectious diseases (tuberculosis in particular).

# TG6002: treatment of solid tumors

TG6002 is an oncolytic immunotherapy developed for the treatment of solid tumors. The program is well advanced in the preclinical testing phase and should enter the clinical phase in 2016.

#### Marketing outlook

Transgene is not currently able to provide information on the timing to file for marketing approval for this product.

#### **Tuberculosis program**

The Transgene tuberculosis program focuses on the development of a targeted immunotherapy to treat active tuberculosis, including drug-resistant tuberculosis. It uses Transgene's viral vector technology, inserting into vectors proteins that are expressed by mycobacterium during both the latent and active phases of infection.

In October 2013, the Company announced that its tuberculosis immunotherapy program would receive \$5 million from the U.S. National Institute of Allergy and Infectious Diseases (NIAID, an agency of the National Institutes of Health or NIH), which has awarded the funds to Emergent BioSolutions Inc. The Company has a collaboration agreement with Emergent BioSolutions Inc. to develop a cell line production process and manufacture the anti-tuberculosis immunotherapy product that the Company chooses to develop. The significant expertise of Emergent BioSolutions in this field will complement the capacity and know-how of the Company, which retains all the rights associated with the development and commercialization of the candidates generated as a result of this program.

Pre-clinical experiments are underway and the Company will define, as necessary, the next development stages in relation to these experiments during the year.

## Marketing outlook

Transgene is not currently able to provide information on the timing to file for marketing approval for this product.

# 1.4.2 Material contracts

# Consortium agreement in the context of the ADNA (Advanced Diagnostics for New Therapeutic Approaches) project

Transgene is a partner in a research program coordinated by Institut Mérieux, which brings together bioMérieux, Transgene and Genosafe and the Genethon association. The program's goal is to develop a new generation of diagnostics and therapies focusing on cancers and infectious and genetic diseases. This program is called "ADNA" (Advanced Diagnostics for New Therapeutic Approaches). It was supported by the Industrial Innovation Agency, which merged with OSEO in 2007 and became Bpifrance in 2013.

Under this program, Transgene receives grants and reimbursable advances of up to €8.3 million and €15.9 million, respectively, over the duration of the program, from 2008 to 2017. If the project is a success, which is defined as the marketing of a product for which a grant has been awarded and reaching a lower limit of revenue, Transgene must pay back, under certain conditions, the advances in installments and then, if applicable, pay interest (1.75% of revenue) over a certain length of time. The agreement was approved by the European authorities on October 22, 2008.

# Licensing agreement with Jennerex, Inc. ("Jennerex")

In August 2010, Transgene and Jennerex (a wholly-owned subsidiary of the South Korean-based company SillaJen since 2014) signed an exclusive partnership agreement for the development and commercialization in Europe, the Commonwealth of Independent States (CIS) and the Middle East of Jennerex's oncolytic virus Pexa-Vec for the treatment of solid tumors. In November 2015, SillaJen and Transgene announced the amended partnership agreement to streamline the conduct of clinical studies reflecting the areas of interest of each partner and to redefine the territories. Transgene has returned rights to SillaJen for all Middle Eastern countries, Russia, Ukraine, Belarus and Turkey. SillaJen assumed the responsibility of conducting the phase 3 trial in hepatocellular carcinomas. Transgene remains responsible for submitting requests for marketing approval and retains commercialization rights in its territories. Transgene will pay SillaJen a global amount of \$6 million whereas under the terms of the original agreement it was responsible for all development costs in its territories. Under the amended agreement, Transgene has committed to independently initiate an exploratory trial evaluating Pexa-Vec in combination with nivolumab for the treatment of hepatocellular carcinomas. Transgene will be responsible for all costs related to this trial, as well as any other exploratory studies it launches independently.

As part of the development activities, Transgene may have to pay Jennerex up to \$116 million (including \$9.25 million that have already been paid) in milestone and market authorization payments, as well as royalties from the sale of Pexa-Vec by Transgene and its sub-licensees. Jennerex also has an option to co-promote the product in the five major European countries in the exclusive territory of Transgene.

# Collaboration and Licensing Agreement with VALNEVA (previously VIVALIS)

In July 2011, Transgene and Vivalis signed a collaboration and commercial licensing agreement for the development of a production process using the Vivalis EB66® cell line, suitable for the production of Transgene MVA therapeutic vaccines.

As part of this agreement, Transgene made an initial payment to Vivalis and could be required to make milestone payments at certain stages of clinical development and pay royalties related to sales of Transgene products made from Vivalis EB66\*. Vivalis will also receive income related to GMP manufacturing of initial clinical batches.

# **Agreement with SANOFI**

In March 2013, Transgene announced the signing of a collaboration agreement for the creation of a new advanced platform dedicated to the manufacturing of immunotherapy products, including Transgene therapeutic products. The platform will be built on the Genzyme Polyclonals site in Lyon, in the Gerland district, with an investment of €10 million, funded equally by Sanofi and Transgene. The platform will remain the exclusive property of Sanofi.

Sanofi and Genzyme will act as a bioproduction services company (Contract Manufacturing Organization or CMO) for Transgene and will manufacture clinical and commercial batches for Transgene's immunotherapy products, including the therapeutic MVA vaccines. Transgene will be a preferred customer of the commercial manufacturing platform for 15 years.

The construction, approval and certification of the manufacturing site started in January 2014 and should be completed in the second quarter of 2016.

# License agreement with ASCEND

In July 2013, Transgene granted Ascend BioPharmaceutical ("Ascend"), a new biotechnology company based in Australia, a license for the immunotherapy product TG1042 to treat a common form of skin cancer, basal cell carcinoma (BCC), and two other cancer indications, with Transgene retaining rights to other potential indications.

# **Agreement with EMERGENT**

In October 2013, Transgene announced that its new tuberculosis immunotherapy program would receive funding of \$5 million from the U.S. National Institute of Allergy and Infectious Diseases (NIAID, part of the U.S. National Institute of Health or NIH), granted by the latter to Emergent BioSolutions Inc. (NYSE: EBS).

In relation to this funding, Transgene signed a collaboration agreement with Emergent BioSolutions to develop a cell line production process and to manufacture the antituberculosis immunotherapy product that Transgene selects for development.

Transgene retains all rights associated with the development and marketing of candidates generated by this program funded by the NIAID.

# Agreements with ABL Europe for the manufacturing of clinical batches

On February 1, 2016, as part of the finalization of the Company's industrial strategy, the Company and ABL Europe announced ABL Europe's acquisition of Transgene's production assets, namely the real estate complex including a manufacturing building with a logistics annex and related facilities. Alongside this transaction, the two companies signed a 3-year agreement under which Transgene has secured the production of the necessary clinical batches for its clinical development plan.

# Loan agreement with the European Investment Bank (EIB)

In early January 2016, the Company obtained a €20 million loan from the European Investment Bank (EIB) under the IDFF (Infectious Diseases Finance Facility). This is a five year facility with principal and interest repayable only from the fourth year. It will be drawn down in two tranches in 2016 at the Company's request and no security has been provided.

# 1.4.3 Financial position

# 1.4.3.1 General information

Transgene is a biotechnology company that develops innovative products in the field of immunotherapy treatment of cancers and infectious diseases. Through strategic partnerships with ABL Europe and Sanofi, Transgene has access to manufacturing capacities on both clinical and commercial scales. The Company seeks to enhance the value of all its assets. Several products are in development, including four in the clinical development phase: TG4010, a therapeutic vaccine initially developed for lung cancer; Pexa-Vec, an oncolytic virus initially developed for liver cancer; TG1050 a therapeutic vaccine developed to treat patients chronically infected with the hepatitis B virus; and TG4001, a therapeutic vaccine developed for cancers caused by the human papilloma virus (HPV). The other products are in preclinical development stage.

# 1.4.3.2 Major accounting principles

#### Revenue recognition

At the date of this *Document de référence*, with no products on the market, Transgene generates revenue from (i) collaboration and licensing agreements signed with other companies in its sector (see Section 1.4.2) and (ii) public funding of research expenses (grants and research tax credits).

Some collaboration and licensing agreements provide for research or manufacturing services by the Company, with obligations to customers. The Company invoices its services at a contractually defined price that is generally based on time spent, and billings are recorded in operating income as and when the services are performed. Some of these contracts provide for manufacturing services with a performance obligation. In these cases, the services are recorded in operating income in the income statement after satisfactory quality control and customer acceptance. Cash receipts corresponding to income not yet recognized as income in accordance with the principles outlined above are recorded as deferred income on the balance sheet until they meet the criteria for recognition as operating income. Income from patent licenses generally consists of an upfront non refundable payment on the signing of the agreement, milestone payments and other payments such as royalties on sales.

The Company may be required to grant an option right for a license. Income associated with the concession is recorded as *deferred income on the balance sheet* and recognized as income on a straight line basis until the estimated date of exercise of the option by the beneficiary. The expected date of exercise of the option is reviewed periodically.

In the event that the Company is not committed to perform work for the development of technology after signature, the non-refundable fees for technology usage rights paid when the license is signed are recognized as operating income upon the fulfillment of the contractual obligations. In the event that the Company should continue some development work in the technology after signature, or if it has a higher obligation to deliver the product, these rights are recognized in deferred operating income over the period of development or delivery of the product.

Milestone payments received under collaboration and licensing agreements are recognized as income when the operative event has occurred and there are no longer any conditions precedent to the payment by the third party. Operative events are usually the scientific or clinical results obtained by Transgene, the commencement of studies or external factors such as regulatory approvals.

Royalties on sales received under collaboration and licensing agreements are based on sales by licensees of products or technologies. They are recognized on the basis of the license terms, when the sales can be reliably measured and recovery of the related receivables is reasonably assured.

Certain research and development expenses in France are entitled to a research tax credit recognized at the end of the year in which the expense was recorded and the tax credit claimed. If it has not been used by allocation to a tax charge, the tax credit may be redeemed in accordance with the tax provisions. Research tax credits are recognized in the income statement under "Government grants", in accordance with IAS 20.



## Research and development expenses

Research and development expenses are recognized on the income statement in the period in which they are incurred. Development expenses are capitalized only when IAS 38 requirements are met. At the current development stage of its products, the Company believes that, at the date of this *Document de référence*, these conditions were not met, and therefore, it did not capitalize its development expenses.

# Payment in shares

The Company distributes stock options and bonus shares to its officers and employees. The charge for these distributions is evaluated and spread over time, according to the principles of IFRS 2.

#### Benefits at retirement

In accordance with the prevailing laws and practices in France, Transgene SA offers certain advantages that ensure eligible employees are paid a lump sum upon retirement (benefit plan at retirement). In accordance with the obligations and regulations, these defined benefit plans may be funded by investments in various instruments. The rights acquired by active staff are estimated using actuarial valuations based on the probability of death and continued employment by the Company, as well as expected future salaries. The benefit obligation is measured by the projected unit credit method. This provision does not apply to employees of entities located abroad.

# 1.4.4 Foreseeable changes, outlook and significant events after the balance sheet date

# 1.4.4.1 Information on trends

At the date of the present *Document de référence*, the Company expects cash outflow of around €35 million in 2016.

# 1.4.4.2 Profit forecasts or estimates

None.

1.4.4.3 Significant change in the Company's financial or trading position

None.

# 1.4.5 Cash flow, financing and capital resources

To date, the Company has been funded by capital increases. Historically, the Company has mainly been financed by its majority shareholder, due to that shareholder's wish to maintain its level of control and interest (see 1.5.2.1.3 Financial liquidity risk related to cash requirements).

# **Investments**

Investments in tangible and intangible assets (net of disposals) amounted to  $\leqslant$ 1.4 million in 2015 ( $\leqslant$ 2.3 million in 2014).

# Repayable advances and loans

In 2015, the Company used its 2014 research tax credit of €8.9 million. To this effect, it took out a bank loan with Bpifrance that matures in mid-2018, at which time the receivable is expected to be paid by the French government.

In 2015, Transgene also received €0.9 million (versus €0.8 million in 2014) in repayable advances under the ADNA program, which receives public funding from Bpifrance. Since the start of the ADNA program, the Company has received

€14.3 million in repayable advances under this program. The Company may receive up to €1.7 million in additional repayable advances over the remaining term of the ADNA program, i.e., until 2017.

# Liquidity and capital resources

Cash assets are invested in very short-term mutual funds or invested at market conditions in a cash pool organized by Institut Mérieux, the majority shareholder of Transgene.

At December 31, 2015, the Company had €31.7 million in cash (€65.9 million at December 31, 2014).

At the date of this *Document de référence*, the Company had no bank debt subject to covenants.

#### Cash flow

Excluding the issuance of shares, the Company's net cash consumption amounted to  $\leqslant$ 34.8 million in 2015 versus  $\leqslant$ 44.9 million in 2014.

# 1.4.6 Presentation of the financial statements and appropriation of net income/(loss)

The Company has incurred losses since 1993 and expects to continue to incur more losses over the next few years, due to costs incurred by its research and development programs and preclinical and clinical trials. In previous years, the main sources of Transgene revenue were the remuneration of research and bio-manufacturing contracts for third parties and government

subsidies. Future revenues should be limited to payments related to existing and future strategic partnerships with pharmaceutical companies, third-party research contracts, current license agreements, investment income from cash investments and public funding.

# **Comments on Operating Results (IFRS standards)**

# Fiscal years ended December 31, 2015 and 2014

## **○** INCOME STATEMENT

(in € thousands, except for per share data)	12/31/2015	12/31/2014
Revenue from collaboration and licensing agreements	1,465	1,837
Public funding for research expenses	8,100	9,262
Operating income	9,565	11,099
Research and development expenses	(32,138)	(41,731)
General and administrative expenses	(5,798)	(7,578)
Other income and (expenses), net	(7,436)	(1,282)
Net operational expenses	(45,372)	(50,591)
Operating income from continuing operations	(35,807)	(39,492)
Interest income (expense), net	(930)	(801)
Share of income from equity affiliates	(1,172)	(823)
Loss before tax	(37,909)	(41,116)
Tax on profits	-	-
Net income from continuing operations	(37,909)	(41,116)
Net income from discontinued operations	(8,465)	(7,440)
Net loss	(46,374)	(48,556)
Basic earnings (loss) per (€) share	(1.20)	(1.26)
Diluted earnings (loss) per share(€)	(1.20)	(1.26)

# **Operating income**

During the periods under review, revenues from collaborations and licensing agreements mainly included the following:

- research and development services for third parties (including for Emergent Biosolutions, Inc., for a product candidate against tuberculosis) amounting to €0.8 million in 2015 (€1.0 million in 2014); and
- income related to commercial use of technologies or products provided under license by Transgene SA, amounting to €0.7 million in 2015 (€0.6 million in 2014).

At December 31, 2015, public funding of research expenses included grants received and receivable, as well as research tax credits. Research grants amounted to 0.2 million in 2015 (0.6 million in 2014).

Research tax credits (CIR) totaled €7.9 million in 2015 (€8.8 million in 2014). The eligible expenses base (net of subsidies received during the fiscal year) amounted to €25.8 million in 2015 and €29.8 million in 2014. The reduction in the eligible base stems from the fall in eligible research and development expenses between 2014 and 2015 (€26.9 million

in 2015 versus €31.2 million in 2014) in both operating expenses and expenses for clinical services and research sub-contracting.

#### **Operating expenses**

R&D expenses amounted to €32.1 million in 2015 compared to €41.7 million in 2014 on a like-for-like scope. This sharp

decrease reflects reduced employee benefits expenses and lower operating costs in light of the cost-cutting plan that the Company began in 2015, as well as reining in tightly on external expenditures on other projects during 2015.

The following table outlines research and development expenses:

(in € millions)	12/31/2015	12/31/2014	Change
Employee benefits expenses	14.6	16.1	-9%
Payment in shares	0.3	0.5	-40%
Expenses for intellectual property and licensing costs	1.5	1.3	+15%
External expenses for clinical projects	4.2	7.6	-45%
External expenses for other projects	4.4	7.6	-42%
Operating expenses	5.1	6.7	-24%
Depreciation and provisions	2.0	1.9	+5%
RESEARCH AND DEVELOPMENT EXPENSES	32.1	41.7	-23%

Employee benefits expenses allocated to R&D (salaries, expenses and related expenditures), amounted to €14.6 million in 2015, compared to €16.1 million in 2014. This decrease reflects the cost-cutting measures taken by the Company prior to the deploying the redundancy plan (plan de sauvegarde de l'emploi), such as not replacing departures and not renewing fixed-term contracts.

Intellectual property and licensing expenses amounted to €1.5 million in 2015, compared to €1.3 million in 2014.

External expenses for clinical trials were €4.2 million in 2015, compared to €7.6 million in 2014. This significant decrease (-45%) was due to the following:

- the sharp drop in 2015 in the number of patients treated in phase 2b of phase 2b/3 of the TIME study with TG4010 in lung cancer upon completion of the study, as well as development costs for related companion tests (€1.5 million in external expenses for this product in 2015 versus €4.8 million in 2014);
- the completion in 2014 of the TRAVERSE study, a phase 2b clinical trial with Pexa-Vec for the second-line treatment of advanced liver cancer (no external expenses in respect of this product in 2015 versus €1.4 million in 2014);

 conversely, the external costs for launching the new clinical trials for phase 3 with Pexa-Vec and for phase 1 with TG1050 amounted to €1.7 million and €0.8 million, respectively, in 2015.

Other external expenses, including expenses for research, preclinical and manufacturing projects, amounted to €4.4 million in 2015 versus €7.6 million in 2014. This decrease in expenses is primarily attributable to the lower level of expenses incurred on the regulatory toxicology studies and on subcontracting the manufacturing of the immunotherapy product TG1050 (€0.3 million in external expenses in 2015 versus €1.5 million in 2014), and on the construction of a commercial production unit with Sanofi/Genzyme (€1.8 million in external expenses in 2015, versus €2.6 million in 2014).

General and administrative expenses amounted to €5.8 million in 2015 versus €7.6 million in 2014.



The following table outlines overhead expenses by type of expense:

(in € millions)	12/31/2015	12/31/2014	Change
Employee benefits expenses	2.9	3.7	-22%
Payment in shares	0.1	0.2	-50%
Professional and management fees	1.7	2.5	-32%
Other fixed costs	1.0	1.1	-9%
Depreciation and provisions	0.1	0.1	N/S
GENERAL AND ADMINISTRATIVE EXPENSES	5.8	7.6	-24%

Employee benefits expenses amounted to €2.9 million in 2015 versus €3.7 million in 2014. This decrease reflects reduced headcount in the financial and administrative support services.

Professional and management fees amounted to €1.7 million in 2015, compared to €2.5 million in 2014.

#### Other revenue and expenses, net

Other net expenses amounted to  $\ensuremath{\mathfrak{C}}$ 7.4 million in 2015 versus  $\ensuremath{\mathfrak{c}}$ 1.3 million in 2014.

A net restructuring cost of  $\ensuremath{\mathfrak{C}}$ 7.5 million was recorded in 2015 subsequent to the June 2015 decision to restructure the Company.

In 2014, the equity transactions with Platine Pharma Services SAS resulted in an expense of 0.7 million for Transgene and the sale of shares in Jennerex, Inc. generated a net expense of 0.2 million.

# Financial income (expense)

A net financial expense of €0.9 million was recognized in 2015 versus €0.8 million in 2014.

Interest income (investment income) amounted to 0.5 million in 2015 (0.3 million in 2014).

The main financial expenses consisted of bank interest on the financing of the research tax credit (€0.4 million), the discounting of the advances received by Bpifrance under

# Net income/(loss) from continuing operations

The net loss from continuing operations was €37.9 million in 2015 (€41.1 million in 2014) on a like-for-like basis.

#### Net income/(loss) from discontinued operations

The net loss from discontinued operations was €8.5 million in 2015 compared to €7.4 million for the same period in 2014 on a like-for-like basis. This net loss breaks down as follows:

- €0.5 million in production revenue in 2015 (€0.7 million in 2014);
- €6.0 million in expenses in 2015 (€8.1 million in 2014);
- €2.9 million in depreciation of assets held for sale.

# Overall net profit/(loss)

The total net loss was €46.4 million in 2015 (€48.6 million in 2014). Net loss per share was €1.20 in 2015 (€1.26 in 2014).

# Dividend policy

The Company has not distributed a dividend since its formation. In the coming years, it plans to use all available funds to finance the business and future growth.

# 1.5 RISK FACTORS

The Company conducted a review of the risks that could have a material adverse effect on its activity, financial position or earnings (or its ability to achieve its goals) and believes that there are no significant risks other than those presented. Investors should carefully consider the following risk factors. They must also take note of the other information provided in this *Document de référence*, in particular information related

to the financial statements and notes thereto. In view of the Company's business sector and the fact that its products are still at a very early stage of development, it is generally not possible to assess and quantify the probability of the occurrence of a specific risk and its individual impact on the Company's outlook.

# 1.5.1 Specific risks related to the Company's business

# 1.5.1.1 Risks specific to the Company

# 1.5.1.1.1 Risks related to the therapeutic approaches selected by the Company

The Company is developing immunotherapy products to treat cancer and infectious diseases. These products are primarily therapeutic vaccines and oncolytic viruses. At the date of this Document de référence, there are very few authorized immunotherapy products on the market. The most recently approved products (Opdivo from Bristol-Myers-Squibb and Keytruda from Merck) belong to a new class of immunotherapies against cancer called immune checkpoint inhibitors. The products developed by the Company are medical technologies for which preclinical and clinical data on safety and efficacy remain limited. Furthermore, as is increasingly the case in oncology, the Company's products must be administered in combination with other treatments such as chemotherapy or other immunotherapies. As a result, there will still be a number of uncertainties relating to the prospects for development and profitability of products manufactured using this technology until their safety, efficacy and acceptance by patients, doctors and healthcare providers have been established.

As of the date of this *Document de référence*, none of the Company's products has reached an advanced stage of development, with the sole exception of Pexa-Vec codeveloped with SillaJen, which has just entered phase 3 of its clinical development (the final phase before filing). All other products are in the research stage, in preclinical studies or in the first or second stages of clinical trials. Not only do animal tests not necessarily predict results obtained in humans, but positive results in early clinical stages obtained on a limited number of patients may not be borne out in later phases on a larger number of patients.

In such cases, the development of the product candidate would not be continued and this could have a material adverse effect on the Company's earnings, financial position and development.

#### 1.5.1.1.2 Risks related to clinical trials

Before marketing in Europe or the United States, each product is subject to rigorous preclinical studies and clinical trials and an extended regulatory approval process by the European Medicines Agency (EMA), the French Agence nationale de sécurité du médicament et des produits de santé (ANSM) or the U.S. Food and Drug Administration (FDA). These clinical trials are performed in three successive phases pursuant to specific regulations referred to as "Good Clinical Practices." In phase 1, clinical trials normally involve a smaller number of subjects to establish the preliminary safety profile, the dosing regimen and drug metabolism. In phase 2, clinical studies are conducted in a larger group of patients with a specific disease in order to confirm the safety of the product and determine the efficacy of the product by researching the optimum dosage and method of administration. In phase 3, comparative clinical trials on a larger scale are conducted in several medical centers, on patients with a specific disease, to obtain sufficient data to complete an acceptable statistical test on the efficacy and safety of the product.

The approval processes are long and expensive and the result is not certain. Approval granted by the regulatory authorities in one country does not guarantee that the product will be approved in another country. Factors that affect the uncertainty of obtaining these regulatory approvals include:

- immunotherapy as a treatment approach is still developing;
- the regulatory requirements governing immunotherapy, in particular therapeutic vaccines and oncolytic viruses, are uncertain and likely to be modified; and
- the data obtained from preclinical studies and clinical trials may give rise to different interpretations that could delay, limit or prevent approval.

Other risk factors affect the clinical trials themselves:

- the clinical protocols, which describe the objectives of the study and the parameters to be used to measure the safety and efficacy, must be approved by the regulatory authorities in the country in which the clinical studies are being conducted. Further, each clinical study must be approved by each study center's independent Ethics Committee. In particular, the Ethics Committee will assess the need for the study, the safety of the people involved in the trial and the potential liability of the medical center. The Ethics Committee is also responsible for monitoring the application of the protocols approved for the clinical trials in progress. The Ethics Committee could demand modifications to a protocol and there is no guarantee that it will authorize a study to commence or continue. This procedure can be conducted at the same time as the approval procedure by the national regulatory authorities however it could cause delays and considerable extra costs in addition to those relating to the regulatory examination procedure. The majority of countries have also put in place special committees that study the protocols using recombinant DNA products before authorizing them for marketing (the Haut Conseil des biotechnologies in France, the National Institutes of Health's Recombinant DNA Advisory Committee in the United States and the Gene Therapy Advisory Committee in the United Kingdom);
- the recruitment of patients for inclusion in the trials: clinical trials with the Company's products in development are conducted with people suffering from the target diseases. The number of patients who can and want to participate in a clinical trial is limited and recruitment can be a difficult and slow process, especially when competing clinical trials are soliciting the same group of patients. The Company has already been faced with this risk and it could occur again, leading to excessive delays in the implementation of trials. In order to mitigate this problem, the Company may need to increase the number of clinical centers, which adds to the complexity of follow-up and increases the cost of the trial;
- access to appropriate clinical sites may be difficult, preventing the initiation or conduct of the trial within a reasonable timeframe:
- at each stage of a product's clinical trials, there is a significant risk of failure that could prevent development from continuing: the product may be poorly tolerated, have little or no therapeutic benefit, or even cause serious adverse effects that could result in the banning of the product. The competent regulatory authorities can suspend the clinical trials at any time if they believe that the patients are exposed to unacceptable health risks or if they detect any deficiencies in the clinical trial process or as part of their inspections:
- in the field of immunotherapy to which the Company's products belong, the search for biomarkers (particular biological characteristics) in patients, in order to determine their response to treatment, has become indispensable. The biomarkers identified in this way will be incorporated into diagnostic tests, called companion diagnostics, which

- will then accompany the treatment so that it can be administered to those most likely to benefit. Validation of companion diagnostic tests is an entirely separate clinical development process that happens concurrently with the clinical trials for a treatment and adds a level of complexity and additional costs. It may happen that a biomarker identified retrospectively in a clinical trial cannot be verified or cannot be confirmed as a predictive tool of the benefit of treatment for patients with this biomarker. In this case, it may be that the treatment under development does not achieve the quantitative criteria of positive clinical results necessary to obtain marketing authorizations;
- the cost per patient of clinical trials is particularly high, especially in immunotherapy, which makes the later clinical testing phases (phase 3) particularly costly in indications that require a large number of patients to prove a therapeutic benefit, such as, for example, lung cancer. These costs could exceed the Company's available cash resources and the Company would then need to seek financing, for example through partnerships with the pharmaceutical industry. There is no guarantee that the Company will be able to enter into such partnerships or that such alternative financing can be arranged.

If one or more of these risks were to occur, it could have a material adverse effect on the Company's business, earnings, financial position and development.

#### 1.5.1.1.3 Risks related to manufacturing

Since February 1, 2016, the Company no longer has its own manufacturing unit and instead subcontracts the manufacturing of the product batches required for its clinical studies. The manufacturing unit of the sub-contractor, ABL Europe, does not have sufficient capacity to guarantee the commercialscale production of these products beyond the initial phase. The Company recently secured its ability to sub-contract the commercial-scale manufacture of its products by entering into a partnership with Sanofi Genzyme. The Company would need to make substantial additional investment to have its products manufactured on a commercial scale by third parties or to manufacture the products internally again. In this case. the regulatory authorities may require new clinical studies due to the specificities linked to bioproduction. Therefore the Company's ability to switch sub-contractors within a reasonable timeframe is limited, resulting in production delays. The Company may not be able to set competitive prices for its products, which would have a material adverse effect on its business, earnings, financial position and development.

The Company uses raw materials from different suppliers in its manufacturing processes; some of the suppliers are the sole source of the material in question. The Company certifies its suppliers pursuant to pharmaceutical best manufacturing practices. If one of the sole-source suppliers should default, the Company must find and certify another source. However, identifying and certifying such a supplier could take several months and their products could not be used in the Company's processes until certification is complete. Moreover, the current volumes ordered by the Company do not allow it to negotiate

agreements guaranteeing a supply of certain key raw materials from qualified critical suppliers. The Company therefore cannot ensure that it could be supplied by certain critical suppliers, that it could secure a second supplier or that it could do so in a timely manner.

This would have a material adverse effect on the Company's business, results, financial situation and development.

#### 1.5.1.1.4 Risks related to product adverse side effects

The commercial success of the Company's products essentially depends on their acceptance by the public and medical professionals that use immunotherapy products to treat human diseases. This acceptance could be negatively affected by adverse side effects caused by the products developed by the Company and others. These adverse side effects may cause the regulatory authorities to limit or prohibit the use of these products or similar products and thereby limit the potential market for the Company's products.

This could have a material adverse effect on the Company's business, earnings, financial position and development.

# 1.5.1.1.5 Risks related to the funding of the Company's development and activities

The Company has and will have significant capital requirements to finance its research and development, particularly preclinical studies and clinical trials of its products under development, the subcontracting and production of its clinical products and commercial-scale production, and the expansion of its regulatory, commercial and administrative capabilities. It shall also require substantial funds to distribute any products approved for commercial sale. If the Company is unable to obtain funding on a timely basis, it may be required to significantly curtail one or more of its research and development programs or to cease operations altogether. Its future capital requirements will depend on many factors, including the following:

- the continued development of research & development programs and the extension of such programs;
- the extent and results of preclinical studies and clinical trials;
- the time and costs required to obtain regulatory authorizations:
- its ability to enter into partnership agreements to continue developing certain products;
- the necessity for large-scale manufacturing and distribution;
- the deadline, and amounts of payments under its collaboration agreements;
- the deadline, payment and amount of sales and royalties for future products;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights; and
- the cost of obtaining and maintaining licensing rights to use patented technologies.

The Company has limited sources of funding. As a result, it is required to finance itself primarily through the issuance of new shares. Historically, the financing of the Company was provided, for the most part, by its majority shareholder, due in particular to the shareholder's interest in maintaining its level of investment and control. The financing of the Company by future capital increases could be complicated by poor capital market conditions, and, even if financing transactions are successful, shareholders may be exposed to a dilution of their shareholdings.

This could have a material adverse effect on the Company's business, earnings, financial position and development.

The Company also entered into a €20 million loan facility with the European Investment Bank that it can draw down in two €10 million tranches by the end of 2016. This five-year interest-bearing loan is repayable as from its fourth year. If the Company had to reimburse this loan earlier than expected or was unable to reimburse it at maturity, this could have a material adverse effect on the Company's business, earnings, financial position and development.

## 1.5.1.1.6 Risks related to previous and future losses

The Company has reported operating losses for several years. At December 31, 2015, the accumulated deficit since 1993 amounted to approximately €538 million under IAS/IFRS standards, as a result of significant investments in research and development programs and the absence of significant revenues (see consolidated statement of changes in equity, page 80). Further substantial losses are expected to be incurred in the future as long as the Company continues its research & development activities and preclinical studies and clinical trials. None of its products has yet to generate sales or revenue. The only sources of revenue expected in the near future would not come from the commercialization of products but from payments made by partner companies under certain agreements (see Section 1.4.2) and, where applicable, public funding and financial revenue. The Company cannot guarantee that it will generate revenue in the short term from the sale of products and achieve profitability.

This could have a material adverse effect on the Company's business, earnings, financial position and development.

# 1.5.1.1.7 Specific risks related to development, manufacturing and marketing partnerships

The Company's strategy in terms of research and development and the commercialization of certain of its products is based on signing collaboration agreements with partner companies or third parties (see Section 1.4.2). At the date of this *Document de référence*, the Company has signed the following agreements for the products it is developing:

 the license option agreement with Novartis signed in March 2010: Transgene granted Novartis an exclusive license option to develop and market TG4010 for the first-line treatment of non-small cell lung cancer and other potential oncology indications. In April 2014, Novartis notified the Company of its decision not to exercise this option. The Company had not found a new partner for the TG4010 product as of the date of this *Document de référence*;

• the agreement for the development and marketing of Pexa-Vec signed with Jennerex (now called SillaJen, Inc.) signed in August 2010 and amended in December 2015: under the terms of this amended agreement, Transgene holds exclusive rights to develop and market Pexa-Vec in Europe, the CIS and the Middle East, as well as manufacturing rights for its territories. Transgene and Jennerex will co-develop the product globally with SillaJen assuming responsibility of ongoing phase 3 trials of Pexa-Vec and Transgene taking on independently the Pexa-Vec combination studies with immune checkpoint inhibitors.

The development and marketing of Pexa-Vec, including in Transgene's territories, could be affected if SillaJen were not to comply, or were unable to comply, with its regulatory obligations in its territories or with its contractual obligations with respect to Transgene and third parties.

This would have a material adverse effect on the Company's business, results, financial position and development;

- the collaboration agreement signed in March 2013 with Sanofi for the creation of a new platform dedicated to the manufacture of immunotherapy products, including Transgene's therapeutic products. The launch phase of the platform's construction began in early 2014. The platform remains the exclusive property of Sanofi. If the construction were not completed in time, or if the qualification and validation phases of the unit and its teams were delayed, the platform might not be available for manufacturing the first market-stage Transgene product;
- the exclusive service agreement signed in February 2016 with the company ABL to have ABL Europe manufacture the clinical batches of Transgene products for its clinical studies subsequent to the Company's decision to outsource the manufacturing which up until then it had conducted inhouse. While ABL Europe is operating in Transgene's former manufacturing facilities, staffed mainly by reassigned employees who had been laid off under the Transgene redundancy plan (plan de sauvegarde de l'emploi), ABL Europe might be unable to perform the requested services within the timeframes and specifications imposed by Transgene or obtain the required authorizations for its operations. This could delay the Company in executing its clinical development plan.

This could have a material adverse effect on the Company's business, earnings, financial position and development.

## 1.5.1.1.8 Dependence on qualified personnel

The Company is highly dependent on the quality of its scientific personnel and management. It faces stiff competition from other companies and academic institutions for the recruitment of qualified personnel. If it cannot attract and retain qualified

personnel, its ability to market its products and processes could be impeded or delayed.

This could have a material adverse effect on the Company's business, earnings, financial position and development.

# 1.5.1.2 Risks related to the Company's business segment

# 1.5.1.2.1 Risks related to competition and technological development

The Company is in competition with various other companies, including large pharmaceutical and biotechnology companies that develop treatments and prevention methods for the same diseases, including more traditional therapies. It could also be in competition with companies that have acquired or could acquire technologies developed by universities or research institutes or other companies. These companies may have, due to the development of their own technology or technologies acquired from third parties, a portfolio of intellectual property rights that could prevent the Company from successfully marketing its products.

Other companies may develop products earlier, obtain approval more quickly or develop products that are more effective or less expensive than those of the Company. Although the Company endeavors to increase its technological capacities to remain competitive, the research and development activities conducted by its competitors could make the Company's products obsolete or not competitive, or they could offer better treatments. Moreover, consumers and professionals could prefer other existing therapies or therapies recently developed by the Company's competitors.

This could have a material adverse effect on the Company's business, earnings, financial position and development.

# 1.5.1.2.2 Specific risks related to patents and third-party intellectual property rights

The biotechnology industry is a growing industry that generates a large number of patents. The risk is higher when third parties consider that the Company's products or technologies infringe their intellectual property rights. Discoveries are only published or form part of a patent application months or even years later. The monitoring implemented by the Company to prevent the counterfeit risk may be insufficient due to (i) delays in publishing patent applications (18 months after the filing or priority date), (ii) failure to publish certain patent applications in the United States and (iii) the principle of delivery of the patent or the first to invent and not the first to file in the United States up to the entry into force in March 2013 of the America Invents Act of September 16, 2011. This is why the Company cannot be sure that certain third parties have not been the first to invent products or to file patent applications relating to inventions also covered by their own patent applications or those of their partners. Any dispute or claim against the Company, regardless of outcome, could result in substantial financial and reputational costs. Some of its competitors with greater resources could be better able to withstand the costs of a complex proceeding. Any litigation of this type could seriously affect the Company's ability to continue its business. More specifically, disputes over intellectual property could require it to:

- cease to sell or use any of its products that depend on the disputed intellectual property, which could reduce its revenues; or
- obtain a license from the holder of the intellectual property rights that could not be obtained under reasonable conditions, if at all.

This could have a material adverse effect on the Company's business, earnings, financial position and development.

# 1.5.1.3 Regulatory risks

The main regulatory risks are as follows:

# 1.5.1.3.1 Risks related to the Company's regulatory environment

At the date of this Document de référence, none of the Company's products have yet to receive marketing authorization from a regulatory agency. It cannot be certain that it will receive the authorizations necessary to market one of its products. Its products are subject to extensive and strict legislation, and regulatory requirements are complex, sometimes difficult to apply and subject to change. The Agence nationale de sécurité du médicament et des produits de santé (ANSM), the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), as well as their counterparts in other countries, regulate, among other things, research and development, pre-clinical studies, clinical trials, manufacturing, safety, efficacy, archiving, labeling, commercialization and distribution of therapeutic products. In particular, without FDA approval, it would be impossible for the Company to access the U.S. market, which is the largest pharmaceutical market in the world in value. The regulatory approval process for new pharmaceutical products requires the submission of detailed product, manufacturing process and control descriptions, as well as pre-clinical and clinical data and information to establish the safety and efficacy of the product for each indication. It may also require ongoing studies after marketing authorization, as well as controls on manufacturing quality. These regulatory actions are costly and can take many years, and the result is unpredictable.

Moreover, the authorities may conduct inspections in order to check that the drug candidate is being developed in accordance with the regulations in force. During an inspection, the authorities could find a significant regulatory deviation, which could delay or stop a development program and, in the worst case scenario, even cause the Company's business to be discontinued.

In Europe, the United States and in other countries, regulation may:

 delay and/or significantly increase the cost of development, testing, manufacture and marketing of the Company's products;

- limit the indications for which the Company is authorized to market its products:
- impose strict new requirements, suspend the authorization of its products, or require the cessation of clinical trials or marketing, if unexpected results are obtained during testing by other researchers on products similar to the Company's;
- impose burdensome labeling.

Finally, if the Company does not comply with the laws and regulations governing its activities, it could be subject to penalties, which could include a refusal to allow pending requests, product recalls, sales restrictions, temporary or permanent suspension of its operations as well as civil or criminal proceedings.

The occurrence of one or more of these risks could have a material adverse effect on the Company's business, prospects, financial condition, performance and development.

# 1.5.1.3.2 Risks related to obtaining marketing authorizations

To obtain a marketing authorization for one or more of its products, the Company or its partners must demonstrate to the competent regulatory authorities the pharmaceutical quality of their products, their safety in use and their effectiveness in the targeted indications. Although the Company is not immediately affected by a marketing authorization issue, a marketing authorization application is built for the entire duration of development of a drug candidate and the Company ensures its compliance with good practices to avoid jeopardizing its chances of obtaining future marketing authorization under good conditions.

The Company's ability to obtain a marketing authorization for its products will depend on several factors, including:

- the possibility of continuing the development of its products that are, as of the date of this *Document de référence*, in early clinical phases or of getting its products, as of the date of this *Document de référence*, in pre-clinical development to the clinical stage;
- if the Company or its partners were unable to carry out clinical trials in a timely manner and with the human, technical and financial resources originally planned;
- whether its products have previously received marketing authorization for another indication; and
- whether its competitors announce clinical results that may cause the competent regulatory authorities to modify their evaluation criteria.

If the Company does not obtain marketing authorizations, it will not be able to market its product. In addition, its product may not obtain a marketing authorization in a given geographic area, which could significantly restrict marketing.

The occurrence of one or more of these risks could have a material adverse effect on the Company's business, prospects, financial condition, performance and development.

# 1.5.1.3.3 Risks related to changes or announcements about drug reimbursement policies

The Company's ability to successfully market its products will depend in part on the setting by public authorities, private health insurers and other organizations in Europe and the United States of reimbursement rates sufficient for its medications and the treatments associated with them. Third-party payers increasingly challenge prices of pharmaceutical products and medical services. Measures to control costs that health care providers and reimbursement organizations

establish and the effect of potential health system reforms could adversely affect the Company's operating profit. It could also not obtain satisfactory reimbursement for its products, which would adversely affect their acceptance by the market, in which case it would be unable to earn a sufficient return on its investment in research and development.

The occurrence of one or more of these risks could have a material adverse effect on the Company's business, prospects, financial condition, performance and development.

# 1.5.2 Other risks

# 1.5.2.1 Financial risks

Financial risks are also mentioned in Note 22 to the consolidated financial statements.

# 1.5.2.1.1 Foreign exchange risks

The Company publishes its consolidated financial statements in euros. However, a portion of its revenue and expenses is

recognized in U.S. dollars. An increase or decrease in the euro exchange rate relative to the US dollar could impact operating results.

The Company has U.S. dollar bank accounts. Net disbursements totaled USD 3.4 million in 2015.

The following table shows the sensitivity of the Company's expenses to a 10% change in the U.S. dollar rate during the fiscal years ended December 31, 2014 and 2015 (before tax and any exchange rate hedging):

(in € thousands)	12/31/2015	12/31/2014
Expenditures denominated in US dollars	3,431	2,293
Equivalent in euros on the basis of an exchange rate of €1 = U.S.\$1.0887	3,154	1,735
Equivalent in euros in the event of an increase of 10% USD vs. EUR	3,505	1,909
Equivalent in euros in the event of a decrease of 10% USD vs. EUR	2,868	1,562

The Group's foreign exchange position as at December 31, 2015 is as follows:

(in thousands)	USD
Assets	5,153
Liabilities	1,586
Net position	3,567
Adjusted	3,567
Off-balance sheet position	-

#### 1.5.2.1.2 Interest rate risk

The Company is exposed to market risks related to interest rates on its finance lease liability and cash investment in mutual funds

The Company holds a variable market-rate liability as part of a finance lease on its main building, a mixed-use property of offices and laboratories. Twenty-five percent of the 15 year, €16 million contract consists of reimbursable advances made by local authorities at very low interest rates. The effective date was January 1, 2009. A 1% rise in the 3-month Euribor would cause a yearly increase in financial expense of €120 thousand. In the first six months of 2009, the Group proceeded with partial coverage of the interest rate risk related to this financing according to the following terms:

Nominal value	€5.9 million (depreciable)
Hedging instrument	Interest rate (swap) contract
Residual maturity	8 years
Underlying interest rate	3 month Euribor
Fixed rate	3.46%

As the hedge is perfect, the variations in market value for the instrument are recognized at net value. At December 31, 2015, the market value for the hedging instrument totaled -€544 thousand.

The Company also has variable market rate liabilities under finance leases financing laboratory equipment. At December 31, 2015, the total obligation under these contracts was €397 thousand.

# 1.5.2.1.3 Liquidity risk

The Company undertook a special review of its liquidity risk and concluded that its liquidity reserves as of December 31, 2015 would enable it to finance its current operating costs for the next 24 months (see Note 2 to the consolidated financial statements).

Financial visibility has improved by securing an additional  $\in$ 30 million in January 2016 under a loan facility with the EIB and through the Institut Mérieux.

The Group controls the risks related to cash management through centralized tracking and approval procedures. Cash assets are invested in highly rated marketable securities.

Cash, which was invested as at December 31, 2015 in very short-term money market funds or at market conditions in the cash pooling managed by the Institut Mérieux, stood at €30.8 million. The Company needs, and shall continue to require, substantial funds to continue its research and development activities, including pre-clinical and clinical testing of future products, further development of manufacturing processes and accessing industrial- and commercial-scale manufacturing, and enhancing its quality control and its regulatory, marketing and administrative capabilities. It shall also require substantial funds to manufacture and market any products approved for commercial sale.

The Company has limited access to debt due to the Group's losses and the high-risk nature of the business sector (pharmaceutical research and development) in which it

operates. The Company plans to finance operations mainly through equity until its profitability situation changes such that it has access to debt instruments.

## 1.5.2.1.4 Equity risk

Like many other biotechnology companies, the Company's stock price is especially volatile. In addition to the risks described in this Chapter, the following factors among others could have a significant influence on the stock price:

- reactions to reported performance and to the reports of financial analysts; and
- more broadly, market conditions affecting biotechnology shares.

The Company does not have any interests in listed companies and its cash is invested primarily in common shares of short-term money market funds not directly exposed to equity market risk.

# 1.5.2.2 Legal risks

Neither the Company nor the Group are currently party to a significant legal dispute, with the exception of a proceeding brought by an employee of the Company before the Strasbourg labor relations court (Conseil des Prud'hommes), for which an accounting provision of €125 thousand has been made in the Company's financial statements for the period ended December 31, 2015. See also Section 1.5.2.3. "Legal and arbitration proceedings" of this Document de référence.

# 1.5.2.2.1 Risk related to patents

The Company's success will depend largely on its ability to obtain patents for its products and processes in order to be able to benefit from the exclusive use of inventions. Its success will also depend upon its ability to prevent other parties from using its intellectual property. Furthermore, the Company must conduct on its business without infringing the intellectual property rights of others. Failing this, it might be unable to successfully commercialize its products.

Transgene has filed and plans to continue to file numerous patent applications for various aspects of its operations (such as viral vectors and methods for preparing and administering them, genes and gene combinations, monoclonal antibodies, biomarkers, etc.). The Company believes that, in some cases, these patent applications cover important technologies for the future marketing of its products and benefit from priority dates that precede those of competitors. However, due to the length of the application review process, particularly in the biotechnology area, when an application will be awarded or rejected cannot be foreseen. Neither can there be any certainty whether a given application will result in a patent, nor, if a patent is granted, whether owning it will give the Company a competitive advantage or will be contested or overturned. As the R&D process for its products is very long, the Company may face the risk that the granted patents expire prior to the market launch of its products.

The Company's situation with regard to patents, like that of all biotechnology and pharmaceutical companies, is especially uncertain. The standards used by the European Patent Office (EPO), the United States Patent and Trademarks Office (USPTO) or other patent offices to grant patents are not always applied in a predictable way and can change. In addition, there is no uniform worldwide policy as to these rights, to the extent of applications made or sought in terms of biotechnology patents or on the amount of protection offered to patent holders.

Transgene believes that several elements of its program involve technology, processes, know-how, data, including culturing and production processes, as well as purification technology, which cannot be patented.

With regard to technologies, know-how and data that are not patentable or are only potentially patentable, and to processes, other than production processes, for which patents would be difficult to enforce, Transgene has chosen to protect its interests by relying on non-disclosure agreements with its employees, consultants and certain contractors. All of its employment contracts include confidentiality clauses. These confidentiality clauses do not provide sufficient protection and may be terminated. In that event, the Company believes that there is no satisfactory remedy possible. Its manufacturing secrets could be revealed and used independently by its competitors.

The occurrence of one or more of these risks could have a material adverse effect on the Company's business, prospects, financial condition, performance and development.

# 1.5.2.2.2 Risk specifically related to patent proceedings

Obtaining and protecting intellectual property rights can be costly. After the United States adopted the "first to file, first to invent" rule, two challenges were brought, as had been done in Europe. These proceedings, though shorter and simpler than the previous interference proceeding, which determined the first to invent when patents claimed the same invention, still

remain very expensive, particularly for the work of law firms specializing in U.S. law.

In Europe a challenge before the European Patent Office (EPO) allows anyone to contest the validity of a patent awarded by the EPO, and that patent may be revoked or its scope restricted. The challenge is an administrative proceeding, not a legal one.

Following the EPO's final decision in December 2015 to revoke a Bavarian Nordic patent on an MVA production process, the Company, at the date of this *Document de référence*, is a party to opposition proceedings against the third-party patent before the EPO, as described below:

on January 23, 2009, with four other opponents against
a European patent held by Bavarian Nordic, related to
a culture medium for the production of MVA. The oral
proceedings took place on January 26, 2011. The patent
was maintained in a modified form. An appeal was filed in
May 2011 by the patent holder as well as by two challengers,
including Transgene.

An unfavorable outcome of an interference contest or of a challenge to one of the Company's patents or by the Company to the patent of another party (like those cited above) could strip the Company of protection of its own products or oblige it to cease using the technology in question or seeking licensing fees from other parties. Its business could be adversely affected if a third party having priority does not grant license rights or grants them under conditions the Company could not accept.

This could also oblige the Company to license the disputed rights from an outside party. The Company's business would be affected if it could not obtain the license or if the conditions in which it obtained the license were considered unacceptable. The same would hold if it were unable to redesign the products or processes so as to avoid being sued for infringement.

The occurrence of one or more of these risks could have a material adverse effect on the Company's business, prospects, financial condition, performance and development.

# 1.5.2.2.3 Product liability risks

The Company is exposed to product liability and to other claims if its processes are challenged. These risks are inherent in the control, manufacturing and marketing of human therapeutic products. If it were sued for damages on account of its products or processes, its liability might exceed the coverage provided by its insurance policies and threaten all of its assets.

This could have a material adverse effect on the Company's business, earnings, financial position and development.

# 1.5.2.2.4 Risks related to the use of products hazardous to health and the environment

The Company's research and development activities, preclinical studies and clinical trials require the controlled storage, use and

disposal of hazardous materials, both chemical and biological. The Company is subject to laws and regulations relating to the use, manufacture, storage, handling and disposal of materials and waste. Even though it believes that its safety procedures for the handling and disposal of these hazardous materials comply with legal and regulatory standards, the risk of contamination or accidental injury caused by these hazardous materials cannot be completely ruled out. In the event of an accident, it could be held liable for all consequent harm, and its liability could exceed the limits of its insurance policies or not be covered. It might be unable to maintain its insurance coverage on acceptable terms or possibly at all. It might have to bear significant expenditures in order to comply with present or future provisions of environmental law. As of the date of this Document de référence, the Company has made no specific provision for industrial and environmental risks.

The occurrence of one or more of these risks could have a material adverse effect on the Company's business, prospects, financial condition, performance and development.

#### 1.5.2.3 Legal and arbitration proceedings

In the ordinary course of its business, the Company is involved or risks being involved in some number of administrative or legal proceedings. As part of some of these proceedings, financial claims are or may be made against the Company.

One proceeding has been brought by employees against the Company before the Arbitration Tribunal of Strasbourg, under which the Company recorded a total provision of about €125 thousand. Otherwise, there are to date, to the knowledge of the Company, no exceptional act or governmental, legal or arbitration proceedings (including any proceedings of which the Company is aware or are pending or threatened) that may have or have had, in the last twelve months, a material effect on the financial position or profitability of the Company and/or Group.

#### 1.5.3 Insurance and risk hedging

The Company has adopted a policy of covering its main insurable risks with amounts of coverage it deems compatible with its cash usage requirements. Total premiums paid for all insurance policies in force in 2015 amounted to €282 thousand (versus €281 thousand in 2014 and €284 thousand in 2013). These policies have limited excesses. In the absence of a claim by the Company or indicators of claims made in the same business sector, the Company is not in a position to determine the rate of risk coverage offered by these insurance policies and the portion of risk carried by the Company, particularly as to civil liability.

The Company's main policies are as follows:

a so-called "multi-risk" or comprehensive policy that covers the traditional hazards of fire, water damage, theft and machine breakdowns in its facilities, with maximum coverage of €36 million. This policy also covers business interruption with maximum coverage of €20 million. Given the absence of significant revenues for the Company, this coverage is intended to enable it to resume work in progress that may have been destroyed by a hazard and to support its general and administrative and operating expenses for one year. The Company has implemented limited procedures to store its proprietary biological materials and computer data;

a "civil liability" policy which insures the civil liability of the Company and its agents that arises from its operations, along with its product liability, with an annual ceiling of €10.7 million. In addition, the Company's liability for clinical trials is covered by special contracts attached to the civil liability policy, the premiums and coverage of which depend on local regulations governing the clinical investigation site in question. In France, for example, the Public Health Code requires the sponsors of clinical trials to carry insurance and specifies the terms of such insurance. The total premiums paid and coverage taken out for trials therefore depends on the number of trials and where they occur.

The Company has also taken out insurance for the civil liability of its senior managers in the event that action is brought against it in the performance of their duties, with an annual total ceiling of €15 million.

Since coverage of risks cannot be perfect, the occurrence of any one of the risks covered by the insurance policies mentioned above could, despite the coverage purchased, have a material adverse effect on the Company's business, earnings, financial position and development.



# CORPORATE GOVERNANCE

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# 2.1 ADMINISTRATIVE AND MANAGEMENT BODIES

#### 2.1.1 Membership of administrative and management bodies

#### 2.1.1.1 Composition

#### 2.1.1.1.1 Board of Directors

Transgene is governed by a Board of Directors consisting as of the date of this *Document de référence* of ten members, six of whom qualify as independent directors. The directors' term of office is three years. Each independent director must own at least the number of shares equal in value to one half-year of directors' fees.

The table below summarizes the mandates and roles of the members of the Board of Directors:

#### PHILIPPE ARCHINARD

# Chairman and Chief Executive Officer - Director

Age: **56** 

First appointment: 2004
Term expires (1): 2017

Number of Company shares held: **6,500** Number of Company options held: **108,219** 

#### **Principal role outside of the Company:**

Director of the Immunotherapy Unit at Institut Mérieux

#### Management experience and expertise:

Graduated from the Management Program at Harvard Business School

Director of bioMérieux Inc. (3) (5) Deputy CEO of bioMérieux SA (3) (4)

CEO of Innogenetics BV (5)

#### Other offices held as of December 31, 2015:

Permanent representative of TSGH (3) on Board of ABL, Inc. (3) (5)

Representative of Lyon Biopôle on the Boards of Directors of FINOVI, an

association, and Synergie Lyon Cancer, a foundation

Representative of the FPUL

Director: bioMérieux SA (3) (4); ERYtech Pharma (4)

Chairman: Association Lyon Biopôle (6)
Chief Executive Officer: TSGH (3)
Chairman: Association BioAster (6)

Director: CPE Lyon

#### JEAN-LUC BÉLINGARD

#### Director

Age: **67** 

First appointment: **2013**Term expires (1): **2016** 

Number of Company shares held: **0** Number of Company options held: **0** 

#### **Principal role outside of the Company:**

Chairman & CEO of bioMérieux SA (3) (4)

#### Other offices held as of December 31, 2015:

Director: LabCorp of America (5), Stallergenes Greer UK (4), Pierre Fabre SA, Institut Mérieux (5)

#### Former directorships held during the last five years:

Director of NicOx (end 2011), Celera Corporation (USA) (end 2011), AES Laboratoire

Groupe SA (end 2012)

Chairman & CEO of IPSEN (end 2010) AES Chemunex SA (ended 12/31/2013)

- (1) The directors' terms expire on the date of the Annual General Shareholders' Meeting held in the year indicated to approve the financial statements for the year ended on the 31st day of December preceding the meeting.
- (2) Independent director per the following criteria (MiddleNext Code of Corporate Governance):
  - is not an employee or executive corporate officer of the Company or a company in its Group (the Company and its subsidiaries), and has not been in the last three years;
  - is not the Company's leading shareholder;

#### JEAN-PIERRE BIZZARI

#### Independent director (2)

Age: 61

First appointment: 2008
Term expires (1): 2016

Number of Company shares held: **5,000** Number of Company stock options held: **0** 

#### **Principal role outside of the Company:**

Executive Vice-President Clinical Development of Celgene (5)

#### Management experience and expertise:

Doctor of medicine

30 years clinical experience in oncology (held clinical development management positions)

#### Other mandates held:

Director: Halozyme (U.S.), Ceutor (U.S.), Pieris Pharmaceuticals (U.S.), ITEOS Therapeutics (Belgium)

Member of the international scientific committee of the National Cancer Institute

#### **ARNAUD FAYET**

#### Independent director (2)

#### Member of the Audit Committee (chairman)

#### Age: **74**

First appointment: **2000** Term expires <sup>(1)</sup>: **2016** 

Number of Company shares held: **5,501** Number of Company stock options held: **0** 

#### **Principal role outside of the Company:**

Sits on Corporate Boards

#### Management experience and expertise:

Member of the Executive Committee of Wendel Investissements since 1995 Former Chief Executive Officer, Vice-Chairman and Director of Carnaud Metalbox Graduate of the École Centrale de Paris Holds an MSA from Stanford University

#### Other mandates held:

Director: Vaucrains Participations

#### BENOÎT HABERT

#### Independent director (2)

Member of the Audit and Compensation Committees (chairman)

Age: 51

First appointment: **2000**Term expires (1): **2017** 

Number of Company shares held: **74,403**Number of Company stock options held: **0** 

#### **Principal role outside of the Company:**

Deputy Chief Executive Officer and Director, Groupe Industriel Marcel Dassault (GIMD) (SAS)

Chairman of Dassault Développement (SAS)\*

#### Management experience and expertise:

Holds an M.B.A. from INSEAD and a masters degree in business law

#### Other mandates held:

Chairman: Habert Dassault Finance; Dassault Développement (SAS)

Director: Groupe Figaro (SAS)\*; Dassault Medias (SA)\*; Mérieux NutriScience Corp. (USA); Figaro classifieds (SA)\*; Éditions Dupuis (5); Dargaud (SA); ZEWAOW (SAS);

Eclosion (5); KTO TV (6); Fondation KTO (6)

Non-voting observer: Relaxnews (SA); UNOWHY (SAS); HOWTO Media Member of the Supervisory Board: John Paul (SAS) Colombus Family Holding Member of the Supervisory Committee: Cooltech applications (SAS)\*

#### Former directorships held during the last five years:

As a permanent representative of GIMD: bioMérieux SA <sup>(3) (4)</sup>; Silliker <sup>(3)</sup>; Sport 24 (SA), Intigold <sup>(5)</sup>

\* Controlled by GIMD

- is not a customer, supplier or significant banker of the company or its group or for which the Company or Group represents a significant share of business:
- has no close family tie with a Corporate Officer or a leading shareholder;
- has not been an outside auditor of the Company during the last three years.
- (3) Company in the Institut Mérieux Group.
- (4) Publicly-traded French company.
- (5) Foreign corporation.
- (6) Association, foundation or other.



#### PIERRE-PATRICK HURTELOUP

# Independent director (2) Member of the Compensation Committee

Age: **66** 

First appointment: 2005 Term expires (1): 2017

Number of Company shares held: **390**Number of Company stock options held: **0** 

#### Management experience and expertise:

Chairman of various companies in the Pierre Fabre Group since 2000 Former Medical Director. Pierre Fabre Oncologie

#### Other mandates held:

Chairman and director: Pierre Fabre Ltd;

Concept Pharmaceuticals International Ltd. (5); Pierre Fabre Médicament Benelux (5); Pierre Fabre Farmaka AE (5) – Greece; Pierre Fabre Pharma Norden AB (5) – Sweden; Tema Medical Pty Ltd. (5) South Africa

#### JEAN-FRANÇOIS LABBÉ

# Independent director (2) Member of the Audit Committee

Age: **65** 

First appointment: **2010**Term expires (1): **2016** 

Number of Company shares held: **400** Number of Company stock options held: **0** 

#### **Principal role outside of the Company:**

Companies director and corporate officer

#### Management experience and expertise:

Graduate of HEC

35 years of experience in financial management of pharmaceutical companies both in France and abroad

Managing Director of SpePharm Holding BV (Netherlands)

Founder of specialty pharmaceutical companies (OTL and SpePharm)

#### Other mandates held: Director: NicOx SA (4)

#### Expired mandates:

Supervisory Board of Cavadis BV (Netherlands) (2010) Chairman of the Supervisory Board: Libragen SAS

#### ALAIN MÉRIEUX

#### Director

Age: **77** 

First appointment: **1991** Term expires (1): **2017** 

Number of Company shares held: **100** (excluding 19,987,011 shares held by TSGH, a subsidiary of Institut Mérieux, ultimately controlled by the family of Mr. Mérieux)

Number of Company stock options held: **0** 

#### Principal role outside of the Company:

Chairman & CEO of Institut Mérieux (SA)

#### Management experience and expertise:

Graduated from Harvard Business School (1968) Chairman of bioMérieux from 1965 to 2011

#### Other mandates held:

Director: bioMérieux (SA) (3) (4), CIC Lyonnaise de banque, Cie Plastic Omnium SA (4), Mérieux NutriSciences (3) (5) (United States), bioMérieux Italia SpA (3) (5) (Italy) Director and Honorary Chairman: Fondation Christophe et Rodolphe Mérieux Institut de France (6), Fondation Mérieux (Chairman)

Director of these foundations: Pierre Fabre, Pierre Vérots,

#### **Expired mandates:**

Foundation for the Université de Lyon (Chairman) (ended in October 2015) Institut de Recherche Techonologique BioAster (ended in March 2014)

(1) The directors' terms expire on the date of the Annual General Shareholders' Meeting held in the year indicated to approve the financial statements for the year ended on the 31st day of December preceding the meeting.

- (2) Independent director per the following criteria (MiddleNext Code of Corporate Governance):
  - is not an employee or executive corporate officer of the Company or a company in its Group (the Company and its subsidiaries), and has not been in the last three years;
  - is not the Company's leading shareholder;

#### **TSGH**

#### Director

17, rue Bourgelat 69002 Lyon First appointment: **2002** Term expires <sup>(1)</sup>: **2017** 

Number of Company shares held: **19,987,011** Number of Company stock options held: **0** 

#### **Principal role outside of the Company:**

Director of ABL, Inc.

#### Represented by: **DOMINIQUE TAKIZAWA**

# Permanent representative of TSGH <sup>(4)</sup> Member of the Audit Committee

Age: 59

Ms. Takizawa does not own any Company stock or options.

#### **Principal role outside of the Company:**

Corporate Secretary at the Institut Mérieux (since 2006)

#### Management experience and expertise:

Graduate of the École des Hautes Études Commerciales and degreed in accounting Corporate Secretary of bioMérieux (3) (4) (2004-2006)

Vice President, Finance and Controller at Institut Mérieux, Mérial and Aventis Cropscience

#### Other mandates held:

Director: ABL, Inc. (United States), ADOCIA, April, ElsaLys Biotech <sup>(3)</sup>, Platine <sup>(3)</sup>, Mérieux NutriSciences Corporation <sup>(3) (5)</sup> (United States), Lyon Pôle Bourse <sup>(6)</sup>, Lyon Place Financière et Tertiaire <sup>(6)</sup>

#### **Expired mandates:**

MACSF (mutual insurance) (end 2010), Avesthagen (end 2011)

#### **LAURENCE ZITVOGEL**

#### Independent director (2)

Age: **52** 

First appointment: **2013**Term expires (1): **2016** 

Number of Company shares held: **469** Number of Company stock options held: **0** 

#### **Principal role outside of the Company:**

Professor at the Université Paris Sud in Immunology Biology and Oncologist-researcher-immunotherapist at the Institut Gustave Roussy

Director of Research at INSERN (U1015)

Co-Director of IGR/Curie/INSERM Clinical Investigations Center

#### Management experience and expertise:

Doctor of medicine

Director of Research and INSERM Unit (jointly approved by the Ligue contre le cancer) and Co-Director of the IGR/Curie/INSERM Biotherapy Clinical Investigations Center

#### Other mandates held:

None

(6) Association, foundation or other.

<sup>•</sup> is not a customer, supplier or significant banker of the company or its group or for which the Company or Group represents a significant share of business:

<sup>•</sup> has no close family tie with a Corporate Officer or a leading shareholder;

<sup>•</sup> has not been an outside auditor of the Company during the last three years.

<sup>(3)</sup> Company in the Institut Mérieux Group.

<sup>(4)</sup> Publicly-traded French company.

<sup>(5)</sup> Foreign corporation.

As far as the Company is aware:

- there are no family ties among the members of the Board;
- no conviction for fraud has been rendered over the past five years against any of the members of the Board of Directors;
- over the past five years, no member has been associated, as the member of a supervisory, executive or oversight body or as the Chief Executive Officer, with any insolvency, bankruptcy or liquidation proceedings;
- over the past five years, no member of the Board of Directors has been prohibited by a court from acting as a member of a supervisory, executive or oversight body or from being involved in the management of a Company or conducting its business; and

 no incrimination and/or official public penalty has been made against any of the members of the Company's Board of Directors by statutory or regulatory authorities (including designated professional bodies).

No member of the Board of Directors was elected by the employees. Two employees, one of whom represents managers, represent the Works Council and participate in the Board of Directors' meetings.

#### 2.1.1.1.2 Executive Committee

The following table gives the names of those on the Transgene Executive Committee, their current positions in the Company and the date they assumed those duties.

Name	Age	Current position	Seniority in the post
Philippe Archinard	56	Chairman and Chief Executive Officer	2004
Éric Quéméneur	52	Deputy CEO - R&D Director	2014
Christophe Ancel	52	Responsible Pharmacist - Vice President, Quality and Deputy Chief Executive Officer	2014
Maud Brandely	62	Vice President, Clinical Development, Clinical Operations and Regulatory Affairs	2016
Jean-Philippe Del	36	Vice President, Finance	2014
Thibaut du Fayet	48	Vice President, Strategic Alliance, Project Management and Marketing	2008
John Felitti	46	General Counsel and Corporate Secretary	2016
Hemanshu Shah	55	Vice President, Medical Affairs and International Development	2014

Philippe Archinard was appointed Chairman and Chief Executive Officer of Transgene on June 17, 2010; he had been CEO since December 6, 2004. Previously he had been CEO of Innogenetics from March 2000. From 1985 to 2000, he held various positions at bioMérieux, including management of bioMérieux, Inc. in the United States. He is a chemical engineer and has a doctorate in biochemistry from the University of Lyon, and supplemented his education with a management program at the Harvard Business School. He is Chairman of the Lyon competitiveness cluster, Lyon Biopôle.

**Eric Quéméneur** joined Transgene in 2014 as Deputy CEO, in charge of Research and Development. Before joining Transgene he served as Director of Programs and Reclamation in the Life Sciences Department of the CEA, after a 20-year career in that organization. His responsibilities included managing the Research and Development programs and transferring them into applications, leading multi-disciplinary teams and developing national and international alliances. He is a biochemical engineer, INSA Lyon (1986), with a doctorate in science, a D.U. degree in Industrial Pharmaceuticals from Université Claude Bernard Lyon 1 and a Certificate in Research Management from Université Pierre et Marie Curie – Paris VI. He is the author of some 80 publications in international scientific journals.

**Christophe Ancel** joined Transgene in 2008 as Head of Quality Assurance, and then as Director of Operational Quality.

Previously he worked as a quality consultant to a variety of international pharmaceutical laboratories. From 2001 to 2005 he was Quality Manager, Deputy Pharmacist and acting Responsible Pharmacist at the French production plant of E. Lilly. In 2001 he was Quality Manager and acting Qualified Pharmacist at a Cardinal Health plant. From 1992 to 2000, he worked at Alcon Laboratories in the quality area and was Deputy Pharmacist at their production site. His various professional experiences have led him to work in an international settings of sterile product manufacturing and marketing. Christophe Ancel has a doctorate in pharmacology.

Maud Brandely joined Transgene in March 2016 as Vice President, Clinical Development, Clinical Operations and Regulatory Affairs. She was the Director of Oncology Clinical Development at Pierre Fabre until February 2016, where she oversaw all phase 1 - phase 3 clinical trials. She played a role in the registration of oral Navelbine products for the treatment of both breast and lung cancer and for vinflunine in bladder cancer. Prior to Pierre Fabre, she was Director of Taxotere Clinical Development at Rhône Poulenc (RPR, now Sanofi), where she was responsible for setting up clinical studies with the aim of registration in the United States and Europe. As such, she divided her time between Collegeville and Paris to oversee her U.S. and European teams. Prior to RPR, she worked for Hoechst-Roussel-Uclaf (now Sanofi) and was involved in the development of cytokines (II2, IFN) and cytotoxics. She is an MD and has a Ph.D. in immunology.

Jean-Philippe Del became Transgene's Vice President, Finance and a member of the Executive Committee in 2014. Before that, he had been Director of Administration and Finance. He joined the Company in 2005 and oversaw the management control system, accounting and purchasing. Before joining Transgene, he was a financial auditor at Mazars and began his career in 2001 as a financial controller at Brasseries Kronenbourg. Mr. Del holds a DESCF degree and is a finance and accounting graduate of Université de Strasbourg.

**Thibaut du Fayet** joined Transgene in 2008. He is responsible for project management, strategic alliance management and marketing for the Company. From 2007 to 2008, he headed up marketing at Stallergenes after holding various Strategy and Business Development positions at bioMérieux from 2003 to 2007, and Rhodia/Rhône-Poulenc from 1999 to 2003. His diverse experience in industry was preceded by six years working as a consultant, at Bossard Consultant/Gemini Consulting. Thibaut du Fayet has an MBA from the ESSEC management school and an MA in International Finance from Brandeis University (Boston).

**John Felitti** joined Transgene in March 2016 as General Counsel and Corporate Secretary. Prior to his appointment, he was Associate Vice President, Corporate Law, Finance and Securities Law at Sanofi and previously held other positions in the Sanofi and Aventis legal departments. From 1996 to 2003, he was an associate attorney at the Paris offices of the U.S. law

firm Shearman & Sterling. He is admitted to practice in New York and is a former member of the Paris Bar. After majoring in economics at Harvard University (AB 1991) and the College of Europe (MA 1993), John Felitti studied law at the University of Michigan (JD 1996) and the University of Paris II – Panthéon (LLM 1997). He also holds a business degree from INSEAD (GEMBA 2015).

Hemanshu Shah joined Transgene in May 2014 as Director of Medical Affairs. He has over 25 years of experience acquired in various functional and therapeutic fields in the pharmaceutical and biotechnology industries, particularly oncology. Before joining Transgene, he was Global Vice-President of Marketing and Head of the Infectious Diseases Therapeutic Area, Transplantation, Immunology and Dermatology at Astellas (2012-2014). Before Astellas, he was Head of Operations at AROG Pharmaceuticals (2010-2011), Business Director at Innate Pharma (2008-2010) and Vice-President for Commercial Operations at GPC Biotech (2003-2008). Mr. Shah was Global Sales Manager for oncology at Johnson & Johnson (2002-2003) and held various management jobs at Bristol-Myers-Squibb (1988-2002). He holds a doctorate in pharmaceutical science from Rutgers University and an MBA from the State University of New York (Buffalo).

#### 2.1.1.1.3 Dates and expiration of terms

See Section 2.1.1.1.1. Administrative, management and supervisory bodies (table of directors).

# 2.1.2 Functioning of administrative and management bodies and conflicts of interest

# 2.1.2.1 Service contracts between the issuer and the members of the Board of Directors

There are no service contracts linking any member of the Board of Directors to the Company or to any of its subsidiaries and providing benefits.

# 2.1.2.2 Conflicts of Interest in administrative and management bodies

No director has indicated the existence of an agreement with a major shareholder, client or supplier of the Company for which he is representative.

As of the date of this *Document de référence*, and to the Company's best knowledge, there is no current or potential conflict between the private interests of the members of the Board of Directors or of the Company's management and the interests of the Company.

Jean-Luc Bélingard, a director of the Company, is also Chairman and Chief Executive Officer of bioMérieux SA, of which the Institut Mérieux held 58.9% of the capital as of December 31, 2015. Institut Mérieux holds 98.66% of the capital and voting rights in TSGH SAS, which itself owns, as of the date of this Document de référence, 51.85% of the capital and 66.3% of the voting rights in the Company. Philippe Archinard, Chairman and CEO of the Company, is also a director of bioMérieux SA and owns 1.34% of the capital in TSGH.



# 2.1.2.3 Declaration concerning the administrative and management bodies

To the Company's knowledge as of the date of this *Document de référence*, there is no family connection between the members of the Board of Directors and the Company's senior management. Neither is there, as far as the Company is aware, as of the date of this *Document de référence*, any arrangement or agreement made between the major shareholders, customers, suppliers or others, apart from those listed in Note 17 to the consolidated financial statements in this *Document de référence*.

Moreover, to the Company's knowledge as of the date of this *Document de référence*, no member of the Board of Directors has been:

- convicted of fraud in at least the past five years;
- subject to a bankruptcy, receivership or liquidation as a director or corporate officer in at least the past five years;
- indicted and/or officially and publicly sanctioned by statutory or regulatory authorities in at least the last five years.

Finally, to the Company's knowledge as of the date of this *Document de référence*, no directors have been disqualified by a court from acting as a member of an administrative, management or Supervisory Board of an issuer or from acting in the management or conduct of the affairs of any issuer within at least the past five years.

#### 2.1.3 Special committees

The Audit Committee, consisting of Messrs. Fayet (Chairman of the committee) Habert and Labbé, independent directors, and Ms. Takizawa, the working methods of which are described in Section 2.3, examined the following points among others during the 2015 fiscal year:

- review of the consolidated and corporate financial statements for fiscal year 2014;
- review of the consolidated financial statements of the first half of 2015;
- review of the 2016 budget;
- determination of the Statutory Auditors' fees;
- initial review of the financial press releases;
- definition of the cash investment and performance followup policy;

- review of financial risks and insurance policy;
- interview with an independent expert on the terms and conditions of the sale of the production asset to ABL Europe;
- prior review of the conditions of the loan granted by the EIB.

The Compensation Committee, consisting of Messrs. Habert (Committee Chairman) and Hurteloup, both independent directors, whose working methods are described in Section 2.3, examined, among other subjects: the compensation of senior management and the Executive Committee during 2015; reviewed the Company's general compensation policy, including yearly bonuses, and set the collective objectives and their weighting. The Committee has also begun working on a new equity remuneration policy.

# 2.2 COMPENSATION AND BENEFITS TO SENIOR EXECUTIVES AND BOARD MEMBERS

#### 2.2.1 Compensation paid to corporate officers

The tables below set out the information relating to the compensation of corporate officers in compliance with AMF recommendations.

Note that in 2015, the Company did not pay compensation to Messrs. Bélingard and Mérieux or to TSGH and its permanent representative (Dominique Takizawa). Philippe Archinard received from Institut Mérieux gross compensation of €661,500

(including €450,000 in variable compensation and €9,700 in benefits in kind - company car), which were charged in part to the Company until March 31, 2015 through a contract for services rendered by Institut Mérieux (see *Note* 21 to the financial statements). Alain Mérieux received from Institut Mérieux gross compensation of €198,300 (no variable compensation or payment in kind).

#### Table 1

#### SUMMARY OF THE COMPENSATION, STOCK OPTIONS AND SHARES GRANTED TO EACH CORPORATE OFFICER

(in € thousands)	FY 2014	FY 2015
PHILIPPE ARCHINARD, CHIEF EXECUTIVE OFFICER		
Compensation payable for the year (details in Table 2)	72.2	305.0
Valuation of options assigned during the year (details in Table 4)	None	None
Valuation of performance shares assigned during the year (details in Table 6)	None	None
TOTAL	72.2	305.0
CHRISTOPHE ANCEL, RESPONSIBLE PHARMACIST, DEPUTY CHIEF EXECUTIVE OFFICER (SINCE JANUARY 2014)		
Compensation payable for the year (details in Table 2)	112.0	115.2
Valuation of options assigned during the year (details in Table 4)	None	None
Valuation of performance shares assigned during the year (details in Table 6)	None	None
TOTAL	112.0	115.2

#### Table 2

#### SUMMARY OF COMPENSATION OF EACH EXECUTIVE CORPORTE OFFICER

	FY 2014		FY 20	15
(in € thousands)	Amount due	Amount paid	Amount due	Amount paid
PHILIPPE ARCHINARD, CHIEF EXECUTIVE OFFICER				
Fixed compensation	72.2	72.2	305.0	305.0
Variable compensation	-	-	-	-
Exceptional compensation	-	-	-	-
Director's fees	-	-	-	-
Payments in kind	-	-	-	-
Share of Institut Mérieux compensation charged to the Company	625.7	625.7	386.2	386.2
TOTAL	697.9	697.9	691.2	691.2
CHRISTOPHE ANCEL, RESPONSIBLE PHARMACIST, DEPUTY CHIEF EXECUTIVE OFFICER (APPOINTED IN JANUARY 2014)				
Fixed compensation	94.5	94.5	94.5	94.5
Variable compensation	12.2	12.2	15.0	15.0
Exceptional compensation*	1.8	1.8	1.8	1.8
Director's fees	-	-	-	-
Payments in kind	3.5	3.5	3.9	3.9
TOTAL	112.0	112.0	115.2	115.2

<sup>\*</sup> Bonus per individual objectives (largely operational and qualitative) of the person, set yearly and tied to his position as Director of Quality Assurance and not to his position as a corporate officer.

#### Table 3

#### SUMMARY OF DIRECTOR'S FEES AND OTHER COMPENSATION RECEIVED BY NON-EXECUTIVE DIRECTORS

Non-executive directors (in € thousands)	Amount paid in 2014	Amount paid in 2015
JEAN-PIERRE BIZZARI		
Director's fees	12.5	12.5
Other compensation	None	None
JEAN-LUC BÉLINGARD (1)		
Director's fees	None	None
Other compensation	None	None
ARNAUD FAYET		
Director's fees	23.0	9.5
Other compensation	None	None
BENOÎT HABERT		
Director's fees	21.0	20.5
Other compensation	None	None
PIERRE-PATRICK HURTELOUP		
Director's fees	16.5	14.5
Other compensation	None	None
JEAN-FRANÇOIS LABBÉ		
Director's fees	15.5	15.5
Other compensation	None	None
ALAIN MÉRIEUX (1)		
Director's fees	None	None
Other compensation	None	None
TSGH DOMINIQUE TAKIZAWA (1)		
Director's fees	None	None
Other compensation	None	None
LAURENCE ZITVOGEL		
Director's fees	12.5	11
Other compensation	None	None
TOTAL	101.0	83.5

(1) Mr. Bélingard, Mr. Mérieux, TSGH and Ms. Takizawa do not receive director's fees or other compensation in relation to their directorship of the Company.

Tables 4 and 5: see Section 2.2.3 below.

Table 6: performance shares allocated to each corporate officer:

None. The Company did not allocate any performance share during the fiscal year nor any prior fiscal year.

Table 7: performance stock that became available for sale during the period for each corporate officer:

None (see comment above).

Tables 8 and 9: see Section 2.2.3 below.

#### Table 10

Executive corporate officers		oyment ontract		ditional on plan	due may k due as of term or ch	nsation or that become a result nination ange in ositions	Compe related to compete	
	YES	NO	YES	NO	YES	NO	YES	NO
Philippe Archinard, Chief Executive Officer								
Dates of term: 2004-2017		Χ		Χ		Χ		Χ

As far as the Company is aware:

 none of the directors benefit from an undertaking on the part of the Company or its subsidiaries in terms of elements related to compensation, indemnities or benefits of any kind which are or may be due in light of the employment, termination of employment or change in position, or afterwards;

 none of the directors have received compensation from TSGH, which directly controls Transgene, during the fiscal year.

#### 2.2.2 Total provisions for retirement

At December 31, 2015, retirement provisions set up by the Company for the corporate officers totaled €128,900 for Philippe Archinard and €27,400 for Christophe Ancel.

#### 2.2.3 Stock options

#### 2.2.3.1 History of option plans

As of the date of this *Document de référence*, three stock option plans have been authorized by the General Shareholders' Meeting, in 2006, 2008, and 2010 respectively, and were implemented by the Board of Directors. The status of these plans at December 31, 2015 is summarized in the following table.

No stock options were awarded in 2013, 2014, and 2015. In accordance with regulations, the rights of option holders were adjusted as to number of options and exercise price, following the capital increase with preferential subscription rights of shareholders that was raised in March 2014 and that led to the granting of 28,802 options for an equal number of new shares.

	Plan No. 3	Plan No. 4	Plan No. 5	Plan No. 6
	6/9/2004	6/9/2006	6/9/2008	6/17/2010
	2/9/2005	12/6/2006	12/16/2008	12/7/2010
	5/18/2005	10/4/2007	12/9/2009	12/13/2012
Shareholders' Meeting date	1/1/2006	12/19/2007	12/7/2010	
Board of Directors meeting date	12/6/2006	12/16/2008		
Total number of shares to be subscribed or purchased	300,000	450,000	250,000	400,000
Of which, number that can be subscribed by				
corporate officers:				
Philippe Archinard, Chairman & Chief Executive Officer	-	72,186	36,093	None
Christophe Ancel, Responsible Pharmacist, Deputy Chief Executive Officer (since January 2014*)	None	2,566	2,064	5,125
the top 10 employee recipients:	126,000	113,000	60,500	153,000
Start date for exercise of options		2010	2012	
	2009	2011	2013	2015
	2010	2012	2015	2017
Expiration date	2015	2016	2018	
	2016	2017	2019	2020
		2018	2020	2022
	6.38	10.78	11.09	
Subscription price (euros) (equal to the average of the	7.12	16.23	17.26	
market price of the 20 trading days prior to the grant date, excluding discount) adjusted following the capital increases—	7.38	15.14	14.31	14.31
with preferential subscription rights in 2010 and 2014	10.78	11.09		7.92
Exercise terms and conditions				
(when the plan has several tranches)	None	None	None	None
Number of shares subscribed in 2015	17,429	24,220	-	-
Total number of options cancelled or forfeited	145,242	45,498	84,013	50,225
Of which: allocated and cancelled options	12,000	45,498	84,013	50,225
Number of outstanding granted options at end of period	-	477,619	245,541	277,301

<sup>\*</sup> Grants made before appointment as a corporate officer.

Pursuant to Article L. 225-185, par. 4 of the French Commercial Code, the Board set at 10% the quantity of shares issued from the exercise of options granted starting in December 2007 that the corporate officer will be obliged to hold as registered shares until they leave their position.

Stock options granted to corporate officers or exercised by them during FY 2015: NONE  $\,$ 

# STOCK OR PURCHASE OPTIONS ALLOCATED DURING THE FISCAL YEAR TO EACH COMPANY EXECUTIVE CORPORATE OFFICIER BY THE ISSUER AND BY ANY COMPANY IN THE GROUP

Name of company executive corporate officer	Plan No. and date	Type of options	Valuation (in euros per option)	Number of options granted	Exercise price (in euros)	Exercise period
Philippe Archinard	-	-	-	None	-	-
Christophe Ancel	-	-	-	None	-	-
TOTAL	N/A	N/A	N/A	N/A	N/A	N/A

## STOCK OR PURCHASE OPTIONS EXERCISED DURING THE FISCAL YEAR BY EACH COMPANY EXECUTIVE CORPORATE OFFICER

Name of company executive corporate officer	Plan No. and date	Number of options exercised during the year	Exercise price
Philippe Archinard	-	None	-
Christophe Ancel	-	None	-
TOTAL	N/A	N/A	N/A

Summary information on stock subscription options granted to the 10 non-corporate officer employees who received the highest number of options and options they exercised during FY 2015: None.

Stock options granted to the 10 non-corporate officer employees who received the highest number of options and options they exercised	Total number of options granted or exercised	Weighted average price (in euros)	Plan No. and date
Options granted during the year by the issuer and by any company within the option plan scope, to the 10 non-corporate officer employees of the issuer and of any company within this scope, who received the highest number of options.	None		
Options held on the issuer and the previously mentioned companies exercised during the year by the 10 employees of the issuer and these companies, who subscribed in this way the highest number of options.	10,791	€7.30	3

Individual information on options granted by the issuer or any company within the option plan scope to the 10 non-corporate officer employees of the issuer and of any company within this scope, who received the highest number of options in this way and the number of shares subscribed by the 10 individuals who subscribed the most shares during the period: No options

were granted in 2015 and eight employees (neither corporate officers nor Executive Committee members) exercised options in 2015. Three of them exercised 2,064 options each; three others exercised 1,033 options each and the remaining two exercised 1,538 and 1,500 options, respectively, all at a peroption strike price of  $\[ \in \]$ 7.30.

#### 2.2.4 Awards of free shares

Two free share award plans were authorized as of the date of this *Document de référence* by the General Shareholders' Meetings, in 2008 and 2010, and implemented by the Board of Directors. A total of 108 managers (non-Executive Committee members) each received 450 shares and 84 non-managers each received 300 shares. In December 2009, the Board of Directors made an additional grant of 11,100 shares to 30 employees (non-Executive Committee members) who met the condition of working under open-ended contracts as of the grant date.

On December 7, 2010, the Board of Directors voted to make another general grant, under the same rules as in 2008, of 450 free shares for managers (126 non-Executive Committee members) and 350 free shares for non-managers (99 people). No free shares were awarded in 2011.

In December 2012, the Board made a new award of free shares, along the same lines as before: 200 shares for each manager (154 people) (excluding members of the Executive Committee, senior management and corporate officers) and 130 shares for non-managers (104 people).

No free shares were awarded in 2013, 2014 or 2015.

The status of these plans at the end of 2015 is summarized in the following table:

	Plan No. 1	Plan No. 2
Shareholders' Meeting date	6/9/2008	6/17/2010
Total number of shares to be subscribed or purchased	100,000	120,000
Of which allocations granted, during the year, by the issuer and by any company included in the scope of the allocation to corporate officers.	None	None
Of which, grants made during the year by the issuer and by any company in the scope of awards, to the 10 non-corporate officer employees of the issuer and of any company within this scope, whose number of free shares awarded is greatest.	None	None
	12/16/2008	-
	12/9/2009	12/7/2010
Date of Board of Directors' meeting	12/7/2010	12/13/2012
Total number of bonus shares allocated	73,800	-
	11,100	74,900
Of which: number of shares allocated to corporate officers and members	15,100	44,320
of the Executive Committee	None	None
Vesting date and expiration date of holding period	12/15/2012	-
(both periods are taken into account)	12/8/2013	12/6/2014
	12/6/2014	12/12/2016
Share value on the date of allocation (opening price on the date of allocation)	€12.10	-
	€19.67	€14.37
	€14.37	€8.36

# 2.3 REPORT BY THE CHAIRMAN ON CORPORATE GOVERNANCE AND INTERNAL CONTROLS, AND REPORT BY THE STATUTORY AUDITORS ON THE CHAIRMAN'S REPORT

The Company complies with the corporate governance recommendations contained in the MiddleNext Code of Corporate Governance for mid- and small-cap companies of December 2009 ("MiddleNext Code").

This paragraph restates in its entirety the Chairman's report required by Article L. 225-37 of the French Commercial Code, relating to the manner in which the Company's Board of Directors prepares and organizes its work and to the internal controls installed by the Company.

# Report of the Chairman required by Article L. 225-37 of the French Commercial Code

The Company complies with the corporate governance recommendations contained in the MiddleNext Code of Corporate Governance for mid- and small-cap companies of December 2009 ("MiddleNext Code"). The MiddleNext Code can be consulted on the MiddleNext website.

This report was prepared by senior management and presented to the Board of Directors for approval at its meeting of April 8, 2016. Unless otherwise indicated, the scope it covers relates only to Transgene SA (hereinafter "the Company").

# Conditions related to the Preparation and Organization of the Tasks of the Board of Directors

#### **Composition of the Board of Directors**

The Company is governed by a Board of Directors currently consisting of ten members, of whom nine are individuals and

the tenth is the majority shareholder, TSGH. Two women sit on the Board: Dominique Takizawa, as permanent representative of TSGH, and Laurence Zitvogel, an independent director.

The term of the directors' mandates is three years. The independent directors, who alone may collect directors' fees, must hold a number of shares corresponding to the investment of a half-year of directors' fees. The table below indicates the number of shares or options providing future rights to shares (stock options) held by each individual director:

Director	Number of shares held	Number of options
Philippe Archinard	6,500	108,279
Jean-Luc Bélingard	-	None
Jean-Pierre Bizzari (1)	5,000	None
Arnaud Fayet (1) (2)	5,501	None
Benoît Habert (1) (3) (4)	74,403	None
Pierre-Patrick Hurteloup (1) (5)	350	None
Jean-François Labbé (1) (4)	400	None
Alain Mérieux*	100*	None
Laurence Zitvogel (1)	469	None

- \* Besides the 19,987,011 shares held by TSGH, a 98.66% owned subsidiary of the Institut Mérieux, itself 100% owned by Compagnie Mérieux Alliance, controlled by the family of Mr. Mérieux.
- (1) Independent director.
- (2) Chairman of the Audit Committee.
- (3) Chairman of the Compensation Committee.
- (4) Member of the Audit Committee.
- (5) Member of the Compensation Committee.

In its current composition, the Board of Directors has six independent directors as defined by Recommendation R8 of the MiddleNext Code.

The complete list of directors and the dates and expiration of their terms appears in Section 2.1 of the Company's *Document de référence*.

No member of the Board of Directors was elected by the employees. Two employees, one of whom represents managers, represent the Works Council and participate in the Board of Directors' meetings.

In addition to the Statutory Auditors, who participate in most Board meetings (all meetings in 2015), the representatives of the Works Council are also in attendance at the meetings, as is the Vice President, Finance, the Deputy CEO and the Corporate Secretary, who acts as secretary to the Board. The Directors of the Board with scientific and medical backgrounds will from time to time hold ad hoc scientific or medical meetings with the Company's scientists and its medical, clinical and regulatory staff to discuss issues related to the products under development.

#### **Operation of the Board of Directors**

The Board of Directors met six times in 2015, with an average attendance rate by the directors of 88%. At each of these meetings, the Board was informed in detail of the Company's situation in terms of the development of its business, the progress of its research projects, clinical programs and its financial position. In addition to performing its legal duties

to approve the annual and interim financial statements and to arrange and convene General Shareholders' Meetings, the Board discussed the Company's strategic issues. Such issues included the outsourcing of the manufacturing of its clinical batches and the consequences of selling its production asset and related equipment, as well as the Company's restructuring and the redundancy plan (plan de sauvegarde de l'emploi) initiated in June 2015. The independent members therefore held two special meetings where they discussed the plan to sell the production asset and equipment to ABL Europe, a member of the Institut Mérieux. They were also presented the report and the conclusions of the independent appraiser retained by the Company to ensure the fairness of the financial conditions of the transaction. The Board regularly speaks with the Audit Committee and Compensation Committee and deliberates on recommendations they make. The duties of the Chairmanship of the Board and the senior management of the Company are performed by the same individual.

In accordance with Recommendations R6 and R7 of the MiddleNext Code, the Board of Directors has adopted internal rules (available on the Company's website: www.transgene.fr). A securities trading Code, following the recommendations of the MiddleNext Guide, "Management of inside information and the prevention of insider trading," was adopted by the Board and posted on the Company's intranet site for all employees.

In 2015, the Company also complied with Recommendation R15 of the MiddleNext Code dealing with the yearly assessment by Board members of the Board's operations and preparation of its work. In addition, the Board of Directors undertook a review of the MiddleNext Code's "Points of attention".

# CORPORATE GOVERNANCE

Report by the Chairman on corporate governance and internal controls, and report by the Statutory Auditors on the Chairman's report

#### **Committees**

The Board of Directors is assisted by two committees:

- the Audit Committee, consisting of four directors, three of whom are independent. The Vice President, Finance is invited to each meeting to present the Company's financial data and answer questions from the committee. The Statutory Auditors attend all committee meetings. The committee is responsible for preparing the work of the Board of Directors on financial and accounting issues and advising it, in particular regarding financial statements, their audit and their compliance with accounting standards, the selection, renewal methods and fees for the Statutory Auditors, internal controls and the details of certain capital expenditures. It approves the internal audit and monitors its progress. Furthermore, the Audit Committee monitors the cash investment policy. The Audit Committee met five times in FY 2015, with at least two members in attendance at each meeting. The work of the Audit Committee is governed by a charter that is reviewed and adapted as necessary to changes in corporate governance best practices. In 2015, the committee regularly reported on its work and provided recommendations to the Board of Directors after each of its meetings:
- the Compensation Committee, consisting of two independent directors. The committee reviews the proposed compensation (salary and bonus, proposed stock options) for the Company's senior managers and key people. It also reviews the overall compensation policy implemented by the Company regarding the set up of stock option plans and bonus share allocation plans. It also assesses and determines the achievement of the corporate objectives and their weighting in the amount of the annual bonuses granted to employees. The committee submits recommendations for approval on these items to the Board. It meets and deliberates, by telephone conference if necessary, and has met twice in 2015, with all its members present (in person or by telephone).

# Limits on the powers of the Chief Executive Officer

No special limits have been set on the powers of the Chief Executive Officer, with the exception of the following points that require the CEO to refer the following matters to the Roard:

- the strategic plan of the Company and its subsidiaries;
- the annual budget and, on a quarterly basis, its implementation and, if necessary, revision;
- any strategic transaction (acquisition, sale, disposal of Company assets, trading, transaction, creation of security interests, regardless of the terms of financing, etc.) not described in the strategic plan, or whose individual budget impacts cash consumption in relation to projected cash consumption by more than 5%.

# Participation by shareholders in the General Shareholders' Meeting

The Company has not established any special rules as to shareholder participation in General Shareholders' Meetings; the Statutes in this regard refer to the provisions of law in the French Commercial Code.

# Information relating to the capital structure and elements that may influence a public offering

This information is presented and discussed in the Board's management report and in Chapter 5 of the Company's *Document de référence*.

#### Compensation paid to corporate officers

In this report a distinction is drawn between the compensation of directors who are not company executives and those who are. The latter are the Chairman and Chief Executive Officer and the Deputy Chief Executive Officer (see Section 2.2 of the Document de référence for further details on compensation paid in 2015).

Directors who are not company executives: only independent directors receive directors' fees. These consist of a set yearly lump sum of €5 thousand to which is added an amount tied to the director's actual attendance at Board meetings of €1.5 thousand per meeting, in accordance with Recommendation R14 of the MiddleNext Code. Additional compensation of members of the Audit Committee and the Compensation Committee are €1,500 and €1,000 per committee meeting, respectively. No other form of compensation, including deferred compensation, such as warrants or stock options, was paid by the Company to these directors.

The gross amount of directors' fees paid over the last two years to directors in office as of December 31, 2015 are shown in Section 2.2 of the Company's *Document de référence*.

Company executives: the Chairman and CEO does not have an employment contract with the Company. He receives compensation from the Company on the basis of his responsibilities. In 2015, this compensation was the same as in 2014. The Chairman and CEO also receives compensation from the Institut Mérieux on the basis of his responsibilities as Director of the Immunotherapy Division in that company, a portion of which compensation is billed back to the Company under a regulated agreement between the Institut Mérieux and the Company, termed "management fees".

The Responsible Pharmacist, who was appointed Deputy Chief Executive Officer pursuant to the French Public Health Code, has an employment contract in his capacity as Director of Quality Assurance. The Board believes that the continuation of this employment contract is justified in this particular case, as the term of office of the Qualified Pharmacist is a regulatory

requirement. He receives a salary pursuant to his employment contract and any change to his compensation is completely individualized to reflect his personal performance against the collective objectives. The salaries and bonuses of members of the Executive Committee are determined based on proposals by the Chairman and CEO and are submitted for review by the Compensation Committee, which also authorizes the proposals, if any, for deferred compensation in the form of stock options. No stock options or free shares were awarded in 2014 or 2015.

The Board believes that the terms for setting the salaries of its two corporate officers executives comply with the principles defined in Recommendation R2 of the MiddleNext Code of Corporate Governance. For option plans already awarded, the

Board decided not to subject the exercise of options granted to corporate officers to performance conditions to be satisfied over a number of years. The analysis done by the Compensation Committee, with which the Board agrees, concluded that such a rule was inappropriate for the Company, whose development in the absence of ongoing revenues from business activities remains subject to great technological risk, the uncertainty of which is already factored into the lock-up period for options, which was lengthened from four years to five by the Board at its December 7, 2010 meeting for awards made after that date. This five-year period subsequent to allocation is a mediumterm horizon, in itself sufficient to represent an incentive for long-term performance.

#### Internal control procedures

The Company has implemented operating procedures, in particular related to the control of the commitment of financial and human resources, thereby creating a control environment. As it has evolved, the Company has adjusted its control objectives and methods, in particular to control its cash assets, which are its main financial resource, its key performance risks associated with the management of its projects and strategic partnerships, and, more generally, its compliance with regulatory duties applicable to biopharmaceutical companies and to listed companies. Therefore, in 2015, the Company had to reconsider and adapt its quality assurance system, given the new sub-contracting arrangement as part of its strategic decision to outsource the manufacturing of its clinical batches.

#### **Internal Control Objective and Definition**

Internal control is a Company system, defined and implemented on its own responsibility, which aims to ensure:

- compliance with applicable regulations and laws;
- the application of instructions and guidelines fixed by senior management;
- the proper functioning of the Company's internal processes, particularly those designed to protect its assets;
- the reliability of financial information.

Generally speaking, the Company's internal controls contribute to controlling its activities, the effectiveness of its operations and the efficient use of resources. By contributing to the prevention and control of risks of not achieving the Company's objectives, the internal control system plays a key role in the conduct and management of the Company's various activities. Accordingly the Company has put in place an enhanced control system on the key items of its main risks: liquidity risk and cash conservation, the risk of executing its clinical development plan through tight project management and the quality risk through

a quality assurance system. However, internal controls cannot provide an absolute guarantee that the Company's objectives will be achieved.

Transgene has adopted the internal control reference framework provided by the AMF for mid- and small-cap companies.

#### **Control environment**

#### Internal control bodies and contributors at Transgene

#### **Board of Directors and its committees**

The first part of the report describes the conditions under which the Board of Directors contributes to the optimization of the Company's activities. The Audit Committee oversees the internal control process, specifically with respect to validation of the internal control action plan and the Company's financial communications. In that connection, it familiarizes itself before every interim and annual reporting with the Group's financial statements and the accompanying notes. The independent directors who are physicians (Drs. Bizzari, Hurteloup and Zitvogel) take part in special meetings to monitor the Company's clinical development policy. They act as advisors to the Company's Medical and Regulatory Affairs Department.

#### **Executive Committee**

Under the leadership of the Chairman and CEO, every month the Executive Committee brings together the eight members representing each of the Company's functional and operating departments. Other than tasks related to project management, it considers the Company's operations, monitors all aspects of management in terms of the operating plan and objectives assigned by the Board of Directors, and deliberates on all organizational and operational strategy items placed on the agenda by its members. Twice a year the Executive Committee reviews quality management.



#### "Project" organization

Transgene's organization is based on functional departments, the coordination of which is ensured via a strong "project" strategy. Research programs, products under development and subcontracting are managed by project, headed by a project leader, and are the subject of reports. The project leader is responsible for coordinating, leading and optimizing the various cross-functional tasks required to ensure the project's success. The project leader prepares a development plan and schedule and provides monthly reports on the milestones achieved and unforeseen difficulties. A specialized project management committee meets at least monthly to track project management. The committee comprises primarily Executive Committee members and project managers, who present an overview of the projects that they oversee. The meetings are an opportunity to track all the research projects and preempt, where necessary, any conflicts regarding resources and priorities.

The Company uses collaborative project management software, which is shared by all departments and whose main functions are:

- consolidated management of the project portfolio;
- detailed project and resource planning;
- tracking the progress of tasks and time spent.

#### **Finance Department**

The Finance Department's role is to provide administrative and budgetary support to the line departments, to prepare management analyses for senior management, to enable effective financial decisions and to ensure compliance with financial and accounting regulations, particularly for a publicly-traded company. Within this department, the head of administration and finance is charged with implementing and improving accounting and financial procedures, along with overseeing the action plan established after the annual audit.

#### **Corporate Secretary**

The Corporate Secretary monitors the legality of the Company's activities and ensures compliance with the laws and regulations in effect and also supervises internal controls and risk management.

#### The control environment in the pharmaceutical industry

Research and development, preclinical tests, clinical trials, facilities and equipment and the manufacture and marketing of therapeutic products are subject to very thorough regulations devised by numerous governmental authorities in France, Europe, the United States and other countries. The European Medicines Agency (EMA), the French Agence nationale de sécurité du médicament et des produits de santé (ANSM), the Food and Drug Administration (FDA) in the United States and others, require compliance with stringent conditions for the manufacturing, development and commercialization of products such as those developed by Transgene. Pharmaceutical companies are subject to regular visits by these bodies to identify deficiencies and appropriate remedies.

Such an environment of rigorous controls calls for an internal control system capable of ensuring compliance with standards. This is why the Company has set up:

- a Quality Assurance Department, whose purpose is to meet regulatory requirements in terms of the quality and the safety of pharmaceutical products for human use. This Department's role and organization were amended in early 2016 to take into account the outsourcing arrangement for the manufacture of clinical batches. All new partnership agreements for outsourcing are subject to more stringent controls. The Quality Department regroups:
- System Quality, which rolls out, manages and improves all Quality Assurance processes, handles the quality documentation system, in-house and third-party quality audits, clinical audits of suppliers' Quality Assurance, quality training, as well as checking IT systems and the Company's ongoing compliance with pharmaceutical standards. This entity is also in charge of managing regulatory inspections and partner audits and follow-up,
- a group overseeing the quality of clinical operations which audits the documents and checks that the procedures have been properly applied in clinical studies. Transgene complies with the rules described in the Good Clinical Practices of the International Conference on Harmonization or national regulations, if the latter are stricter,
- a Quality Research team that initiates the quality system upstream of the product development process. It has technological experts who liaise with sub-contractors for technology transfers.

#### The control environment within the Institut Mérieux group

Since late 2010, member companies of the Institut Mérieux group have been participating in a comprehensive internal control program coordinated by the Institut Mérieux. Each group company analyzes its risks and approves its own audit program. The audit itself is performed by a cross-functional team of internal auditors from group companies who are specially trained in internal audit techniques. An audit was not performed in 2015 due to the operations related to the restructuring.

#### Internal Control And Risk Management Procedures

Procedures have been developed and implemented within the Company to ensure that the principal risks are managed internally in compliance with the policies and objectives set by management.

#### Determination of priority risks and processes

#### Risk management procedure

The Company identifies the main risk factors that might significantly affect its operations and outlook, as described in Section 1.5 of its *Document de référence*. It has established a formal review that surveys the risks and the procedures to be put in place to manage them.

Transgene believes that certain operational and financial risks are significant either due to the probability of their occurrence or by their impact on the Company. They are subject to the following procedures:

# Protection of the integrity of strategic scientific, medical and computerized data; protection of strategic biological materials and equipment

Backup of the Company's strategic data takes place primarily through archiving, duplication and separate storage procedures. The data is stored with a specialized operator offering a high level of data protection. However, the Company maintained equipment for local backups of the most critical data.

#### Protection of cash and cash equivalents

Cash and cash equivalents are the Company's main financial assets. The controls in place are intended to ensure the proper use and safety of the funds invested, in particular:

- preparation of a detailed budget by Section and quarterly budgetary control;
- a cash balance statement;
- determination of the investment policy by the Audit Committee.

The Company's cash is currently invested in investment funds, directly or in the Institut Mérieux group cash pool. This cash pool is placed under the supervision of a committee of the Group's liquidity managers (representing Transgene: the Vice President, Finance), which meets once a month to study the cash position of the participants (both lenders and borrowers), the yields and the investment decisions. The Audit Committee provides an update on the cash position at each of its meetings.

#### Reliability of financial and accounting information

To ensure the quality and reliability of the financial and accounting information it prepares, the Company uses a framework of accounting principles and standards as well as a management reporting system that analyzes accounting data along the following lines: by cost center, type of income and expense, and project.

#### Policy concerning insurance

In order to outsource a portion of the financial expense of operational risks, the Company has implemented a policy of insuring the main insurable risks with coverage amounts that it believes are compatible with its cash usage requirements.

#### Managing relations with strategic partners

The Company has entered into licensing and development partnerships for the final development stages of its products, their manufacturing and their commercialization. In order to maintain the highest level of collaboration with its partners and thus ensure optimum development of the product, a dedicated project leader ensures that the program is run properly, under the supervision of a monitoring committee that meets monthly. In addition, strategic partnerships are under special governance, usually in the form of a joint steering committee that meets regularly, or on an ad hoc basis to make key decisions (new strategic directions, new commitments, management of differences, etc.) throughout the life of the agreement.

#### A progressive approach to the evaluation of internal controls

As a result of the restructuring at end-2015, the Company had to revise its internal control plan to reflect the operations that it no longer had to track internally (i.e., production-related purchases and suppliers) along with new ones (sub-contracting related to these operations).

# Internal Controls related to the Preparation of Accounting and Financial Information

The Company prepares the annual consolidated financial statements under IAS/IFRS, as well as the parent company financial statements for Transgene SA. The Group prepares interim consolidated financial statements under IAS/IFRS



that are given a limited review by the Statutory Auditors. The consolidation process is not especially complex as the 2015 scope of consolidation included Transgene SA, its wholly-owned subsidiary, Transgene, Inc., whose purpose is representing Transgene SA before the U.S. health authorities (one employee as of March 1, 2016), and a wholly-owned subsidiary in Shanghai, Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd., which hosts collaborative academic research led by Transgene in China (two employees as of March 1, 2016). The Company's interests in ElsaLys Biotech SAS (France), and Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. (China) are accounted for by the equity method.

The Documents de référence filed every year with the French *Autorité des marchés financiers* are prepared jointly by the Finance Department and the Corporate Secretary. They are reviewed by the Group's legal counsel and auditors, under the responsibility of the Chairman and Chief Executive Officer.

The closing of the accounts is performed with the financial IT system (ERP). ERP manages procurement and supplies, warehouses, general and analytical accounting, as well as budgetary reporting. It allows for dividing up tasks by means of individual user profiles, while ensuring the integrity of the information. Computerized hierarchical approval procedures for purchases, travel authorizations and expense reports are in place.

ERP provides for the integration and traceability of restatement entries under IAS/IFRS standards, which limits the risk of error.

A list of tasks and controls to be effected by the accounting department for each closing ensures the appropriate rollout of closing procedures.

Quarterly reporting is prepared by the Finance Department and presented to the Executive Committee. This report is composed of the various Company activity financial and operational monitoring reports and analyzes actual and projected accounting data.

The budgeting process is designed and coordinated during the fourth quarter by the Finance Department in close cooperation with the project managers and operating managers. A managing controller is fully dedicated to the collection and monitoring of financial information relating to projects.

The budget process is based on the validation of project priorities based on the annual portfolio review and on the project management software that ensures financial and human resources are adequate to meet project requirements and schedules. The budget is presented for validation by the Management Committee, which then submits it to the Board of Directors, after it has been reviewed by the Audit Committee. The budget is adjusted every half year and a re-estimate is presented to the Board of Directors during the third quarter.

Statutory Auditors' report, prepared pursuant to Article L. 225-235 of the French Commercial Code, on the report by the Chairman of the Board of Directors of Transgène S.A.

# STATUTORY AUDITORS' REPORT, PREPARED PURSUANT TO ARTICLE L. 225-235 OF THE FRENCH COMMERCIAL CODE, ON THE REPORT BY THE CHAIRMAN OF THE BOARD OF DIRECTORS OF TRANSGÈNE S.A.

#### Dear Shareholders

In our capacity as Statutory Auditors of Transgène S.A., and pursuant to Article L. 225-235 of the French Commercial Code, we present to you on the report prepared by the Chairman of your Company in accordance with Article L. 225-37 of the French Commercial Code for the period ended December 31, 2015.

The Chairman is responsible for preparing a report describing the internal control and risk management procedures established within the Company, and submitting this report for approval by the Board of Directors. They are also responsible for providing any other information required by Article L. 225-37 of the French Commercial Code, including information relating to the corporate governance system in particular.

#### Our role is to:

- report to you on the information contained in the Chairman's report with respect to the internal control and risk management procedures relating to the preparation and treatment of accounting and financial information; and
- to certify that this report contains the further information required by Article L. 225-37 of the French Commercial Code, with the understanding that we are not expected to verify the accuracy of such further information.

We performed our tasks in accordance with professional standards applicable in France.

# Information concerning the internal control and risk management procedures related to the preparation and treatment of accounting and financial information

Good professional practices require that diligence be applied when evaluating the accuracy of the information provided in the Chairman's report on the internal control and risk management procedures related to the preparation and treatment of accounting and financial information. This specifically involves:

- identifying the internal control and risk management procedures related to the preparation and treatment of accounting and financial information underlying the information provided in the Chairman's report and in the existing documentation;
- identifying the work carried out in the preparation of this information and existing documentation;
- determining if any major deficiencies with the internal control related to the preparation and treatment of accounting and financial information that we note in the context of our mission have been properly reported in the Chairman's report.

On the basis of our work, we have no observations to make in connection with the information given on the internal control and risk management procedures relating to the preparation and processing of financial and accounting information, as contained in the Chairman's report, prepared in accordance with the provisions of Article L. 225-37 of the French Commercial Code.



Statutory Auditors' report, prepared pursuant to Article L. 225-235 of the French Commercial Code, on the report by the Chairman of the Board of Directors of Transgène S.A.

#### Other information

We hereby certify that the Chairman's report includes the other disclosures required by Article L. 225-37 of the French Commercial Code.

Lyon, April 27, 2016 Statutory Auditors

**DIAGNOSTIC REVISION CONSEIL** 

Hubert de Rocquigny du Fayel

**ERNST & YOUNG et Autres** 

Marc-André Audisio

3

# INFORMATION REGARDING THE COMPANY'S SOCIAL, ENVIRONMENTAL AND SOCIETAL RESPONSIBILITY

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# 3.1 NOTE ON METHODOLOGY

In 2015, the Company announced its strategic restructuring which primarily entailed outsourcing the manufacturing of its clinical batches and shutting down its industrial development activities. A redundancy plan (plan de sauvegarde de l'emploi) making nearly half the staff redundant was conducted alongside the restructuring. This plan has not yet reached its final outcome. Some employees are still reported as staff under their reclassification leave, but are no longer actively working for the Company. Given these special circumstances, it did not appear appropriate to retain a 3-year reporting period for the indicators affected by the restructuring and the redundancy plan. These indicators are (1) environmental indicators, due to the sale on February 1, 2016 of the production asset and the related equipment, and (2) the employee-related indicators. For the second point, the indicators are reported as from March 1, 2016 and exclude the employees on reclassification leave.

For the other social indicators (training, compensation and absenteeism), the calculations were effected using the headcount in 2015, which corresponded to 258 employees (171 women and 87 men).

Unless otherwise indicated, the items in the following report concern the Company (Transgene SA), located in France, where its business is primarily conducted in two facilities located in Illkirch-Graffenstaden and Lyon. Its two wholly-owned subsidiaries serve as a representative office (Transgene, Inc. in the United States, which has only one employee at March 1, 2016) and to collaborate on academic research (Transgene Biopharmaceuticals Technology (Shanghai) Co. Ltd. in China has two employees). Neither of them conducts any commercial activities. Accordingly, given their small number of employees, these subsidiaries are not included in the indicators in this report. Figures are provided for the fiscal years 2013, 2014 and 2015 only when such figures are relevant.

#### Methodologies - details and limitations

Methodologies for reporting social, environmental and safety indicators are likely to have certain limitations inherent in the practicalities of collecting and consolidating such information.

The definitions and reporting methodologies are suitable for the following indicators:

#### **Environment indicators**

The indicators on water consumption only cover the Group's activities in the building housing the registered office, the administrative and regulatory activities and the R&D labs (the TUR building) at its facility in Illkirch-Graffenstaden (France). Activities of the production building (TUP) sold on February 1, 2016 could not be included as technical difficulties prevented

the checks from being conducted. Electricity consumption relates to the two TUP and TUR buildings. The power supplies were being separated at the time of drafting this report. The manufacturing building is the only one to use gas, the TUR building being heated by a heat pump and electricity. This indicator again covers the TUP building.

#### Social indicators

#### **Total workforce**

This indicator covers only the activities of the Group located in France. Employees on a permanent or temporary employment contract (CDI or CDD) with Transgene SA at March 1, 2016 are counted in the total workforce. Employees on reclassification leave are excluded.

#### Hires and departures

This indicator covers only the activities of the Group located in France.

Temporary contracts are included in the reporting of this indicator. The following are excluded from the reported data on hires and departures: employees on vocational training contracts and the conversion of temporary employment contracts to permanent ones when the end of the prior contract coincides with the start of the new contract.

#### Rate of absenteeism

The absenteeism rate is reported only for within France. It refers to the ratio of the number of working hours missed (illness and workplace accidents) to the number of hours worked. Only the rate calculated under this method for 2015 is reported. The 2013 and 2014 rates are no longer included in this report as they were calculated including parental leave and unpaid leave and are therefore not comparable to the 2015 rate.

#### Number of hours worked

This indicator covers only the activities of the Group located in France for the period from January 1 to December 31, 2015.

The number of hours worked is taken from the payroll and/or the DADSU social information declaration.

#### Safety indicators

# Frequency rate and severity of accidents with work stoppage

These indicators cover only the activities of the Group located in France. The frequency rate of accidents with work stoppage equals the number of accidents with work stoppage of greater than or equal to one day occurring during a 12-month period per million hours worked. The severity rate of workplace accidents is equal to the number of days lost due to temporary disability, excluding commuting accidents, occurring during a period of 12 months per thousand hours worked. Commuting accidents from the home to the workplace are excluded from the calculation of these indicators.

#### Consolidation

The consolidation of the data is under the responsibility of the Corporate Secretary.

# 3.2 EMPLOYEE INFORMATION

# 3.2.1 Responsibility as an employer

#### 3.2.1.1 Employment

#### • TOTAL NUMBER AND DISTRIBUTION OF EMPLOYEES BY SEX, AGE AND GEOGRAPHICAL REGION AT DECEMBER 31

Data specific to the Company

	Men	Women	Total
Geographical area and age distribution	3/1/2016	3/1/2016	3/1/2016
France	53	112	165
of whom: under 25 years	-	2	2
25 to 39 years	19	38	57
40 to 49 years	20	27	47
And over 50 years	14	45	59

#### HIRES AND DEPARTURES

For the period January 1, 2015 to March 1, 2016 (Including apprenticeships, vocational contracts and CIFRE [research training])

Hires	13
Departures	54

NB: the following indicators were established based on a headcount of 256 employees as of December 31, 2015.

#### COMPENSATION AND CHANGES OVER TIME

The following table shows the breakdown of average gross annual compensation (wages/salary and bonuses) for men and women for 2013, 2014 and 2015, in euros:

Businesses (Classification groups - collective agreemen of pharmaceutical companies)	t	Operator/ Employees (2-3)	Assistant/ Technician (4-5-6)	Clinical research assistant (CRA)/ Engineer/ Supervisor (6-7)	Project leader/ Physician/ Med Tech/ Researcher (7-8)	Senior Manager/ Director (8-9)
	Men	25,666	35,647	47,731	66,758	84,188
2013	Women	29,508	34,904	49,019	59,709	76,533
	Men	23,111	35,643	49,019	68,994	80,775
2014	Women	29,622	36,411	48,454	61,020	75,593
	Men	27,982	36,077	48,603	66,037	74,693
2015	Women	28,923	34,170	48,073	58,716	80,997

Total payroll for 2015 was €20.07 million (€21 million in 2014, €21.4 million in 2013).

#### Work organization

#### Organization of working time

The Company collective labor agreement in effect in the Company's sites located in France call for a reduction in the work week of non-managers to 37 hours, 40 minutes and a reduction of 9 working days per year; for managers, the annual workload is a fixed 215 days. In 2003, a corporate agreement on flexible time for non-managers completed this structure.

An agreement was signed in December 2003, which completed the Company agreement and was based on the collective agreement for the pharmaceutical industry relating to the treatment of overtime and exceptional overtime during nights, weekends and statutory holidays for non-manager employees.

#### Absenteeism

The absenteeism rate was 3.92% in 2015.

#### Labor relations

# Organization of social dialogue, including employee information and consultation procedures and negotiations with staff

Social dialog takes place in accordance with the French Labor Code, through the respective representative bodies, trade union delegation, Works Council and employee representatives based on the duties and tasks of each body. Due to the structure and size of the Company, it does not need to arrange specific procedures to inform, consult or negotiate with employees. Video- and teleconferencing equipment are available to employee representatives based in Lyon for active participation in meetings of bodies held at the head office.

In 2015, the parties focused primarily on negotiating the terms and conditions of the redundancy plan (*plan de sauvegarde de l'emploi*) which took place from June to October 2015. These negotiations were conducted in an atmosphere of dialog and mutual respect.

#### **Collective bargaining agreements**

No new agreements were signed in 2015.

#### Health and safety

#### Health and safety conditions in the workplace

The Company's policy regarding the safety and protection of individuals has the following main objectives:

- to ensure the safety of those who work at the Company; and
- to ensure the protection of the Company's tangible and intangible assets.

The laboratories are designed and equipped both to protect the experiments being conducted from any outside contamination and to protect the employees as they do their work from accidental exposure to potentially hazardous products.

The Company's operations are subject to pharmaceutical standards (Laboratory and Clinical Best Practices) and to the provisions of the French Environmental Code that refer to the confined use of genetically modified organisms. In this regard, it is subject to administrative authority approval, given upon recommendation of the French High Council for Biotechnologies, for its viral vector constructions. Authorization includes the classification of these constructs and the confinement conditions for their handling. The Company's investments in the quality of its products have a safety and protection dimension, but are not necessarily recorded as specific costs related to this issue.

In its facilities, the Company applies high standards to its equipment and operations and is also committed to training its staff in the different safety requirements of their work station.

The Company has a Health, Safety and Environmental Officer to oversee workplace safety and prevention.

The Health, Safety and Working Conditions Committee operates within the Company pursuant to the regulations in force.

# Review of agreements signed with trade unions or staff representatives on health and workplace safety

The CHSCT holds its ordinary meetings every quarter, makes periodic visits to the sites and facilities, and may choose to hold extraordinary meetings following a serious accident or incident. The procedures for serious and imminent danger were not called upon in 2015, or in 2014 and 2013. An analysis was performed in 2015 in the wake of workplace accidents (three in 2014 and four in 2013).

#### WORKPLACE ACCIDENTS, FREQUENCY AND SEVERITY; OCCUPATIONAL DISEASES

Number of accidents (including onsite aid in the infirmary)	2013	2014	2015
Total Company accidents resulting in recording in the infirmary logs or being reported	55	22	20
Number of accidents reported	11	6	4
of which, commuting accidents (home-workplace)	4	1	-
workplace accidents	7	5	3
travel accidents (away from the workplace)	-	-	1
Number of accidents with work stoppage	7	2	1
Frequency rate (1)	9.82	4.10	2.16
Severity rate (2)	0.055	0.02	0.002

- (1) Number of workplace accidents with stoppage (excluding during travel) multiplied by 1,000,000 and divided by the number of hours worked.
- (2) Number of days lost due to temporary disability (excluding during travel) multiplied by 1,000 and divided by the number of hours worked.

No occupational illnesses were recognized in 2015 (one in 2014 and none in 2013). The employer did not file any reports indicating any processes that could cause occupational illnesses in 2015 or in 2014 and 2013.

#### **Training**

#### Training policies implemented

Employees enter the Company with a high level of prior training. Over 86% of them have an educational level of two or more years of post-secondary education. The continued training of employees in technology-based knowledge and skills of the highest level is necessary to maintain the Company's competitiveness. To preserve and develop this

human capital, the Company devotes considerable effort to continuing training (3.36% of payroll in 2014, 3.40% in 2013 and 4.34% in 2012 – data not yet available for 2015) and to the development of knowledge and know-how, primarily through a policy of sending people to leading internationally recognized conferences and seminars and through numerous collaborations within the scientific community, and an extensive and constantly updated document base. In 2014, the Company also paid an apprenticeship tax of 1.6%.

#### Total number of hours of training

2,566 hours were given to occupational training in 2015 (5,038 in 2014 and 4,849 in 2013). 59% of employees took at least one training course in 2015 (882 in 2014 and 79% in 2013).

#### Non-discrimination

# Measures taken to promote equality between men and women

In accordance with the law of November 9, 2010, a company agreement on professional equality was signed on September 25, 2012 with the social partners. This agreement was renegotiated in 2016.

Based on findings about the comparative situation of men and women at Transgene, the agreement resulted in an action plan put in place in 2012 in four areas: promotion, training, compensation and work/life balance. A number of key measures were introduced, such as formal interviews when taking and returning from parental leave (maternity leave, adoption leave, child-rearing leave) to make sure that these leaves do not penalize the employees involved.

Since it was founded, the Company has striven to adopt numerous measures that help balance its employees' work and private lives. These measures include: possibility of part-time work (47 employees, including 2 male managers, 45 women, 26 of them managers in 2015; 42 employees, including 1 male manager and 41 women, 24 of them managers in 2014; 39 employees, including 1 male manager in 2013); maternity and paternity leave at full pay, funding 8 places in the nearby daycare center (annual cost was €65,288.30 in 2015; €64,090.18 in 2014 and €62,250 in 2013).

# Measures taken to promote employment and integration of disabled workers

Under the terms of the pharmaceutical companies collective agreement (Leem) of September 25, 2008 to promote the employment and retention of people with disabilities, as amended by the Protocol of September 24, 2009, Transgene has implemented a number of measures.

To encourage the hiring of disabled workers, the Company uses application management software on which it displays its non-discrimination policy, which allows disabled workers to identify themselves, if they wish, by checking a box. Their applications can be prioritized accordingly.

In 2015, the Company employed 13 people with reported disabilities (8 in 2014). The Company also uses three work assistance centers for various services and pays an additional contribution to Handi-Em. In addition, it calls on the services of several of the French organizations to aid the disabled in employment known as ESATs (ARSEA, HANDIRECT, AVS and ESSOR).

In 2015, the Company forged ahead with efforts to combat stereotypes on disabilities. It offered all employees the opportunity for outside consultations on health matters as well as on how companies accommodate illness and disabilities at the workplace for both themselves as well as their families. Assistance was also offered in having a disability formally recognized.

#### Policy against discrimination

The Company ensures that its hiring and management practices are non-discriminatory.

# Promotion and enforcement of the provisions of the fundamental conventions of the International Labor Organization

# Respect for freedom of association and the right to collective bargaining

The Company declares that it strictly upholds the freedom of association of employees. The right to collective bargaining is exercised in its institutions within the framework defined by the Labor Code.

## Elimination of discrimination in respect of employment and occupation

See above, Non-discrimination.

#### Elimination of forced or compulsory labor

The Company has no operations in countries where such practices occur.

#### Effective abolition of child labor

The Company has no operations in countries where such practices occur.

# 3.3 ENVIRONMENTAL INFORMATION

#### 3.3.1 Environment

The products designed and developed by the Company result from biological sciences (specifically, molecular and cellular biology) and use biotechnology processes (cell culture, purification processes, etc.) to enable a transition from laboratory work to the production of quantities of products controlled and approved for human clinical trials.

The processes to realize these products are extremely complex and require materials that present potential risks to individuals and the environment in the case of accidental exposure. These processes occur within several levels of containment.

Thus, for example, the research laboratories are designed and equipped both to protect the product during its development

from any outside contamination and to protect the employees as they do their work from accidental exposure to potentially hazardous products. The Company's operations are subject to pharmaceutical standards (Laboratory and Clinical Best Practices) and to the provisions of the French Environmental Code that refer to the confined use of genetically modified organisms. In this regard, it is subject to administrative authority approval, given upon recommendation of the French High Council for Biotechnologies, for its viral vector constructions. Authorization includes the classification of these constructs and the confinement conditions for their handling. The Company's investments in the quality of its products have a safety and protection dimension, but are not necessarily recorded as specific costs related to this issue.

#### 3.3.2 Environmental responsibility

# 3.3.2.1 General policy in environmental matters

Organization of the Company to take into account environmental issues and, where appropriate, approaches to environmental evaluation and certification

The Company believes that its research has very little impact on the environment, since operations relating to this activity take place in a confined environment.

At this stage, the Company has not taken any steps to obtain environmental certification.

The impact of this activity on the environment is controlled in two ways:

 by strictly applying pharmaceutical quality standards that permit monitoring and tracking at all stages of the activity (air testing and treatment, quality of materials used, controlled flow of materials and personnel, etc.); and  by observing the environmental regulations in force with respect to aspects not directly imposed by those standards (classification of research in terms of the regulations on genetically modified organisms, confinement of operations, effluent and waste handling and treatment, etc.)

# Training and information for employees regarding environmental protection

The Company has not taken special measures to train and inform employees concerning environmental protection.

# Resources devoted to the prevention of environmental risks and pollution

The Company has a Health, Safety and Environmental Officer. In addition, research takes place in a confined environment and related resources and equipment (air treatment filters, microbiological safety cabinets, autoclaves etc.) help prevent environmental risks.

#### Provisions and guarantees for environmental risks

The Company has made no provisions or guarantees of this kind.

#### 3.3.2.2 Pollution and waste management

#### Prevention, reduction and repair measures for air, water and soil discharges that seriously affect the environment

The Company's research and development activity is conducted in a confined environment. This confinement is obtained through several levels of air treatment and controls including microbiological safety cabinets, air depressurization to prevent its exit, absolute filters on ventilation ducts, etc. Effluents from some areas are collected and subjected to heat treatment for decontamination before release into the sewage system.

#### Prevention, recycling and waste disposal measures

The Company's activity generates various types of waste that require sorting for special treatment. The Company has entered into agreements with qualified service providers for removal and treatment in accordance with the standards and rules that govern these various categories.

In addition, the Company conducts separate sorting and removal of non-hazardous waste and special waste requiring special precautions.

# Consideration of noise and other forms of pollution specific to an activity

Neither the activity nor the facilities of the Company generate noise pollution.

#### 3.3.2.3 Sustainable use of resources

# Water use and water supply according to local restrictions

The Company's activities involve the use of water. This use is directly related to changes in R&D projects and does not trigger relevant indicators. The water used comes from the urban network; there are no specific supply constraints in the Alsace region.

#### **○** WATER (M³)

Year	Volume	Change
2013	8,401	-
2014	6,249	-25.6%
2015	5,502	-12%

# Consumption of raw materials and measures to improve efficiency of their use

The Company does not directly consume raw materials.

# Energy consumption, measures to improve energy efficiency and use of renewable energy

The equipment in the research laboratories and the facilities for producing clinical batches run exclusively on electricity. There

is a very strict equipment maintenance plan to ensure optimal energy consumption.

The laboratory and office building use heat pumps for heating and cooling and electricity for steam production.

#### **▶ ELECTRICITY** (KWH)

Year	Total	Change
2013	5,518,118	-
2014	5,493,263	-0.42%
2015*	5,545,160	+0.09%

<sup>\*</sup> The reported data covers the TUR building and the former TUP building sold in February 2016, as the buildings were still connected to the same electric meter at the time of the sale.

#### NATURAL GAS (KWH)

In 2015, the former TUP building consumed 5,538,145 kwh of natural gas (5,069,559 kwh in 2014 and 5,048,929 kwh in 2013).

#### Land use

Not applicable to the Company's business.

#### Climate change

#### Greenhouse gas emissions

Conversion of the above energy consumption figures into  ${\rm CO_2}$  emission equivalents by applying the International Energy Agency's conversion factors, gives:

- 333 metric tons of CO<sub>2</sub> equivalent (IEA factors of 0.06 as of December 31, 2015) for electricity consumption; and
- 1,117 metric tons of  $CO_2$  equivalent (IEA factors of 201.6 as of December 31, 2015) for gas consumption.

#### Adaptation to the impacts of climate change

The Company has no activity requiring special measures to adapt to climate change impacts.

#### 3.3.2.4 Protection of biodiversity

#### Measures to preserve or enhance biodiversity

Neither the activities nor the facilities of the Company have an impact on biodiversity.

# 3.4 SOCIETAL INFORMATION: SOCIETAL COMMITMENTS TO PROMOTE SUSTAINABLE DEVELOPMENT

## 3.4.1 Local, economic and social impact of the Company

#### In employment and regional development

Since its inception in 1979, the Company has located most of its activities in Strasbourg and in the suburbs of that city. As the first genetic engineering company founded in France, it had a strong local attraction, with professional opportunities for scientists, researchers and technicians in the life sciences. In 2015, the Company had to impose a redundancy plan (plan de sauvegarde de l'emploi), laying off half of its employees in France, primarily in the facility in Illkirch-Graffenstaden. Some employees are still on reclassification leave and receive assistance provided under the plan, whether they are looking

for work, waiting to take their retirement or taking training to set up their own business project. ABL Europe, which bought the building and production unit equipment from the Company, hired 29 employees working at this site.

#### Local or neighboring populations

The principal office of the Company is located in an area dedicated to scientific and technical activities, the *Parc d'Innovation* in Illkirch-Graffenstaden. There are therefore no immediate neighboring populations that its business could impact.

# 3.4.2 Relationships with persons or organizations who have an interest in the Company's activities

# Conditions for dialogue with such persons or organizations

The Company is active locally, albeit on an informal basis and through some of its employees, with various associations such as Alsace Biovalley, an association for the development of activities related to life sciences in the Alsace Region,

Strasbourg Sud Développement, which conducts actions to promote employment in this sector, or the *Pôle Solidaire*, which collects funds for children in the *Parc d'Innovation*.

#### Partnerships or sponsorships

There are no formal partnerships or sponsorships.

## 3.4.3 Subcontractors and suppliers

# Consideration of social and environmental issues in the procurement policy

The Company has not established specific procedures for consideration of these issues in its procurement policy.

# Importance of subcontracting and consideration in relations with suppliers and subcontractors of their social and environmental responsibility

The Company makes significant use of the services of companies specializing in the conduct of clinical trials and related services, known as CROs (Contract Research Organizations) for most of its clinical trials. The Department of Medical and Regulatory Affairs oversees that these subcontractors perform the services properly. Control management ensures that subcontractors are within budget and the Quality Assurance Department checks for quality.

These providers operate within a strictly regulated framework that aims to ensure the quality of the clinical trials conducted and are audited by the Company's Quality Assurance group.

On February 1, 2016, the Company began subcontracting out the manufacturing of its clinical batches for clinical studies. ABL Europe, the subcontractor, belongs to the Institut Mérieux, as does the Company. It operates in the Company's old manufacturing premises and has hired former Transgene employees. The Responsible Pharmacist, who is the Director of Quality Assurance, closely oversees the services provided by this subcontractor.

Compliance of subcontractors working for and/or in the Company in relation to their social obligations to personnel involved in the Company is part of their specifications.

## 3.4.4 Fair commercial practices

#### Actions taken to prevent corruption

The Company has not initiated specific actions to prevent corruption. It considers the internal control procedures for expenditure commitments related to the protection of its cash, at this stage of its development, effective prevention measures.

#### Measures for consumer health and safety

The Company has no products on the market. Products in clinical development, or in research, are intended for the treatment of patients with cancer or chronic infectious diseases; they are the subject of clinical trials that fall within a strict regulatory framework whose purpose is to ensure the efficacy of therapeutic products. For the Company's products to be marketed, they must receive an authorization to market issued by the health authorities of the various countries in which they will be distributed.

# Other actions undertaken in this part 3 to promote human rights

The clinical trials being conducted for the Company's products are conducted in strict compliance with the informed consent of the persons participating in biological research trials.

# Commitments to promote the circular economy and the fight against food waste

Given the immaterial impact of its activities in this area, the Company does not have a specific commitment to promote the circular economy and the fight against food waste.

## 3.5 INDEPENDENT THIRD-PARTY REPORT

# Report of independent third party on the consolidated social, environmental and societal information contained in the management report

#### **Transgene**

Fiscal year ended December 31, 2015

Dear Shareholders,

In our capacity as an independent third-party organization accredited by COFRAC <sup>(1)</sup> under number 3-1050 and member of the network of one of the Statutory Auditors of Transgene, we submit to you our report on the consolidated social, environmental and societal information pertaining to the fiscal year ended December 31, 2015 and presented in Chapter 3 of the management report (hereinafter the "CSR information") pursuant to Article L. 225-102-1 of the French Commercial Code.

#### Company responsibility

It is the duty of the Board of Directors to prepare a management report that includes the CSR information mentioned in Article R. 225-105-1 of the French Commercial Code and to do so in accordance with the guidelines used by the Company (hereinafter the "Guidelines"), a summary of which appears in the introduction to Chapter 3 of the management report.

#### Independence and quality control

Our independence is defined in the regulations, the code of ethics of the profession, as well as the provisions of Article L. 822-11 of the French Commercial Code. In addition, we have implemented a quality control system that includes documented policies and procedures to ensure compliance with ethical standards, professional standards and applicable legal and regulatory texts.

#### Responsibility of the independent third party

It is our responsibility, based on our work, to:

- certify that the CSR information required is present in the management report or, if omitted, that an explanation is provided pursuant to paragraph 3 of Article R. 225-105 of the French Commercial Code ("Certification of the presence of CSR information");
- express a conclusion of moderate assurance that the CSR information taken as a whole is presented honestly and fairly in all material respects in accordance with the Guidelines (opinion, stating reasons, as to the honesty and fairness of the CSR information).

Our work was carried out by a team of three people for a period of approximately two weeks between October 2015 and the date of our report.

We conducted the work described below in accordance with professional standards applicable in France and the Order of May 13, 2013, determining the conditions under which the independent third party conducts its mission.

#### 1. Attestation of the presence of the CSR information

We reviewed, based on interviews with officials of the relevant departments, the presentation of guidelines for sustainable development based on the social and environmental consequences of the activities of the Company and its social commitments and, where appropriate, actions or programs arising therefrom.

We compared the CSR Information presented in the management report with the list described in Article R. 225-105-1 of the French Commercial Code.

In the absence of some consolidated information, we verified that the explanations were provided in accordance with Article R. 225-105, paragraph 3 of the French Commercial Code.

(1) Scope of accreditation available at www.cofrac.fr.

We verified that the CSR information covered the scope of consolidation, i.e., the parent company and its subsidiaries within the meaning of Article L. 233-1 of the French Commercial Code and the companies that it controls within the meaning of Article L. 233-3 of that Code, within the limitations stated in the note on methodology given in Chapter 3 of this management report.

Based on this work and given the above-mentioned limitations, we attest to the presence in the management report of the required CSR information.

#### 2. Substantiated opinion on the truthfulness of the CSR information

#### Nature and scope of work

We conducted five interviews with the persons responsible for preparing the CSR information in the departments in charge of the process of gathering the information and, when necessary, those responsible for the internal control and risk management procedures, in order to:

- assess the appropriateness of the Guidelines in terms of their relevance, completeness, reliability, neutrality and understandability, taking into account, where appropriate, industry best practices;
- verify the implementation of a process of collecting, compiling, processing and control for the completeness and consistency
  of the CSR information and obtaining an understanding of internal control and risk management procedures relating to the
  development of the CSR information.

We determined the nature and extent of our tests and controls depending on the nature and importance of the CSR information, in relation to the characteristics of the Company, social and environmental challenges of its business, its guidelines on sustainable development and good industry practices.

For the CSR information we considered to be most important (1):

for the entity, we consulted documentary sources and conducted interviews to corroborate the qualitative information (as to
organization, policies, actions, etc.), employed analytical procedures on the quantitative information, and checked, by sampling,
the calculations and the consolidation of the data, checking them for consistency and agreement with the other information
given in the management report.

For more consolidated CSR information, we assessed its consistency in relation to our knowledge of the Company.

Finally, we assessed the relevance of the explanations, if any, for the total or partial absence of certain information.

We believe that the methods of sampling and sample sizes we used by exercising our professional judgment allow us to make a conclusion of moderate assurance; a higher level of assurance would have required a more extensive audit. Because of the use of sampling techniques, as well as other limits inherent in the operation of any information and internal control system, the risk of not detecting a material misstatement in the CSR information cannot be completely removed.

#### **Conclusion**

Based on our work, we did not identify any material anomalies likely to call into question the fact that CSR information, taken as a whole, is presented in an accurate way, in accordance with the Guidelines.

Paris, La Défense, April 27, 2016

The independent third party

#### **ERNST & YOUNG et Associés**

Éric Duvaud

Sustainable Development Partner

Bruno Perrin

#### (1) Environmental and societal information:

Indicators (quantitative information): energy and water consumption.

Qualitative information: general policy as to the environment, the sustainable use of resources; regional, economic and social impact (jobs, regional development, impact on neighboring or local populations), relationships with stakeholders (basis for dialog, partnership or sponsorship initiatives), the importance of subcontracting and the consideration given to social and environmental issues in the purchasing policy and relations with suppliers and subcontractors, fair business practices (anti-corruption measures, health and safety measures to protect consumers).

#### Employee information:

Indicators (quantitative information): total reported workforce, hires and departures, absenteeism rate, frequency and severity rate of work accidents, total number of hours of training.

Qualitative information: employment (total workforce and distribution, hires and dismissals, compensation and its change over time), work schedules, absenteeism, employer-employee relations (arrangements for dialog, status report on collective agreements), workplace health and safety conditions, training policies, diversity and equal opportunity and treatment (measures in respect of gender equality, the hiring and inclusion of disabled people, anti-discrimination).

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## 4.1 CONSOLIDATED FINANCIAL STATEMENTS AND NOTES

## 4.1.1 Consolidated financial statements

#### **CONSOLIDATED BALANCE SHEET, IFRS** (IN € THOUSANDS)

Assets	Notes	12/31/2015	12/31/2014
CURRENT ASSETS			
Cash and cash equivalents	2	3,285	3,513
Other current financial assets	2	28,365	62,422
Cash, cash equivalents and other current financial assets:	2	31,650	65,935
Trade receivables		1,784	1,540
Inventories		1,164	1,149
Other current assets	3	12,930	10,614
Assets available for sale	4	3,500	-
Total current assets		51,028	79,238
NON-CURRENT ASSETS			
Property, plant and equipment	5	16,559	23,641
Intangible assets	6	485	1,056
Non-current financial assets	7	4,050	3,852
Investments in associates	7	1,148	2,320
Other non-current assets	8	27,599	30,846
Total non-current assets		49,841	61,715
TOTAL ASSETS		100,869	140,953

12/31/2015

12/31/2014

Note

CURRENT LIABILITIES			
Trade payables		6,521	8,296
Financial liabilities	9	9,396	8,992
Provisions for risks		7,038	127
Other current liabilities	10	3,770	4,148
Total current liabilities		26,725	21,563
NON-CURRENT LIABILITIES			
Financial liabilities	9	44,401	43,199
Employee benefits	11	3,196	4,352
Other non-current liabilities		-	-
Total non-current liabilities		47,597	47,551
Total liabilities		74,322	69,114
EQUITY			
Share capital	12	88,196	88,156
Issue premium and reserves		476,788	476,255
Retained earnings		(491,263)	(442,707)
Profit (loss) for the period		(46,374)	(48,556)
Other comprehensive income		(800)	(1,309)
Total equity attributable to Company shareholders		26,547	71,839
TOTAL EQUITY AND LIABILITIES		100,869	140,953

Liabilities and equity

#### CONSOLIDATED INCOME STATEMENT, IFRS

(in thousands of Euros, except for per-share data)	Notes	12/31/2015	12/31/2014
Revenue from collaborative and licensing agreements	13	1,465	1,837
Public funding for research expenses	13	8,100	9,262
Operating income		9,565	11,099
Research and development expenses	1.4.1	(32,138)	(41,731)
General and administrative expenses	1.4.2	(5,798)	(7,578)
Other income and (expenses), net	14	(7,436)	(1,282)
Net operating expenses		(45,372)	(50,591)
Operating income from continuing operations		(35,807)	(39,492)
Interest income (expense), net	15	(930)	(801)
Share of profit (loss) of associates		(1,172)	(823)
Income (loss) before tax		(37,909)	(41,116)
Income tax expense	16	-	-
Net income from continuing operations		(37,909)	(41,116)
Net income from discontinued operations		(8,465)	(7,440)
NET INCOME/(LOSS)		(46,374)	(48,556)
Basic loss per share (€)	12	(1.20)	(1.26)
Diluted earnings per share (€)	12	(1.20)	(1.26)

#### STATEMENT OF COMPREHENSIVE INCOME, IFRS

(in € thousands)	12/31/2015	12/31/2014
Net income/(loss)	(46,374)	(48,556)
Foreign exchange gains/(losses)	28	18
Revaluation of hedging instruments	115	(159)
Other elements of comprehensive income subsequently restated as income	143	(141)
Actuarial gains and losses on pension provision	366	459
Other elements of comprehensive income subsequently non-recyclable as income	366	459
Other comprehensive income	509	318
NET COMPREHENSIVE INCOME	(45,865)	(48,238)
Of which, attributable to parent company	(45,865)	(48,238)
Of which, attributable to minority interests	-	-

#### • CASH FLOW STATEMENT, IFRS

CASH FLOW STATEMENT, IFRS			
(in € thousands)	Notes	12/31/2015	12/31/2014
CASH FLOW FROM OPERATING ACTIVITIES			
Net income/(loss)		(46,374)	(48,556)
Cancellation of financial income		930	801
ELIMINATION OF NON-CASH ITEMS			
Income of associates		(1,172)	824
Provisions		8,697	267
Depreciation	5, 6, 7	2,636	3,039
Share-based payments	17.2	462	721
Other	14	11	1,034
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow		(32,466)	(41,870)
CHANGE IN OPERATING WORKING CAPITAL REQUIREMENTS			
Current receivables and prepaid expenses	21	73	(977)
Inventories and work in progress		(14)	(174)
Research tax credit	13.2	(8,532)	(8,702)
Other current assets	3	(2,150)	(61)
Trade payables	21	(1,685)	(899)
Prepaid income	10	461	(533)
Employee benefits	11	(841)	(1,036)
Other current liabilities	9	2	16
Net cash used in operating activities		(45,152)	(54,236)
CASH FLOWS FROM INVESTING ACTIVITIES			
(Acquisitions)/disposals of property, plant and equipment	5	(1,527)	(2,463)
(Acquisitions)/disposals of intangible assets	6	-	(139)
Other (acquisitions)/disposals	7	3,843	3,134
Net cash used in investing activities		2,316	532
CASH FLOWS FROM FINANCING ACTIVITIES			
Net financial income proceeds	15	(165)	(4)
Gross proceeds from the issuance of shares	12	477	65,664
Share issue costs		-	(2,929)
Conditional subsidies	13.2	923	955
(Acquisitions)/disposal of other financial assets	2	34,176	(19,445)
Financing of tax credits	9	8,209	8,438
Financial leases	9	(1,040)	(618)
Net cash generated from/(used in) financing activities		42,580	52,061
Exchange rate differences on cash and cash equivalents		28	18
Net increase/(decrease) in cash and cash equivalents		(228)	(1,625)
Cash and cash equivalents at beginning of period		3,513	5,138
Cash and cash equivalents at end of period		3,285	3,513
Investments in other current financial assets		28,365	62,422
CASH, CASH EQUIVALENTS AND OTHER CURRENT FINANCIAL ASSETS		31,650	65,935

#### STATEMENT OF CHANGES IN EQUITY, IFRS

	Common	shares					Total attributable to
(in € thousands)	Number of shares	Share capital	Share premiums et Reserves	Retained earnings	Other comprehensive income	Profit (loss) for the period	shareholders business activity
As of December 31, 2013	31,874,858	72,933	428,023	(399,849)	(1,627)	(42,858)	56,622
Share-based payments	99,559	228	622	-	-	-	850
Capital increase	6,553,551	14,995	47,611	-	-	-	62,606
Net profit/(loss) appropriation 2013	-	-	-	(42,858)	-	42,858	-
Net loss 2014	-	-	-	-	-	(48,556)	(48,556)
Fair value gains on available-for-sale financial assets	-	-	-	-	18	-	18
Actuarial gains and losses on pension provision	-	-	-	-	459	-	459
Rate Swap	-	-	-	-	(159)	-	(159)
Net comprehensive income	-	-	-	-	318	(48,556)	(48,238)
As of December 31, 2014	38,527,968	88,156	476,256	(442,707)	(1,309)	(48,556)	71,840
Share-based payments	-	-	461	-	-	-	461
Capital increase	17,429	40	71	-	-	-	111
Allocation of net income 2014	-	-	-	(48,556)	-	48,556	-
2015 net income (loss)	-	-	-	-	-	(46,374)	(46,374)
Fair value gains on available-for-sale financial assets	-	-	-	-	28	-	28
Actuarial gains and losses on pension provision	-	-	-	-	366	-	366
Interest rate swap	-	-	-	-	115	-	115
Net comprehensive income	-	-	-	-	509	(46,374)	(45,865)
AS OF DECEMBER 31, 2015	38,545,397	88,196	476,788	(491,263)	(800)	(46,374)	26,547

# 4.1.2 Notes to the consolidated financial statements (in thousands of Euros, unless otherwise stated)

#### **Foreword**

The consolidated financial statements of Transgene (the "Company") at December 31, 2015 were prepared in accordance with the principles and methods defined by IFRS (International Financial Reporting Standards) as adopted by the European Union. They were approved by the Board of Directors on March 7, 2016.

The consolidated financial statements include:

- the balance sheet and statement of comprehensive income (including the income statement);
- the cash flow statement;
- the statement of changes in net position; and
- the notes to the financial statements.

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#### NOTE 1 • ACCOUNTING PRINCIPLES

### **Accounting basis**

The accounting principles used to prepare the consolidated financial statements comply with IFRS standards and interpretations as adopted by the European Union at December 31, 2015 and are available on the website

 $http:/\!/ec.europa.eu/internal\_market/accounting/ias\_en.htm\#adopted-commission.$ 

## NEW STANDARDS/AMENDMENTS APPLICABLE FOR FINANCIAL YEARS STARTING ON OR AFTER JANUARY 1, 2015 IN EUROPE

Standard/Interpretation	Date of application per IASB (periods beginning on or after)	Date of application in the European Union (periods beginning on or after)
IFRIC 21 - Levies	1/1/2014	6/17/2014
Annual improvements to IFRS (2011-2013)		
IFRS 3 Exclusion of partnerships from the application scope	7/1/2014	1/1/2015
IFRS 13 Scope of paragraph 52 ("portfolio" exception)	7/1/2014	1/1/2015
IAS 40 Clarification of the interrelationship between IFRS 3 and IAS 30 for the classification of a building as investment property or as owner-occupied property	7/1/2014	1/1/2015
Defined-benefit schemes: personnel contributions (IAS 19 amendments)	7/1/2014	2/1/2015
Annual improvements to IFRS (2010-2012)		
IFRS 2- Definition of vesting conditions	Application to plans whose grant date is subsequent to 7/1/2014	2/1/2015
IFRS 3- Recognition of a contingent consideration in a business combination	Application to business combinations subsequent to 7/1/2014	2/1/2015
IFRS 8 Aggregation of operating segments	7/1/2014	2/1/2015
IFRS 8 Reconciliation of the total of reported segment assets and the entity assets	7/1/2014	2/1/2015
IFRS 13 short-term receivables and payables	n/a	
IAS 16 Revaluation method - proportionate restatement of accumulated depreciation	7/1/2014	2/1/2015
IAS 24 Key management personnel	7/1/2014	2/1/2015
IAS 38 Revaluation method - proportionate restatement of accumulated depreciation	7/1/2014	2/1/2015

The impact of the application of these amendments is not significant.

Consolidated financial statements and notes

#### OTHER STANDARDS/AMENDMENTS ADOPTED BY THE IASB BUT NOT YET APPLICABLE AS OF DECEMBER 31, 2015

Standard/Interpretation	Date of application per IASB (periods beginning on or after)	Date of EU application (financial years starting on or after)
		Endorsement
Amendments to IFRS 11: Accounting for acquisition of interests in Joint Operations	1/1/2016	expected in Q4 2015
Amendments to IAS 16 and IAS 38: Clarification of acceptable methods of depreciation and amortization	1/1/2016	Endorsement expected in Q4 2015
IFRS 15 Revenue from contracts with customers	1/1/2018	Endorsement expected in Q2 2016
Amendments to IAS 16 and IAS 41 Agriculture: bearer plants	1/1/2016	Endorsement expected in Q4 2015
Amendments to IFRS 10 and IAS 28: Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	1/1/2016 Amendment expected	Suspended or pending draft IASB amendment
Annual improvements to IFRS (2012-2014)		Endorsement expected in Q4 2015
IFRS 5 Non-Current Assets Held for Sale and Discontinued Operations	Changes occurring in financial years beginning after 1/1/2016	
IFRS 7 Financial Instruments: Disclosures	1/1/2016	
IFRS 9 - Financial Instruments	1/1/2018	Endorsement expected in Q1 2016
IAS 19 Employee benefits	1/1/2016	
IAS 34 Interim Financial Reporting	1/1/2016	
Amendments to IAS 1: Disclosure initiative	1/1/2016	Endorsement expected in Q4 2015
Amendments to IAS 10, IFRS 12 and IAS 28: Investment Entities - Applying the Consolidation Exception	1/1/2016	Endorsement expected in Q1 2016

Transgene is currently analyzing the impacts and practical consequences of applying these new standards.

## Basis of preparation of financial statements

The consolidated financial statements have been prepared in accordance with the general principles of IFRS: fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality and business combinations. They have been prepared on a historical cost basis except for available-for-sale financial assets, which are measured at fair value.

Transgene's management made estimates and assumptions in preparing the financial statements in accordance with IFRS, particularly with respect to provisional estimates and deferred tax assets, that may have an impact on the assets and liabilities, and the reported amounts of income and expenses for the financial period. Actual results may be significantly different from these estimates.

In view of the Group's business, management considers that the fixed assets form part of a single cash-generating unit. At each balance sheet date, the Company assesses whether there is any indication that an asset may be impaired. In the presence of such a presumption, or when annual impairment testing is required for an asset, the Company makes an estimate of the

recoverable amount of the asset. The recoverable amount of an asset or a cash-generating unit is the higher of its fair value less costs of disposal and its value in use. The recoverable amount is determined on an individual basis unless the asset generates cash inflows that are largely dependent on other assets or groups of assets. An impairment is recognized when the asset's carrying amount is higher than its recoverable amount. Its carrying amount is then written down to its recoverable amount. The value in use corresponds to the estimated future cash flows, discounted at a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the asset.

#### **Basis of consolidation**

The consolidated financial statements include the financial statements of Transgene SA, Transgene, Inc. and Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd. ("Transgene Shanghai"), wholly owned subsidiaries whose headquarters are located respectively in Rockville, Maryland (USA) and Shanghai (China). These companies are fully consolidated.

Intragroup balances and transactions are eliminated in consolidation, together with intragroup profits included in the carrying amount of assets.

The following investee companies of Transgene SA are consolidated by the equity method:

Company	Percent ownership	Nature of control
Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.	50.00%	Joint control
		Significant
ElsaLys Biotech SAS	14.41%	influence

Transgene SA's significant influence over ElsaLys Biotech SAS as of December 31, 2015 was attributable to the continued role of Transgene as a member of ElsaLys's Board of Directors.

In 2015, Transgene's reduced its stake in Platine Pharma Service SAS to 0.04% as of December 31, 2015, and therefore no longer exercises significant influence over this company.

# Presentation of the consolidated income statement

The consolidated income statement is presented by function (research and development expenses and general and administrative expenses). The tables below break down these expenses by type.

#### RESEARCH AND DEVELOPMENT EXPENSES

(in millions of euros)	12/31/2015	12/31/2014	Change
Payroll costs <sup>(1)</sup>	14.6	16.1	-9%
Share-based payments <sup>(2)</sup>	0.3	0.5	-40%
Expenses for intellectual property and licensing costs(3)	1.5	1.3	+15%
External expenses for clinical projects <sup>(4)</sup>	4.2	7.6	-45%
External expenses for other projects <sup>(5)</sup>	4.4	7.6	-42%
Operating expenses <sup>(6)</sup>	5.1	6.7	-24%
Depreciation, amortization and provisions <sup>(7)</sup>	2.0	1.9	+5%
RESEARCH AND DEVELOPMENT EXPENSES	32.1	41.7	-23%

- (1) Represents salaries, wages and social security charges, retirement charges and other such costs.
- (2) Represents expense for share-based payments offered to employees.
- (3) Represents expenses for filing and maintaining patents as well as the costs of licenses acquired or granted.
- (4) Represents expenses for services, subcontractors and consulting on clinical development projects.
- (5) Represent expenses for services, subcontractors and consulting on other research or manufacturing projects.
- (6) Represents operating expenses of research and production laboratories (energy, consumables and raw materials, maintenance, technical services, overheads, etc.).
- (7) Represents the depreciation on the real estate and property allocated to R&D and to operating provisions.

#### GENERAL AND ADMINISTRATIVE EXPENSES

(in millions of euros)	12/31/2015	12/31/2014	Change
Payroll costs <sup>(1)</sup>	2.9	3.7	-22%
Share-based payments <sup>(2)</sup>	0.1	0.2	-50%
Professional and management fees <sup>(3)</sup>	1.7	2.5	-32%
Other general and administrative expenses <sup>(4)</sup>	1.0	1.1	-9%
Depreciation, amortization and provisions <sup>(5)</sup>	0.1	0.1	N/S
GENERAL AND ADMINISTRATIVE EXPENSES	5.8	7.6	-24%

- (1) Represents salaries, wages and social security charges, retirement charges and other such costs.
- (2) Represents expense for share-based payments offered to employees.
- (3) Represents expenses for services, subcontracting and consulting for general and administrative departments.
- (4) Represents operating expenses of general and administrative departments.
- (5) Represents depreciation and operating provisions allocated to general and administrative activities.

#### **Account conversions of foreign subsidiaries**

The currency used by the Company for the preparation of the consolidated financial statements is the euro.

The financial statements of Transgene Inc. are prepared in US dollars.

The financial statements of Transgene Shanghai are prepared in Yuan.

The balance sheets of Transgene Inc. and Transgene Shanghai have been converted into euros using the exchange rate at the balance sheet date and in the income statement using the exchange rate of the month of accounting. Differences arising from conversion are recognized in equity.

#### Foreign currency transactions

Foreign currency transactions are converted into euros at the average exchange rate for the month preceding the transaction.

At the balance sheet date, foreign currency cash and cash equivalents, receivables and payables are converted into euros at the exchange rate on the balance sheet date. The resulting translation differences are recognized in the income statement.

Transgene did not use any currency hedging instruments in 2015 and 2014.

#### **Current assets**

#### Cash and cash equivalents

Transgene's cash reserves are invested mainly in low volatility and highly liquid, highly rated mutual funds (net asset value known daily). They are classified in assets as cash equivalents and evaluated at fair value in the income statement if their sensitivity and volatility to changes in interest rates is less than 0.5 and 1.0 respectively. In all other cases, they are classified as available-for-sale financial assets and valued at their fair value under equity.

#### Receivables

Receivables are measured at nominal value. All receivables are exclusively short term.

#### Inventories

Inventories consisting mainly of chemicals and laboratory supplies are measured at the lower of cost and market. Cost is determined by the weighted average cost method.

#### Other current financial assets

These are cash investments with the Institut Mérieux, the principal shareholder of Transgene, under a "Group" cash management agreement. Contractually, investments made by the Company as part of the centralized cash management are liquid within a maximum period of four business days and bear interest based on a rate equal to Euribor +0.15% when Institut Mérieux is in a net borrowing position at the group level and to Euribor when Institut Mérieux is in a net surplus at the Group level.

#### Other current assets

Prepaid expenses and the other current assets are initially recognized at cost and are subsequently measured at the lower of cost and net realizable value.

# Assets available for sale and discontinued operations

IFRS 5 Non-current Assets Held for Sale and Discontinued Operations outlines how to account for non-current assets held for sale and the disclosures required for discontinued operations.

A non-current asset or group of assets and directly associated liabilities are considered to be held for sale when the carrying amount will largely be covered by a sale. In order for this to apply, the asset must be available for immediate sale and the sale must be highly probable. These available-for-sale assets or disposal groups are measured at the lower of their carrying amount and the estimated disposal price.

A discontinued operation represents a significant business line for the Group that either has been disposed of or is classified as held for sale. The income items related to these discontinued operations are presented on separate lines of the consolidated financial statements for all periods reported.

#### Non-current assets

#### Property, plant and equipment

Property, plant and equipment are measured at cost less accumulated depreciation and any accumulated impairment losses, in accordance with the benchmark treatment under IAS 16.

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Straight-line amortization is recognized based on the useful life of the asset by the Group, using the following periods:

Type of asset	Period of depreciation
Buildings	20 to 50 years
Fixtures and fittings	10 to 20 years
Machinery and equipment (machinery and laboratory equipment)	5 to 10 years
Office equipment and furniture	5 to 10 years
IT equipment	3 to 5 years

Intangible asset elements and their residual value are accounted for in the depreciation if the value thereof is deemed significant.

Property, plant and equipment are tested for impairment whenever there is an indication that their recoverable amount may be less than their carrying amount.

In accordance with IAS 17, assets held by finance leases are capitalized and amortized over the life of the asset. The corresponding amortization expense is recognized in the income statement under "Depreciation and amortization expenses".

#### Intangible assets

Straight-line amortization is recognized based on the useful life of the asset by the Group, using the following periods:

Type of intangible asset	Period of depreciation
Computer software and licenses	1 to 5 years
Patents acquired	5 years

#### Purchased intangible assets

Intangible assets consist of the acquisition costs of software and intellectual property licenses that are capitalized and amortized over their useful lives. The elements of intellectual property acquired are recognized as assets in accordance with IAS 38.

#### Internally developed intangible assets

Research expenses are expensed in the income statement in the period in which they are incurred.

Development costs incurred for the development of pharmaceutical products are capitalized when the requirements of IAS 38 are met. Given the nature of its products, the Company believes that the six criteria set out in IAS 38 Intangible assets are deemed to be met only at the time of the filing of an application for market authorization. The development expenses capitalized will be appropriately amortized over their useful life.

Patents and licenses acquired in connection with internal R&D projects are also recognized according to an identical principle. They are recognized as an expense during the research phase and are capitalized during the development phase when IAS 38 criteria are met.

#### Financial fixed assets

Financial assets consist of deposits and guarantees concerning leased assets or debt from a financial institution, equity securities, and cash advances made to certain subsidiaries. They are recorded at cost and depreciated, as needed, if their carrying value exceeds their recoverable amount as estimated by the Company.

The valuation of equity securities is based on an analysis using the discounted cash flow method (DCF). This valuation is periodically reviewed at each balance sheet date.

#### Investments in associates

Equity consolidated affiliates consist of the stakes held by Transgene SA in Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. and ElsaLys Biotech SAS (50% and 14.41%, respectively), which are accounted for using the equity method. These securities are recorded at cost less the share of losses attributable to Transgene SA.

The valuation of investments is based on an analysis using the discounted cash flow method (DCF). This valuation is periodically reviewed at each balance sheet date.

#### Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.

The value of Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. is currently, for the most part, related to its cash flow as well as a project in pre-clinical development. This value thus depends largely on the discounting assumptions adopted to value the products.

These estimates mainly concern the probability of technical and regulatory success ("PTRS") of the product and potential market. The market potential is regularly reviewed by the Company. The PTRS, which depends on the stage of development of the product, is calculated from reference publications in the field.

#### **ElsaLys Biotech SAS**

For the most part, the value of ElsaLys Biotech SAS is currently tied to the value of its programs, which are in pre-clinical stage, and the company's market value. Therefore this value depends on the discounted cash flow assumptions used to value the products, or the value of the company, based on recent capital transactions.

These assumptions mainly concern the probability of signing a license agreement for these products in the short or medium term, as well as agreement to the financial terms of such license agreements.

#### **Deferred taxes**

Transgene uses the balance sheet method for recognizing deferred taxes. Using this method, deferred taxes are calculated on the basis of the temporary differences between the tax values and the carrying amount of assets and liabilities presented in the balance sheet.

Deferred taxes are evaluated using the liability method, on the basis of the tax provisions and tax rates applied when these differences invert.

Deferred tax assets are recognized for all deductible temporary differences, as well as for unused tax loss carry-forwards, carryback credits and other tax credits when it is probable that sufficient taxable profit shall be available against which the unused tax losses or unused tax credits can be used. Their posting is limited to the amount of deferred tax liabilities.

Deferred tax liabilities are recognized for all taxable temporary differences.

The carrying amount of deferred tax assets is reviewed at each period end and reduced to the extent that it is no longer probable that a taxable profit will be available to allow the deferred tax asset to be used. To assess the likelihood that taxable income will be available, consideration was given to the history of the results of previous years, forecasts of future results, non-recurring items not likely to recur in the future and the entity's fiscal policy. As a result, assessing the probability that unused tax losses or tax credits can be used involves a degree of judgment on the part of management. If the Group's future taxable results were considerably different from those anticipated, the Company would be obliged to revise the carrying value of deferred tax assets upward or downward, which could have a significant effect on the Group's balance sheet and results.

Deferred taxes on items recognized directly in equity are also recorded in equity without affecting the income statement.

#### **Current liabilities**

#### Provisions for contingencies and charges

Provisions are made to cover liabilities and expenses related to the Group's operations.

#### **Provision for restructuring**

In accordance with IAS 37 Provisions, Contingent Liabilities and Contingent Assets, the criteria for recognition of provisions for restructuring are (i) the Company has an obligation to a third party on the balance sheet date, (ii) it is probable (more than probable) that a liability has been incurred, and that (iii) the liability can be reliably estimated.

To meet these criteria, the provision for restructuring is recognized when we estimate that the reorganization plan has been approved and announced to employees by senior management as of the balance sheet date, the measures to be implemented have been identified in detail (number of employees concerned, their job classification, position and location) and the financial compensation provided for. Moreover, the schedule for completion of the restructuring must be relatively short (under one year).

The provision for restructuring and the restructuring costs essentially comprise redundancy pay, the cost of failure to provide advance notice, training expenditure, and all other compensation related to support measures for the employees affected by the restructuring measures, including transfers within the Company.

#### Non-current liabilities

#### Share issue costs

Capital increase expenses net of deferred tax where applicable are charged directly against the issue premium, once the increase is completed.

#### Conditional advances

Conditional advances are only reimbursed if the research and development projects that they finance are successful. They are recognized under long-term financial debt in accordance with IAS 20.

#### **Employee** benefits

In accordance with the prevailing laws and practices in France, Transgene SA offers certain benefits to ensure eligible employees receive a lump sum payment at the time of retirement (severance retirement plan). The Group's obligation under these defined benefit plans may be funded by plan assets consisting of various instruments, in line with the relevant government regulations.

The rights acquired by active staff are estimated using actuarial valuations based on the probability of death and continued employment by the Company, as well as expected future salaries. Commitments are valued using the projected credit unit method.

In 2014, the Company also introduced an incentive program for its executive managers that provides for an additional bonus based on the Company's five-year share price performance.

The obligations are estimated according to the actuarial valuations, which include among other factors the volatility of the stock price and the probability that the Company will stay in business. The methodology applied is the standard valuation method absent the possibility of negotiation.

#### **Operating income**

#### Revenue from collaboration and licensing agreements

Transgene has entered into certain contracts for the provision of research or manufacturing services on a best-efforts basis. Transgene bills for its services at a contractually defined price, which is generally based on time spent, and billings are recorded in operating income as and when the services are performed.

Revenue from these contracts is recognized when the services are performed. In these cases, the services are recorded in operating income in the income statement after satisfactory quality control and customer acceptance.

Cash receipts corresponding to income not yet recognized in income in accordance with the principles outlined above are recorded in *Deferred income* on the balance sheet, until they meet the criteria for recognition in operating income.

Income from patent licenses generally consists of fees for access to technology paid and non-refundable on the signing of the agreement, and financing by milestone payments and other payments such as royalties on sales.

#### Right of option agreement

Transgene may be required to grant a right of option agreement. Income associated with the concession is recorded as *Deferred income* on the balance sheet and recognized as income on a straight-line basis until the estimated date of exercise of the option by the beneficiary. The expected date of exercise of the option is reviewed periodically.

## Non-refundable fees for technology usage rights paid when the license is signed

In the event that Transgene is not committed to perform work for the development of technology after signature, these rights are recognized in operating income upon the fulfillment of the contractual obligations.

In the event that Transgene continues some technology development work after signature or Transgene has a higher obligation to deliver the product, these rights are recognized in operating income to be deferred over the period of development or delivery of the product.

#### Milestone payments

Milestone payments under collaborative agreements are recognized as revenue upon achievement of the incentive milestone events and when Transgene has no future performance obligations related to the payment. Operative events are usually the scientific or clinical results obtained by Transgene, the commencement of studies or external factors such as regulatory approvals.

#### Royalties on sales

Royalties on sales are based on sales by licensees of products or technologies. They are recognized on the basis of the license terms, when the sales can be reliably measured and recovery of the related receivables is reasonably assured.

#### Government financing for research expenditure

#### Research tax credit (CIR)

Certain research and development expenses in France are entitled to a research tax credit recognized at the end of the year in which the expense was recorded and the tax credit claimed. If it has not been used by allocation to a tax charge,

the tax credit may be redeemed in accordance with the tax provisions.

Research tax credits are recognized in the income statement under "Government grants" in accordance with IAS 20.

#### Research and development grants

Transgene receives government subsidies from local, national or regional bodies that cover all or part of the research and development done on specific projects or topics. This assistance can take the form of subsidies or reimbursable advances.

In that case, the Company recognizes on the income statement at the line "Public financing of research expenses" the portion of subsidies due under the agreements based on the percentage of expenses incurred as of the reporting date.

Reimbursable advances (received or due) are not recognized on the income statement. They are recognized on the liabilities side of the balance sheet at the time they are received.

#### Research and development expenses

Research expenses are expensed in the income statement in the period in which they are incurred.

Development costs will be capitalized only when the requirements of IAS 38 are met.

#### **Share-based payments**

Transgene distributes options to its officers and employees to subscribe to shares and bonus shares. The corresponding expense for these distributions is evaluated and spread over time, according to the principles of IFRS 2.

#### Basic loss per share

Earnings per share are calculated on the basis of the weighted average number of shares outstanding during the period.

# Contribution to Value Added Enterprises (CVAE)

The CVAE is recorded, if any, in operating expenses under *Overhead expenses*.

# Tax credit for Competitiveness and Employment (CICE)

The CICE, if any, is recognized as a decrease under *Employee* benefits expenses.

## NOTE 2 CASH, CASH EQUIVALENTS AND OTHER CURRENT FINANCIAL ASSETS

(in € thousands)	12/31/2015	12/31/2014
Cash	747	638
Marketable securities	2,538	2,875
Cash and cash equivalents	3,285	3,513
Other current financial assets	28,365	62,422
TOTAL	31,650	65,935
Impact of applying the fair value recognized in financial income to the income statement	-	0.5

Marketable securities consists of shares of short-term mutual funds.

Other current financial assets consists of investments made through a cash pool set up by the Institut Mérieux group.

#### NOTE 3 OTHER CURRENT ASSETS

(in € thousands)	12/31/2015	12/31/2014
Research tax credit, current portion	8,288	7,555
State - recoverable VAT and tax receivables	386	879
Accrued credit notes	32	115
Employee benefits expense	33	44
Accrued subsidies	1,004	941
Prepaid expenses, current portion	513	1,080
Receivables from the sale of participating interests, current portion	2,674	-
TOTAL	12,930	10,614

The current portion of research tax credits represents the amount receivable for 2012 that is expected to be paid by the State in the first half of 2016 (see Note 7). The receivable from the sale of equity interests is the current portion of the earn-out due on the sale of our interest in Jennerex Inc. (see Note 8)

#### NOTE 4 ASSETS AVAILABLE FOR SALE AND DISCONTINUED OPERATIONS

As part of the Company's restructuring, which was presented to the Works Council at the end of June 2015, Transgene is refocusing on its core expertise and disposing of the production business line located at Illkirch-Graffenstaden. This production site will be sold to a third party, which will continue to produce clinical batches of products for Transgene's needs.

As of December 31, 2015, assets held for sale are measured at the estimated market value of the Illkirch site property, plant and equipment and intangible assets in the amount of €3.5 million. (see Notes 1.4, 5 and 6)

As of December 31, 2015, the share of income attributable to discontinued operations is as follows:

(in € thousands)	12/31/2015	12/31/2014	Change
Revenue from collaborative and licensing agreements	511	653	-22%
Payroll costs	2,740	3,684	-26%
External costs on other projects	-	2	-100%
Operating costs	2,809	3,441	-18%
Depreciation expense			
for property, plant and equipment	451	888	-49%
for intangible assets	33	78	-58%
Research and development expenses	6,033	8,093	-25%
Allowance for impairment of assets held for sale	2,943	-	
NET INCOME FROM DISCONTINUED OPERATIONS	(8,465)	(7,440)	14%

The share of the research tax credit attributable to these discontinued operations has not been included in this net income figure. It is estimated at approximately 0.7 million in fiscal 2015.

## NOTE 5 PROPERTY, PLANT AND EQUIPMENT

(in € thousands)	12/31/2014	Increase	Decrease	Reclassification	12/31/2015
ACQUISITION COSTS					
Buildings under finance leases	19,653	-	-	-	19,653
Land, buildings and fixtures	8,075	90	-	(7,294)	871
Laboratory equipment	17,605	999	(244)	(8,607)	9,753
Vehicles, office and computer equipment	2,244	23	(124)	(487)	1,656
Assets in progress	638	1,207	(880)	-	965
Total	48,215	2,319	(1,248)	(16,388)	32,898
DEPRECIATION AND PROVISIONS					
Buildings under finance leases	(8,739)	(915)	-	461	(9,193)
Land, buildings and fixtures	(3,196)	(180)	-	3,302	(74)
Laboratory equipment	(11,103)	(1,002)	235	6,022	(5,848)
Vehicles, office and computer equipment	(1,536)	(176)	120	368	(1,224)
Total	(24,574)	(2,273)	355	10,153	(16,339)
NET TOTAL	23,641	46	(893)	(6,235)	16,559

Net property, plant and equipment reclassified to Assets held for sale amounted to €6,235 thousand. (See Note 4)

(in € thousands)	12/31/2013	Increase	Decrease	12/31/2014
ACQUISITION COSTS				
Buildings under finance leases	19,653	-	-	19,653
Land, buildings and fixtures	7,346	779	(50)	8,075
Laboratory equipment	16,294	1,425	(114)	17,605
Vehicles, office and computer equipment	2,168	119	(43)	2,244
Assets in progress	652	1,151	(1,165)	638
Total	46,113	3,474	(1,372)	48,215
DEPRECIATION AND PROVISIONS				
Buildings under finance leases	(7,671)	(1,068)	-	(8,739)
Land, buildings and fixtures	(2,917)	(322)	43	3,196
Laboratory equipment	(10,168)	(1,045)	110	(11,103)
Vehicles, office and computer equipment	(1,369)	(205)	38	(1,536)
Total	(22,125)	(2,640)	191	(24,574)
NET TOTAL	23,988	834	(1,181)	23,641

The depreciation expense for the property, plant and equipment reported in Transgene's income statement is as follows:

(in € thousands)	12/31/2015	12/31/2014
Research and development expenses	2,215	2,582
General and administrative expenses	58	58
TOTAL DEPRECIATION EXPENSES FOR PROPERTY, PLANT AND EQUIPMENT	(2,273)	(2,640)

Disbursements for acquisitions of property, plant and equipment totaled €1,437 thousand in 2015 (€2,295 thousand in 2014).

#### NOTE 6 INTANGIBLE ASSETS

(in € thousands)	12/31/2014	Increase	Decrease	Reclassification	12/31/2015
ACQUISITION COSTS					
Intangible assets	4,089	159	-	(440)	3,808
Intangible assets in progress	161	55	214	-	2
Total	4,250	214	214	(440)	3,810
DEPRECIATION AND PROVISIONS					
Intangible assets	(3,194)	(363)	-	232	(3,325)
Total	(3,194)	(363)	-	232	(3,325)
NET TOTAL	1,056	(149)	214	(208)	485

Net intangible fixed assets reclassified to Assets held for sale amounted to €208 thousand. (See Note 4)

(in € thousands)	12/31/2013	Increase	Decrease	12/31/2014
ACQUISITION COSTS				
Intangible assets	3,945	144	-	4,089
Intangible assets in progress	166	175	(180)	161
Total	4,111	319	(180)	4,250
Amortization of intangible assets	(2,782)	(412)	-	(3,194)
Total	(2,782)	(412)	-	(3,194)
NET TOTAL	1,329	(93)	(180)	1,056

The depreciation expense for the intangible assets reported in Transgene's income statement is as follows:

(in € thousands)	12/31/2015	12/31/2014
Research and development expenses	332	387
General and administrative expenses	31	25
TOTAL AMORTIZATION AND DEPRECIATION OF INTANGIBLE ASSETS	(363)	412

No cash outflows related to the acquisition of intangible assets were booked in 2015 (€139 thousand in 2014).

#### NOTE 7 FINANCIAL ASSETS

#### **○** NON-CURRENT FINANCIAL ASSETS

(in € thousands)	12/31/2014	Increase	Decrease	12/31/2015
ACQUISITION COSTS				
Non-current financial assets	3,947	1,193	(795)	4,345
Participating interests	29	294	-	323
Total cost	3,976	1,487	(795)	4,668
Provisions for impairment	(124)	(494)	-	(618)
Total	(124)	(494)	-	(618)
NET TOTAL	3,852	993	(795)	4,050

The increase of €1,193 thousand in non-current financial assets in 2015 mainly represents €886 thousand of holdback on the financing in the first half of 2015 of the 2014 research tax credit, as well as a conversion granted to ElsaLys Biotech SAS of a note receivable into a non-interest bearing current account, in the amount of €258 thousand.

The decrease of €795 thousand in non-current financial assets relates to refunding the holdback in connection with the financing of the 2011 research tax credit paid by the French government in 2015.

The €294 thousand increase in equity securities relates to the deconsolidation of Platine Pharma Services SAS. The securities and a portion of the shareholder loans granted to this company have been impaired in full.

#### **○** INVESTMENTS IN ASSOCIATES

The table below shows the gross amounts (acquisition cost), provisions for impairment, and income for the above equity affiliates:

(in € thousands)	12/31/2014	Increase	Decrease	12/31/2015
ACQUISITION COSTS				
Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.	3,976	-	-	3,976
ElsaLys Biotech SAS	501	-	-	501
Total (at historical cost)	4,477	-		4,477
Share of profit (loss) of Transgene Tasly (Tianjin) BioPharmaceuticals Co. Ltd.	(1,656)	(1,172)	-	(2,828)
Share of profit (loss) of ElsaLys Biotech SAS	(501)	-	-	(501)
Total impairment and share of profit (loss) attributable to Transgene	(2,157)	(1,172)		(3,329)
Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.	2,320	-	-	1,148
ElsaLys Biotech SAS	-	-	-	-
NET VALUE OF EQUITY INVESTMENTS IN AFFILIATES	2,320	(1,172)	-	1,148

#### Transgene Tasly (Tianjin) BioPharmaceutical Co Ltd.

At December 31, 2015, Transgene held 50% of Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. and the net valuation of its interest stood at €1,148 thousand.

This valuation was reviewed as of the December 31, 2015 balance sheet date. This review is based on an analysis using the discounted cash flow (DCF) method described in Note 1.7.4.

The discounted cash flow of Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. is calculated from the weighted average cost of capital (WACC), which is in turn based on a so-called market-comparable approach. A 1 percentage point increase in the WACC would have a negative impact of about 15% on the valuation of Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. A change amounting to a 5%

decrease in the PTRS used for the two most advanced products would have a negative impact of about 50% on the valuation of Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.

At December 31, 2015, the Company considered that the balance sheet value for its interest in Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. reflected its fair value and reasonably possible changes in key assumptions would not lead to a fair value lower than the balance sheet value.

#### **ElsaLys Biotech SAS**

At December 31, 2015, Transgene held 14.41% of ElsaLys Biotech SAS and the net valuation of its interest was zero. The Company also held a shareholder current account of €977 thousand and receivables of €78 thousand. These receivables are fully recoverable.

#### NOTE 8 OTHER NON-CURRENT ASSETS

(in € thousands)	12/31/2015	12/31/2014
Research tax credit, non-current portion	25,546	25,924
CICE, non-current portion	767	485
Prepaid expenses, non-current portion	26	59
Receivables from the sale of participating interests, non-current portion	1,260	4,378
OTHER NON-CURRENT ASSETS	27,599	30,846

#### Research tax credits and CICE

At December 31, 2015, the Company had a receivable of €33,834 thousand (the non-current portion of which was €25,546 thousand) for the research tax credits for 2012, 2013, 2014 and 2015 and a receivable of €767 thousand on the CICE

for 2013, 2014 and 2015. These receivables can be used to offset income tax payments. In the event of non-use, a refund in cash can be requested according to the following schedule, in accordance with the tax rules in force (in thousands of euros).

Reference Year	Year of expected reimbursement	12/31/2015	12/31/2014
CURRENT PORTION			
2011	2015	-	7,894
Tax adjustment	2015	-	(339)
2012	2016	8,289	-
Total current portion		8,289	7,555
NON-CURRENT PORTION			
2012	2016	-	8,289
2013	2017	8,852	8,852
2014	2018	8,943	8,783
2015	2019	7,751	-
Total non-current portion		25,546	25,924
TOTAL CIR		33,835	33,479
NON-CURRENT PORTION			
2013	2017	210	210
2014	2018	275	275
2015	2019	282	-
Total non-current portion		767	485
TOTAL CICE		767	485

# Receivables from the sale of participating interests

The receivable from the sale of participating interests of €3,934 thousand represents the estimated net present value of the balance of the price that Transgene expects to receive on the sale of its interest in Jennerex, Inc. the payment of which is spread over time and subject to certain conditions. This receivable is distributed between other current assets for the portion expected in under one year, *i.e.* €2,674 thousand (see Note 3), and other non-current assets for the portion due in over one year, or €1,260 thousand. This receivable was

valued using the best possible estimate of the dates on which payment milestones would be achieved. Such dates could extend to 2020. These future cash flows have been discounted and their probability calculated. The discounted cash flow rate is calculated on the basis of the weighted average cost of capital (WACC), which is itself based on a so-called market-comparable approach. A 1 percentage point increase in the WACC would have a negative impact of about 1% on the value of the receivable. A 10% decrease in the probability used for the occurrence of future payments would have a negative impact of approximately 12% on the value of the receivable.

#### NOTE 9 FINANCIAL LIABILITIES

The following table breaks down financial liabilities by maturity:

(in € thousands)	12/31/2015	12/31/2014
Financial liabilities, current portion	9,396	8,992
Financial liabilities, non-current portion	44,401	43,199
FINANCIAL LIABILITIES	53,797	52,191

As of December 31, 2015, the main financial liabilities related to financing the research tax credits for 2012, 2013 and 2014 and the competitiveness and employment tax (CICE) for 2013, 2014 and 2015, the property financial lease (headquarters and main research and development laboratories) and conditional Bpifrance advances under the ADNA subsidized program.

#### FINANCIAL LIABILITIES, CURRENT PORTION

(in € thousands)	12/31/2015	12/31/2014
Property leasing	979	942
Equipment leasing	174	156
Financing of research tax credit in 2012	8,243	7,894
FINANCIAL LIABILITIES - CURRENT PORTION	9,396	8,992

#### FINANCIAL LIABILITIES, NON-CURRENT PORTION

(in € thousands)	12/31/2015	12/31/2014
Property leasing	8,280	9,259
Equipment leasing	216	332
Interest rate swaps - fair value (see Note 21)	544	659
Conditional advances	16,844	15,324
Funding of research tax credit for 2013 and 2014	17,712	17,095
Financing of 2013, 2014 and 2015 CICE	805	530
FINANCIAL LIABILITIES - NON-CURRENT PORTION	44,401	43,199

#### **Property leasing**

In December 2008, Transgene invested in a new building housing labs and offices on the Illkirch site, in the suburbs of Strasbourg. Land and construction costs for the 6,900 sq. m

building totaled €15.6 million. This investment was financed by a 15-year finance lease, signed with a banking consortium in October 2007, with a residual value of €1.1 million. The first lease payment was made on January 1, 2009.

The balance of the principal amount at December 31, 2015 was €9,259 thousand, compared to €10,200 thousand at December 31, 2014. The following table shows the breakdown of this debt, based on the maturity, financial costs and present value of individual payments:

	12/31/2015		12/31/2	2014
	Minimum payments	Present value of the payments	Minimum payments	Present value of the payments
Due within one year	1,085	1,065	1,056	1,037
Due in one to five years	4,646	4,349	4,520	4,233
Total future minimum lease payments	9,761	8,910	10,817	9,789
Finance costs included in the total	502	471	617	575
Outstanding principal:	9,259	8,439	10,200	9,214
of which current	979	961	941	924
of which non-current	8,280	7,478	9,259	8,290

#### **Equipment leasing**

Transgene acquired equipment under a financial lease in 2013, in 2014 and in 2015.

#### Conditional advances

At December 31, 2015, conditional advances referred mainly to repayable advances received under the ADNA ("Advanced Diagnostics for New Therapeutic Approaches") program, which receives public funding from Bpifrance, for €16,664 thousand.

This amount represents the €13,351 thousand in advances received since the start of the program in 2007, plus €923 thousand in 2015, as well as the cumulative interest on this financing of €2,390 thousand. These advances are reimbursable provided our product TG4010 reaches a revenue threshold and in proportion to this revenue until a reimbursement ceiling is reached,

The Company may receive up to  $\[ \]$ 1.7 million in additional repayable advances over the remaining term of the ADNA program, *i.e.* until 2017.

#### Funding of the research tax credit

The table below breaks down the components of the bank financing of receivables for the Company's research tax credit (CIR):

					ASSETS			LIABILI	TIES
				eceivables her assets	Security deposit	Prepaid interest	TOTAL		Financing I liabilities
	Gross Amount	Bank Financing	Current portion	Non- current portion	Non-current financial assets	Current portion	Assets	Current portion	Non- current portion
CIR 2012	8,289	Yes	8,289	-	825	-	9,114	8,243	-
CIR 2013	8,852	Yes	-	8,852	885	-	9,737	-	8,852
CIR 2014	8,942	Yes	-	8,942	886	-	9,828	-	8,861
CIR 2015	7,751	No	-	7,751	-	-	7,751	-	-
TOTAL CIR	33,834	-	8,289	25,545	2,596	-	36,430	8,243	17,713
CICE 2013	210	Yes	-	210	10	-	220	-	210
CICE 2014	275	Yes	-	275	48	-	323	-	320
CICE 2015	282	Yes	-	282	41	-	323	-	275
Total CICE	767	-	-	767	99	-	866	-	805

#### NOTE 10 OTHER LIABILITIES

#### OTHER CURRENT LIABILITIES

(in € thousands)	12/31/2015	12/31/2014
Tax and social liabilities	3,110	3,951
Prepaid income	571	111
Of which:		
production revenue	555	21
• subsidies	16	81
• other	-	9
Other short-term payables	89	86
TOTAL	3,770	4,148

#### 

In accordance with French law, Transgene SA participates in the funding of pensions for employees in France through the payment of contributions calculated on the basis of wages to bodies that manage retirement programs. For certain of its

employees in France, Transgene also makes contributions, again based on wages, to private supplementary pension entities. There are no other obligations related to these contributions.

#### Provisions for retirement benefit obligations

Transgene is also liable for statutory length-of-service awards payable to employees in France upon retirement. The compensation benefits are due only to employees on the Company's payroll at the time of retirement. The assumptions used to calculate these provisions for retirement are as follows:

	12/31/2015	12/31/2014
Discount rate	2.35%	2.25%
Rate of future salary increases	1.50%	2.00%
Retirement age:		
• managers	65	65
non-managers	63	63

The following table summarizes the conditions and amounts of actuarial pension obligations at December 31, 2015 and 2014 according to IAS 19 revised:

(in € thousands)	12/31/2015	12/31/2014
CHANGE IN THE VALUE OF COMMITMENTS		
Projected benefit obligation at January 1	4,176	4,344
Cost of services rendered for the year	316	332
Cost of discounting	94	124
Change in assumptions	(308)	(338)
Reductions/terminations	(994)	(133)
Actuarial (gain)/loss	(57)	(121)
Benefits paid during the year	(31)	(32)
Projected benefit obligation for retirement	3,196	4,176
DEFINED BENEFIT COST FOR THE YEAR		
Cost of services rendered for the year	316	332
Cost of discounting	94	124
Reductions/terminations	(994)	(133)
Cost of services and discounting	(584)	323
REVALUATIONS OF NET LIABILITIES/(ASSETS)		
Actuarial losses (gains) related to changes in demographic assumptions	4	(468)
Actuarial losses (gains) related to changes in financial assumptions	(312)	130
Actuarial losses (gains) related to experience	(57)	(121)
Total	(365)	(459)
CHANGE IN NET LIABILITIES/(ASSETS)		
Liability/(asset) at beginning of year	4,175	4,344
Amount recognized in the income statement	(584)	323
Disbursements	(31)	(32)
Amount recognized in other comprehensive income	(365)	(459)
Liability/(asset) at end of year	3,195	4,176
ACCUMULATED AMOUNTS RECOGNIZED IN OTHER COMPREHENSIVE INCOME		
Accumulated amounts recognized at beginning of year	193	652
Revaluations of net liabilities/(assets) for the year	(365)	(459)
Accumulated amounts recognized at end of year	(173)	193
Deferred taxes	60	(66)
Net cumulative amounts recognized as income at end of year	(113)	126

A sensitivity test of the discount rate quantified the impact on the value of the obligation and the cost of services:

- a discount rate of 2.10% would cause an increase in the obligation of 3.0% and in the cost of services of 3.3% for the year;
- a discount rate of 2.60% would cause a decrease in the obligation of 2.9% and in the cost of services of 3.2% for the year.

# Incentive program linked to the increase in the Company's valuation

In 2014 Transgene introduced an incentive program linked to an increase in the Company's valuation. an additional bonus based on the Company's five-year share price performance. The Company estimates that its financial commitment to this program is no longer material as of December 31, 2015 and the  $\ensuremath{\in} 75$  thousand recognized as of December 31, 2014 was reversed in full during 2015.

## NOTE 12 • EQUITY

#### **Share capital**

38,545,397 Transgene shares were in issue as of December 31, 2015, amounting to share capital of €88,195,793.51.

Shareholders have preferential subscription rights during capital increases in proportion to their existing interests. This right may be waived in certain circumstances by a resolution voted in an Extraordinary General Meeting. preferential subscription rights that have not been waived are negotiable during the subscription period.

In 2015 the following capital increase was made:

 issuance of 17,429 new shares on the exercise of stock options and the issuance of new corresponding shares at a weighted average price per share of €6.38.

#### **Earnings per share**

The following table reconciles basic and diluted earnings per share. The number of shares is calculated on a prorated basis.

	12/31/2015	12/31/2014
BASIC EARNINGS PER SHARE		
Available net profit attributable to equity holders of the Group (in € thousands)	(46,374)	(48,556)
Average number of shares outstanding	38,545,397	38,527,968
Basic earnings per share (in €)	(1.20)	(1.26)
Diluted earnings per share (in €)	(1.20)	(1.26)

At December 31, 2015 and 2014, instruments granting rights to deferred capital (stock options and free shares) were considered anti-dilutive since they resulted in an increase in

earnings per share from continuing operations. As a result, the diluted earnings per share in 2015 and 2014 were the same as basic earnings per share for the year concerned.

## **Stock option plans**

#### SUMMARY TABLE OF STOCK OPTION PLANS

	Plan no. 3	Plan no. 4	Plan no. 5	Plan no. 6
Shareholders' Meeting date	6/9/2004	6/9/2006	6/9/2008	6/17/2010
Board of Directors meeting date	2/9/2005	12/6/2006	12/16/2008	12/7/2010
	5/18/2005	10/4/2007	12/9/2009	12/13/2012
	1/1/2006	12/19/2007	12/7/2010	
	12/6/2006	12/16/2008		
Total number of shares to be subscribed or purchased	300,000	450,000	250,000	400,000
Starting point for exercise of options	2009	2010	2012	2015
	2010	2011	2013	2017
		2012	2015	
Expiration date	2015	2016	2018	2020
	2016	2017	2019	2022
		2018	2020	
Subscription price (EUR) (equal to the average of the	6.38	11.78	11.097	14.31
market price of the 20 trading days prior to the grant	7.12	16.23	17.26	7.92
date, excluding discount) adjusted following the capital increase with subscription rights in 2010, in accordance	7.38	15.14	14.31	
with the French Commercial Code.	11.78	11.09		

#### OPTIONS OUTSTANDING AND EXERCISABLE OPTIONS AT DECEMBER 31, 2015

	Number of shares
Options outstanding at December 31, 2014	1,188,097
Options exercisable at end of period	886,231
Options awarded in 2015	-
Options exercised in 2015	17,429
Canceled or expired options in 2015	169,842
Options outstanding at December 31, 2015	1,000,826
Options exercisable at end of period	949,576

#### Expense calculated for share-based payments:

The cost of services rendered is recognized as an expense over the vesting period. The expense amounted to  $\leq$ 392 thousand in 2015, down from  $\leq$ 421 thousand in 2014.

## Free share plans

#### **SUMMARY TABLE OF SHARE PLANS**

	Plan no. 1	Plan no. 2
Shareholders' Meeting date	6/9/2008	6/17/2010
Total number of shares to be subscribed or purchased	100,000	120,000
Board of Directors meeting date	12/16/2008	12/7/2010
	12/9/2009	12/13/2012
	12/7/2010	
Total number of bonus shares allocated	73,800	74,900
	11,100	44,320
	15,100	
Date of final allocation and expiration date (as both periods are taken into account)	12/15/2012	12/6/2014
	12/8/2013	12/12/2016
	12/6/2014	
Share value on the date of allocation (opening price on the date of allocation)	€12.10	€14.37
	€19.67	€8.367
	€14.37	

#### • FREE SHARES AWARDED AND ACQUIRED AT DECEMBER 31, 2015

	Number of shares
Free shares awarded at December 31, 2014	42,590
Free shares cancelled in 2015	1,460
Free shares awarded in 2015	-
Free shares vested to the beneficiaries in 2015	-
Free shares awarded at December 31, 2015	41,130

#### Expense calculated for share-based payments:

The cost of services rendered is recognized as an expense over the vesting period. The expense amounted to €70 thousand in 2015 and €300 thousand in 2014.

#### NOTE 13 OPERATING INCOME

#### ▶ REVENUE FROM COLLABORATIVE AND LICENSING AGREEMENTS

(in € thousands)	12/31/2015	12/31/2014
Revenue from research and development collaboration	798	1,015
License fees and royalties	667	822
TOTAL REVENUE FOR CONTINUED OPERATIONS	1,465	1,837

Revenue from research and development collaboration for third parties mainly concerned Emergent Biosolutions, Inc. for a candidate drug to treat tuberculosis.

Revenue from license fees comprises revenue from commercial use of technologies or products provided under license by Transgene SA, which amounted to  $\leqslant$ 667 thousand in 2015 ( $\leqslant$ 566 thousand in 2014).

#### GOVERNMENT FINANCING FOR RESEARCH EXPENDITURE

(in € thousands)	12/31/2015	12/31/2014
Research and development grants	245	551
Research tax credit	7,855	8,711
TOTAL	8,100	9,262

At December 31, 2015 the research and development subsidies came principally from the ADNA program ("Advanced Diagnostics for New Therapeutic Approaches") financed by

Bpifrance (€6 thousand in 2015 vs. €181 thousand in 2014). Transgene could receive up to €0.8 million in additional subsidies over the remainder of the program, *i.e.*, until 2017.

#### NOTE 14 OTHER OPERATING INCOME AND EXPENSES

(in € thousands)	12/31/2015	12/31/2014
Investment subsidies	-	11
Income from sale of fixed assets	-	2,705
Other income	384	4,266
Total income	384	6,982
Net carrying value of disposals of fixed assets	(11)	(7,758)
Restructuring costs	(7,536)	-
Other expenses	(272)	(506)
Total expenses	(7,819)	(8,264)
TOTAL	(7,436)	(1,282)

As of December 31, 2015, Other income and expenses from operations related in the main to  $\ref{7,536}$  thousand in restructuring costs.

At December 31, 2014 "Other income and expenses from operations" referred largely to the sales of the Jennerex, Inc.

shares to SillaJen, Inc.  $\$ 7,045 thousand of net carrying amount of "Non-current asset disposals",  $\$ 2,700 thousand of "Income from non-current asset disposals" (of which  $\$ 2,332 thousand was received in 2014) and  $\$ 4,117 thousand of "Other income", representing the estimated earn out on the sale of the shares (see Note 7).

## NOTE 15 FINANCIAL INCOME (EXPENSE)

(in € thousands)	12/31/2015	12/31/2014
Investment income	213	420
Debt servicing costs	(554)	(671)
Net interest income	(341)	(251)
Other financial income and expenses	(761)	(792)
Foreign exchange gains (losses)	172	242
Total	(589)	(550)
FINANCIAL INCOME/(EXPENSE), NET	(930)	(801)

#### NOTE 16 INCOME TAX EXPENSE

#### **Current taxes**

Since the Company is in a tax loss position, its current tax charge is zero. The US and Chinese subsidiaries did not recognize any current tax income or expense in 2015 or 2014.

#### **Deferred taxes**

Net deferred tax assets were zero at December 31, 2015 due to non-recognition of deferred tax assets related to the uncertainty of taxable profits in the foreseeable future.

The difference between the standard corporate income tax rate in France and the Company's effective tax rate can be explained as follows:

	12/31/2015	12/31/2014
Standard income tax rate in France	34.43%	34.43%
Unrecognized deferred tax assets	-37.30%	-40.73%
Other	3.60%	6.8%
Effective tax rate	0%	0%
Income (loss) before tax	(46,374)	(48,556)
Income tax expense	-	-

At December 31, 2015, Transgene had tax loss carry-forwards in France, which can be carried forward indefinitely, totaling €597,886 thousand. Transgene has no tax loss carryforwards from its US and Chinese subsidiaries.

Transgene's deferred tax assets broke down as follows:

(in € thousands)	12/31/2015	12/312014
Tax loss carry-forwards	597,886	547,390
Capitalized licensing costs not yet deducted	17	19
Provision for restructuring	2,923	-
Provisions for pensions and other post-employment benefits	2,964	3,268
Provisions for contingencies and charges	194	32
Share of profit (loss) of associates	795	2,452
Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd. and Platine	883	724
Contribution in kind to Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.	1,234	1,234
Other	-	181
Total basis of deferred tax assets	606,896	555,300
Tax rate	34.43%	34.43%
Deferred tax assets	208,954	191,190
Unrecognized deferred tax assets	(208,608)	(190,872)
DEFERRED TAX ASSETS	346	318

Transgene's deferred tax liabilities broke down as follows:

(in € thousands)	12/31/2015	12/31/2014
Finance leases	1,004	925
Other	-	<u>-</u>
Total tax base	1,004	925
Tax rate	34.43%	34.43%
DEFERRED TAX LIABILITIES	346	318

#### NOTE 17 PERSONNEL

#### **Personnel**

The Company's registered workforce totaled 266 employees at December 31, 2015, including 6 with Transgene Inc. and 4 with Transgene Shanghai. The Company had 296 employees at December 31, 2014.

As of December 31, 2015	Men	Women	Total at 12/31/2015	Including reclassified personnel or internal transfers
Managers	67	94	161	51
Other grades	22	83	105	62
TOTAL	89	177	266*	113

<sup>\*</sup> Including 258 open-ended contracts at December 31, 2015.

The Company's workforce as of December 31, 2015 included 113 employees in the process of reclassification or transfer within the Mérieux group, under the redundancy plan approved by DIRECCTTE in November 2015.

The Company had a total workforce of 153 people at year-end 2015, excluding those being reclassified or transferred.

### **Payroll costs**

Employee benefits expenses included in the Company's income statement (payroll taxes, pension costs, ancillary costs) were as follows:

(in € thousands)	12/31/2015	12/31/2014
Research and development expenses	17,252	19,831
General and administrative expenses	2,796	3,752
TOTAL EMPLOYEE BENEFITS EXPENSES	20,048	23,583
Expenses relating to share-based payments amounted to:  (in € thousands)	12/31/2015	12/31/2014
Research and development expenses	309	542
General and administrative expenses	152	179
TOTAL EMPLOYEE BENEFITS EXPENSES	461	721

#### NOTE 18 • AFFILIATED COMPANIES

Transgene signed a cash pooling agreement with Institut Mérieux and the Cash and cash equivalents placed in the Institut Mérieux cash pooling represented a receivable of €28,365 thousand at December 31, 2015, and the resulting interest income was €196 thousand at December 31, 2015.

The table below does not include these cash items.

	12/31/2015	
(in € thousands)	Receivables	Payables
Institut Mérieux	-	8
Thera Conseil	-	-
Platine Pharma Services SAS	200	-
Transgene Tasly BioPharmaceutical Co. Ltd.	37	-
BioMérieux SA	-	5
BioMérieux Shanghai	-	27
BioMérieux, Inc.	-	192
Advance Bioscience Laboratories, Inc.	-	-
ElsaLys Biotech SAS	1,055	-
Mérieux Development	18	-
Mérieux Université	-	-
TOTAL	1,310	232

	12/31/2	2015
(in € thousands)	Revenue	Expenses
BioMérieux SA <sup>(1)</sup>	-	68
Thera Conseil	-	4
BioMérieux Shanghai	-	183
Institut Mérieux <sup>(2)</sup>	-	681
BioMérieux, Inc. <sup>(3)</sup>	3	946
Advance Bioscience Laboratories, Inc.	-	1,094
Platine Pharma Services SAS	-	316
Transgene Tasly BioPharmaceutical Co. Ltd. (4)	137	-
ElsaLys Biotech SAS <sup>(5)</sup>	65	26
Mérieux Development	18	-
Mérieux Université	-	12
TOTAL	224	3,330

- (1) Expenses related to purchases of laboratory equipment and supplies.
- (2) Expenses relate to the agreement for services provided by Institut Mérieux.
- (3) Costs correspond to the agreement for services, re-invoicing of staff and rent between Transgene, Inc. and BioMérieux, Inc.
- (4) Revenue corresponds to the agreement for services and re-invoicing of staff concluded between Transgene SA and Transgene Tasly BioPharmaceutical Co. Ltd.
- (5) Revenue represents the agreement for services rendered by Transgene SA and to the contract for billing back lease payments. Costs correspond to an agent agreement between ElsaLys Biotech and Transgene SA.

#### NOTE 19 OFF-BALANCE SHEET COMMITMENTS

On April 1, 2009, Transgene signed an occupancy agreement with Lyonbiopôle for its Lyon space. This agreement, which had an initial term of three years, was renewed in 2012. The annual rent was €332 thousand (including charges) in 2015.

Transgene is also bound by contracts with subcontractors. that could have an impact over several accounting periods. At December 31, 2015, the Company considered its financial commitments under these contracts to be approximately €15 million in current value. These commitments equal in amount the cash still to be spent on contracts signed to date.

Under licensing or option agreements, third parties have promised to make milestone payments or pay royalties to the Company that are dependent upon future events whose probability remains uncertain as of the balance sheet date. The Company has promised, with respect to a number of third parties, to pay royalties or milestone payments under collaboration or licensing agreements that are dependent upon future events whose realization remains uncertain as of the balance sheet date.

In return for the financing of research tax credits for 2012, 2013 and 2014 and tax credits for competitiveness and employment for 2013, 2014 and 2015, the Company gave bank guarantees amounting to  $\{2,695\}$  thousand.

#### NOTE 20 SEGMENT INFORMATION

The Company conducts its business exclusively in the research and development of therapeutic vaccines and immunotherapeutic products, none of which is currently on the market. Its main partners, with whom it generates revenue, are

Jennerex Inc. and Emergent, Inc. The majority of its operations are located in France. The Company therefore uses only one sector for the preparation and presentation of its financial statements.

#### NOTE 21 Description Breakdown of Assets and Liabilities by Maturity

December 31, 2015

Assets (in thousands of Euros)	Gross amount	One year or less	More than one year
Non-current financial assets	3,074	825	2,249
Trade receivables	1,784	1,784	-
Research tax credits and CICE	34,601	8,289	26,312
Recoverable VAT and income tax receivables	386	386	-
Personnel and related accounts	33	33	-
Prepaid expenses	539	28	511
Grant receivable	1,004	172	832
Receivables from the sale of equity investment	3,934	2,674	1,260
Other receivables	32	32	-
TOTAL	45,387	14,223	31,164

Liabilities (in thousands of Euros)	Gross amount	One year or less	More than 1 year and less than or equal to 5 years	More than 5 years
Trade payables	6,521	6,521	-	-
Property leasing	9,259	979	4,340	3,940
Equipment leasing	390	174	216	-
Conditional advances	16,844	-	180	16,664
Financing of research tax credit and CICE	26,761	8,243	18,518	-
Provisions for risks and liabilities	7,038	7,038	-	-
Provisions for retirement	3,196	-	707	2,489
Accrued employee benefits and tax expense	3,110	3,110	-	-
Deferred income	571	555	16	-
Other liabilities	633	89	-	544
TOTAL	74,323	26,709	23,977	23,637

#### NOTE 22 OBJECTIVES AND POLICIES OF FINANCIAL RISK MANAGEMENT

#### **Hedging operations**

The Company is not engaged in any foreign exchange hedges.

In the first half of 2009, the Company partially hedged the interest rate risk related to the financial leasing of its administrative and research building in Illkirch (see Note 8), according to the following terms:

- nominal value: €5.9 million (depreciable);
- hedging instrument: interest rate swap contract;
- residual maturity: 8 years;
- underlying rate: 3-month Euribor;
- fixed rate: 3.46%.

As the hedge is perfect, the variations in market value for the instrument are recognized at net value. At December 31, 2015, the market value of this hedging instrument was €544 thousand. The market value is the amount that the Company would have had to pay if it decided to liquidate the hedge at December 31, 2015.

#### **Exchange rate risk**

The Company publishes its consolidated financial statements in euros. However, a portion of its revenue and expenses is recognized in U.S. dollars. An increase or decrease in the euro exchange rate relative to the U.S. dollar could impact operating results.

The Company has U.S. dollar bank accounts. Net dollar disbursements totaled USD 3.4 million in 2015.

The following table shows the sensitivity of the Company's expenses at a 10% change in the US dollar rate during the years ended December 31, 2014 and 2015 (before tax and any hedging):

(in € thousands)	12/31/2015	12/31/2014
Expenditures denominated in US dollars	3,431	2,293
Equivalent in euros on the basis of an exchange rate of EUR 1 = USD 1.0887	3,154	1,735
Equivalent in euros in the event of an increase of 10% USD vs. EUR	3,505	1,909
Equivalent in euros in the event of a decrease of 10% USD vs. EUR	2,868	1,562

The Group's foreign exchange position as at December 31, 2015 is as follows:

(in thousands)	USD
Assets	5,153
Liabilities	1,586
Net position	3,567
Adjusted	3,567
Off-balance sheet position	-

#### Risks related to cash needs

The Group controls the risks related to cash management through centralized tracking and approval procedures. Cash assets are invested in highly rated marketable securities.

Cash invested at December 31, 2015 in mutual funds, directly or through the centralized management of the Institut Mérieux group, amounted to  ${\in}28.2$  million. The Company has and will have significant capital requirements to finance its research and development, particularly pre-clinical and clinical trials of its products under development.

#### Capital management

The Company has limited access to debt due to the Group's losses and the high-risk nature of the business sector (pharmaceutical research and development) under which it operates. The Company plans to finance operations mainly through equity until its profitability situation changes such that it has access to debt instruments.

#### **Financial instruments**

December 31, 2015 (in € thousands)	Financial assets at fair value through profit or loss	Available- for-sale assets	Receivables, payables, borrowings, at amortized cost	Derivative instruments	Carrying value	Fair value	Level
Financial assets							
Cash and cash equivalents	3,285	-	-	-	3,285	3,285	1
Other current financial assets	28,365	-	-	-	28,365	28,365	2
Trade receivables	-	-	1,784	-	1,784	1,784	-
Non-current financial assets	-	-	3,074	-	3,074	3,074	-
Receivable on non-current financial assets	-	-	977	-	977	977	2
Investments in associates	-	-	1,148	-	1,148	1,148	2
Other non-current assets	3,934	-	-	-	3,934	3,934	3
TOTAL FINANCIAL ASSETS	35,584	-	6,983	-	42,567	42,567	-
Financial liabilities							
Borrowings from credit institutions, long-term portion			18,518	-	18,518	18,518	2
Lease commitment, long-term portion			8,496	-	8,496	8,496	2
Conditional advances			16,844	-	16,844	16,844	2
Other non-current financial liabilities			-	544	544	544	2
Non-current financial liabilities			43,858	544	44,402	44,402	-
Borrowings from credit institutions, short-term portion			8,243	-	8,243	8,243	2
Finance leasing, short-term portion			1,153	-	1,153	1,153	2
Current financial liabilities			9,396	-	9,396	9,396	-
Trade payables			6,521	-	6,521	6,521	-
TOTAL FINANCIAL LIABILITIES			59,775	544	60,319	60,319	-

In accordance with IFRS 13, financial instruments are categorized in three levels according to a hierarchy of methods that determine the fair value:

- level 1 inputs are calculated with reference to quoted prices (unadjusted) in active markets for identical assets or liabilities;
- level 2 inputs are calculated with reference to observable market data for the asset or liability, either directly or indirectly (i.e., derived from prices);
- level 3 inputs are calculated with reference to unobservable inputs.

## 4

#### NOTE 23 SUBSEQUENT EVENTS

At the start of January 2016, the Company entered into a €20 million loan facility with the European Investment Bank (EIB) under the IDFF (Infectious Diseases Finance Facility). This is a five-year facility with capital and interest repayable only from the fourth year. It will be drawn down in two tranches in 2016 at the Company's request and no security has been provided.

Also in January 2016, Transgene's main shareholder, Institut Mérieux, confirmed its support for the Company's strategy and committed to providing approximately €10 million in additional financing. The terms and conditions for releasing this funding will be finalized during the year.

On February 1, 2016, Transgene announced the disposal of the assets of its bio-production site located at Illkirch-

Graffenstaden to ABL Europe SAS, a research and production company wholly-owned by ABL, Inc. and a member of Institut Mérieux. Under this deal, the production assets were sold for a total of €3.5 million and ABL Europe becomes the sublessee of the main Transgene building to guarantee the quality control of the batches produced in dedicated labs. The two companies have also agreed a three-year contract under which Transgene has secured production of the necessary batches for its clinical development plan. This sale of its production assets by Transgene marks the final stage in the Company's reorganization initiated in June 2015, and which included outsourcing the manufacture of clinical batches to refocus on the Company's core expertise, immuno-engineering of viral vectors and clinical developments.

#### 4.1.3 Date of latest financial information

December 31, 2014 and June 30, 2015.

## 4.2 STATUTORY AUDITORS' REPORT ON THE CONSOLIDATED FINANCIAL STATEMENTS

Fiscal year ended December 31, 2015

Dear Shareholders,

In compliance with the mission entrusted to us by your General Shareholders' Meeting, we hereby present our report for the year ended December 31, 2015, on:

- the auditing of Transgène S.A.'s consolidated financial statements, as attached to this report;
- the justification for our assessments;
- the specific verification required by law.

The consolidated financial statements were approved by the Board of Directors. Our role is to express an opinion on these financial statements based on our audit.

#### I. Opinion on the consolidated financial statements

We conducted our audit in accordance with the professional standards applicable in France. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. It also consists of assessing the accounting principles used, significant estimates made and the overall financial statement presentation. We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

We certify that the consolidated financial statements fairly present the results of operations for the year and the financial position and assets of the consolidated companies at that date, in accordance with IFRS as adopted by the European Union.

#### II. Justification of our assessments

In accordance with the requirements of Article L. 823-9 of the French Commercial Code relating to the justification of our assessments, we draw your attention to the following matters:

- Note 1 to the consolidated financial statements (Non-current assets Intangible assets) describes the accounting rules and
  methods for intangible assets, including research expenses. In the context of our assessment of the accounting policies and rules
  followed by your Group, we have verified the appropriateness of the accounting methods referred to above and the information
  given in Note 6 to the consolidated financial statements and we are satisfied that they have been applied correctly;
- At each balance sheet date, your Group conducts tests for impairment of equity securities, as described in Note 1 (Noncurrent financial assets and Equity investments) to the consolidated financial statements. We have examined the terms of the implementation of these impairment tests and estimates of cash flows and assumptions used, and we have verified that Note 7 to the consolidated financial statements provides appropriate information.

The assessments were made in the context of our audit of the consolidated financial statements, taken as a whole, and therefore contributed to the formation of the unqualified opinion expressed in the first part of this report.

#### III. Specific verification

We also performed specific verifications provided by law, in accordance with professional standards applicable in France of information relating to the Group given in the management report.

We have no matters to report concerning the fairness of this information or its consistency with the consolidated financial statements.

Lyon, April 27, 2016 Statutory Auditors

**DIAGNOSTIC REVISION CONSEIL** 

Hubert de Rocquigny du Fayel

ERNST & YOUNG et Autres

Marc-André Audisio

## 4.3 COMPANY FINANCIAL STATEMENTS AND NOTES

#### 4.3.1 Annual financial statements

#### **▶** BALANCE SHEET – ASSETS

(in € thousands)	Notes	12/31/2015	12/31/2014
Intangible assets, at cost		4,400	4,400
(accumulated depreciation and provisions)		(3,915)	(3,344)
Intangible assets - net	11	485	1,056
Property, plant and equipment:			
Land		1,234	1,234
Fixtures and fittings		7,192	7,103
Laboratory equipment		17,501	16,816
Vehicles, office and computer equipment		2,130	2,232
Assets in progress		965	638
Total property, plant and equipment, at cost		29,022	28,023
(accumulated depreciation and provisions)		(19,617)	(15,997)
Property, plant and equipment - net	10	9,405	12,026
Financial assets - net	12	9,784	10,393
Total fixed assets		19,674	23,475
Inventories	6	1,163	1,149
Trade receivables	7	1,763	1,399
Research tax credits and competitiveness and employment tax credits due	20	26,313	26,409
Recoverable VAT and income tax receivables and other tax receivables		8,674	8,434
Other receivables, including centralized treasury	8	29,453	63,655
Available cash, cash equivalents	5	3,226	3,264
Total current assets		70,592	104,311
Prepaid expenses	17	539	1,138
Currency translation losses		-	-
TOTAL ASSETS		90,805	128,924

#### **D** BALANCE SHEET – LIABILITIES

(in € thousands)	Notes	12/31/2015	12/31/2014
Subscribed capital	13	88,196	88,156
Share premiums	26	472,564	472,492
Reserves	26	349	349
Retained earnings		(490,044)	(439,160)
Profit (loss) for the period		(45,006)	(50,884)
Statutory provisions		-	-
Equity	13	26,059	70,953
Financial liabilities		26,761	25,519
Conditional advance		16,844	15,324
Other equity	14	43,605	40,843
Provisions for pensions		3,823	4,635
Other provisions for contingencies and charges		7,056	131
Provisions for contingencies and charges	15	10,879	4,766
Payables		6,499	8,217
Accrued employee benefits and tax expense		3,103	3,946
Other liabilities		89	86
Payables		9,691	12,249
Prepaid income	17	571	111
Translation losses		-	2
Liabilities		64,746	57,971
TOTAL LIABILITIES AND EQUITY		90,805	128,924

#### • INCOME STATEMENT

(in € thousands) No	tes	12/31/2015	12/31/2014
OPERATING INCOME			
Revenue from collaborative and licensing agreements	2	1,975	2,490
Research and development grants	2	245	551
Other income	2	2,040	775
Total operating income		4,260	3,816
OPERATING EXPENSE			
Research and development expenses		(40,788)	(48,996)
General and administrative expenses		(5,680)	(7,413)
Other expenses		(9,571)	(840)
Total operating costs		(56,039)	(57,249)
Operating loss		(51,778)	(53,433)
Financial income	3	283	427
Financial expense	3	(1,660)	(1,517)
Exchange rate difference	3	199	273
Current income before tax		(52,956)	(54,250)
Net extraordinary income (expenses)	4	7	(5,097)
Income tax expense	20	7,943	8,463
NET INCOME/(LOSS)		(45,006)	(50,884)

# 4.3.2 Notes to the annual financial statements (for the fiscal year ended December 31, 2015)

- The notes and tables presented below are an integral part of the annual financial statements. The financial statements at
- December 31, 2015 show a balance sheet total of €90,805 thousand and a net loss of €45,006 thousand.

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#### NOTE 1 O NATURE OF ACTIVITY AND SUMMARY OF ACCOUNTING PRINCIPLES

#### **Nature of activity**

Transgene ("the Company") is a French limited liability company ("Société Anonyme") governed by the provisions of French law. It was created in 1979 to apply emerging techniques in genetic engineering in the context of contract research for industrial groups in the fields of molecular and cellular biology, virology, immunology and protein chemistry. The Company designs and develops immunotherapy products for treating cancer and infectious diseases.

## Significant accounting policies and changes to methods

The financial statements are prepared according to generally accepted accounting principles in France, in compliance with ANC regulation No. 2014-03 relative to the national general chart of accounts (French GAAP).

The new regulations on assets (CRC 02-10 and 04-06) have been in application since January 1, 2005.

#### Recognition of revenue

Transgene's revenue is comprised of revenues from patent licenses and collaborations in research (including the reimbursement of costs incurred by Transgene), development and production.

#### Patent licenses

Revenue from patent licenses generally consists of rights to access technology, paid on signing of the agreement and which is not reimbursable, financing by milestone payments and other payments, such as royalties.

### Non-refundable fees for technology usage rights paid when the license is signed

When Transgene is not committed to continuing to develop a technology after a license is signed, the fees are recognized as revenue when the Company's contractual obligations have been fulfilled.

When Transgene is committed to continuing to develop a technology after a license is signed or has a future obligation to deliver products, the fees are recognized as revenue over the development period or the product delivery period.

#### Milestone payments

Milestone payments under collaborative agreements are recognized as revenue upon achievement of the incentive milestone events and when Transgene has no future performance obligations related to the payment. Milestone

payments are triggered either by the results of Transgene's research efforts or by events external to Transgene, such as regulatory approvals, the commencement of clinical trials or selection of candidates for drug development.

#### Royalties

Royalties are based on the licensee's sales of products or technologies. They are recognized on the basis of the license terms, when the sales can be reliably measured and recovery of the related receivables is reasonably assured. Provisional estimates of royalties receivable are based on sales statistics and trends.

#### Service and manufacturing contracts

Transgene has entered into certain contracts for the provision of research or manufacturing services on a best-efforts basis.

Transgene bills its services at a pre-agreed rate, generally on a time-spent basis, and billings are recorded as revenue as and when the work is done.

Revenue from these contracts is recognized when the services are performed. Revenue from contracts for manufacturing services, where the Company has an obligation to achieve a specified result, is recognized as revenue on the income statement when a product has successfully undergone quality controls and has been accepted by the customer.

Revenue received but not yet recognized in the income statement based on the above principles is recorded as a liability under "Deferred revenue" and is reclassified to the income statement when the revenue recognition criteria are met.

#### Research tax credits (CIR)

Research and development costs entitled the Company to a research tax credit, which is recognized at the end of the fiscal year in which the costs are recognized and the credit is claimed. Unused research tax credits are refundable from the fourth year. The 2012, 2013, 2014 and 2015 research tax credits will be reimbursed in 2016, 2017, 2018 and 2019, respectively. Since 2011 (for the research tax credit in 2010), the Company has bank refinanced its research tax credit to optimize its cash management.

Research tax credits are recognized in the income statement under "Taxes".

#### Cash and cash equivalents

The Company considers as cash and cash equivalents its highly liquid investments, which can be bought or sold at any time

based on prices that are determined on a daily basis, and which have no material interest or risk. They are in mutual funds mostly invested in underlying monetary assets, bonds and long-term government bonds. Marketable securities are valued at a cost, which is the lower of the first in/first out method or market value.

#### **Inventories**

Inventories consisting mainly of chemicals and laboratory supplies are measured at the lower of cost or market value. Cost is determined by the weighted average cost method. A provision for obsolescence or low rotation may be recognized.

#### Property, plant and equipment

Property, plant and equipment are measured at cost. Depreciation is recognized in the income statement according to the probable useful lives, as follows:

Type of asset	Depreciation method	Period
Buildings	Straight-line	20 to 50 years
Fixtures and fittings	Straight-line	10 to 20 years
Machinery and equipment (machinery and laboratory equipment)	Straight-line	5 to 10 years
Office equipment and furniture	Straight-line	5 to 10 years
IT equipment	Straight-line	3 to 5 years

The application of the new regulations on assets (CRC 02-10 and 04-06) has had no impact on the financial statements. In fact, as with all of its fixed assets, their breakdown level has not resulted in changes in the values of the assets or amortization schedules.

Fixed asset components that have a useful life significantly different from the main asset, have their own depreciation schedule, provided the value of these components represents at least 15% of the value of the whole asset.

#### **Share issue costs**

Share issue costs are charged to share premiums.

#### Research and development costs

Expenses for applied research and development include the direct and indirect costs incurred on the projects, excluding

any allocation of overhead. The direct and indirect costs refer primarily to the salaries of researchers and research technicians, the depreciation expense on assets used and on the cost of materials and other services used.

Research costs are recognized as an expense on the income statement for the period in which they are incurred. Development costs are capitalized when the required conditions are met.

The Company believes that the costs incurred in developing its pharmaceutical products are equivalent to research costs until a marketing authorization request is filed with regulatory authorities. After that, they are considered to be development costs.

#### Other intangible assets

Intangible assets mainly comprise licenses, acquired patents and computer software.

Type of intangible asset	Depreciation method	Period of depreciation
Computer software and licenses	Straight-line	1 to 5 years
Patents acquired	Straight-line	5 years

#### Investments in non-consolidated companies

Investments in non-consolidated companies are recorded at cost and depreciated, as needed, if their carrying value exceeds their recoverable amount as estimated by the Company.

The valuation of equity investments is currently based on a discounted cash flow (DCF) analysis of *future cash* flows. This valuation is reviewed periodically.

For investments to develop immunotherapy products, the assumptions used for the DCF valuation mainly involve the probability of technical and regulatory success (PTRS) and the market potential of portfolio products. The market potential of the products is regularly reviewed by the Company. The PTRS, which depends on the stage of product development, is calculated from reference publications in the field.

The discounted cash flow rate of equity investments is calculated on the basis of the weighted average cost of capital (WACC), which is itself based on a so-called market-comparable approach.

#### Other financial assets

Other financial assets are comprised of deposits and guarantees regarding property rentals and the holdback related to the assignment of debt under the research tax credit and the competitiveness and job creation tax credit. Deposits and guarantees are measured at cost and depreciated as needed to reflect their net realizable value.

#### Prepaid expenses and other current assets

Prepaid expenses and the other current assets are measured at cost and may be impaired to reflect their net realizable value.

## Provisions for risks and liabilities and provisions for employment benefits

Provisions are recorded to cover contingencies and charges arising in the course of the Company's business. With regard to provisions for pensions and other post-employment benefits, in particular, the rights acquired by serving employees are estimated according to actuarial evaluations, taking into account mortality rates, future salary levels and the probability of employees remaining with the Company until retirement.

The Company recognizes actuarial gains and losses using the corridor method. In line with first application of ANC recommendation No. 2003-02 as of December 31, 2014, actuarial gains or losses related to experience and changes in assumptions are amortized in future expenses over the remaining probable average active period for employees, after applying a corridor of 10% of the greater of the value of commitments and the value of the hedging asset.

#### Foreign exchange

Cash liquidity in foreign currencies is converted into euros at the exchange rate on the balance sheet date. The resulting conversion differences are recognized in the income statement.

Receivables and payables in foreign currencies are converted into euros at the exchange rate on the balance sheet date. The resulting conversion differences are recognized under "exchange rate gains/losses" on the balance sheet (under assets for unrealized losses, under liabilities for unrealized gains).

Unrealized losses are booked in a provision for risks under expenses for the year.

#### Income tax expense

Income tax expenses correspond to taxes due calculated at the standard rate in use at year end, taking into account the research tax credit.

The underlying tax position is calculated on the basis of the differences between the tax values and carrying amount of assets and liabilities presented in the balance sheet. These differences are determined according to the tax provisions and discounted tax rates when these differences are inverted.

## Tax credit for Competitiveness and Employment (CICE)

The CICE, if any, is recognized as a decrease under *Employee* benefits expenses.

Since the tax situation of the Company does not make it possible to deduct the tax credit from any taxable profits for the period, this CICE receivable will not be paid by the State until the end of the following three fiscal years.

Transgene received bank pre-financing for this receivable, and the proceeds on this asset were used to extend the Company's working capital.

#### NOTE 2 OPERATING INCOME

#### **○** REVENUE FROM COLLABORATIVE AND LICENSING AGREEMENTS

(in € thousands)	12/31/2015	12/31/2014
Bioproduction and other collaborative projects	1,308	1,668
License fees and royalties	667	822
TOTAL	1,975	2,490

#### OTHER INCOME

(in € thousands)	12/31/2015	12/31/2014
Research and development grants	245	551
Other	2,040	775
TOTAL	2,285	1,326

### NOTE 3 FINANCIAL INCOME (EXPENSE)

(in € thousands)	12/31/2015	12/31/2014
REVENUE		
Revenues from marketable securities	17	421
Revenues from capitalized accounts receivable	7	-
Discounts received	-	-
Other interest income	259	6
Total financial interest income	283	427
EXPENSES		
Interest expense related to debt	(757)	(981)
Total financial expenses	(903)	(536)
Exchange rate differences	(1,660)	(1,517)
EXCHANGE RATE DIFFERENCES		
Exchange rate loss	185	284
Total exchange rate differences	14	(11)
Total exchange rate differences	199	273
FINANCIAL INCOME (EXPENSE)	(1,178)	(817)

#### NOTE 4 NET NON-RECURRING ITEMS

As of December 31, 2015, non-recurring income consisted mainly of a tax adjustment related to the business land tax (contribution foncière des entreprises) and other non-recurring income from management operations.

#### NOTE 5 CASH AND MARKETABLE SECURITIES

(in € thousands)	12/31/2015	12/31/2014
Cash	688	390
Marketable securities	2,538	2,874
TOTAL	3,226	3,264
Unrecorded unrealized gains	-	0.5

In 2015, marketable securities were composed of short-term mutual fund units.

#### NOTE 6 D INVENTORIES

(in € thousands)	12/31/2015	12/31/2014
Raw materials	210	188
Laboratory supplies	953	961
Total cost	1,163	1,149
Provision for obsolescence	-	-
NET TOTAL	1,163	1,149

#### NOTE 7 TRADE RECEIVABLES

(in € thousands)	12/31/2015	12/31/2014
Total cost	1,763	1,399
Provisions for impairment	-	-
NET TOTAL	1,763	1,399

#### NOTE 8 OTHER RECEIVABLES

(in € thousands)	12/31/2015	12/31/2014
Institut Mérieux centralized cash (cash pool)	28,365	62,422
Accrued credit notes (trade credit)	32	115
Employee benefits expense	33	44
Accrued subsidies	1,004	1,070
Other receivables	18	4
TOTAL	29,452	63,655

Contractually, investments made by the Company as part of the centralized cash management at Institut Mérieux are liquid within a maximum period of four business days and bear interest based on a rate equal to Euribor +0.15% when Institut Mérieux is in a net borrowing position at the group level and to Euribor when Institut Mérieux is in a net surplus at the group level

#### NOTE 9 • ACCRUED INCOME

(in € thousands)	12/31/2015	12/31/2014
Accrued income - customers	376	1,682
VAT credit	291	768
Trade receivables	29	107
VAT on accrued invoices	114	196
Social organizations - accrued revenue	-	2
TOTAL	810	2,755

#### NOTE 10 PROPERTY, PLANT AND EQUIPMENT

(in € thousands)	12/31/2014	Increase	Decrease	12/31/2015
ACQUISITION COSTS				
Land, buildings and fixtures	8,337	90	-	8,427
Laboratory equipment	16,816	929	(244)	17,501
Vehicles, office and computer equipment	2,232	21	(123)	2,130
Assets in progress	638	1,207	(880)	965
Total	28,023	2,247	(1,247)	29,023
DEPRECIATION AND PROVISIONS				
Land, buildings and fixtures	(3,609)	(1,250)*	-	(4,859)
Laboratory equipment	(10,862)	(2,402)*	235	(13,029)
Vehicles, office and computer equipment	(1,526)	(296)*	121	(1,702)
Assets in progress	-	(29)	-	(29)
Total	(15,997)	(3,977)	356	(19,618)
NET TOTAL	12,026	(1,730)	(891)	9,405

<sup>\*</sup> Of which provision for impairment of property, plant and equipment in the amount of €2,395 thousand, relating to the production assets.

#### NOTE 11 DINTANGIBLE ASSETS

(in € thousands)	12/31/2014	Increase	Decrease	12/31/2015
ACQUISITION COSTS				
Licenses and acquired patents	1,788	-	-	1,788
Other intangible assets	2,451	158	-	2,609
Assets in progress	161	55	214	2
Total	4,400	214	214	4,400
DEPRECIATION AND PROVISIONS				
Licenses and acquired patents	(1,490)	(174)	2	(1,662)
Other intangible assets	(1,854)	(399)*	-	(2,253)
Total	(3,344)	(573)	2	(3,915)
NET TOTAL	1,056	(359)	(212)	485

<sup>•</sup> Of which allowance for impairment of intangible assets in the amount of €162 thousand, relating to the production assets.

#### NOTE 12 ONON-CURRENT FINANCIAL ASSETS

(in € thousands)	12/31/2014	Increase	Decrease	12/31/2015
Participating interests				
Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.	5,211	-	-	5,211
Jennerex, Inc.	-	-	-	-
Platine Pharma Services SAS	294	-	-	294
Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd.	875	-	-	875
ElsaLys Biotech SAS	501	-	-	501
• Transgene Inc.	23	-	-	23
Access Investment, Inc.	29	-	-	29
Total	6,933	-	-	6,933
Guarantees and deposits	2,833	940	(795)	2,978
Platine SAS current account and conditional loan	389	-		389
ElsaLys Biotech SAS current account	718	258	-	976
Guarantee on the disposal of Jennerex, Inc. stock	368	-	(368)	-
Depreciation	(848)	(644)		(1,492)
TOTAL (AT HISTORICAL COST)	10,393	555	(1,163)	9,784

#### **Platine Pharma Services SAS**

As of December 31, 2015 Transgene held a 0.04% stake in the capital of Platine Pharma Services SA.

#### **Depreciation**

As of December 31, 2015 the impairment booked was on stock in Access Investment, Inc. for €29 thousand, on stock in Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd. for €1,169 thousand, on the conditional loan to Platine SAS for €94 thousand, and on the Platine current account for €200 thousand.

#### NOTE 13 SHAREHOLDERS' EQUITY

#### General

At December 31, 2015, the number of outstanding shares of Transgene was 38,545,397, representing share capital of \$8,195,793.51.

#### **Preferential subscription rights**

Shareholders have preferential subscription rights during capital increases in proportion to their existing interests. This right may be waived in certain circumstances by a resolution voted in an Extraordinary General Meeting. preferential subscription rights that have not been waived are negotiable during the subscription period.

#### **Stock options**

#### SUMMARY TABLE OF STOCK OPTION PLANS

	Plan no. 3	Plan no. 4	Plan no. 5	Plan no. 6
Shareholders' Meeting date	6/9/2004	6/9/2006	6/9/2008	6/17/2010
Board of Directors meeting date	2/9/2005	12/6/2006	12/16/2008	12/7/2010
	5/18/2005	10/4/2007	12/9/2009	12/13/2012
	1/1/2006	12/19/2007	12/7/2010	
	12/6/2006	12/16/2008		
Total number of shares to be subscribed or purchased	300,000	450,000	250,000	400,000
Starting point for exercise of options	2009	2010	2012	2015
	2010	2011	2013	2017
		2012	2015	
Expiration date	2015	2016	2018	2020
	2016	2017	2019	2022
		2018	2020	
Subscription price (EUR) (equal to the average of the	6.38	10.78	11.09	14.31
market price of the 20 trading days prior to the grant date, excluding discount) adjusted following the capital increase with subscription rights in 2010, in accordance with the French Commercial Code.	7.12	16.23	17.26	7.92
	7.38	15.14	14.31	
	10.78	11.09		

#### OPTIONS OUTSTANDING AND EXERCISABLE OPTIONS AT DECEMBER 31, 2015

	Number of shares
Options outstanding at December 31, 2014	1,188,097
Options exercisable at end of period	886,231
Options awarded in 2015	-
Options exercised in 2015	169,842
Canceled or expired options in 2015	1,000,826
Options outstanding at December 31, 2015	-

#### Free share plans

#### **SUMMARY TABLE OF SHARE PLANS**

	Plan no. 1	Plan no. 2
Shareholders' Meeting date	6/9/2008	6/17/2010
Total number of shares to be subscribed or purchased	100,000	120,000
oard of Directors meeting date	12/16/2008	12/7/2010
	12/9/2009	12/13/2012
	12/7/2010	
Total number of bonus shares allocated	73,800	74,900
	11,100	44,320
	15,100	
Date of final allocation and expiration date (as both periods are taken into account)	12/15/2012	12/6/2014
	12/8/2013	12/12/2016
	12/6/2014	
Share value on the date of allocation (opening price on the date of allocation)	€12.10	€14.37
	€19.67	€8.36
	€14.37	

#### ▶ FREE SHARES AWARDED AND ACQUIRED AT DECEMBER 31, 2015

	Number of shares
Free shares awarded at December 31, 2014	42,590
Free shares vested to the beneficiaries in 2014	-
Free shares cancelled in 2015	1,460
Free shares awarded in 2015	-
Free shares vested to the beneficiaries in 2015	-
Free shares awarded at December 31, 2015	41,130

#### **Changes in equity**

(in € thousands)	Share capital	Premiums and reserves	Retained earnings	Result	Statutory provisions	Equity
At 12/31/2014	88,156	472,841	(439,160)	(50,884)	-	70,953
Appropriation of loss	-	-	-	-	-	-
Net income (loss) 2014	-	-	(50,884)	50,884	-	-
Pension obligations	-	-	-	-	-	-
Net income (loss) 2015	-	-	-	(45,006)	-	(45,006)
Increase in capital (exercise of stock options and final allocation of free shares)	40	72	-	-	-	112
At 12/31/2015	88,196	472,913	(490,044)	(45,006)	-	26,059

17,429 new shares were issued in 2015 on the exercise of stock options and the issuance of new corresponding shares at a weighted average price per share of 6.38.

#### NOTE 14 OTHER EQUITY

#### Financial liabilities

Financial liabilities as of December 31, 2015 related to bank financing of the 2012 research tax credit (current liabilities), the 2013 and 2014 research tax credits (non-current liabilities), and the competitiveness and employment tax credit (CICE) for 2013, 2014 and 2015 (non-current portion). Transgene received the amount of the tax debt less a financing cost and a holdback of 10%.

#### **Conditional advances**

At December 31, 2015, conditional advances related to repayable advances received under the ADNA ("Advanced Diagnostics for New Therapeutic Approaches") program, which receives public funding from the Bpifrance, for €16,664 thousand and under the Helazyme program for €180 thousand.

The Company may receive up to €1.7 million in additional repayable advances over the remaining term of the ADNA program, *i.e.* until 2017.

#### NOTE 15 PROVISIONS FOR CONTINGENCIES AND CHARGES

(in € thousands)	12/31/2014	Provisions	Retained earnings	Reversals not applicable	Use of the provision	12/31/2015
Exchange rate differences	5	13	-	-	-	18
Risk of charge	126	6,912	-	-	-	7,038
Pension obligations	4,635	-	-	(812)	-	3,823
Total provisions for charges	4,766	6,925	-	(812)	-	10,879
Of which allocations and reversals						
Operating	190	6,911	-	(812)	-	6,289
Financial	129	14	-	-	-	143
Extraordinary	-	-	-	-	-	-

Exceptional depreciation expense relates to the restructuring provision.

The above provisions for pension obligations correspond to the estimated current value of the share capital equivalent to accrued future payments, depending on length of service and level of compensation when an employee retires, on the basis of the following actuarial calculation assumptions at December 31, 2015:

	12/31/2015	12/31/2014
Discount rate	2.35%	2.25%
Rate of future salary increases	1.50%	2.00%
Retirement age:		
• managers	65	65
• non-managers	63	63

The provision entered on the balance sheet concerns only retirement payments for serving employees.

The following table summarizes the conditions and amounts of actuarial pension obligations at December 31, 2015 and 2014:

(in € thousands)	12/31/2015	12/31/2014
CHANGE IN THE VALUE OF COMMITMENTS		
Projected benefit obligation at January 1	4,176	4,344
Cost of services rendered for the year	316	332
Cost of discounting	94	124
Change in assumptions	(308)	(338)
Reductions/terminations	(994)	(133)
Actuarial (gain)/loss	(57)	(121)
Benefits paid during the year	(31)	(32)
Projected benefit obligation for retirement	3,196	4,176
Unrecognized actuarial losses	627	459
Unrecognized past service cost	-	-
Total unrecognized items	-	-
PROVISIONS FOR RETIREMENT BENEFIT OBLIGATIONS	3,823	4,635

Changes in actuarial commitments recognized on the liabilities side of the balance sheet for 2015 and 2014 break down as follows:

(in € thousands)	2015	2014
DEFINED BENEFIT COST FOR THE YEAR		
Cost of services rendered for the year	316	332
Cost of discounting	94	124
Net actuarial loss recognized in the year	(3)	-
Reductions/terminations	(1,189)	(133)
COST OF SERVICES AND DISCOUNTING	(782)	323

#### **NOTE 16** • EXPENSES PAYABLE

Detail of accrued expenses (in thousands of euros)	12/31/2015	12/31/2014
Suppliers - accrued invoices	4,870	7,381
Accrued credit notes	-	-
Personnel and related accounts	1,343	1,450
Social organizations	1,103	1,413
VAT on accrued income	9	15
VAT on trade receivables	2	8
Other liabilities	105	29
TOTAL	7,432	10,296

#### NOTE 17 • ACCRUED CHARGES AND DEFERRED INCOME

Deferred revenue and expenses relate exclusively to items recognized under operations.

#### NOTE 18 • AFFILIATED COMPANIES

Transgene signed a cash pooling agreement with Institut Mérieux and the Cash and cash equivalents placed in the Institut Mérieux cash pooling represented a receivable of €28,365 thousand at December 31, 2015, and the resulting interest income was €196 thousand at December 31, 2015.

The table below does not include these cash items.

	2015		
(in € thousands)	Receivables	Payables	
Institut Mérieux <sup>(2)</sup>	-	8	
Thera Conseil	-	-	
Transgene, Inc.	17	192	
Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd.	-	-	
Platine Pharma Services SAS	200	-	
Mérieux Université	-	-	
Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd.	37	-	
BioMérieux SA	-	5	
BioMérieux Shanghai	-	27	
ElsaLys Biotech SAS	1,055	-	
TOTAL	1,309	232	

	2015		
(in € thousands)	Revenue	Expenses	
BioMérieux SA <sup>(1)</sup>	-	68	
Thera Conseil	-	4	
Institut Mérieux <sup>(2)</sup>	-	681	
BioMérieux Shanghai	-	183	
Mérieux Université	-	12	
Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd.	-	178	
Transgene, Inc.(3)	-	2,062	
Platine Pharma Services SAS	-	316	
Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. (4)	137	-	
ElsaLys Biotech SAS	65	26	
TOTAL	202	3,530	

- (1) Expenses related to purchases of laboratory equipment and supplies.
- (2) Expenses relate to the agreement for services provided by Institut Mérieux.
- (3) Expenses relate to the re-invoicing of administrative and personnel expenses by Transgene Inc.
- (4) Income represents services contracts and re-invoicing of personnel.

#### NOTE 19 AGING OF RECEIVABLES AND PAYABLES

Receivables (in thousands of Euros)	Gross amount	One year or less	More than one year
Other financial assets	2,978	825	2,153
Trade receivables	1,763	1,763	-
Research tax credit and tax credit for Competitiveness and Employment	34,601	8,288	26,313
Recoverable VAT and income tax receivables	386	386	-
Personnel and related accounts	33	33	-
Prepaid expenses	539	513	26
Research and development grants	1,004	172	832
Other receivables	1,055	1,055	-
TOTAL	42,359	13,035	29,324

Payables (in thousands of Euros)	Gross amount	One year or less	More than 1 year and less than or equal to 5 years	More than 5 years
Conditional advances	16,844	-	180	16,664
Financing of tax credits	26,761	8,243	18,518	-
Trade payables	6,499	6,499	-	-
Pension obligations	3,823	-	845	2,978
Accrued employee benefits and tax expense	3,103	3,103	-	-
Prepaid income	571	555	16	-
Other liabilities	89	89	-	-
TOTAL	57,691	18,489	19,559	19,642

#### NOTE 20 INCOME TAX EXPENSE

#### **Current taxes**

The 2015 tax ( $\in$ 7,943 thousand) primarily comprises the research tax credit earned during the year ( $\in$ 7,751 thousand), a research tax credit refund ( $\in$ 159 thousand), and an apprenticeship and family tax credit (*crédit d'impôt apprentissage et famille*) ( $\in$ 33 thousand)

The Company had a credit with the French government of €34,601 thousand as of December 31, 2015 in respect of the research tax credit and the competitiveness and employment tax credit. This amount can be used to offset corporate income tax payments. The Company may be asked to repay it in cash, if it is not used, within four years of it being granted. The research tax credits can be reimbursed according to the schedule below:

	Competitiveness a tax credit, in	and employment € thousands	Research tax credit, in thousands of euros	
Year of expected reimbursement	2015	2014	2015	2014
2015	-	-	-	7,555
2016	-	-	8,289	8,289
2017	210	210	8,852	8,852
2018	275	275	8,943	8,783
2019	282	-	7,751	-
TOTAL	767	485	33,835	33,479

#### **Deferred taxes**

Deferred taxes indicate a potential reduction in future tax expenses of €208,348 thousand, which mainly represents tax loss carry-forwards.

Temporary differences between accounting and taxation:

		BASE		INCOME TAX		
(in € thousands)	At the beginning year	Net change in income for the year	At the end of the period	At January 1 - receivables (payables)	Net variations in income for the fiscal year - revenue (expense)	At December 31 - receivables (payables)
Provision for exchange losses	3	15	18	1	5	6
Mutual aid social security contribution	5	(5)	-	2	(2)	-
Provisions for pensions and other post-employment benefits	3,727	(812)	2,915	1,283	(279)	1,004
Provision for restructuring	-	2,923	2,923	-	1,006	1,006
Cost of acquired patents not yet deducted	19	(2)	17	7	(1)	6
Allowance for impairment of intangible assets	-	162	162	-	56	56
Provision for impairment of equity security	754	444	1,198	260	152	412
Provisions for loss	3	-	3	1	-	1
Unrealized capital gains on marketable securities	-	-	-	-	-	-
Translation adjustment	(2)	15	(17)	(1)	(5)	(6)
Tax loss carryforwards	547,422	50,496	597,918	188,477	17,386	205,863
TOTAL	551,931	53,206	605,137	190,030	18,318	208,348

#### NOTE 21 © EXECUTIVE COMPENSATION AND OBLIGATIONS

Directors' fees paid to members of the administrative bodies amounted to &83.5 thousand.

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, has been the Company's main employee since April 2015. As of December 31, 2015, he remained an employee of Institut Mérieux.

In 2015, the Company did not pay any compensation to TSGH and its permanent representative. In 2015, the Company paid its Chairman and Chief Executive Officer, Mr. Philippe Archinard, gross compensation of €305,000.

In 2015, Philippe Archinard received gross compensation of €661.5 thousand (including €450 thousand in variable

compensation and €9.7 thousand in benefits in kind corresponding to the use of a Company car) from Institut Mérieux, re-invoiced in part to the Company pursuant to a contract for services rendered by Institut Mérieux (see Note 18).

The Company paid a gross amount of €1,111 thousand in compensation to its Executive Committee in 2015.

No advances or credits were allocated to executives.

#### NOTE 22 OFF-BALANCE SHEET COMMITMENTS

For the acquisition of a property located in Illkirch, in which the Company installed its main administrative and research buildings, Transgene signed a finance lease with a banking pool. This contract, which is for an amount of €15.6 million, has a term of 15 years. The quarterly rent was determined on January 1, 2009. The financing rate is indexed to the Euribor

rate at 3 months. Transgene engaged in a partial interest rate hedge (see paragraph above). The Company has a purchase option on the land and buildings at the end of the financing agreement for the sum of €1.1 million.

The table below summarizes the main residual obligations of the Company under this contract:

(in € thousands)	2015	2014
Property leasing		
outstanding charges	8,661	9,723
residual purchase price	1,094	1,094

Under the terms of the real estate financing lease for the acquisition of its administrative and research building in Illkirch, Transgene has a pledge granted by Banque Populaire to Alsabail, one of the lessors, for an amount of €1.6 million. In the first six months of 2009, the Company proceeded with partial coverage of the interest rate risk related to this financing, according to the following terms:

- nominal value: €5.9 million (depreciable);
- hedging instrument: interest rate contract;
- residual maturity: 8 years;
- underlying rate: 3-month Euribor;
- fixed rate: 3.46%.

As the hedge is perfect, the variations in market value for the instrument are recognized at net value. At December 31, 2015, the market value of this hedging instrument was €544 thousand. The market value is the amount that the Company would have had to pay if it decided to liquidate the hedge at December 31, 2015.

On April 1, 2009, Transgene signed an occupancy agreement with Lyonbiopôle for its Lyon space. This agreement, which had an initial term of three years, was renewed in 2012. The annual rent was €332 thousand (including charges) in 2015.

The table below summarizes key financial commitments made by the Company:

#### Payments due by period

(in € thousands)	Gross amount	One year or less	From one to five years	More than 5 years
Finance lease obligations (real estate)	8,661	1,079	4,646	2,936
Finance lease obligations (non-real estate)	397	177	220	-
Other long-term obligations (reimbursable advances)	16,844	-	180	16,664
TOTAL	25,902	1,256	5,046	19,600

Transgene is also bound by contracts with subcontractors. that could have an impact over several accounting periods. At December 31, 2015, the Company considered its financial commitments under these contracts to be approximately €14 million in current value.

Under licensing or option agreements, third parties have promised to make milestone payments or pay royalties to the Company that are dependent upon future events whose probability remains uncertain as of the balance sheet date. The Company has promised, with respect to a number of third parties, to pay royalties or milestone payments under collaboration or licensing agreements that are dependent upon future events whose realization remains uncertain as of the balance sheet date.

The Company has not made any material commitment (guarantees, collateral, etc.).

#### NOTE 23 PERSONNEL

At December 31, 2015, the Company had 256 employees, compared with 284 at December 31, 2014.

	Men	Women	Total	Including reclassified personnel or internal transfers
Managers	63	89	152	51
Other grades	22	82	104	62
TOTAL	85	171	256	113

<sup>\*</sup> Including 249 open-ended contracts at December 31, 2015

Employee benefits expense (salaries, payroll taxes, pension costs and related expenses) for 2014 and 2015 totaled  $\leq$ 21,271 thousand and  $\leq$ 19,011 thousand, respectively.

#### NOTE 24 DIDENTITY OF THE CONSOLIDATING ENTITY

The Company's financial statements were fully consolidated by Compagnie Mérieux Alliance, 17 rue Bourgelat, 69002 Lyon.

#### NOTE 25 SUBSEQUENT EVENTS

At the start of January 2016, the Company entered into a €20 million loan facility with the European Investment Bank (EIB) under the IDFF (Infectious Diseases Finance Facility). This is a five-year facility with capital and interest repayable only from the fourth year. It will be drawn down in two tranches in 2016 at the Company's request and no security has been provided.

Also in January 2016, Transgene's main shareholder, Institut Mérieux, confirmed its support for the Company's strategy and committed to providing approximately €10 million in additional financing. The terms and conditions for releasing this funding will be finalized during the year.

On February 1, 2016, Transgene announced the disposal of the assets of its bio-production site located at

Illkirch-Graffenstaden to ABL Europe SAS, a research and production company wholly-owned by ABL, Inc. and a member of Institut Mérieux. Under this deal, the production assets were sold for a total of €3.5 million. and ABL Europe becomes the sub-lessee of the main Transgene building to guarantee the quality control of the batches produced in dedicated labs. The two companies have also agreed a three-year contract under which Transgene has secured production of the necessary batches for its clinical development plan. This sale of its production assets by Transgene marks the final stage in the Company's reorganization initiated in June 2015, and which included outsourcing the manufacture of clinical batches to refocus on the Company's core expertise, immuno-engineering of viral vectors and clinical developments.

#### NOTE 26 PREMIUMS AND RESERVES

The distribution options offered by the accumulated premiums and reserves were as follows:

In € thousands	Total	Reimbursable or available for distribution	Not available for distribution
Premiums	472,564	472,564	-
Legal reserve	248	-	248
Unavailable reserve	101	-	101
TOTAL	472,913	472,564	349

#### NOTE 27 SUBSIDIARIES AND EQUITY INTERESTS

				of securi	g value ties held uros)	Loans and advances	Amount of gua- rantee and				
Selected financial information (In local currency)	Share capital	Share capi- tal other than capital	Proportion of capital held	Gross	Net	granted by the Com- pany not yet reim- bursed	under- takings given by the Com- pany	Reve- nues excl. tax of the period just past	Income (profits or losses for the pre- vious fiscal year)	Divi- dends received during the year	Com- ments
Transgene Inc. 5 Cambridge Center, Suite 0802 Cambridge, Massachusetts 02142 USA	\$30,000	_	100%	23,114	23,114	None	None	None	_	None	_
Transgene BioPharmaceutical Technology (Shanghai) Co. Ltd. Rm 317,379 Bao Tun Lu, Shanghai 200011, China	7,206,186 RMB	(5,932,090) RMB	100%	875,000	_	None	None	None	(1,094,605) RMB	None	-
Transgene Tasly (Tianjin) BioPharmaceutical Co. Ltd. Chenhuan Tower, Tianjin Medicine and Medical equipment indus. parc	85,000,000 RMB	(42,975,883) RMB	50%	5,210,821	5,210,821	None	None	None	(16,306,773) RMB	None	-
Sas ElsaLys Biotech* 321 avenue Jean Jaurès 69007 LYON	183,435 EUR	451,485 EUR	14.41%	500,724	500,724	976,755 EUR	None	76,441 EUR	(1,771,105) EUR	None	
Platine SAS 321 avenue Jean Jaurès - Bâtiment Domilyon - Gerland 69007 LYON	904,050 EUR	(1,082,818) EUR	0.04%	294,423	-	388,696 EUR	None	1,250,925 EUR	(778,678) EUR	None	_

## 4.4 STATUTORY AUDITORS' REPORT ON THE ANNUAL FINANCIAL STATEMENTS

Fiscal year ended December 31, 2015

Dear Shareholders,

In compliance with the mission entrusted to us by your General Shareholders' Meeting, we hereby present our report for the year ended December 31, 2015, on:

- our audit of the accompanying annual financial statements of Transgène S.A.;
- the justification for our assessments;
- the specific verifications and information required by law.

The annual financial statements were approved by the Board of Directors. Our role is to express an opinion on these financial statements based on our audit.

#### I. Opinion on the annual financial statements

We conducted our audit in accordance with the professional standards applicable in France. Those standards require that we plan and perform the audit in order to obtain reasonable assurance about whether the annual financial statements are free from material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the annual financial statements. It also consists of assessing the accounting principles used, significant estimates made and the overall financial statement presentation. We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

We certify that the annual financial statements, under the terms of the significant accounting policies and rules applicable in France, present a true and fair view of the results of operations for the year ended as well as the Company's financial position and assets at the end of this fiscal year.

#### II. Justification of our assessments

In accordance with the requirements of Article L. 823-9 of the French Commercial Code relating to the justification of our assessments, we draw your attention to the following matters:

- Note 1 (Research and Development Costs) to the annual financial statements describes the accounting rules and methods
  relating to the treatment of research and development costs. In the context of our assessment of the accounting policies and
  rules followed by your company, we have verified the appropriateness of the accounting methods referred to above and we are
  satisfied that they have been applied correctly.
- The equity securities listed in your company balance sheets are valued as described in Note 1 (Equity Investments) to the annual financial statements. Our work consisted of assessing the data and assumptions on which these estimates are based. We verified that Note 12 to the annual financial statements provides appropriate information.

The assessments were made in the context of our audit of the annual financial statements, taken as a whole, and therefore contributed to the formation of the unqualified opinion expressed in the first part of this report.

Statutory Auditors' report on the annual financial statements

#### III. Specific verifications and information

We also performed specific verifications provided by law in accordance with professional standards applicable in France.

We have no matters to report concerning the fairness or consistency with the annual financial statements of the information given in the Board's management report and in the documents sent to shareholders on the financial position and the annual financial statements.

With regard to the information provided, pursuant to the terms of Article L. 225-102-1 of the French Commercial Code on compensation and benefits paid to corporate officers and undertakings made in their favor, we have verified consistency thereof with the statements or data used to prepare these financial statements and, if applicable, the items collected by your company from companies controlling your company or that are controlled by it. On the basis of this work, we certify the accuracy and fairness of this information.

In accordance with French law, we are satisfied that the various information relating to the identity of the holders of the share capital and voting rights has been provided to you in the management report.

Lyon, April 27, 2016 Statutory Auditors

**DIAGNOSTIC REVISION CONSEIL** 

Hubert de Rocquigny du Fayel

**ERNST & YOUNG et Autres** 

Marc-André Audisio



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## INFORMATION ABOUT THE COMPANY AND ITS CAPITAL



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### 5.1 SHARE CAPITAL

#### 5.1.1 Paid-in capital

€88,195,793.51 fully paid in, recognized as of the date of this *Document de référence.* 

#### 5.1.1.1 Number of shares issued

38,545,397 shares all of the same class and all fully paid in. No unpaid shares have been issued. The share has no par value.

#### 5.1.2 Unfunded shares

None.

The Company has no knowledge of pledges or other security interests related to its shares at March 31, 2016.

## 5.1.3 Shares held either by the Company itself, on its behalf or by its subsidiaries

None.

## 5.1.4 Convertible securities, exchangeable securities or securities with warrants

None.

# 5.1.5 Conditions governing any right of acquisition and/or any obligation attached to the capital subscribed but not paid or an undertaking to increase the share capital

#### Capital authorized and not issued

At March 31, 2016 the number of shares that could be issued against outstanding stock options (1,035,744) and free share awards (42,590) was 1,087,334, or about 2.7% of the Company's share capital on a fully diluted basis (or 39,623,731 shares).

The Extraordinary General Shareholders' Meeting of June 11, 2015 delegated the following power to the Board of Directors, which the Board had not made use as of the date of this *Document de référence:* 

Nature of the delegation granted	Maximum amount of delegation and effective date	Amount used by the Board
Award of free shares in the Company to Company	600,000 existing or new shares	
and Group employees without preferential subscription rights	Expiration: August 11, 2018	None

The Extraordinary General Shareholders' Meeting of June 18, 2014 delegated the following powers to the Board of Directors, each having been the subject of a separate resolution, of which the Board had not made use as of the date of this Document de référence:

Nature of the delegation granted	Maximum amount of delegation and effective date	Amount used by the Board
Capital increase with preferential subscription rights	17.3 million shares in one or more tranches	
<u>for shareholders</u>	Validity: August 18, 2016	None
	13.45 million shares in one or more tranches	
Capital increase without preferential subscription rights	(included in the ceiling of 17.3 million shares)	
for shareholders	Validity: August 18, 2016	None
	20% of share capital with a price not less than	
Capital increase reserved for qualified investors	the average of the price of three trading sessions	
or a restricted group of investors without preferential	with a maximum discount of 5%	
subscription rights in their favor	Validity: August 18, 2016	None
Setting the price of issuance of shares in the event of the		
waiver of preferential subscription rights in accordance with	10% of share capital per year	
Article L. 225-136 1° para. 2 of the French Commercial Code	Validity: August 18, 2016	None
Capital increase with cancellation of preemptive subscription		
rights to compensate the contribution of securities, in the case	2	
of an exchange offer or contribution in kind applicable	10% of share capital	
to corporate securities	Validity: August 18, 2016	None

# 5.1.6 Information on the equity of any member of the Group subject to an option or a conditional or unconditional agreement to place it under option

None.

## 5.1.7 Changes to share capital

#### ○ CHANGE IN EQUITY OVER THE PAST THREE YEARS

Fiscal year	Type of transaction	Number of securities	Issue of shares (€)	Issue premium per share (€)	Total issue premiums (€)	Total capital (€)	Total number of shares
2013	Capital increase <sup>(1)</sup>	9,600	21,965	-	-	72,908,282	31,864,090
2013	Capital increase (2)	10,768	24,638	6.54	45,784.44	72,932,920	31,874,858
2014	Capital increase (2)	15,697	35,916.33	5.02	78,934.08	72,968,836.33	31,890,555
2014	Increase of share capital <sup>(3)</sup>	6.553.551	14.995.192.04	7.71189817	50,540,317.96	87.964.029.39	38,444,106
2014	Capital increase (1)	81,750	187,052.32	-	-	88,151,081.71	38,525,856
2014	Capital increase <sup>(2)</sup>	2,112	4,832.47	4.091898	8,642.09	88,155,914.18	38,527,968
2015	Capital increase <sup>(1)</sup>	17,249	39,879.33	4.09	71,317.69	88,195,793.51	38,545,397

<sup>(1)</sup> Capital increase by awarding vested free shares to Company employees.

Change in shareholdings over the past three years (see Section 5.2.1 "Name of any person not a member of an administrative or management body directly or indirectly holding more than 5% (statutory and legal reporting threshold) of the Company's capital or voting rights").

<sup>(2)</sup> Capital increase by exercising stock options during the year.

<sup>(3)</sup> Capital increase by issuing new shares.

## 5.2 PRINCIPAL SHAREHOLDERS

# 5.2.1 Name of any person not a member of an administrative or management body directly or indirectly holding more than 5% (statutory and legal reporting threshold) of the Company's capital or voting rights

The following table shows the breakdown of capital and voting rights in the Company at December 31, 2015 based on an analysis of bearer share ownership conducted at the Company's request following the capital increases made at the end of March 2014 and the distribution as at December 31, 2012

and 2013. In 2014 Dassault Belgique Aviation declared that it had passively fallen below the 5% stock ownership threshold. There is no shareholder apart from the majority shareholder TSGH that owns more than 5% of share capital.

Shareholder	As at 12/31/2013			As at 12/31/2014 (3)			As at 12/31/2015		
	Number of shares	% of capital	% of voting rights <sup>(2)</sup>	Number of shares	% of capital	% of voting rights <sup>(2)</sup>	Number of shares	% of capital	% of voting rights <sup>(2)</sup>
TSGH	17,488,634	54.87	69.78 <sup>(1)</sup>	19,987,011	51.9	66.3	19,987,011	51.85	66.3
Dassault Belgique aviation	1,645,440	5.16	3.30	1,884,182	4.9	3.3	1,884,182	4.89	3.3
Moneta Assets Management LLC (4)	550,000	1.73	1.10	1,523,600	3.9	2.7	_ (7)	-	-
Other shareholders (4) (5)	12,190,784	38.2	25.8	15,133,175	39.3	27.7	34,662,514 <sup>(8)</sup>	42.36	30.4
Total	31,874,858	100	100	38,527,968	100	100	38,545,397	100	100
Dilutive impact stock- options + free shares awarded (4) (6)	n/a	n/a	n/a	1,228,687	3		1,087,334	2.7	
TOTAL DILUTED (4)				39,756,655			39,623,731		

- (1) On July 18, 2013, TSGH made an amended shareholding threshold declaration that put its voting rights at below 65% (64.73%) in June 2010 as a result of a capital increase. It again rose above the 65% threshold (to 67.18%) in July of that year as a result of the allocation of double voting rights.
- (2) Article 8 of the bylaws grants double voting rights to all fully paid registered shares, registered in the name of the same shareholder for at least three years. In accordance with the provisions of Article L. 233-8 of the French Commercial Code, Transgene publishes monthly (if the information has changed since the last monthly publication) the total number of shares and voting rights on the AMF website and on its own site www.transgene.fr. At December 31, 2015, the total number of shares was 38,527,968; the total theoretical number of voting rights was 56,540,793 and the number of exercisable voting rights was 56,319,559. No limitation has been placed on voting rights. The double voting rights attached to a share disappear the day the security is assigned or converted to the bearer.
- (3) In 2013, 20,368 new shares were created as a result of the vesting of 9,600 free shares and 10,768 stock options exercised.
- (4) Data from IPREO reports in November 2011, October 2012 and October 2013.
- (5) To the Company's knowledge, there are no other shareholders directly or indirectly owning, alone or in concert, over 5% of the equity or voting rights. The Company does not own any of its own shares. The total percentage of employee ownership is less than 0.5%. Since it is insignificant, the Company does not monitor employee shareholdings. There are not, to the knowledge of the Company, any concert parties or agreements between shareholders.
- (6) The stock options were granted to the employees of the Company and its subsidiary Transgene, Inc., including members of the Executive Committee and to two executive corporate officers (Philippe Archinard, Chairman and Chief Executive Officer, and Christophe Ancel, Qualified Pharmacist and Deputy Chief Executive Officer.) Free shares were awarded exclusively to the employees of the Company and its wholly owned subsidiary Transgene, Inc., excluding all corporate officers and members of the Executive Committee.
- (7) This investor's holding in Company shares is less than 1% according to the data taken from IPREO in October 2015.
- (8) In 2015, 17,429 new shares were created due to the exercise of options.



#### 5.2.2 Special voting rights of the principal shareholders

Major shareholders do not benefit from different voting rights. Pursuant to Article 8 of the corporate bylaws, double voting rights are granted to all fully paid registered shares registered in the name of the same shareholder for at least three years, regardless of the number of shares held by the holder.

#### 5.2.3 Controlling shareholder

The Company's capital is owned 51.9% (66.3% of voting rights) by TSGH SAS, which is in turn owned 98.66% by Institut Mérieux, which is owned by the Mérieux family. No specific measure limits the powers of the principal shareholder. The Company complies with the Code of Corporate Governance for small- and mid-cap companies. The Board of Directors includes a significant proportion of independent directors.

With regard to measures taken to ensure that the control of the Company is not exercised in an abusive manner, the Company has had, since the appointment of Ms. Zitvogel to the Board of Directors by the General Shareholders' Meeting of June 19, 2013, six directors out of ten (instead of five, previously) who qualify as independent using the criteria defined in the MiddleNext Corporate governance Code, one of whom, Mr. Habert, is connected with the Dassault Group, which holds under 5% of the Company stock, through a family relationship and as Chairman and member of the strategy committee of Dassault Développement. Moreover, a majority of the Audit Committee consists of independent directors (three out of four members) and the Compensation Committee is solely comprised of independent directors.

## 5.2.4 Agreement that may result in a subsequent change of control of the Company

To the Company's knowledge, at the date of this Document de référence there is no agreement that could at a later date, if enforced, bring about a change in the controlling interest of the

Company, nor pact outside the Statutes, or any anti-takeover measure, or specific powers of representation or appointment to executive bodies.

## 5.3 ARTICLES OF INCORPORATION AND STATUTES

## 5.3.1 Corporate purpose (Article 2 of the Statutes)

The purpose of the Company, both in France and abroad, on its own behalf and on behalf of third parties:

- all activities of research, development, studies for the refinement of processes of production and marketing, preclinical and clinical development of production and marketing of all products and processes in the areas of bioindustry, biotechnology and more specifically genetic engineering, principally for the purpose of experimenting, developing and exploiting medications for human and veterinary medicine, and generally the application of all
- sciences and techniques that might add to the development of said products and processes;
- the creation, acquisition, by any means and the operation in any form of any company connected directly or indirectly with these activities, as well as the investment by any means in such companies;
- and more broadly, all commercial, industrial and financial operations involving any kind of asset that might relate directly or indirectly to the foregoing purpose or that might lead to its achievement, expansion or development.

## 5.3.2 Company management

# Board of Directors (excerpts and summaries from the relevant Statute Articles and regulations)

The Company is managed by a Board of Directors composed of at least three members and at most fifteen members who are chosen from among the shareholders and elected by the General Shareholders' Meeting.

The directors are appointed for a period of three years. Their directorship ends at the end of the Ordinary General Shareholders' Meeting approving the financial statements for the prior year, which is held during the year in which their term expires. The Board ensures that the number of terms expiring is as regular as possible each year.

The directors may be re-elected and may be recalled by the General Shareholders' Meeting at any time. In the event of a vacancy of one or more seats, the Board may, in the manner prescribed by law, make provisional appointments. The directors so appointed do not serve longer than the remainder of their predecessor's term, and their appointment must be ratified by the next following Shareholders' Meeting.

Each director must, throughout his or her service, own at least one share of stock in the Company.

The Board of Directors elects from among its members who are individuals a Chairman and, possibly, one or more Vice-Chairmen, and sets their term of office that not exceed their term of office as a director, nor the time remaining from their

appointment to the end of the Ordinary General Shareholders' Meeting called to approve the financial statements for the fiscal year in which the Chairman reaches 67 years of age.

However, the Board may under exceptional circumstances extend the period, fiscal year by fiscal year, as long as this extension does not exceed two fiscal years.

In the event of the absence or incapacity of the Chairman, the Board shall appoint a Chairman *pro tempore* from among the Vice-Chairs or, failing that, the directors.

The Board may also appoint a Secretary, who may or may not be a shareholder.

The Board of Directors proceeds with the controls and verifications it deems appropriate. Directors receive all of the information required to accomplish their mission and may request any document they consider useful.

The Chairman of the Board of Directors shall represent the Board of Directors. He organizes and directs its work and reports back to the General Shareholders' Meeting. He ensures the proper operations of the Company's bodies, and, specifically, that the directors are capable of fulfilling their duties.

Except for the powers that the law expressly confers on the Shareholders' Meetings, as well as the powers that it specially reserves to the Board of Directors, and within the limits of the corporate purpose, the Chairman is invested with the broadest powers to act in the Company's name under all circumstances.

No limitation placed on the Chairman's powers by the Board of Directors can be contested by third-parties.

Subject to the terms of the paragraphs above, the Board of Directors may delegate to one or more of its members or third parties, whether or not they are shareholders, any type of specific mandate for one or more specific objects, under conditions it defines, with or without potential substitution, to proceed with all studies and inquiries. When this occurs, the Board defines compensation, both fixed and proportional. If a director is given a paid term of office then the provisions of Articles L. 225-38 et seq. of the French Commercial Code shall apply.

If the Board of Directors decides to separate the positions of Chairman and Chief Executive Officer, subject to the powers that the law confers expressly on Shareholders' Meetings as well as the powers that are specially reserved to the Board of Directors and within the limitations of the corporate purpose, the Chief Executive is invested with the broadest powers to act in the Company's name under all circumstances and represent it in relations with third parties.

On a recommendation from the Chief Executive Officer, the Board of Directors may appoint one or more persons to assist the Chief Executive Officer with the title of Deputy Chief Executive Officer.

The number of Chief Operating Officers may not exceed five.

If they are directors of the Company, the Chief Executive Officer and Chief Operating Officers may not be appointed for longer than their term as directors.

The Board of Directors sets the compensation of the Chairman of the Board, the Chief Executive Officer and, as applicable, the Deputy Chief Executive Officers. This compensation may be fixed or a combination of fixed and variable.

In compliance with Article L. 225-9 of the French Commercial Code, the normal agreements between the Company and a

director, the Chairman of the Board or the CEO must be given by the party in question to the Chairman of the Board of Directors. The list and purpose of said agreements are provided by the Chairman to the members of the Board and to the Statutory Auditors. Shareholders are entitled to be informed of the list and the object of these common agreements.

The directors are invited to the meetings of the Board by any means, including verbally. The Board's rules of procedure may provide for the adoption of resolutions by electronic means.

Deliberations take place in quorum and majority conditions set out by law. In the event of a tie vote, the vote of the session's Chairman shall prevail.

A director may give his or her proxy to another director to represent him or her at a Board meeting.

Minutes are prepared and copies and excerpts of deliberations are issued and certified as defined by law.

The Responsible Pharmacist, who shall be licensed to practice in France (Table B of the Order) and shall file his license on behalf of the Company, will be responsible for the Company's compliance with the rules imposed by law and regulation governing the profession of pharmacist.

In this regard, the Qualified Pharmacist is fully empowered by law with all powers to make direct contact with all authorities or organizations with jurisdiction, to make all applications, solicit all approvals or authorizations, verify raw materials and authorize their use, make frequent inspections of laboratories, oversee manufacturing, and alone authorize the use and marketing of the finished products. In addition, he or she shall approve the hiring of pharmacists and the heads of other technical departments before they start work at the Company.

In the event of a conflict between the Chairman and the Qualified Pharmacist, the Board of Directors will arbitrate without ever imposing a decision that runs counter to the law or regulations and that might incur the liability of the Pharmacist.

## 5.3.3 Share classes

Only one class of shares exists. Each share entitles the holder to one share proportional to the fraction of capital that it represents, in the Company's assets and earnings and in any liquidation surplus.

## 5.4.3 Shareholders' rights

Shareholders' rights may only be changed, and in the manner prescribed by law, by an extraordinary General Shareholders' Meeting that meets the conditions of quorum and majority set by the French Commercial Code. There is no more restrictive term in the statutes. The Company capital may be changed pursuant to the terms of the law.

## 5

## 5.3.5 General Shareholders' Meetings (Article 21 of the Statutes)

General Shareholders' Meetings are called and deliberate pursuant to the terms of the law. Meetings take place either at the corporate headquarters or at another place specified in the notice of meeting.

According to the Article R. 225-85 of the French Commercial Code, the right to participate in General Shareholders' Meeting is justified if shares have been recorded in the shareholder's name or that of a designated intermediary by midnight (Paris time) of the third business day preceding the meeting, in either the Company's record of registered shares or the authorized intermediary's record of bearer shares.

The registration of shares in the financial intermediary's register of bearer shares shall be documented by a certificate of participation delivered by the financial intermediary (or electronically pursuant to Article R. 225-61 of the French Commercial Code) attached hereto:

• the voting by correspondence form;

- the proxy vote;
- the request for an admission ticket in the shareholder's name or on behalf of a shareholder represented by a designated intermediary.

Any shareholder may be represented by another shareholder or by his or her spouse or by any other individual or legal entity they chose in the manner provided by Article L. 225-106 of the French Commercial Code. Shareholders' Meetings are chaired by the Chairman of the Board of Directors or, in his absence, by a Vice-Chairman or by a director appointed for that purpose by the Board of Directors. Failing this, the assembly itself will elect a Chairman. Minutes are prepared and copies certified and delivered pursuant to the terms of the law.

A double voting right attached to registered shares recorded in the name of the same person for at least three years was established by the Extraordinary General Shareholders' Meeting of June 9, 2004 and incorporated into the Statutes (Article 8).

# 5.3.6 Provisions having the effect of delaying, deferring or preventing a change of control

None.

## 5.3.7 Ownership thresholds (Article 7 of the Statutes)

Any individual or legal entity, acting alone or in concert with others, who in any way owns, as defined by Articles L. 233-14 and seq. of the French Commercial Code, a number of shares representing now or in the future a fraction equal to at least 5% of the equity and/or voting rights at Shareholders' Meetings, or any multiple of that percentage, even if this multiple exceeds the legal threshold of 5%, must inform the Company of the total number of shares it holds, by registered letter with confirmation of delivery sent to the Company's registered office within 15 days of the date on which the threshold was reached or exceeded or by any equivalent means, with respect to shareholders residing outside of France.

This information obligation shall apply in the same conditions as those specified above any time that the fraction of the share capital and/or voting rights held should fall below the threshold specified above.

In the event of failure to comply with the above provisions, voting rights will be stripped from the shares in excess of the threshold triggering the duty to notify if such is requested by one or more shareholders who together or separately own at least 5% of the equity and/or voting rights in the Company, as provided in Article L. 233-7, final paragraph, of the French Commercial Code. In the event such non-compliance is remedied, the voting rights in question cannot be exercised until the expiration of the time period prescribed by the applicable laws and regulations.

5.3.8 Conditions imposed in the Statutes, a charter or regulations governing changes to the capital, when such conditions are stricter than those provided by law

None: no such terms exist for the Company.

## 5.4 HISTORY AND INFORMATION ON THE COMPANY DURING THE PERIOD

## 5.4.1 History and development of the Company

#### 5.4.1.1 Legal name and Commercial name

Transgene SA

## 5.4.1.2 Place of registration and registration number

The Company is registered in the Strasbourg Trade and Company Registry under identification No. RCS B 317 540 581. Its economic activity Code (APE) is 7211Z (Biotechnology research and development).

## 5.4.1.3 Date of incorporation and duration

The Company was founded in December 1979 for a period of 99 years that expires on December 31, 2078.

## 5.4.1.4 Registered Office, legal form and applicable law

A French corporation (société anonyme) with a Board of Directors, governed by the French Commercial Code.

#### **Transgene SA**

400, boulevard Gonthier d'Andernach - Parc d'Innovation 67400 Illkirch-Graffenstaden France

Tel. + 33 3 88 27 91 00

## 5.5 INFORMATION ON INVESTMENTS **IN AFFILIATES**

The table of subsidiaries and affiliates is presented in Note 27 to the Company's annual financial statements (page 133).

#### Special report of the Statutory Auditors on regulated agreements and commitments

## 5.6 SPECIAL REPORT OF THE STATUTORY AUDITORS ON REGULATED AGREEMENTS AND COMMITMENTS

General Shareholders' Meeting to approve the financial statements for the fiscal year ended December 31, 2015

Dear Shareholders,

In our capacity as Statutory Auditors of your company, we hereby present our report on related party transactions and undertakings.

It is our duty to inform you, on the basis of the information provided to us, of the features and key terms as well as the reasons justifying their interest for the Company, of the agreements and commitments of which we have been advised or that we discovered during our assignment, without any comment on our part on their usefulness and appropriateness or identification of such other agreements and commitments. Pursuant to the terms of Article R. 225-31 of the French Commercial Code, you are responsible for evaluating the potential interest of entering into these agreements and undertakings with a view to their approval.

Our role is also to provide you with the information stipulated in Article R. 225-31 of the French Commercial Code relating to the implementation during the past year of agreements and commitments previously approved by the General Shareholders' Meeting, if any.

In this engagement we have made such investigations as we judged necessary in light of the professional Code of the French association of Statutory Auditors, the *Compagnie nationale des commissaires aux comptes*. These diligences consisted of verifying the conformity of the information we received with the source documents from which said information arises.

## Agreements and commitments submitted for approval to the General Shareholders' Meeting

#### Agreements and commitments authorized during the fiscal year

Pursuant to Article L. 225-40 of the French Commercial Code, we have been advised of the following agreements and commitments previously authorized by your Board of Directors.

As your company undertook a procedure to outsource its industrial activities, your Board of Directors at its meeting on September 30, 2015, was asked to rule on the single offer received from Advanced Bioscience Laboratories Inc. (wholly owned by IMEurope SAS, itself wholly owned by Institut Mérieux) to buy the real estate and other assets for €3.5 million and the concurrent signing of a provision of services agreement amounting to €3 million per year for a 3-year period. Your company's interest in completing this transaction was to move ahead with the planned restructuring and achieve the related structural cost savings, while, at the same time, securing the ongoing and uninterrupted manufacture at the same site of its clinical batches using operators trained on Transgene's products, by reassigning about 30 of its employees to ABL Europe SAS. Moreover, an independent appraisal firm reviewed whether the financial terms and conditions offered by Advanced Bioscience Laboratories Inc. were fair and submitted its findings to your Board of Directors.

With ABL EUROPE SAS (wholly-owned subsidiary of ADVANCED BIOSCIENCE LABORATORIES Inc., wholly-owned by IMEUROPE SAS, in turn wholly-owned by the INSTITUT MÉRIEUX)

Related parties: Alain Mérieux, Philippe Archinard, Jean-Luc Bélingard, and Dominique Takizawa.

Purchase agreement of a bio-production asset

**Nature and purpose:** As part of the sale of your company's bio-production asset to ABL Europe SAS, your company entered into an Asset Purchase Agreement, including the following related agreements:

- $\bullet \quad \hbox{preliminary sales agreement for the land and manufacturing building in Illkirch-Graffenstaden};\\$
- notarial deed on the land and manufacturing building in Illkirch-Graffenstaden;
- a Transition Services Agreement;
- agreement for subleasing a part of the QC laboratory at the Company's headquarters.



**Terms:** The Asset Purchase Agreement sets forth the conditions for the sale by your company to ABL Europe SAS of the bioproduction asset, including the dedicated building and land, for a total of €3.5 million.

The Transition Services Agreement sets forth the terms and conditions for the transitional period between the start of your company's restructuring plan and the effective sale of the bio-production asset.

Lastly, the sublease agreement stipulates the terms of use by ABL Europe SAS of a part of your company's quality control laboratory.

As the sale of the bio-production asset took place on February 1, 2016, these agreements had no effect during the fiscal year ended December 31, 2015.

With ABL EUROPE SAS (wholly-owned subsidiary of ADVANCED BIOSCIENCE LABORATORIES Inc., wholly-owned by IMEUROPE SAS, in turn wholly-owned by the INSTITUT MÉRIEUX)

Related parties: Alain Mérieux, Philippe Archinard, Jean-Luc Bélingard, and Dominique Takizawa.

Employee reclassification agreement

**Nature and purpose:** As part of the sale of your company's bio-production asset to ABL Europe SAS, your company entered into an agreement to reclassify employees, called the Social Agreement.

Terms: This agreement stipulates the conditions of partially redeploying the employees assigned to bio-manufacturing.

As the sale of the bio-production asset took place on February 1, 2016, this agreement had no effect during the fiscal year ended December 31, 2015.

With ABL EUROPE SAS (wholly-owned subsidiary of ADVANCED BIOSCIENCE LABORATORIES Inc., wholly-owned by IMEUROPE SAS, in turn wholly-owned by the INSTITUT MÉRIEUX)

Related parties: Alain Mérieux, Philippe Archinard, Jean-Luc Bélingard, and Dominique Takizawa.

Exclusive Services Agreement

**Nature and purpose:** As part of the sale of your company's bio-production asset to ABL Europe SAS, your company entered into an Exclusive Services Agreement.

**Terms:** This agreement sets forth the terms for the exclusive sale of bio-manufacturing services by ABL Europe SAS to your company. The amount under this agreement is €3 million per year for a three-year period.

As the sale of the bio-production asset took place on February 1, 2016, this agreement had no effect during the fiscal year ended December 31, 2015.

#### Agreements and commitments previously approved by the General Shareholders' Meeting

#### Agreements and commitments approved during previous fiscal years

#### a) Whose performance was continued during the fiscal year most recently ended

Pursuant to Article R. 225-30 of the French Commercial Code, we were informed that the performance of the following agreements and commitments already approved by the General Shareholders' Meeting during previous fiscal years continued during the financial year just ended.

#### With INSTITUT MÉRIEUX

Related parties: Alain Mérieux, Philippe Archinard and Jean-Luc Bélingard.

Contract for the provision of services

**Nature and purpose:** In 2014, your company tacitly extended the services agreement signed with Institut Mérieux from January 1, 2002 (amended by two riders in 2007).

#### Terms:

- the first rider provides that compensation is based on the services rendered by the Institut Mérieux (costs and employee benefits expenses plus 8%) and is allocated among the companies of the Institut Mérieux group according to three allocation factors based on the respective size of fixed assets, revenue and total payroll;
- the second rider addresses with the manner of allocating the cost of free shares if the employee beneficiary was transferred within the Institut Mérieux group during the vesting period. The Institut Mérieux group company, that allocates bonus shares, rebills without margin costs related to the bonus shares in proportion to the time spent by the employee concerned in each company during the vesting period.

#### INFORMATION ABOUT THE COMPANY AND ITS CAPITAL

Special report of the Statutory Auditors on regulated agreements and commitments

For the period ended December 31, 2015 your company recognized a charge of €456,284.

The new contract authorized by the Board of Directors on December 10, 2014 replaced the previous services agreement and its riders. It amends the term of the contract to an indefinite term and restates the manner of compensation as follows:

In exchange for the performance of the services described in the contract (including both the services continuously provided to all the Group companies and other services that might be provided specially to your company), the Institut Mérieux in its capacity as an active holding company will receive compensation calculated on the basis of the costs borne to perform said services (in particular personnel costs including salaries/wages and social security charges and any other direct costs of employees), to which an 8% markup will be applied. The allocation factors for the services shared by the Group entities will be based on the respective size of fixed assets, revenue and total payroll.

The travel expenses of the Institut Mérieux employees tasked with the services will be invoiced at cost, supported by receipts. The costs of consultants hired by the Institut Mérieux will be invoiced at cost, supported by the related receipts.

The services will be invoiced quarterly by the Institut Mérieux based on a projected budget adjusted annually no later than June 30 of the following year.

#### b) Not implemented during the year most recently ended

In addition, we were informed of the following agreements and commitments already approved by the General Shareholders' Meeting in previous years that were not implemented during the year most recently ended.

With INSTITUT MÉRIEUX, BIOMÉRIEUX, and MÉRIEUX NUTRISCIENCES CORPORATION, ADVANCED BIOSCIENCE LABORATORIES Inc., MÉRIEUX DÉVELOPPEMENT

Related parties: Alain Mérieux, Philippe Archinard and Jean-Luc Bélingard.

Agreement to share the cost of contract termination fees related to the departure of one of the Group's employees.

**Nature and purpose:** In 2014, your company tacitly renewed the agreement of January 1, 2007 providing for the financial allocations consequent to a possible termination of the employment contracts of employees who have worked at more than one company in the Institut Mérieux group.

**Terms:** The company terminating the employee's contract pays all of the "contract termination expenses" to the employee in question and then allocates these "expenses" among the other companies in proportion to the compensation paid by each group company since the employee first began working in the Group.

The new agreement authorized by the Board of Directors on December 10, 2014 amends the term of the open-ended contract, leaving the other features of the contract largely unchanged.

This agreement had no effect for the fiscal year ended December 31, 2015.

Lyon, April 27, 2016

Statutory Auditors

**DIAGNOSTIC RÉVISION CONSEIL** 

**ERNST & YOUNG et Autres** 

Hubert de Rocquigny du Fayel

Marc-André Audisio

## 5.7 EMPLOYEES

## 5.7.1 Workforce

See the headcount table at Section 3.2.1.1.

## 5.7.2 Profit-sharing agreement

A profit-sharing agreement has existed since 1993, pursuant to the regulations in effect. In light of the Company's deficit situation, no profit has been shared with employees under this agreement as of the date of this Document de référence.

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## 6.1 PERSONS RESPONSIBLE

## 6.1.1 Persons responsible for the information

Philippe Archinard

Chairman and Chief Executive Officer

Jean-Philippe Del

Vice President, Finance

**Ghislaine Gilleron** 

Corporate Secretary

Telephone: 03 88 27 91 21 Fax: 03 88 27 91 11 www.transgene.fr

## 6.1.2 Declaration by the person responsible

I, the undersigned, having taken all reasonable measures for the purpose, hereby certify that the information contained in this *Document de référence* gives, to the best of my knowledge, a true and fair view of facts and is free from material misstatements.

I hereby certify that, to my knowledge, the financial statements have been drawn up in accordance with applicable accounting standards and give a true and fair view of the assets, financial position and profits and losses of the Company and of all the companies within the scope of consolidation, and the management report on pages 164 to 168 includes a statement setting out a true and fair view of the business, profits and financial position of the Company and of all the companies within the scope of consolidation and a description of the principal risks and uncertainties they face.

I have received an audit completion letter from the Statutory Auditors, in which they state that they have verified the information regarding the financial position and financial statements presented in this document and have reviewed the entire document.

The historical financial information presented in this document is described in reports by the Statutory Auditors, which contain no matters to report, on pages 112, 134, 135.

Philippe Archinard

Chairman and Chief Executive Officer

## 6.2 PERSONS RESPONSIBLE FOR AUDITING THE FINANCIAL STATEMENTS

## 6.2.1 Statutory Auditors

#### **Statutory Auditors**

**ERNST & YOUNG et Autres** 

1/2, place des Saisons 92400 Courbevoie - Paris-La Défense represented by Marc-André Audisio Commissariat Contrôle Audit 20, rue Garibaldi 69006 Lyon represented by Hubert de Rocquigny du Fayel

69006 Lyon

Ernst & Young et Autres is a member of the Compagnie Régionale des Commissaires aux Comptes de Versailles and of the Ernst & Young network.

**Commissariat Contrôle Audit - C.C.A** is a member of the Compagnie Régionale des Commissaires aux comptes de Lyon and the PricewaterhouseCoopers network.

#### DATES OF APPOINTMENT AND EXPIRATION OF TERM

Appointed May 29, 1996 and renewed February 16, 1998, and again on June 9, 2004 and June 17, 2010 until the General Shareholders' Meeting called to approve the 2015 financial statements.

Appointed February 16, 1998 and renewed June 9, 2004, and again June 17, 2010 until the General Shareholders' Meeting called to approve the 2015 financial statements.

#### ALTERNATE STATUTORY AUDITORS

#### Auditex

Tour Ernst & Young 1/2, place des Saisons 92400 Courbevoie - Paris-La Défense 1 **Diagnostic Révision Conseil** 20, rue Garibaldi

#### DATES OF APPOINTMENT AND EXPIRATION OF TERM

Appointed June 17, 2010 until the General Shareholders' Meeting called to approve the 2015 financial statements.

Appointed February 16, 1998 and renewed June 9, 2004, and again June 17, 2010 until the General Shareholders' Meeting called to approve the 2015 financial statements.

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## **6.2.2** Fees paid to the Statutory Auditors

	Ernst & Young et Autres			C.C.A.				
	Amount (before tax) %		Amount (b		efore tax) 9		%	
(in € thousands)	2015	2014	2015	2014	2015	2014	2015	2014
Audit	-	-	-	-	-	-	-	-
Statutory Auditors, certification, examination of individual and consolidated financial statements								
Issuer	60.0	60.0	72%	79%	21.1	24.7	100%	100%
Fully consolidated subsidiaries	-	-	-	-		-	-	-
Other due diligence and services directly related to the audit								
Issuer	23.8	16.0	28%	21%	-	-	-	-
Fully consolidated subsidiaries	-	-	-	-	-	-	-	-
Sub-total	83.8	76.0	100%	100%	21.1	24.7	100%	100%
Other services provided by networks to fully consolidated subsidiaries	-	-	-	-	-	-	-	-
Legal, tax and social	-	-	-		-	-	-	-
Other (specify if > 10% of the audit fees)	-	-	-	-	-	-	-	-
Sub-total	-	-	-	_	-	-	-	-
TOTAL	83.8	76.0	100%	100%	21.1	24.7	100%	100%

## • 6.3 THIRD PARTY INFORMATION, STATEMENTS BY EXPERTS AND DECLARATIONS OF INTEREST

None.



## 6.4 DOCUMENTS AVAILABLE TO THE PUBLIC

Throughout the validity period of this *Document de référence*, the following documents may be consulted:

- the corporate statutes;
- all the reports, correspondence and other documents, background financial information, evaluations and declarations prepared by experts at the Company's request, a portion of which is included or referred to in the registration document;
- the Company's background financial information and that of its subsidiary for each of the two fiscal years preceding the publication of the *Document de référence*;
- the Board's rules of procedure.

These documents may be viewed on the website:

www.transgene.fr or obtained from Jean-Philippe Del, Vice President, Finance.

## • 6.5 CROSS-REFERENCE TABLES

In order to facilitate the reading of the *Document de référence*, the following table identifies the main information required by annex 1 of European Regulation no. 809/2004/EC.

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## 6.6 GLOSSARY

**Adenovirus:** a member of a family of DNA viruses responsible for diseases of the respiratory tract, eye, and gastrointestinal tract. The forms of adenovirus used in immunotherapy, particularly the type 5 adenovirus for Transgene, are safe and cause no symptoms or pathology. Genes with an ability to boost the immune system or to repair genetic defects can be inserted into the genome of the virus.

**Antibody:** Antibodies are proteins used by the immune system to identify and neutralize foreign bodies such as bacteria and viruses. The antibody binds itself to a specific location on its target, called the antigen. This binding activates several functions of the immune system, since antibodies have different modes of action depending on their type: some neutralize or disarm the antigens directly while others prepare them for destruction by white blood cells.

**Antigen:** an antigen is a substance that causes the organism to mount an immune defense against it. Antigens can be produced by the organism itself (self antigens) or come from the environment (non-self antigens). The latter include toxins, chemicals, bacteria, viruses, parasites and other substances from outside the body. Usually the immune system does not react against self antigens; but nevertheless certain pathologies called auto-immune diseases involve self-destruction by this defense system (multiple sclerosis, rheumatoid arthritis, type 1 diabetes, etc.).

**Biomarker:** a biomarker is an indicator used in diagnosis to define or predict the course of an illness: a viral, bacterial or parasitic infection and cancers. This biomarker can be used to adapt a treatment to a particular pathology in a given patient.

**Cytokine:** a large category of small proteins involved in the immune defense system. Some cytokines boost or inhibit the immune system, as needed.

Cytolysis - cytolitic: tending to dissolve (destroy) cells.

**Epithelial cells:** these constitute a tissue that covers either the outer surfaces of the organism (like skin or oral mucoses) or the inside of the body (heart cavity, digestive canal, etc.). These cells also help to make up certain glands such as the prostate, the thyroid, and the mammary and salivary glands.

**Gene:** the functional and physical unit of heredity, transmitted from parent to child. Genes are components of DNA and most of them contain the information necessary to manufacture a specific protein.

**GM-CSF:** (granulocyte-macrophage colony stimulating factor) a cytokine that acts as a growth factor on white corpuscles, especially granulocytes, macrophages and cells that become platelets.

**Histology:** the study of the appearance of cells under a light or electronic microscope.

**Interleukin-2 (IL2):** a cytokine that stimulates the growth of certain cells in the immune system involved in the defense of the organism.

**Lymphocytes:** immune cells (white corpuscles) produced by bone marrow and found in blood and lymph. The two principal types of lymphocytes are B cells and T cells. B lymphocytes produce antibodies and T lymphocytes help destroy tumor cells and control the immune response.

**Metastasis:** the spread of cancer cells from one part of the body to another.

**Metronomic:** cancer treatment with regularly repeated low doses of drugs, like a metronome. This method acts not only on the tumor environment, by destroying the blood vessels that nourish the tumor, but also on the immune system by destroying blocking cells.

**Monoclonal antibodies:** monoclonal antibodies are antibodies produced by a given cell that can bind to only one substance. Monoclonal antibodies are used in the treatment of certain types of cancer, as well as other diseases. They may be used alone or to transport therapies such as toxins or radioactive substances directly into the cancerous cells.

**MUC1:** protein found in certain epithelial cells, which line the internal surfaces of the organism (lungs, stomach, breasts, ovaries, intestines, etc.). The aberrant form of MUC1 is found in abnormal quantities in cancerous patients.

MVA (Modified Virus Ankara): a highly attenuated strain of the vaccine developed towards the end of the campaigns to eradicate smallpox, primarily for people sensitive to conventional vaccination. MVA is an attenuated virus often used to develop vaccines for antigen expression. The MVA virus is a desirable vaccine strain for clinical studies because of its outstanding safety.

**Myeloid:** having to do with a specific category of cells produced by the bone marrow that become the reserve for renewing certain white blood cells, red blood cells and platelets.

**Objective tumor response:** an objective tumor response is measurable. It is most often evaluated with medical imaging and is one of the major indicators in evaluating a cancer therapy.

**Oncolytic virus:** a virus that selectively infects cancer cells and destroys them. When the infected cancer cells are destroyed by lysis, they liberate new infectious viral particles that in turn help destroy the surrounding tumor cells. Besides directly destroying tumor cells, oncolytic viruses stimulate tumor-fighting immune responses in the patient.

**Orphan designation drug:** a classification that regulatory authorities (the Food and Drug Administration in the USA, the European Medicines Agency in Europe) may apply to a drug or biological product for the treatment of a rare, fatal or chronically debilitating disease.

**Phase 1 (clinical study):** the first step in testing of a drug in humans, either in healthy volunteers or in patients with various diseases. The phase 1 study tests a medication or treatment on a small number of people in order to evaluate safety and tolerability.

**Phase 2 (clinical study):** phase 2 clinical studies include a greater number of patients than phase 1 and are designed to evaluate the safety, dosage and sometimes the effectiveness of the new drug or treatment.

**Phase 3 (clinical study):** phase 3 clinical studies typically involve hundreds or thousands of patients depending on the disease, and are designed to evaluate the safety and effectiveness of a drug in a controlled setting.

**Poxvirus:** a large family of DNA viruses, the best known of which are the vaccine viruses that enabled the eradication of smallpox in the late 1970s, which remains to date the only example of the elimination of a worldwide pandemic. Because it is so effective, this virus family is used today for other infectious diseases (HIV, tuberculosis, RSV, ebola) or in oncology (therapeutic vaccines, oncolytic agents).

**Protein:** a molecule made up of chains of units called amino acids. There are 21 of these amino acids, and some are known as essential amino acids since our bodies cannot synthesize them. These molecules play a number of roles: structural, as sensors, for repair, etc.

**Protocol:** the detailed plan of a scientific or medical experiment, a treatment or procedure. The protocol of a clinical study describes what is done, how and why.

**Randomized:** in a randomized clinical study the patients are assigned by chance to separate groups to compare different treatments.

**Receptor:** a molecule inside or on the surface of a cell that binds to a specific substance and causes a biological reaction in the cell

**Recombinant:** a molecule (DNA or protein) is recombinant when a new combination is made of its genetic material. For example, when DNA segments from different sources are joined to produce an original sequence.

**Refractory:** a disease is said to be refractory if it does not respond to a treatment.

**Solid tumor:** an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors can be benign (non-cancerous) or malignant (cancerous).

**Stage:** the level of growth of a cancer. Stage is generally determined by the volume of the tumor, whether or not the lymphnodes have been affected and by the extent to which the cancer has spread from the original site to other areas of the body. Stages run from 0 to IV, with IV being the most advanced stage.

**T cells or T Lymphocytes:** type of white blood cells belonging to the immune system and developing from stem cells in bone marrow. They help protect the body from infections and can help fight cancer.

**Targeted therapy:** a treatment that uses drugs to specifically identify, block or destroy cancer cells, with less damage to normal cells.

**Tyrosine kinase inhibitors:** substances that block the action of enzymes called tyrosine kinases. These enzymes have many functions including cellular signaling, growth and division. They can be overly active or present at high levels in certain types of cancer cells. Blocking them can prevent the growth of cancer cells. They are a form of targeted therapy.

**Vascularization:** the formation of blood vessels in the human body or an organ.

**Viral vaccine vector:** an attenuated form of a virus transporting an antigen. The vector is used to produce one or more antigens in the organism and stimulate the immune system, forcing it to 6 mount an immune response against the targeted antigen(s).

Some definitions were adapted from the online dictionary of the National Cancer Institute at www.cancer.gov.

## 6.7 APPENDIX: MANAGEMENT REPORT FOR THE PERIOD ENDED DECEMBER 31, 2015

Ladies and Gentlemen,

We have called this Ordinary General Shareholders' Meeting to approve the financial statements for the fiscal year ended December 31, 2015 and to vote on several other resolutions.

This management report in addition to the topics it is legally obliged to cover, discusses the business and operations of our Company during the fiscal year ended, points out the highlights, analyzes the financial statements and provides an outlook for 2016.

2015 was a year of striking contrasts. It stands out for the Company's decision to carry out a strategic restructuring in order to focus on its core business lines, the outsourcing of the manufacturing of its clinical product batches and the redundancy plan (plan de sauvegarde de l'emploi) impacting half of its employees.

## A refocused strategy and a restructured organization

On June 29, 2015, the Company announced its restructuring plans to focus its resources on R&D, reposition its vertical integration strategy by outsourcing bio-manufacturing and pharmaceutical development activities, and redefine its organization to remain competitive and ensure a sustainable future. Its focus is now on its core business, immuno-engineering of viral vectors and clinical developments.

With its plan to mobilize its resources on developing its clinical portfolio, the Company's focus is on the ongoing development of innovative immunotherapy products for treatment of cancers and infectious diseases, by building up its technology platforms. In this context, it is no longer strategic for Transgene to retain its independent pre-industrial development and biomanufacturing capabilities.

In January 2016, the Company announced that its reorganization plan, essentially the exit from and outsourcing of the biomanufacturing and pre-industrial development activities, was nearly completed and would entail laying off 50% of the workforce (compared to the workforce at the end of 2014). Its estimated cost is approximately  $\ensuremath{\in} 7.5$  million and its impact on the cash position will be primarily felt in 2016. The reduction in operating costs generated by the reorganization is forecast at more than  $\ensuremath{\in} 15$  million per year, starting this year.

On February 1, 2016, the Company announced the disposal of the assets of its bio-production site located at Illkirch-Graffenstaden to ABL Europe SAS, a research and production company wholly-owned by ABL, Inc. and a member

of Institut Mérieux. Under this deal, the production assets were sold for a total of  $\mathfrak{S}3.5$  million and ABL Europe becomes the sub-lessee of a part of the main Transgene building to guarantee the quality control of the batches produced in dedicated labs. The two companies have also agreed a three-year contract under which Transgene has secured production of the necessary batches for its clinical development plan. Transgene's sale of its production asset marked the final step of the reorganization undertaken by the Company in June 2015

#### New funding of up to €30 million secured

In January 2016, the Company disclosed that it had two sources of funding in addition to existing cash reserves to carry out this new strategic plan. With this additional funding, the Company has the resources to achieve a number of value-creating milestones in the next two years:

- a €20 million loan facility with the EIB (European Investment Bank) under the IDFF (Infectious Diseases Finance Facility) program. This five-year loan has a deferred repayment schedule for the principal and accumulated interest, beginning in the fourth year. It will be released in two tranches at the Company's request;
- a commitment from its leading shareholder, Institut Mérieux, to provide funding of approximately €10 million, for which the terms and conditions will be confirmed at a later date. The funding affirms Institut Mérieux's support for the Company's strategy.

These new sources of funding allow the Company to optimize its resources and adapt them to its development program.

A development and commercialization agreement with SillaJen, Inc., amended to streamline the conduct of clinical studies on the oncolytic Pexa-Vec virus in line with each partner's strategic interests

Key changes to the agreement between Transgene and SillaJen are outlined below:

• management and funding of the phase 3 study (PHOCUS) in hepatocellular carcinoma (HCC). SillaJen now assumes operating responsibility for conducting the study. Transgene remains responsible for submitting requests for marketing approval and retains commercialization rights in its territories. In return, Transgene will pay SillaJen a fixed total amount of \$6 million over four years, with the first payment installment due this year. Under the terms of the original contract, Transgene bore all the development costs in its territories:

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- redefined territories. Transgene has returned to SillaJen the rights for all Middle Eastern countries, Russia, Ukraine, Belarus and Turkey. Transgene is now able to focus on Europe, its core strategic area;
- launch and funding of key exploratory combination studies. Under the amended agreement, Transgene has agreed to independently launch an exploratory study evaluating Pexa-Vec in combination with nivolumab for the treatment of HCC. Transgene will be responsible for all costs related to this study, as well as any other exploratory studies it independently performs. Data from this study will belong to Transgene and SillaJen may buy such data if needed for regulatory matters in its territories.

#### Development of key products in 2015

The key events and operating results in 2015 of products in development are outlined below:

- TG4010 (an active target immunotherapy treatment for solid tumors expressing MUC1):
- presentation of the data from phase 2b of the TIME study in non-small cell lung cancer (NSCLC) at ASCO (American Society of Clinical Oncology) annual conference and at the World Conference on Lung Cancer,
- publication of the TIME study data in the medical journal, The Lancet Oncology.
- presentation at the AACR (American Association for Cancer Research) annual meeting of TG4010's new pre-clinical data in combination with immune checkpoint inhibitors (ICIs);
- Pexa-Vec (oncolytic immunotherapy for treating solid tumors):
- agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for phase 3 in the PHOCUS study in advanced hepatocellular carcinoma (HCC, liver cancer),
- treatment of the first patient in phase 3 of PHOCUS;
- TG1050 (treatment for chronic hepatitis B):
- presentation of new pre-clinical data at the annual meeting of the International Liver Congress™,
- launch of the initial clinical study of patients with chronic hepatitis B infection.

After finalizing its restructuring plan, the Company has been rolling out its strategy focusing on the studies combining its products with other immunotherapy products, including ICIs (Immune Check Point Inhibitors).

The Company is in talks with clinical and biopharmaceutical partners to team up to launch at least five clinical trials combining its two most-advanced products with ICIs. These clinical trials should start in the second half of 2016. Two new products developed by Transgene should begin clinical studies

in 2016, such as TG6002 (oncolytic immunotherapy for the treatment of solid tumors).

The key combination programs are:

- combination of TG4010 with ICI in first- and second-line treatment of NSCLC:
- combination of Pexa-Vec with an ICI in first-line treatment of advanced liver cancer (HCC).

#### New pre-clinical program: MVA-TB

The Company is also conducting research for the design and development of an immunotherapy product against tuberculosis, including tuberculosis that is resistant to antibiotics. Several potential candidates have been generated and are presently under evaluation to select the best one to move into development. Transgene has entered into a partnership with U.S.-based Emergent Biosolutions for this immunotherapy program against tuberculosis. The program also received a grant from the U.S. National Institutes of Health (NIH).

## The main forecasts for 2016 regarding products under development are as follows:

- TG4010: launch of phase 2b clinical studies on TG4010 in combination with ICIs (immune checkpoint inhibitors) as first- and second-line treatments in NSCLC. Given the promising results of TG4010 thus far, the Company is now setting its sights on filing for Conditional Marketing Approval (CMA) in Europe. The review of the conditions of filing for CMA as well as of the related phase 3 study is ongoing;
- Pexa-Vec: launch in the next twelve months of phase 1/2 studies on Pexa-Vec in the treatment of liver and other cancers in combination with ICIs;
- TG1050: initial results of the safety profile of phase 1 in patients with chronic hepatitis B;
- TG6002: launch of first-in-humans trial in glioblastoma.

#### Review of research activities

 The R&D efforts for the products under development have produced results supporting the strategy of combining them with ICIs as well as the mode of action and their advancement to clinical trials. Academic collaborations are ongoing to increase the efficacy of Transgene's product candidates under development and to ramp up the technological platforms.

The Company's R&D was extremely active in 2015. It obtained key results in clinical programs and proved its innovation potential with new products and technologies with partnership opportunities. A seven-member Scientific Committee was set up in early 2016; it met for the first time on March 2 and 3. It performed a comprehensive review of the product portfolio and technological platforms.

#### **Regulated Agreements**

As part of its withdrawal from bio-manufacturing and quality control activities, the Company received a proposal from ABL (wholly-owned by IMEurope SAS, itself wholly-owned by Institut Mérieux), which sought to establish a Contract Manufacturing Organization (CMO) in Europe. This proposal offered to buy the real estate and related assets for €3.5 million as well as reassign the former Transgene employees. As Transgene would no longer have the manufacturing capacities to satisfy its requirements, it would guarantee ABL an order volume for services of €3 million per year over a three-year period. In return, ABL would commit to providing these services to Transgene on a priority basis. To the extent that this transaction between two companies in the same group could lead to a conflict of interest, the Group appointed a specialized firm to perform an independent appraisal of the terms and conditions of this transaction. The firm's appraisal focused on whether the financial conditions proposed by ABL were fair. The firm's opinion stated that ABL's offer was the most cost effective for the Company and that it was not detrimental to minority shareholders.

Accordingly, the Board of Directors approved the signing of the following agreements in relation to the sale of the production asset and related equipment,

While, the directors involved (Messrs. Archinard, Bélingard and Mérieux and Ms. Takizawa) abstained from voting:

- asset Purchase Agreement and the following related agreements:
- preliminary sales agreement for the land and manufacturing building in Illkirch-Graffenstaden;
- notarial deed on the land and manufacturing building in Illkirch-Graffenstaden;
- Transition Services Agreement;
- agreement for subleasing a part of the QC laboratory at the Company's headquarters;
- Social Agreement for reclassifying employees; and
- Exclusive Services Agreement.

These agreements were signed and became effective on February 1, 2016.

Agreements previously authorized by the Board of Directors that remained valid in 2015:

- agreement on allocation of employment contract termination costs, concluded between the Institut Mérieux, Mérieux NutriSciences, Transgene, Théra Conseil, Mérieux Développement, ABL Inc., and bioMérieux SA. No fees were invoiced to the Company under this agreement in 2015;
- service agreement between Transgene and Institut Mérieux: an amount of €456,284 was invoiced to the Company in 2015 under this agreement.

### Change in financial position

The 2015 corporate financial statements, which will be put to your Ordinary General Shareholders' Meeting for approval, show a loss of €45 million and shareholders' equity of less than half of the share capital. In order to turn the shareholders' equity position around, at the Extraordinary General Shareholders' Meeting, we will propose a share capital reduction (by reduction in the nominal value) to absorb the losses.

## Significant events after the balance sheet date

In early January 2016, the Company obtained a €20 million loan from the European Investment Bank (EIB) under the IDFF (Infectious Diseases Finance Facility). This is a five-year facility with principal and interest repayable only from the fourth year. It will be drawn down in two tranches in 2016 at the Company's request and no security has been provided.

Also in January, Transgene's leading shareholder, Institut Mérieux, confirmed its support for the Company's strategy and committed to providing approximately €10 million in additional financing. The terms and conditions for releasing this funding will be finalized during the year.

In February, the Company announced the sale of the assets at its bio-manufacturing site to ABL Europe SAS for a total of €3.5 million. ABL Europe is now the sub-lessee of the main Transgene building to guarantee the quality control of the batches produced in dedicated labs. The two companies have also agreed a three-year contract under which Transgene has secured production of the necessary batches for its clinical development plan. Transgene's sale of its production asset finalized the reorganization undertaken by the Company in June 2015. One of the main components of the reorganization was to outsource the manufacturing of clinical batches.

#### Other items

Transactions by corporate officers and directors in the Company's securities

None.

## Factors that could have an impact in the event of a public offering

Shareholder structure: the majority shareholder, as stated above, is TSGH. The Company is thus ultimately *controlled* by Alain and Alexandre Mérieux through Compagnie Mérieux Alliance that owns 100% of Institut Mérieux that itself owns 98.66% of TSGH. The Company does not directly or indirectly own its own shares and has not implemented any program to repurchase its shares. The Belgian corporation Dassault

Belgique Aviation, the sole shareholder who held over 5% of the Company stock, declared on January 14, 2015 that it fell below this threshold passively after additions to the Company's equity and voting rights and held 1,880,502 shares representing as many voting rights, or 4.88% of the equity and 3.33% of the voting rights at the date of the declaration.

Furthermore, the Company has not set up any measures, statutory or conventional, that may impact a public offering and has no knowledge of any agreements between shareholders likely to affect them.

#### Information on supplier payment terms

Article L. 441-6 paragraph 9 of the French Commercial Code provides that the time agreed upon between the parties for the payment of sums due may not exceed 45 days from the last day of the month or 60 days from the invoice date. Absent an agreement, the maximum period is 30 days from the date of receipt of the merchandise or performance of service.

With regard to Transgene's suppler invoices that were not paid at the end of the year, the breakdown by settlement date is as follows:

	At 12/31/201	15	At 12/31/2014		
Maturity	Euros	% of total	Euros	% of total	
Past due	264,164	18%	298,329	39%	
Between 1 and 30 days	993,707	68%	432,624	57%	
Between 31 and 45 days	125,100	9%	13,643	2%	
Between 46 and 60 days	71,892	5%	15,214	2%	
Between 61 and 75 days	-	-	-	-	
Between 76 and 90 days	-	-	-	-	
Between 91 and 105 days	-	-	-	-	
Between 106 and 120 days	-	-	-	-	
More than 120 days	-	-	-	-	
TOTAL	1,454,864	100%	759,810	100%	

#### CROSS-REFERENCE TABLE, MANAGEMENT REPORT/DOCUMENT DE REFERENCE

Other parts of the management report in	Please refer to the Document de référence	
	2015 Corporate Financial Statements	Section 4.3
Annual financial statements	2015 Consolidated Financial Statements	Section 4.1
	List of corporate offices	Paragraph 2.1.1
Corporate officers	Compensation	Section 2.2
Subsidiaries and investments		Paragraph 4.3.2 Note 27
	Risk factors	Section 1.5
	Table of authorizations for the Board to increase the capital	Paragraph 5.1.5
	Shareholders structure	Section 5.2
Other information	Corporate Social Responsibility	Chapter 3
	Paragraph 2.2.3	Special reports
Stock options report	Report on free shares awards	Paragraph 2.2.4



#### **○** TABLE OF TRANSGENE FINANCIAL INCOME OVER THE LAST FIVE FISCAL YEARS

(Articles R. 225-81, R. 225-83 and R. 225-102 of the French Commercial Code)

(in thousands of euros except for per share data)

Category	2011	2012	2013	2014	2015
Financial position at year end					
a) Shavwre capital	72,523	72,886	72,933	88,156	88,196
b) Number of shares issued	31,695,882	31,854,490	31,874,858	38,527,968	38,545,397
2. Comprehensive operating net income					
a) Revenue excl. VAT	3,020	2,362	2,958	2,340	1,821
b) Profit before tax, depr., amort. & provisions	(47,898)	(46,635)	(47,782)	(56,685)	(41,646)
c) Income tax expense	7,821	8,463	8,901	8,463	7,943
d) Profit after tax, depreciation and provisions	(41,873)	(40,436)	(41,454)	(50,884)	(45,006)
e) Earnings distributed	-	-	-	-	-
3. Operating earnings per share					
<ul> <li>a) Profit after tax but before depreciation and provisions</li> </ul>	(1.26)	(1.20)	(1.22)	(1.25)	(1.08)
b) Profit after tax, depreciation and provisions	(1.32)	(1.27)	(1.30)	(1.32)	(1.17)
c) Dividend per share	-	-	-	-	-
4. Personnel					
a) Number of employees	298	299	287	284	256
b) Total payroll	13,833	13,882	14,149	14,055	12,341
c) Amount paid in social benefits (social security, welfare plans, etc.)	6,836	7,324	7,439	7,216	6,670



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