Genkyotex, a French limited company (*société anonyme*) organized with a Board of Directors and with share capital of €11,548,562
Registered office: 218 avenue Marie Curie – Forum 2 Archamps Technopole,
74166 Saint-Julien-en-Genevois Cedex, France

# UNIVERSAL REGISTRATION DOCUMENT

# including the Annual Financial Report

This Universal Registration Document was filed on April 30, 2020 with the AMF (*Autorité des marchés financiers* — the French Financial Markets Authority), as competent authority under Regulation (EU) No. 2017/1129, without prior approval in accordance with Article 9 of said Regulation.

The Universal Registration Document may be used for a securities offering to the public or for the admission of securities to trading on a regulated market if supplemented by a securities prospectus and, where appropriate, a summary and all amendments to the Universal Registration Document. The resulting document package has been approved by the AMF in accordance with Regulation (EU) No. 2017/1129.

A table of concordance is provided in the Appendix to this document to help readers understand the information incorporated by reference and the information that has been updated or amended.

Pursuant to Article 19 of Regulation (EU) No. 2017/1129 of June 14, 2017, the information contained in the following documents is incorporated by reference in this Universal Registration Document (the "**Universal Registration Document**"):

- Section "9. Analysis of financial position and results," Section "10. Cash and equity," and the consolidated financial statements prepared in accordance with IFRS for the financial year ended December 31, 2018 presented on pages 157 to 208 of the 2018 Registration Document (the "**2018 Registration Document**"), filed with the AMF on April 26, 2019 under R.19-014 and available on the Company's website: https://www.genkyotex.com/en/investors/regulated-information/financial-information/2019;
- the Statutory Auditors' report presented on pages 239 to 243 of the 2018 Registration Document.
- Section "9. Analysis of financial position and results," Section "10. Cash and equity," and the financial statements of Genkyotex SA prepared in accordance with IFRS as adopted by the European Union as of December 31, 2017, as well as the related Statutory Auditors' report respectively presented on pages 86 to 93, 94 to 96, 151 to 198 and 227 to 233 of the 2017 Registration Document (the "**2017 Registration Document**") filed with the AMF on April 27, 2018, under number R.18-037 and available on the Company's website: https://www.genkyotex.com/en/investors/regulated-information/financial-information/2018;
- The parent company financial statements of Genkyotex for the financial year ended December 31, 2017, as well as the related Statutory Auditors' report, presented on pages 199 to 226 and 233 to 239, respectively, of the 2017 Registration Document;

This document is available free of charge from the Company's registered office and in electronic form on the AMF website (www.amf-france.org) and the Company's website (www.genkyotex.com).

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## GENERAL OBSERVATIONS

*Definitions*

For the purposes of this universal Registration Document and unless otherwise indicated:

- "**Genkyotex**" or "**Genticel**" or the "Company" refers to Genkyotex (formerly Genticel), a limited company (*société anonyme*) with capital of €11,548,562 whose shares are admitted to trading on the Euronext Paris and Euronext Brussels regulated markets, and whose registered office is at 218 avenue Marie Curie – Forum 2 Archamps Technopole, 74166 Saint-Julien-en-Genevois Cedex, France. It should further be noted that the General Shareholders' Meeting of February 28, 2017 approved the change to the Company's management and governance structure and adopted a one-tier board system. Prior to that date, it was organized with a management board and a supervisory board;

- "**Genkyotex Suisse**" refers to Genkyotex Suisse SA, a Swiss limited liability company (*société anonyme*) with capital of CHF 5,262,133, whose registered office is at Chemin des Aulx 16, 1228 Plan-les-Ouates, Switzerland, and which is registered with the Geneva Commercial Register under number CHE-112.747.508;

- "**Genkyotex Innovation**" refers to Genkyotex Innovation SAS, a simplified joint-stock company (*société par actions simplifiée*) with capital of €7,785,000.60, whose registered office was previously located at 218 avenue Marie Curie – Forum 2 Archamps Technopole, 74166 Saint-Julien-en-Genevois Cedex, France, and which was registered with the Thonon-Les-Bains Trade and Companies Register under number 528 733 132, and which merged with Genkyotex SA in 2017;

- The "**Group**" refers to Genkyotex SA and its subsidiary Genkyotex Suisse SA.

*Disclaimer*

This Universal Registration Document contains information about the Company's activities as well as the market and the industry in which it operates. This information was obtained from internal studies or external sources (e.g. industry publications, specialized studies, information published by market intelligence providers, analysts' reports etc.). In the Company's opinion, at the time of writing, this information gives a true and fair view of its reference market and its competitive position in that market. However, this information has not been independently verified by the Company and the Company cannot guarantee that a third party using different methods to collate, analyze or calculate market data would obtain the same results.

This Universal Registration Document also contains information about the Company's objectives and development strategies. Such statements may be identified by the use of the future or conditional tense and by terms of a prospective nature such as "estimate," "consider," "have as objective," "expect to," "intend," "should," "hope," "could," "may" or similar terminology. The readers' attention is drawn to the fact that these objectives, forward-looking statements and development strategies are not historical data and should not be interpreted as a guarantee that the stated facts or data will occur, that the assumptions will be borne out or that the objectives will be achieved. By their very nature it is possible that the objectives or forward-looking statements may not be achieved and that the information in this Universal Registration Document may be proven incorrect, the Company being under no obligation to update them, subject to applicable regulations, in particular the General Regulations of the French Financial Markets Authority (the "**AMF**"). In addition, some of these data, assumptions and estimates originate or are based, in whole or in part, on assessments or decisions of

the governing bodies, directors or shareholders of the Company, which might change or be modified in the future.

Investors are also advised to take into careful consideration the risk factors described in this Universal Registration Document before making an investment decision. Should any or all of these risks materialize, they may have a negative impact on the Company's activity, financial position, profits or objectives. Furthermore, other risks, not yet identified or considered not significant by the Company, may have a similar negative impact and investors may lose all or part of their investment.

A glossary defining certain technical terms to which reference is made and concordance tables are provided at the end of this document.

A table of concordance is provided in the Appendix to this document to help readers understand the information incorporated by reference and the information that has been updated or amended.

# SECTION 1. PERSONS RESPONSIBLE, THIRD PARTY INFORMATION, EXPERTS' REPORTS AND COMPETENT AUTHORITY APPROVAL

## 1.1. IDENTIFICATION OF THE PERSON RESPONSIBLE FOR THIS DOCUMENT

Ilias (Elias) Papatheodorou, Chief Executive Officer

## 1.2 DECLARATION OF THE PERSON RESPONSIBLE FOR THIS DOCUMENT

Saint-Julien-en-Genevois, April 30, 2020.

*"I hereby certify, after having taken every reasonable measure to this effect, that the information contained in this Universal Registration Document is, to the best of my knowledge, accurate and does not contain any omission that could affect its meaning.*

*I certify that, to the best of my knowledge, the financial statements have been prepared in accordance with the applicable accounting standards and present fairly the Company's assets and liabilities, its financial position and results of operations and of that of all the companies included in the scope of consolidation, and that the information provided in the management report on pages 276 to 280 presents an accurate picture of the Company's business developments, results of operations and financial position and that of all the companies included in the scope of consolidation, as well as a description of the main risks and uncertainties they face."*

Ilias (Elias) Papatheodorou, Chief Executive Officer of Genkyotex

## 1.3 STATEMENTS BY EXPERTS AND DECLARATIONS OF ANY INTEREST

None.

## 1.4 THIRD PARTY INFORMATION

None.

## 1.5 DECLARATION BY THE COMPETENT AUTHORITY RELATING TO THE APPROVAL OF THIS DOCUMENT

AUTORITÉ DES MARCHÉS FINANCIERS

AMF

This Universal Registration Document was filed on April 30, 2020 with the AMF (*Autorité des marchés financiers* — the French Financial Markets Authority), as competent authority under Regulation (EU) No. 2017/1129, without prior approval in accordance with Article 9 of said Regulation.

The Universal Registration Document may be used for a securities offering to the public or for the admission of securities to trading on a regulated market if supplemented by a securities prospectus and, where appropriate, a summary and all amendments to the Universal Registration Document. The resulting document package has been approved by the AMF in accordance with Regulation (EU) No. 2017/1129.

# SECTION 2. STATUTORY AUDITORS

## 2.1. PRINCIPAL STATUTORY AUDITORS

**SYGNATURES**, an audit firm registered on the national list of statutory auditors attached to the Compagnie Régionale des Commissaires aux Comptes de Toulouse (Toulouse branch of the French institute of auditors),
8, chemin de la terrasse, BP 45122, 31512 Toulouse Cedex 5, France
Represented by Laure Mulin
Date of reappointment: March 7, 2014
Duration of term of office: 6 years
Expiration date of term: at the General Shareholders' Meeting called to approve the financial statements for the financial year ended December 31, 2019

**KPMG SA**, an audit firm registered on the national list of statutory auditors attached to the Compagnie Régionale des Commissaires aux Comptes de Versailles (Versailles branch of the French institute of auditors),
51 Rue de Saint-Cyr, CS 60409, 69338 Lyon Cedex 9, France
Represented By Stéphane Devin
Date of appointment: June 13, 2019
Duration of term of office: 6 years
Expiration date of term: at the General Shareholders' Meeting called to approve the financial statements for the financial year ended December 31, 2024

Grant Thornton was not reappointed following the expiration of its term of office at the General Shareholders' Meeting called to approve the financial statements for the financial year ended December 31, 2018. At its meeting on April 22, 2020, the Board of Directors adopted a draft resolution to be submitted to the General Shareholders' Meeting to be held on June 10, 2020, and relating to the renewal of the term of office of the Sygnatures firm for a period of six years from the said meeting and until the General Shareholders' Meeting called to approve the financial statements for the financial year ending December 31, 2025.

## 2.2. ALTERNATE STATUTORY AUDITORS

**Philippe Benzoni**, a statutory auditor registered on the national list of statutory auditors attached to the Compagnie Régionale des Commissaires aux Comptes de Toulouse (Toulouse branch of the French institute of auditors),
8, chemin de la terrasse, BP 45122, 31512 Toulouse Cedex 5, France
Alternate for SYGNATURES
Date of reappointment: March 7, 2014
Duration of term of office: 6 years
Expiration date of term: at the General Shareholders' Meeting called to approve the financial statements for the financial year ended December 31, 2019

In accordance with the possibility offered by Article L. 823-1 of the Trade Code, no alternate statutory auditor was appointed to KPMG.

## 2.3. STATEMENT OF FEES PAID TO THE STATUTORY AUDITORS

The following table shows the Statutory Auditors' fees paid by the Company in the past two years:

| STATUTORY AUDITORS' FEES | Financial year 2019 (12 months) | | Financial year 2018 (12 months) | |
|---|---|---|---|---|
| (Amounts exc. VAT in € thousand) | KPMG | SYGNATURES | GRANT THORNTON | SYGNATURES |
| For auditing the financial statements | 60 | 60 | 63 | 59 |
| Services unrelated to the auditing of accounts (1) | - | - | 6 | 6 |
| **Subtotal** | **60** | **60** | **69** | **65** |
| Other services | | | | |
| - Tax | - | - | - | - |
| - Other | - | - | - | - |
| **Subtotal** | **-** | **-** | **-** | **-** |
| **Total fees** | **60** | **60** | **69** | **65** |

*(1) In 2018, services other than certifying the financial statements, covering services required by laws and regulations (reports related to the General Shareholders' Meeting) as well as services provided upon Genkyotex's request (review of the 2017 Registration Document).*

## SECTION 3. RISK FACTORS

The Company operates in an evolving environment with many risks, some of which are beyond its control. The Company has reviewed the risks which, in its opinion, as of the date of this Universal Registration Document, could have a material adverse impact on the Group, its business, financial position, results, outlook or on its ability to achieve its objectives or ensure its growth. Investors are encouraged to consider these significant risk factors, as indicated below, and the information contained in the documents incorporated by reference in this Universal Registration Document, before deciding to subscribe to or acquire Company shares.

In order to identify and assess the other risks that may have an adverse impact on the Group's business, outlook, financial position, results or ability to achieve its objectives, the Company has mapped the risks associated with its business and grouped them into five non-hierarchical categories and has classified them within each category in a descending or equal order of importance.

The following table summarizes the key risk factors identified by the Company and indicates for each of them the likelihood of their occurrence and the magnitude of their negative impact on the Group as of the date of this Universal Registration Document, taking into account any preventive and/or control actions and measures implemented by the Company as of that date. The likelihood of occurrence is assessed on three levels (“low,” “moderate” and “high”) and the magnitude of their negative impact is assessed on four levels (“low,” “moderate,” “high” and “critical”). In each of these five categories, the risks have been grouped together according to this classification, with the highest likelihood of occurrence and the highest negative impact placed first.

<u>COVID-19 Pandemic Health Crisis</u>

The Company draws attention to the risks associated with the pandemic health crisis related to the coronavirus COVID-19. This virus is actively circulating in many countries and measures have been taken to restrict the movement of people and to halt or limit certain human and industrial activities, in particular in France and Switzerland, as well as in some countries where clinical trials of the Company's main product, setanaxib, are currently being conducted, in the process of being launched or could be launched in the coming months or in which the Company's products are manufactured or packaged. In this context, the Company is following the guidelines and recommendations in place to protect its employees and subcontractors. Accordingly, the Company has asked its employees in France and Switzerland to work from home and organize meetings and events remotely as much as possible.

To date, the Company expects only a limited impact on its activities, including ongoing and planned discussions with regulatory authorities, clinical trials, and interactions with the scientific community and other stakeholders. However, this situation makes the future highly uncertain and has led the company to classify this risk with a “*high*” likelihood and a “*critical*” negative impact (see Section 3.1.3.). The Company will continue to closely monitor the potential impact of COVID-19 on the conduct of clinical trials and discussions with health authorities and depending on the development of the health crisis and its potentially significant impact on such trials, will inform the market accordingly.

| *Subsections of the Universal Registration Document* | *Risk Factors* | *Likelihood* | *Negative Impact* |
|---|---|---|---|
| ***3.1*** | **Risks related to the development and future marketing and sale of the Group's product candidates** | | |
| *3.1.1* | In order to treat specific diseases, Genkyotex identifies and develops selective NADPH Oxidase (NOX) inhibitors, a new class of product candidates, the therapeutic benefit of which has not yet been demonstrated | *High* | *Critical* |
| *3.1.2* | Genkyotex may encounter difficulties in obtaining, or not obtain at all, regulatory approval to develop and market its drug candidates and in particular its most advanced product candidate, setanaxib | *High* | *Critical* |
| *3.1.3* | Genkyotex's activity could be significantly disrupted by a health crisis such as the ongoing crisis related to the coronavirus COVID-19. | *High* | *Critical* |
| *3.1.4* | Clinical trials of Genkyotex may be delayed or may not proceed satisfactorily | *High* | *High* |
| *3.1.5* | Genkyotex is subject to regulations that are numerous and uncertain and it may not be able to obtain the necessary authorizations to market and sell its product candidates | *High* | *High* |
| *3.1.6* | Even if setanaxib, the Company's leading drug candidate, obtains a marketing authorization for fibrosis of the liver and/or the kidney, the Company's target market could ultimately turn out to be less significant than previously anticipated and its successful marketing and sale will depend on the Company's ability to gain the support of the medical community | *Moderate* | *High* |
| *3.1.7* | Risks related to the ever-changing legal and regulatory framework in terms of price and reimbursement of drugs | *Moderate* | *High* |
| *3.1.8* | Risks related to development partnerships and to the marketing and sale of drug candidates incorporating the Vaxiclase platform | *Moderate* | *Moderate* |
| ***3.2*** | **Risks related to the Company's financial position and capital requirements** | | |

| | | | |
|---|---|---|---|
| *3.2.1* | The Company will have to strengthen its equity capital or apply for additional financing to ensure its growth | *High* | *Critical* |
| *3.2.2* | The Company has posted operating losses since its formation and believes this situation could continue. | *High* | *High* |
| *3.2.3* | The stake of the Company's shareholders in its capital could be significantly diluted | *High* | *High* |
| *3.2.4* | Risks related to the research tax credit | *Moderate* | *Moderate* |
| *3.2.5* | Foreign exchange risks | *Moderate* | *Low* |

| | | | |
|---|---|---|---|
| ***3.3*** | **Risks related to the Company's organization** | | |
| *3.3.1* | Since Genkyotex is a biopharmaceutical company with no product that has obtained a marketing authorization and with only a single drug candidate, setanaxib, that has reached the clinical trial stage, the absence of revenues from historical products makes it difficult to evaluate its prospects and future financial results. | *Moderate* | *High* |
| *3.3.2* | Genkyotex is dependent on its key staff and must continue to attract and retain its key employees and scientific advisors | *Moderate* | *Moderate* |
| *3.3.3* | The Company's development will depend on its ability to manage growth | *Moderate* | *Moderate* |
| ***3.4*** | **Risks associated with the Company's reliance on third parties** | | |
| *3.4.1* | Genkyotex is exposed to the risks associated with its high reliance on third-party service providers for the conduct of its clinical trials and, in the absence of capabilities and experience in the manufacture of its products, on third-party manufacturers | *Moderate* | *High* |
| ***3.5*** | **Risks related to intellectual property** | | |
| *3.5.1* | Genkyotex may not provide adequate intellectual protection for its clinical candidates and patent portfolio | *Moderate* | *High* |
| *3.5.2* | Specific risks related to the infringement of intellectual property rights | *Moderate* | *Moderate* |
| *3.5.3* | The agreements signed by the Company to protect its technology, its trade secrets and its know-how could prove insufficient | *Moderate* | *Moderate* |

## 3.1. RISKS RELATED TO THE DEVELOPMENT AND FUTURE MARKETING AND SALE OF THE COMPANY'S PRODUCT CANDIDATES

### 3.1.1. In order to treat specific diseases, Genkyotex identifies and develops selective NADPH Oxidase (NOX) inhibitors, a new class of product candidates, the therapeutic benefit of which has not yet been demonstrated

Genkyotex is developing a new therapeutic approach based on the selective inhibition of NOX enzymes which are identified as potentially key factors in the development of certain complex illnesses that are difficult to treat, such as hepatic, pulmonary and renal fibrosis, certain forms of cancer, neurodegenerative diseases or even hearing problems (see Section 5 of the Universal Registration Document).

To date, no NOX inhibitor had yet been approved for marketing or sale by the competent health authorities. The prospects for the development and profitability of Genkyotex's most advanced drug candidate, setanaxib (formerly GKT831), for fibrosis, its safety, its efficacy, and its acceptance by patients, prescribers, and paying agencies, are uncertain.

The results for setanaxib in connection with the Phase 1 trials, the Phase 2 trial for diabetic kidney disease, the Phase 2 trial on primary biliary cholangitis (PBC), the Phase 2 trial launched and led by the Baker Heart and Diabetes Institute of Melbourne to treat diabetic kidney disease (DKD), and, more generally, results relating to all existing or future drug candidates in the Company's portfolio or based on its technology at the time of the research or preclinical phase may or may not be confirmed by subsequent clinical trials. Such a situation could have a highly material adverse effect on Genkyotex's business, results, financial position, and outlook.

### 3.1.2. Genkyotex may encounter difficulties in obtaining, or not obtain at all, regulatory approval to develop and market its drug candidates and in particular its most advanced product candidate, setanaxib

To obtain a marketing authorization for its drug candidates, the Company will be required to show, by long, numerous and very expensive clinical trials, the outcome of which is uncertain, that their use is safe and effective in humans. Clinical trials are subject to the supervision of ethics committees, medical research participant protection committees, as well as regulatory authorities. If the Company does not meet its development schedule, or is unable to conduct the expected clinical trials successfully within applicable time limits, its business could be materially and adversely affected.

The Company's ability to obtain marketing authorization for its product candidates will depend on several factors, including, but not limited to:

- The possibility of pursuing the development of those of its product candidates presently in early clinical trials, or transferring product candidates presently in preclinical development to a clinical stage;
- The ability of its partners or itself to conduct clinical trials successfully and in a timely manner without having to devote significantly greater resources than initially expected;
- Its clinical trials showing efficacy and tolerance of its product candidates;
- Its product candidates being approved for the indication they are intended to treat, or for any indication of any kind; and
- An announcement by its competitors of more promising clinical results with their own products, which makes the Company's economic equation unfavorable.

Traditionally in the pharmaceutical and biotechnology industries, it is often the case that favorable results of preclinical trials and Phase 1 or Phase 2 clinical trials are not confirmed by subsequent clinical trials. Regulatory authorities in various countries in which the Company intends to market its products could, for example, block initiation of clinical trials, or the pursuit of clinical developments, if the proposed clinical trials do not meet applicable regulatory standards.

Such authorities could likewise interpret results differently from the Company and, in any event, request additional tests, on a discretionary basis (relating, among other things, to the study protocols, the characteristics and number of patients, the length of treatment, the analytical methods, and post-treatment follow-up), or impose additional and unexpected requirements at the time of such trials.

Furthermore, the Company might decide to suspend or terminate clinical trials, or regulatory agencies could so require, if patients are exposed to unexpected risks. Death or other adverse events could occur during a clinical trial, because of medical problems linked or not to the treatments administered, forcing the Company to delay or interrupt the trial. In light of the trial's results, the Company could decide to abandon development projects that were initially identified as promising. Finally, products already approved could turn out to be unsafe and be withdrawn from the market, or produce effects different from those initially expected, which could limit or prevent any commercial use. The occurrence of all or some of such events could have material and adverse effects on the Company's business, results, and outlook.

Genkyotex has already completed preclinical trials and Phase 1 and Phase 2 clinical trials for setanaxib, its most advanced drug candidate. Phase 1 trials evaluated the safety and pharmacokinetics of the compound after single and repeated doses, the effect of the compound on cytochrome CYP3A4, and the effect of diet and micronization on pharmacokinetics. Two Phase 2 trials in diabetic nephropathy and primary biliary cholangitis were conducted to assess safety, pharmacokinetic and pharmacodynamic properties, and the efficacy of setanaxib in patients with diabetic nephropathy and patients with primary biliary cholangitis (PBC).

The development of setanaxib, and possibly, later on, other Phase 2 and Phase 3 clinical trials, as well as the preparation for marketing authorization and the manufacture of setanaxib under strict manufacturing conditions require, and will continue to require, significant time and financial investments by Genkyotex as well as the attention of its most qualified staff. Accordingly, if Genkyotex does not obtain regulatory authorization for these treatments following these stages, its financial position, operating results and outlook will be significantly and adversely affected.

### 3.1.3. Genkyotex's activity could be significantly disrupted by a health crisis such as the ongoing crisis related to the coronavirus COVID-19.

The emergence of a contagious disease, such as the new coronavirus strain or COVID-19 which has recently appeared in many countries, can seriously disrupt the Company's activity and have a significant negative impact on its activities including ongoing clinical studies, financial position and outlook.

The COVID-19 epidemic, which emerged in January 2020 in China and now affects several other regions of the world, has led governments in a number of countries in which Genkyotex operates directly (France and Switzerland) or in which clinical trials are being launched, are ongoing or upcoming, to adopt measures to contain and restrict the movement of persons and transport of goods. On March 11, 2020, the World Health Organization officially declared the outbreak a pandemic.

The COVID-19 pandemic impacts the global economy, including the major economic areas of the United States, Europe and China, as well as that of many other countries around the world, and could affect the activities of the Company and those of third parties on which the Company depends (centers where clinical trials are conducted and monitored, including CROs). Although the potential economic

consequences of the COVID-19 pandemic and its duration are difficult to assess or predict, its impact on global financial markets could make it more difficult for the Company to access external funding. In the short and medium term, this could therefore have a negative impact on the Company's liquidity and its ability to raise funds. In addition, the COVID-19 pandemic has for many listed companies resulted in a significant drop in their stock market price. If the high volatility and the downward stock market trend persist in the financial markets, the Company may need to raise funds at a lower price per share, which would compel it to issue a larger number of shares and would ultimately result in a larger dilution of its existing shareholders.

In addition, the COVID-19 pandemic could have an impact on the ability of the Company's teams to continue their work normally. Genkyotex's clinical trials may also be affected. Sites where clinical trials are conducted and registration of patients tested could be delayed, due to, among other things, the mobilization of hospital resources during the COVID-19 pandemic, government travel restrictions, and physical inability to access sites. In addition, some companies providing the Company with certain materials used in the production of its candidate products are located in Germany and Italy, areas affected by the COVID-19 pandemic. This could have a negative impact on the supply of materials for the Company's candidate products.

As of the date of this Universal Registration Document and given the climate of general uncertainty, it is impossible to predict the duration and extent of the damage potentially caused by the current COVID-19 pandemic on the Company's research and development activities, as well as on health systems and the global economy as a whole. However, these effects could have a significant impact on access to capital resources and the activities of the Company and those of the third parties on which it depends.

### 3.1.4. Clinical trials of Genkyotex may be delayed or may not proceed satisfactorily

Genkyotex's ability to conduct clinical trials successfully depends on many factors, especially the pace of recruiting patients, eligibility criteria, the size of the eligible patient population, the type of clinical protocol, the proximity of patients to clinical sites, possible side effects and competition with other clinical trials conducted on product candidates developed by competing companies with, among other things, financial resources that may be greater than the Company's. The occurrence of an epidemic, such as the coronavirus COVID-19, can also make it more complex or impossible to conduct clinical trials, can disrupt recruitment, and the results of trials can be challenged if it is impossible to continue such trials under normal conditions and in accordance with their protocol.

Furthermore, the Company has limited experience in conducting clinical trials and has used, and will in the future use, third parties to assist it in supervising and monitoring its trials. Failure of one of these third parties and especially the companies specialized in the organization of the trials (contract research organizations or CRO) that the Company uses and will use, in the performance of their duties or failure to comply with applicable regulatory standards could result in delays or premature termination of the trials.

Genkyotex and the CROs it will use, or any external investigators (independent research and academic centers) conducting or likely to conduct future clinical trials with setanaxib or other future product candidates of the Company, may find it difficult to recruit and retain patients to participate in clinical trials of the Group's product candidates. Strict criteria for inclusion in trials could also complicate patient recruitment. Once recruited, the patients participating in such trials could likewise suspend or terminate their participation at any time without cause. Delays in patient recruitment could also increase the cost of clinical trials and delay them, or even cause their cancellation. Finally, if too many patients terminate their participation in a clinical trial, the analysis of the results of such trial could lack sufficient statistical significance.

Finally, the appearance during the trials of side effects that are currently unknown could cause delays or even suspend development of the Company's drug candidate. If, after the Company or one of its partners or licensees obtains a marketing authorization, the Company's products cause side effects which are unacceptable or have not been identified during the clinical trial period, it might be impossible to market them, sell them or assign or grant licenses to partners with a view to marketing them, which could have a material adverse effect on its business, outlook, financial position, results and growth.

### 3.1.5. Genkyotex is subject to regulations that are numerous and uncertain and it may not be able to obtain the necessary authorizations to market and sell its product candidates

To date, none of the Company's product candidates, including its most advanced drug candidate, setanaxib, has received marketing authorization from any regulatory authority. The Company cannot be sure that it will receive the necessary authorizations to market and sell any of its product candidates. These are subject to many very stringent laws, and the applicable regulatory requirements are uncertain and subject to modification. The US Food and Drug Administration ("**FDA**"), the European Medicines Agency ("**EMA**") and the *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (French agency for the safety of drugs and healthcare products) ("**ANSM**") in France, as well as their counterparts in other countries, regulate, among other things, research and development, preclinical tests, clinical trials, manufacturing, safety, efficacy, records retention, labeling, and the marketing, sale and distribution of therapeutic products.

The regulatory process for approving new therapeutic products requires the Company to submit detailed characteristics of the product, of the product's manufacturing and quality control process, as well as preclinical and clinical data, and any information making it possible to establish the potential safety and efficacy of the product for each indication. It may also require continual post-marketing studies as well as manufacturing quality controls.

These regulatory steps are costly, may take several years, and their results are unpredictable. The data from preclinical and clinical developments may give rise to different interpretations, which could delay obtaining regulatory authorization or restrict its scope. The requirements of the regulatory process vary greatly from one country to another, so that the Company or its strategic partners may not be able to obtain authorization on a timely basis in each relevant country. Since the Company's product candidates are based on new, constantly changing technologies and have not been tested on an in-depth basis in humans, the applicable regulatory requirements are still uncertain and could be subject to significant changes. Changes in laws and regulations during the development of a product candidate and its regulatory review could cause delays or the denial of authorization.

In the United States, in Europe and in other countries, applicable laws and regulations and changes to them could:

- Delay and/or significantly increase the cost of developing, testing, manufacturing and marketing the Company's product candidates;
- Limit the indications for which it might be authorized to market and sell its products;
- Impose new, stricter requirements, suspend authorization of the Company's products or require that the clinical trials being conducted by the Company or marketing and sales be stopped (for example, if unexpected results are obtained during clinical trials by other researchers of products similar to those of the Company); or
- Impose restrictive labeling.

If the Company does not comply with the laws and regulations applicable to its business and operations, it could incur sanctions or penalties, which could include refusals to authorize pending applications, product recalls, restrictions on sales or the temporary or permanent suspension of its operations as well as civil and criminal proceedings.

### 3.1.6. Even if setanaxib, the Company's leading drug candidate, obtains a marketing authorization for fibrosis of the liver and/or the kidney, the Company's target market could turn out to be less significant than previously anticipated and its successful marketing and sale will depend on the Company's ability to gain the support of the medical community

The revenues that the Company may receive in connection with the marketing and sale of setanaxib will be limited by the number of patients, by the categories of patients in this group who respond to treatment, by the perception of its therapeutic benefit by health prescribers, by the Company's ability to achieve appropriate pricing and reimbursement levels and by the impact of competition.

In particular, the Company will have to compete with drugs already on the market as well as other products which may appear from the discovery and exploitation of new molecules.

If the Company does not market and sell setanaxib successfully, its revenue could be diminished, and it could find itself unable to finance the development and marketing of other product candidates for other indications.

If the Company succeeds in obtaining marketing authorization to introduce products based on its technology, it will need time to gain the support of the medical community, including healthcare providers, patients and third-party payers. The degree of acceptance by the market will depend on many factors, especially:

- The safety and efficacy of its therapeutic products, as demonstrated during clinical trials;
- The existence of undesirable side effects;
- The ease of administration;
- The success in setting up its sales force;
- The success of its marketing, sales, and public relations efforts;
- The availability of alternative treatments;
- The pricing;
- The reimbursement policies of governments and other third parties (see Section 3.1.7 below);
- The effective adoption and implementation of a publication strategy; and
- Obtaining the support of recognized external opinion leaders.

A lack of or insufficient support from the medical community could have a material and adverse effect on the marketing and sale, and on the Company's ability to generate profits, which could have an adverse effect on the Company's financial position, results and outlook.

### 3.1.7. Risks related to the ever-changing legal and regulatory framework in terms of price and reimbursement of drugs

The conditions for setting the sales price for the reimbursement of drugs are beyond the control of pharmaceutical companies. They are decided respectively by the competent public commissions and agencies and by social service agencies or private insurance companies. Against the current backdrop of health expenses management and economic and financial crisis, the pressure on sales prices and the level of reimbursement is increasing, due mainly to the price controls imposed by many governments and the increased difficulty of obtaining and maintaining an acceptable reimbursement rate for drugs. This pressure could also be reinforced by the current context of the coronavirus COVID-

19 epidemic, which has led to the highly significant financial mobilization of welfare organizations and private insurance companies and is likely to place, in the very short term, the issue of health expenditures and their streamlining, at the core of public debate.

When the time comes, the conditions for setting the price and the reimbursement rate for the Company's products will play a key role in their commercial success. The possibility for the Company to receive royalties from its industrial partner(s) on the sale of its treatments will depend on these price setting and reimbursement conditions. If the time spent on price negotiations causes a significant delay in the marketing launch or if one of the Company's drugs does not obtain an appropriate level of reimbursement, its profitability would be reduced.

The Company is also unable to guarantee its ability to maintain, over time, the price level of its drugs or the accepted rate of reimbursement. Under these conditions, its revenues, profitability and outlook could be significantly affected.

### 3.1.8. Risks related to development partnerships and to the marketing and sale of drug candidates incorporating the Vaxiclase platform

Serum Institute of India Private Ltd. (“Serum Institute”) is working in partnership with the Company to develop a Diphtheria-Tetanus-Pertussis (DtaP) prophylactic acellular vaccine incorporating the Vaxiclase platform (see Section 20.1 of the Universal Registration Document for details about this partnership).

The Company's partner may encounter difficulties during one of the various preclinical and clinical development phases of the drug candidate, which could delay the development, production and marketing of the drug candidate concerned or even bring its development to a halt. Similarly, Serum Institute may encounter difficulties in the technical and clinical validation of the Company's Vaxiclase technology. The resulting delays or failures could delay or even jeopardize the marketing and sale by Serum Institute of the product candidates concerned. Serum Institute may also fail to take all the necessary measures to achieve the desired results under the license agreement signed with the Company. Budgetary restrictions within Serum Institute or priority given by Serum Institute to other development programs, in particular, could delay validation of the potential of product candidates incorporating Vaxiclase technology. A conflict of interest could even arise between certain activities of Serum Institute and the activities that Serum Institute undertakes for the Company. This would cause a loss of know-how and expertise for the Company.

Any failure or delay in the development of these product candidates would have an adverse effect on the partnership entered into by the Company, in particular by jeopardizing all or part of the potential revenues to be received under this contract (e.g. development and commercial milestone payments, single-digit royalties on net sales). This would have an adverse effect on the Company's results, financial position and outlook. The occurrence of such events could also have the adverse effect of causing an impairment loss on the intangible asset corresponding to the SIIPL contract (€9.1 million as of December 31, 2019).

## 3.2. RISKS RELATED TO THE COMPANY'S FINANCIAL POSITION AND CAPITAL REQUIREMENTS

### 3.2.1. The Company will have to strengthen its equity capital or apply for additional financing to ensure its growth

Since its creation, the Company has financed its growth by strengthening its equity capital through successive capital increases, obtaining government aid for innovation, convertible debenture loans, and reimbursements of outstanding research tax credit.

Considerable expenditure on clinical study research and development has been incurred since the Group began operating, which has, to date, generated negative cash flows related to operating activities. The latter amounted to -€8.9 million and -€7.6 million for the financial years ended December 31, 2018 and December 31, 2019 respectively and -€5.2 million and -€5.6 million for the six-month periods from January 1 to June 30, 2018 and 2019.

As of December 31, 2019, the Group had cash and cash equivalents of €2.4 million. In view of the capital increase carried out by the company in February 2020, which enabled it to raise €4.9 million, the Company believes that its cash flow should enable it to finance its planned operations until the end of February 2021. To fund its operations as a going concern beyond the end of February 2021, its development and its future investments, the Company will have to resort to equity financing and/or borrowing, particularly in the very deteriorated economic context given the huge economic crisis caused by the coronavirus COVID-19 health crisis.

The Company will continue to have major financing needs in the future for the development of its technology, the continuation of its clinical development program and the equipping of its own pharmaceutical laboratory and, in the longer term, for the production, marketing and sale of its products. The Company could find itself unable to self-finance its growth, which could lead it to seek other sources of financing, particularly via new capital increases.

The Company's level of financing needs and their scheduling over time depends on matters that are largely beyond the Company's control, including:

- Higher costs and slower progress than those anticipated for its research and development programs and clinical studies;
- The costs of preparing, filing, defending, and maintaining its patents and other intellectual property rights;
- Costs associated with possible requests to change studies, or to include a greater number of patients;
- Higher costs and longer lead times than those anticipated to obtain regulatory authorizations for the marketing of its products and access to reimbursement, including time spent preparing application dossiers for the competent authorities; and
- New opportunities for the development of new products or the purchase of technologies, products or companies.

It is possible that the Company may not be able to secure additional capital when it is needed, or that such capital may not be available on financial terms and conditions acceptable to the Company. If the necessary funds were not available, the Company may be forced to:

- Delay, reduce, or eliminate the number or scope of its preclinical and clinical trials;
- Grant licenses of its technologies to partners or third parties;

- And/or enter into new collaboration agreements on terms and conditions less favorable to it than those that it might have been able to obtain in different circumstances.

To the extent that the Company can raise capital by issuing new shares, the stake of its shareholders could be diluted. Debt financing, where available, could however require the Company and its shareholders to make restrictive commitments.

The occurrence of one or more of such risks could have a highly material adverse effect on the Company, its business, financial position, results, growth, and outlook.

### 3.2.2. The Company has posted operating losses since its formation and believes this situation could continue. It is possible that it may never be profitable

Since it began operating, the Company has posted operating losses. Such losses reflect both the significance of the expenses incurred in research and development and the weakness of its revenues.

The Company foresees that such losses will continue over the next few years, at least until the marketing and sale of its drug candidates, because of the significant investments required for research, development, manufacture, quality control and distribution of its drug candidates, preclinical and clinical trials, administrative activities, and activities linked to the development of intellectual property, as well as license agreements for new drug candidates and for the acquisition of new technologies that may become necessary, as the case may be. The Company may never market or sell any drug candidates and, as a result, may never become profitable.

As of December 31, 2019, the accumulated losses under IFRS over the last two financial years totaled €18,620 thousand, including a loss of €7,203 thousand for the financial year ended December 31, 2019.

The Company expects that its operating losses will increase in the near future, particularly when:

- Some of its drug candidates move beyond the stage of preclinical development to clinical development;
- It is confronted with increased regulatory requirements for the manufacturing and trials of its drug candidates (including setanaxib, which is its only product candidate in an advanced stage of development);
- It increases its portfolio of drug candidates by adding new drug candidates for future development;
- It develops its research and development activities and buys new technologies, drug candidates or licenses, as the case may be; and
- It has to finance structural expenses consistent with the growth of its business.

The amount of net losses and the time needed to reach sustained profitability are difficult to estimate and will depend on several factors, including:

- The degree of advancement of the Company's research and development activities, particularly preclinical developments and clinical trials;
- The schedule of regulatory procedures in connection with the preparation, review, and protection of patents and intellectual property rights;
- Changes in collaboration arrangements made by the Company, as the case may be; and
- Other factors, a great number of which are beyond the Company's control.

The increase of these expenses could have a material adverse effect on the Company, its business, financial position, results, growth and outlook.

### 3.2.3. The stake of the Company's shareholders in its capital could be significantly diluted

Since its inception, the Company has issued and awarded share subscription warrants (BSA) and stock options. As of the date of this Universal Registration Document, the full exercise of all of the instruments granting access to the capital awarded and in circulation as of the date of this Universal Registration Document would allow for the subscription of 346,712 new shares, generating a dilution equal to 3.00% based on the existing capital as of that date and 2.91% based on the fully diluted capital (see Section 19.1.4 of the Universal Registration Document for detailed information on dilutive instruments).

In connection with its incentive strategy to motivate its executives and employees and to attract and retain qualified personnel, the Company may issue or award shares or new equity securities carrying the right to acquire shares in the future, which could cause further dilution, potentially material, for present and future shareholders of the Company.

In the context of its development, the Company might also use sources of funding that potentially have a dilutive effect for the Company's shareholders.

### 3.2.4. Risks related to the research tax credit

*The Company could see the amounts of research-tax credit that the Group has received and could receive in the future challenged if it fails to comply with the terms of the tax credit*.

In order to finance its activities, the Company uses the Research Tax Credit ("**CIR**") granted by the French government to companies with significant research and development investments. The research expenses that are eligible for the CIR include wages and salaries, the amortization of research material, services subcontracted to approved research entities (public or private), and intellectual property expenses.

The amounts received by the Group in 2018 for the 2017 CIR and in 2019 for the 2018 CIR amounted to €558 thousand and €893 thousand respectively (the latter amount was received in October 2019). The CIR received in April 2020 for financial year 2019 amounted to €0.9 million.

The Company cannot rule out the possibility that the tax authorities might challenge the methods used by the Company in calculating research and development expenses or that the CIR may be might be challenged, for past or future financial years, because of a change in regulations or a challenge by the tax authorities, even though the Company was in compliance with the requirements in terms of documentation and eligibility of expenses, given that the authorities' recapture right can be exercised until the end of the third year following the date of filing of the special declaration provided for the calculation of the tax credit. The amounts declared by Genkyotex SA (formerly Genticel) and Genkyotex Innovation SAS (which merged with Genkyotex SA in 2017) for the 2017 to 2019 financial years amount to €2,350 thousand.

If the tax authorities were to challenge the methods of calculating the research and development expenses used by the Company or if the CIR is reviewed, for past or future financial years, due to a change in regulations or a challenge by the tax authorities, this could have an adverse effect on the Company's results, financial position and outlook.

### 3.2.5. Foreign exchange risks

*Conducting its business abroad could expose the Company to a higher foreign exchange risk*

As of December 31, 2019, the Company's cash was primarily denominated in euro and Swiss francs. Moreover, the initial valuation of intangibles relating to the SIIL contract was based on a business plan for which revenues are denominated in US dollars and euro. A fluctuation of the US dollar or the Swiss franc against the euro could have an adverse effect on the value of this contract.

The Company has not, at the current stage of its development, entered into any hedging arrangements to protect its business against fluctuations in exchange rates, as the expenses anticipated at this stage by the Company are primarily in euro and Swiss francs. However, the Company cannot rule out that a significant increase in its business abroad, particularly resulting from the license agreement with the pharmaceutical company SIIL (whose revenues are denominated in US dollars and in euro), would not subject it to a higher exposure to exchange rate risk.

If the Company does not manage to take effective hedging arrangements against exchange rate fluctuations in the future, its operating results could be impacted.

## 3.3. RISKS RELATED TO THE COMPANY'S ORGANIZATION

### 3.3.1. Since Genkyotex is a biopharmaceutical company with no product that has obtained a marketing authorization and with only a single drug candidate, setanaxib, that has reached the clinical trial stage, the absence of revenues from historical products makes it difficult to evaluate its prospects and future financial results

Genkyotex is a biopharmaceutical company with a limited operating history that does not make it possible to estimate its prospects and future revenues. The development of biopharmaceutical products is highly speculative and involves a high degree of uncertainty. The Company's operations have so far been primarily limited to identifying and developing therapeutic molecules capable of selectively inhibiting NOX enzymes and, on the basis of such technology, conducting preclinical and clinical trials for the purpose of developing, marketing and selling therapeutic solutions. Setanaxib, the Company's most advanced drug candidate, has demonstrated good safety results with some 260 subjects exposed to the product in Phase 1 and Phase 2 clinical trials, as well as statistically significant effects on several efficacy endpoints in its Phase 2 clinical trials.

The Company has not yet shown an ability to overcome the great number of risks and uncertainties frequently encountered by companies active in new and rapidly evolving areas such as biopharmaceuticals. The Company's ability to evaluate its future results or commercial prospects with precision, likewise, is more limited than if it had a long operating history or products that had already received marketing authorization.

As a result, the probability of the Company's success must be evaluated in light of the numerous potential challenges and contingencies faced by a company in the business of developing drugs at an early stage, most of which are beyond its control. The occurrence of any setback in this connection could significantly harm the Company's operations and outlook.

### 3.3.2. Genkyotex is dependent on its key staff and must continue to attract and retain its key employees and scientific advisors

The Company's success depends largely on the work and experience of its executive management and its key scientific personnel. The loss of their expertise could impair the Company's ability to reach its objectives. Furthermore, the Company will need to recruit new qualified executives and scientific staff as it expands in areas that require additional abilities, such as marketing, manufacturing, clinical trials, and regulatory affairs.

The Company competes with other companies, research organizations, and academic institutions to recruit and retain highly qualified scientific, technical, and management staff. To the extent that such competition is very intense, the Company may be unable to attract or retain such key staff on terms and conditions that are acceptable from an economic point of view. Its inability to attract and retain such key staff could prevent it from reaching its overall objectives.

### 3.3.3. The Company's development will depend on its ability to manage growth

As part of its growth strategy, the Company will likely need to develop its operational capabilities, which could require a significant mobilization of its internal resources.

For this purpose, the Company will, in particular, have to:

- Anticipate expenses linked to this growth and the associated financing needs;
- Be prepared, if necessary, to set up its sales force;
- Increase the capacity of its existing operating IT, financial and management systems;
- Manage the outsourcing of production of its drug candidates and, where applicable, its drugs;
- Manage partnership agreements with the Company's industrial partners in charge of continuing the clinical development, marketing and sale of its products.

To meet demand within the time frame agreed upon with its future partners, the Company may also need to enter into new subcontracting agreements. If the Company could not, in the future, make adequate arrangements to develop its operational capabilities, its operating results and outlook could be altered.

## 3.4. RISKS ASSOCIATED WITH THE COMPANY'S DEPENDENCY ON THIRD-PARTY VENDORS AND MANUFACTURERS

### 3.4.1. Genkyotex is exposed to the risks associated with its high reliance on third-party service providers for the conduct of its clinical trials and, in the absence of capabilities and experience in the manufacture of its products, on third-party manufacturers

The organization of the Company's clinical trials has so far been entrusted and may continue to be entrusted in the future to CRO-type service providers, who, as appropriate, are mainly in charge of handling the logistics of the trials, monitoring studies, and collecting and analyzing data. The quality of the work (population selection, baseline measurements, compliance with protocols, doses, number of administrations and with interim deadlines and data retrieval times) performed by these service providers is crucial in the assessment and accuracy of results. The performance of such service providers in respect of their assignment, over which the Company has only financial control, is and will be essential to the quality and timeliness of the results achieved. Similarly, since clinical trials are complex and are conducted in several countries, they could be exposed to quality problems or substantial delays.

If the Company is unable to maintain its existing collaboration agreements with such partners or enter into new agreements, it will have to develop and sell its products at its own expense, or turn to other partners. This could increase its capital requirements and adversely affect the development of its products and their marketing, including for indications other than those currently targeted, where applicable. In addition, even if the Company, in accordance with its agreements, has included provisions designed to impose strict compliance by its partners with their commitments, it cannot control either the significance or the timing of the resources that its existing and future partners will devote to the development or sale of its products. These partners, in particular CROs, may not fulfill their obligations as described in existing or future binding contracts between them or as it anticipated

(especially in exceptional circumstances such as a pandemic similar to that of coronavirus COVID-19 that may lead to halting or limiting the operation of production machines and/or movement of persons or products). Even though the Company tries to include non-compete clauses in its collaboration agreements, no assurance can be given that such restrictions will provide sufficient protection. Its partners could pursue alternative technologies alone or together with others, including its competitors.

Similarly, other clinical trials are currently underway or could be initiated in the future by investigators external to the Group (independent academic research centers) based on the Company's existing product candidates; such trials are known as “Investigator-Initiated Trials” (IIT). These investigators have autonomy in carrying out these clinical trials (pace, recruitment, protocol, etc.); the Company has only limited control over how they are conducted. As such, the Phase 2 IIT study with setanaxib conducted by the Baker Heart and Diabetes Institute of Melbourne (Australia) with financial support from the Australian Juvenile Diabetes Research Foundation (JDRF) or Phase 2 IIT study evaluating the role of NOX enzymes In idiopathic pulmonary fibrosis (IPF) and to be initiated in 2020 by Professor Victor Thannickal of the University of Alabama at Birmingham as part of a multi-year program funded by the American National Institutes of Health (NIH) for research, may not be completed for a variety of reasons, including failure in patient recruitment, the occurrence of an unsuspected significant event, termination of trial funding by JDRF and the NIH, may not proceed satisfactorily or may take longer to complete than expected.

Furthermore, the Company has chosen to outsource the manufacture of its product candidates. Its dependence on third parties to manufacture and assemble some of its product candidates, especially its most advanced drug candidate, setanaxib, and its lack of experience in manufacturing other product candidates on an industrial scale could affect its ability to develop and sell its products within a reasonable time frame and on a competitive basis.

Moreover, reliance on third-party manufacturers poses additional risks that it would not face if it produced its drug candidates itself, namely, non-compliance with regulatory and quality control standards, breach of its agreements by third parties, termination or non-renewal of these agreements for reasons beyond its control or bankruptcy of such third parties.

If products manufactured by such third-party suppliers do not comply with regulatory standards, sanctions and penalties could be imposed to it. Such sanctions could include fines, court orders, civil penalties, the refusal of regulatory authorities to grant marketing authorization for its products, delays, the suspension or withdrawal of authorizations, the revocation of product licenses, the seizure or recall of its products, operating restrictions and criminal prosecutions. All such measures could have a material adverse effect on the Company's business, financial position and results.

## 3.5. RISKS RELATED TO INTELLECTUAL PROPERTY

### 3.5.1. Genkyotex may not provide adequate intellectual protection for its clinical candidates and patent portfolio

It is important for the success of its business that Genkyotex and any of its future licensees be in a position to obtain, maintain and uphold their patents, intellectual property rights and similar rights (such as trade secrets, business secrets and know-how) in Europe, the United States and in other countries in which Genkyotex may sell its products directly or indirectly. In particular, it cannot be ruled out that:

- The Company may fail to develop new inventions, methods or compounds that are patentable;

- The Company may be unable to file all necessary or appropriate patents at a reasonable price and within the required or appropriate time;
- The patent applications that are being reviewed, including certain important patents in several jurisdictions, are not granted;
- The Company may not be granted patents in all countries likely to offer significant prospects for commercial development;
- The patents which are granted or licensed to its partners or itself are contested or held to be invalid, or the Company may be unable to enforce them;
- The scope of protection granted by a patent may not be sufficient to protect the Company from competition;
- Third parties may claim proprietary rights to the patents or other intellectual property rights that the Company owns outright or to which it holds a license;
- Third parties may produce competing products based on our patent applications and falling outside the protection provided by our patents.

The validity and scope of a patent in the area of biotechnology is highly uncertain and raises complex legal and scientific questions. Since the grant of a patent does not guarantee its validity or applicability, patents and patent applications may be challenged in court or other proceedings, which could result in a loss of exclusivity, a reduction in scope, or invalidity or partial or total inapplicability of the Company's patents. In addition, legal action may be necessary to enforce Genkyotex's intellectual property rights, protect its trade secrets or determine the validity and scope of its intellectual property rights. In an industry where disputes over the protection or infringement of intellectual property are frequent, any dispute could result in considerable expense, reduce profits and fail to provide the protection sought. In addition, such patents could be successfully infringed or circumvented as a result of innovations. Due to the time required for development, trials, regulatory review and/or marketing authorization procedures for new product candidates, patents protecting these product candidates may expire before or immediately after they are marketed and sold.

Obtaining and maintaining a patent portfolio involves significant expenditures and resources. Some of this expenditure includes periodic maintenance fees, renewal fees, annuities, various government patent fees and/or multi-step applications throughout the life of the patents and/or applications, as well as costs associated with fulfilling the numerous legal formalities during the patent application process. There are also situations in which non-payment or non-compliance with certain requirements of the patent process may result in the forfeiture or lapse of a patent or patent application, resulting in a partial or total loss of patent rights in the jurisdiction concerned. If the Company waives patent protection or if it deliberately or inadvertently allows a patent application or patent to lapse, the Company could lose all or some of its technological and competitive advantage.

To the best of the Company's knowledge, its technology is currently effectively protected by the patents and patent applications it has filed. However, if it is unable to maintain or protect its intellectual property rights, or if current or future patents expire or cannot be extended before the products they protect are marketed and sold, the Company could be materially and negatively impacted by the loss of its technological and/or competitive advantages or be unable to operate profitably.

### 3.5.2. Specific risks related to the infringement of intellectual property rights

The Company's success will partly depend on its ability to develop products or technologies which do not infringe patents or other rights of third parties. It is important, for the success of its business, that the Company be in a position to freely exploit its products without them undermining patents or other intellectual property rights, and, in turn, without third parties undermining the Company's rights, in particular those relating to intellectual property.

The growth of the research industry and the associated increase in the number of patents filed heighten the risk that the Company's products and technologies may infringe the rights of third parties, in particular those relating to intellectual property.

The Company therefore continues to speed up, as it has done up to now, the preliminary studies it deems necessary in relation to the aforementioned risks, before committing investments aimed at developing its different products/technologies. In particular, it monitors the activities (patent filing in particular) of its competitors.

To the extent that patents combine the use of multiple molecules, the Company should examine and monitor the rights which could have been obtained or which would be obtained in the future by third parties over these molecules or antigens. The Company will therefore possibly be required to take action to challenge the rights of third parties so as be to be free to exploit its product candidates, or may in some cases have to obtain licenses on specific aspects within the composition of its product candidates or its immunotherapies and for which the Company has not been able to secure protection, mainly because they concern products or processes prior to its research in the field or concern fields which are different, yet related.

Patents belonging to third parties have, for example, been identified by the Company in the field of adjuvants required for preparation, and these third-party patents are monitored by the Company to determine their relevance with a view to a prospective operation in due course. If necessary, the Company may have to take action to challenge these patents.

On the other hand, monitoring the unauthorized use of the Company's products and technology, and the infringement of its rights, including its intellectual property rights, is a sensitive matter and may require the Company to incur expenses that it could not or would not be able to handle in a timely manner. The Company can therefore not guarantee:

- That it will be able to prevent and seek redress for unauthorized misappropriations or uses of its products and technology, particularly in foreign countries where its rights would not be as well protected due to the territorial scope of industrial property rights;
- That there are no prior patents or other rights, in particular intellectual property rights, of third parties that are likely to cover certain products, processes, technologies, results or activities of the Company which would result in third parties bringing infringement or violation proceedings against the Company in order to obtain damages and/or the cessation of its manufacturing and/or marketing activities for such offending products, processes, etc.;
- That there are no prior trademarks or other rights of third parties likely to provide grounds for an infringement or liability action against the Company; and/or
- That the Company's domain names will not be the subject of, by a third party with former rights (e.g. trademark rights), a UDRP (Uniform Domain-Name Dispute-Resolution Policy) or similar procedure or infringement proceedings.

Should disputes arise regarding the intellectual property it uses, the Company may be obliged to:

- Cease or oversee the cessation of the development, sale or use of any product(s) dependent upon the challenged intellectual property;
- Review the design of some of its products/technologies or, in the case of requests concerning trademarks, rename its products to avoid infringing the intellectual property rights of third parties, which could prove impossible or be long and costly, and could in fact impact efforts to market and sell the products concerned by the Company and/or its partners.

Third parties (including employees of the Company) could use or try to use elements of the Company's technology protected by an intellectual property right, which would place the Company in a harmful

situation. The Company may therefore be obliged to take legal or administrative litigation action against these third parties and/or employees to assert its rights, particularly those relating to intellectual property (patents, trademarks, drawings and models or domain names) in court.

Any litigation or dispute, whatever the outcome, could result in substantial costs that the Company could not or would not be able to assume in a timely manner, and may affect the Company's reputation, negatively influence the results and financial position of the Company and potentially fail to provide the protection or compensation sought. The Company's competitors that have greater resources than the Company could be in a better position to bear the cost of litigation proceedings.

As of the date of the Universal Registration Document, the Company has not been faced with any of these situations, nor has it been involved in any disputes, as claimant or defendant, concerning its intellectual property and other rights or those of a third party.

### 3.5.3. The agreements signed by the Company to protect its technology, its trade secrets and its know-how could prove insufficient

It is important for the Company to protect itself against the unauthorized use and disclosure of its confidential information, its know-how and its trade secrets. Its technologies, processes, methods, know-how and data which are not patented and/or patentable are considered trade secrets that the Company partly attempts to protect through confidentiality agreements. Furthermore, the rules for giving the Company control over any inventions that its employees have created or may create, and their terms of remuneration, are governed by Article L. 611-7 of the Intellectual Property Code, which is public policy for the Group's French entity.

Under collaboration, partnership, research or any other type of cooperation agreements entered into between the Company and researchers from university institutions and with other public or private entities, subcontractors or any co-contracting third party, various information and/or products may be entrusted to them particularly for the purposes of conducting certain tests and clinical trials. In such cases, the Company requires the signature of confidentiality agreements. Furthermore, the Company ensures that the collaboration, partnership or research agreements that it signs give it access to the full ownership or, at least, the co-ownership of any results and/or inventions resulting from such a collaboration, where it has effectively participated in the creation of such results and/or inventions. The Company also seeks, through the license agreements it signs with its partners, to retain control over the management of patents or to only grant licenses in specific fields in which it does not operate.

It cannot be ruled out that the agreements established to protect the Company's technology and trade secrets and/or know-how may not provide the protection sought or may be violated, that the Company may not have effective recourse against such violations or that its trade secrets may be disclosed to its competitors or developed independently by them. Furthermore, the Company has very limited control over the conditions under which the third parties with which it has a contract themselves engage third parties and protect their confidential information. This is independent of the fact that the Company takes into account in its agreements with its co-contractors that they undertake to pass on these confidentiality obligations to their own co-contractors.

Such agreements therefore expose the Company to the risk of the third parties concerned (i) claiming entitlement to intellectual property rights over inventions or other intellectual property rights of the Company, (ii) failing to ensure the confidentiality of unpatented innovations or enhancements of the Company's confidential information and know-how, (iii) disclosing the Company's trade secrets to its competitors or independently developing these trade secrets and/or (iv) breaching such agreements, without the Company having a suitable solution against such breaches.

As a result, the rights of the Company over its confidential information, its trade secrets and its know-how may not confer the expected protection against the competition, and the Company cannot guarantee:

- That its know-how and trade secrets will not be obtained, usurped, circumvented, transferred without its authorization or used by unauthorized third parties;
- That the Company's competitors have not already developed technologies, products or devices comparable or similar in nature or purpose to those of the Company;
- That no co-contractor will claim entitlement to all or part of the intellectual property rights over inventions, knowledge or results that the Company owns itself or in co-ownership, or for which it would be required to hold a license; or
- That the Company's employees will not claim the rights or the payment of additional compensation or a fair price in consideration of inventions for which they have contributed to the creation.

The occurrence of one or more of such risks could have an adverse effect on the Group's business, outlook, financial position, results and growth.

# SECTION 4. INFORMATION ABOUT THE ISSUER

## 4.1 LEGAL AND COMMERCIAL NAME OF THE COMPANY

The Company's corporate name is: Genkyotex SA.

## 4.2 PLACE OF REGISTRATION, REGISTRATION NUMBER AND LEI OF THE COMPANY

The Company is registered with the Thonon-les-Bains Trade and Companies Register under number 439 489 022.

The Company's NAF code (French business code, formerly "APE" code) is 7211Z.

The Company's Legal Entity Identifier (LEI) code is 969500O5EBFI0TMRJM30.

## 4.3 DATE OF INCORPORATION AND LENGTH OF LIFE OF THE ISSUER

The Company was incorporated on October 15, 2001, for a period of 95 years expiring on October 15, 2096, barring early dissolution or extension.

## 4.4 REGISTERED OFFICE, LEGAL FORM, GOVERNING LAW AND WEBSITE

The Company's registered office is at 218 avenue Marie Curie – Forum 2 Archamps Technopole, 74166 Saint-Julien-en-Genevois Cedex, France.

The Company's contact details are as follows:
Telephone: +33 4 80 16 06 07
Website: www.genkyotex.com

The reader should note that unless otherwise stated in this Universal Registration Document, the information on the website is not part of this document.

The Company is a limited company (*société anonyme*) with a Board of Directors since the General Shareholders' Meeting of February 28, 2017. Prior to that date, it was organized with a management board and a supervisory board.

The Company, governed by French law, is subject, in operational matters, to Articles L.225-1 *et seq.* of the French Commercial Code.

## 4.5 HISTORY

| | |
|---|---|
| **2001** | • Creation of Genticel. |
| **2006** | • Creation of Genkyotex |
| **2013** | • Completion of four Phase 1 clinical trials led by Genkyotex, which showed GKT831 to have a very good safety and pharmacokinetics profile. |
| **2014** | • IPO of the Company on the regulated markets of Euronext Paris and Euronext Brussels. |
| **2015** | • Completion of a Phase 2 trial with GKT831 in diabetic kidney disease. Without reaching its primary efficacy endpoint, the trial did enable the Company to demonstrate a statistically significant effect on several predefined secondary efficacy endpoints. |

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| | • License Agreement signed between the Company and the Serum Institute of India regarding the use of the Vaxiclase platform. |
| **2016** | • Termination of the Company's research projects in the field of HPV.<br>• Announcement of the alliance with the Genkyotex group (Switzerland) and signature of the contribution agreement. |
| **2017** | • Decision of the Company's Combined General Shareholders' Meeting of February 28, approving the merger with the Genkyotex group (Switzerland) through an in-kind contribution of all the shares of Genkyotex (Switzerland) to Genticel, and leading to the creation of a listed French-Swiss group whose activity is mainly dedicated to the development of a portfolio of NOX inhibitors, a new therapeutic class in fibrosis and inflammatory pain. Issuance of 62,279,951 new shares to those tendering their shares with an exchange ratio of 11.8355 Genkyotex SA shares (formerly Genticel SA) for each Genkyotex SA share (Switzerland) tendered.<br>• Initiation at the end of June 2017 of a clinical trial in primary biliary cholangitis (PBC) with GKT831.<br>• Initiation of a 48-week Phase 2 clinical trial with GKT831, in patients with type 1 diabetes and kidney disease led by the Baker Heart and Diabetes Institute of Melbourne (Australia) with financial support from the Australian Juvenile Diabetes Research Foundation (JDRF) for a study at several centers in Australia in diabetic kidney disease. |
| **2018** | • Extension of the initial licensing agreement covering emerging markets only, signed in 2015, for the Vaxiclase platform with the Serum Institute of India Private Ltd (SIIPL) to include industrialized countries in their addressable markets. Following the extension of the agreement, the Company may now receive an additional €100 million, bringing the total amount of the agreement to approximately €150 million in the form of an initial payment and development and sales milestone payments. The Company is also eligible to receive single-digit royalties on sales. The signing of this extension resulted in the recognition of €750 thousand in revenue in financial year 2018.<br>• The NIH (National Institutes of Health) in the United States awarded Professor Victor Thannickal of the University of Alabama at Birmingham (UAB) $8.9 million in grant funding to finance a multi-year research program evaluating the role of NOX enzymes in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in scarring (fibrosis) of the lungs. The core component of the program will be a 24-week Phase 2 trial of the Company's lead candidate product, GKT831, in patients with IPF. Recruitment of patients for the study is scheduled to begin in the first half of 2019.<br>• The Company obtained financing enabling the raising of up to €7.5 million through the issuance of bonds convertible into shares with share subscription warrants (“OCABSAs”) for the benefit of YA II PN, Ltd, an investment fund managed by Yorkville Advisors Global LP, a US management company. Only the first tranche of OCABSAs for a nominal amount of €5 million was issued by the Company.<br>• The Company met the primary and secondary interim efficacy endpoints in its Phase 2 study with GKT831 in primary cholangitis. |
| **2019** | • The Company announced that a university partner has received a Cancer Research UK grant to further develop NOX research in oncology.<br>• The Company announced that the reverse stock split of Genkyotex shares (1 new share for 10 existing shares) has taken effect. |

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| | • The Company published the final results of the Phase 2 study in PBC (primary biliary cholangitis).<br>• The WHO endorsed NOX inhibitors as a new therapeutic class and approved setanaxib for GKT831.<br>In August, the Company extended the conversion period of its convertible bonds into shares outstanding by 12 months for a total par value of €1.6 million. |
| **2020** | • All bonds convertible into shares were converted into new shares of the Company in January.<br>• Completion in February of a capital increase with shareholders' pre-emptive rights maintained in the amount of €4.9 million. |

# SECTION 5. BUSINESS OVERVIEW

## 5.1. GENERAL PRESENTATION OF THE COMPANY'S ACTIVITIES

Genkyotex is a clinical-stage biopharmaceutical company specializing in the discovery and development of small therapeutic molecules capable of selectively inhibiting an enzyme complex called NADPH oxidase (or NOX).

NOXs catalyze the reduction of molecular oxygen and generate reactive oxygen species (ROS) that are oxidizing and toxic to cells. As an increase in NOX activity results in an undesirable increase in ROS, NOXs have been identified as potentially key factors in the development of several complex and difficult-to-treat diseases, including many fibrotic, inflammatory, neurodegenerative and oncological disorders. To date, no NOX inhibitor has yet been approved, and the technological challenge is to identify selective inhibitors with an optimal efficacy and safety profile to treat specific disorders.

Given the major role that the NOX1 and NOX4 isoforms appear to play in the initiation and maintenance of inflammatory and fibrotic disorders, Genkyotex has focused on the development of its main drug candidate, setanaxib (formerly GKT831), which is a NOX1 and NOX4 inhibitor.

A leader in the development of NOX therapies, the Company conducted a Phase 2 clinical trial from June 2017 to May 2019 using setanaxib to treat primary biliary cholangitis (PBC), a chronic orphan autoimmune disease. PBC causes progressive destruction of the intrahepatic bile ducts and, if not adequately treated, can lead to cirrhosis, liver failure and death. Patients with PBC, mostly women, also have an increased risk of liver cancer. Their quality of life is severely compromised, mainly due to intense fatigue and itching. This 24-week clinical trial, involving 111 patients in nine countries (the United States, Canada, Germany, Belgium, Great Britain, Spain, Israel, Greece and Italy), was aimed at evaluating the efficacy of setanaxib on bile and hepatic duct disorders, hepatic hardness (a noninvasive indicator of hepatic fibrosis), and quality of life. This clinical trial also evaluated the safety profile and tolerance of setanaxib in patients with PBC.

In May 2019, the Company released the final results of this study. The primary efficacy endpoint predefined in the test protocol, decrease in gamma glutamyl transpeptidase (GGT) at week 24, was not achieved. However, the 400 mg-dosed setanaxib taken twice daily produced a statistically significant decrease in GGT ( $p$ =0.0002) and alkaline phosphatase (ALP, $p$ =0.0001) over the entire 24-week treatment period (analysis of repeated measurements). These favorable results are consistent with the statistically significant decrease in GGT and ALP observed in the interim analysis conducted after six weeks of treatment, with results announced in November 2018. The reasons for the loss of statistical significance in week 24 were thus explored in the context of predefined post-hoc analyses in a statistical analysis plan. The post-hoc analysis showed that GGT data did not follow a normal distribution in the group treated with the 400 mg dose once a day. The initial statistical analysis plan required verification of the normal distribution of GGT data before applying the statistical test. When all of the test groups were evaluated, the distribution of GGT data passed normality test. However, the post-hoc statistical analysis indicated that this was not the case for the group treated with 400 mg once a day. Although limited to the 400 mg group once a day, this non-normal distribution had an adverse effect on the comparisons of each of the two groups treated with placebo. The data structure for each group is taken into account in the statistical model which is then used for these comparisons. When this distribution aberration in the 400 mg group once a day is corrected by different methods (non-parametric statistical tests or logarithmic transformation), the value is greatly improved, including a statistical significance reached after logarithmic transformation ($p$ =0.02) for the 400 mg group twice a day compared to the placebo. It appears, therefore, that the main reason for the lack of statistical significance in week 24 is related to a non-normal distribution of GGT data in one of the groups.

An important objective of the clinical trial was to assess the effect of setanaxib on liver fibrosis. This effect was assessed by measuring hepatic stiffness, a non-invasive indicator of hepatic fibrosis. There is an excellent correlation between hepatic stiffness and the histological fibrosis score ("F Score"). Remarkably, the 400 mg setanaxib twice a day induced a 22% decrease in hepatic stiffness in patients with hepatic stiffness equal to or greater than 9.6 kPa ($p$ =0.038 compared to the placebo). This subgroup analysis was part of the protocol and statistical analysis plan. Hepatic stiffness of 9.6 kPa or more corresponds to an F score of F3 or F4. These scores indicate advanced liver fibrosis and are a very significant risk factor for the progression of these patients to cirrhosis, liver transplant, or death. It is therefore a population at risk. Interestingly, in these patients at risk setanaxib at 400 mg twice a day also leads to very large decreases in GGT and ALP (respectively -32% and -24%).

In addition, setanaxib at 400 mg twice a day also leads to a significant improvement in quality of life, for fatigue in particular ($p$ =0.023). This is a remarkable result, since no drug has shown a favorable effect on quality of life.

In addition, setanaxib was also able to demonstrate a very favorable safety profile at all doses where no safety signal was identified. The safety profile of both doses of setanaxib is similar to that of the placebo.

Positive results pave the way for further development in PBC and, possibly, in other inflammatory and fibrotic liver disorders such as primary sclerosing cholangitis (PSC) and nonalcoholic steatohepatitis (NASH), which also have significant unmet needs.

Since May 2017, a Phase 2 study with setanaxib in type 1 diabetes and diabetic kidney disease (DKD) has been ongoing, initiated by the Baker Institute in Melbourne, Australia. This 48-week study, initiated by the investigator and funded by the Australian Juvenile Diabetes Research Foundation (JDRF Australia), involves 142 patients in 10 research centers in Australia and three centers in New Zealand for which the researchers have obtained an extension authorization. An extension application for two European countries (Germany and Denmark) has also been filed. This study is currently recruiting patients. As of the date of this Universal Registration Document, patient randomization is ongoing and 24 patients have already completed the full 48-week treatment without any report of a safety issue.

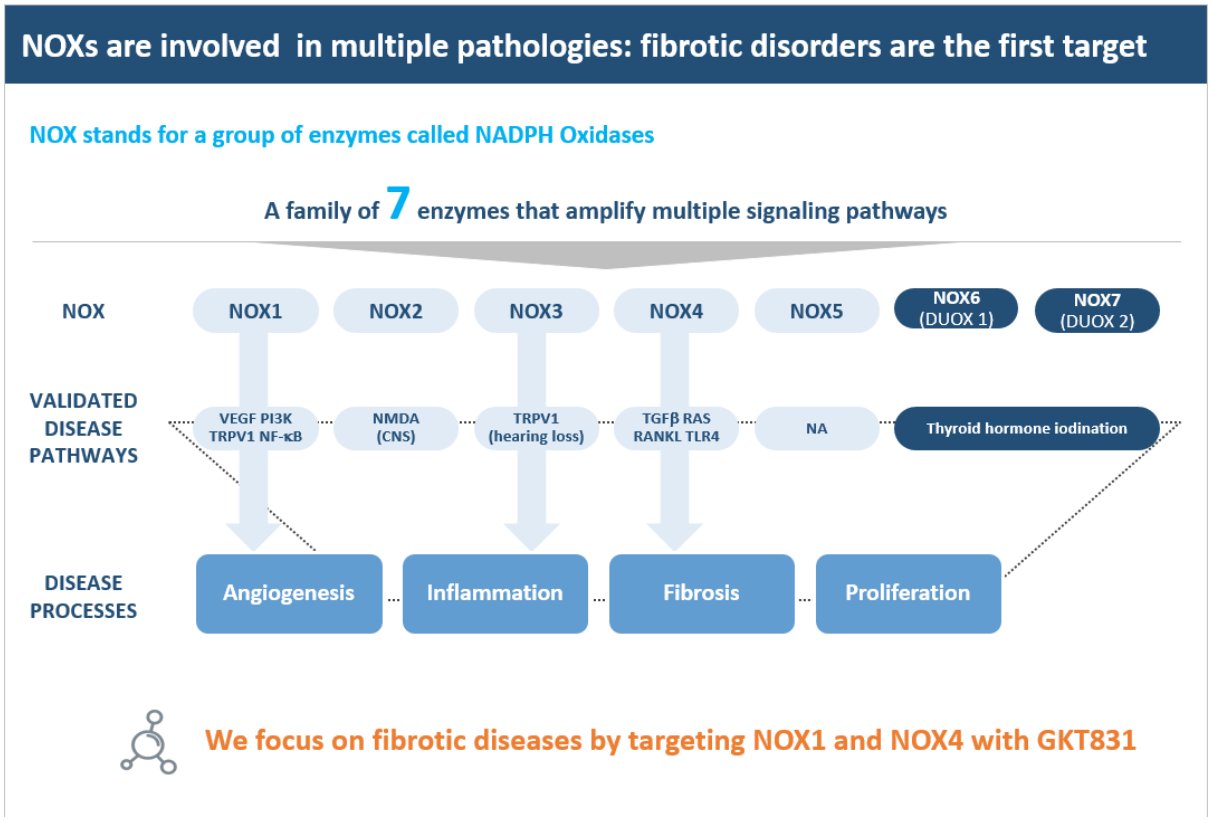
Finally, in July 2018, the Company announced that the National Institutes of Health (NIH) in the United States had awarded a US$8.9 million grant to Professor Victor Thannickal of the University of Alabama at Birmingham (UAB) to fund a multi-year research program evaluating the role of NOX enzymes in a chronic lung disease, idiopathic pulmonary fibrosis (IPF). The central focus of the program will be the completion of a 24-week Phase 2 study with setanaxib in IPF patients by UAB, the investigator that initiated the trial (IIT). In this randomized, double-blind, placebo-controlled study, setanaxib would be administered to 60 patients treated in accordance with current care standards for this indication (pirfenidone or nintedanib). The US FDA and the Ethics Committee have approved the protocol for this clinical trial. Patient recruitment could begin in the first half of 2020, as soon as the COVID-19 situation in the United States permits.

Research and development work, preclinical studies, clinical trials, facilities and the manufacture, marketing and sale of the Company's product candidates are subject to the regulatory authorities in France (*Agence nationale de sécurité du médicament et des produits de santé* (ANSM)), Europe (European Medicines Agency (EMA)), the United States (the Food and Drug Administration (FDA)) and in other countries.

The Company's registered office is located in Archamps, France. The Group has 12 employees, including nine employees dedicated to research and development. It conducts research (biotechnology, molecular screening and pharmacology) and develops clinical trials managed both internally and in collaboration with third parties (via contract research organizations (CRO)). The Group notably uses CROs to conduct and monitor its clinical trials, produce compounds and perform toxicology studies. Its clinical teams also collaborate with medical research institutions in investigator-initiated trials (IIT) on the Group's product candidates. The Company also relies on the unrivaled expertise of the members of its Scientific Advisory Board, which includes top global experts in NOX science.

***A unique therapeutic approach: selective inhibition of NOXs***

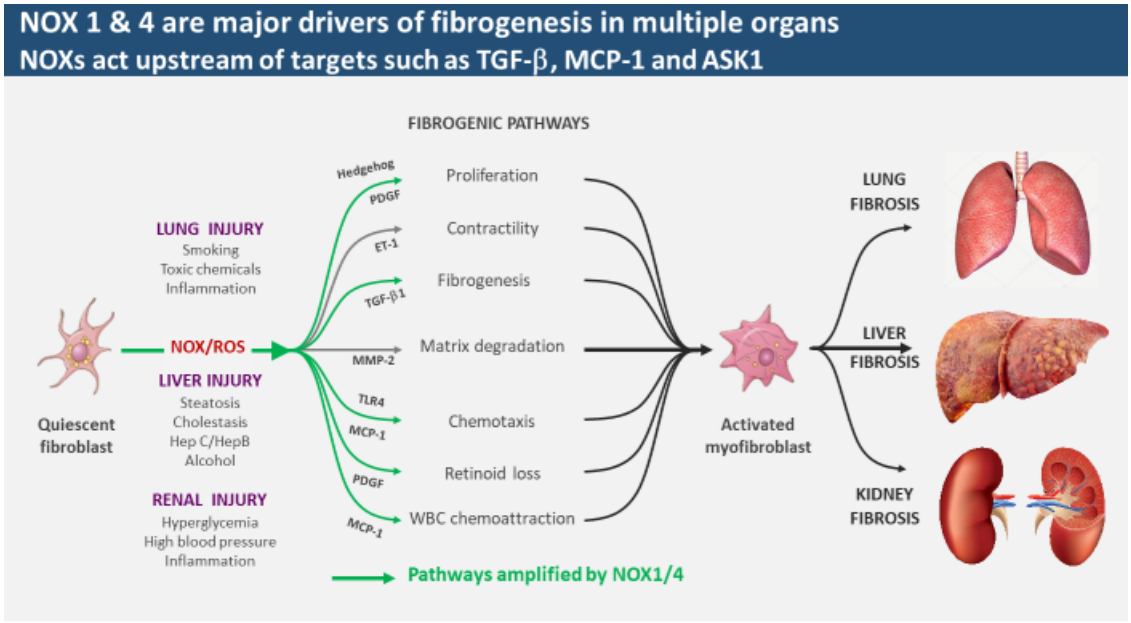
The NOX family contains seven enzymes called NOX isoforms (NOX1 to NOX5, as well as DUOX1 and DUOX2). The first NOX isoform to be discovered in the 1960s was NOX2, which is considered to be the phagocytic NOX involved in the elimination of foreign pathogens that enter the body through white blood cells called neutrophils. The other NOX enzyme isoforms were discovered in the late 1990s and early 2000s.




The role of NOX enzymes, most of which have been discovered and characterized by the Company's founders and current members of its Scientific Advisory Board, is to catalyze the reduction of molecular oxygen to generate very large quantities of reactive oxygen species (ROS), which act as secondary messengers that oxidize target proteins and thus modify their functions. These proteins have a signaling function in relation to a large number of cellular phenomena, and their oxidation by the ROS generated by NOX enzymes will cause this signaling role to be modified. This affects such varied functions as the regulation of inflammatory processes, pain-related processes or pathways

involved in fibrotic processes. Through this mechanism, NOX enzymes modulate many biological pathways involved in multiple pathophysiological processes.

This phenomenon, whereby inflammatory and fibrotic pathways are amplified by ROS generated by NOX1 and NOX4, involves a process common to many organs and concerning the same types of cells. The pharmacological and selective inhibition of NOX1 and NOX4 thus opens the way to the treatment of many inflammatory and fibrotic diseases affecting the liver, kidney, lungs, heart and skin, as well as certain types of cancer.




*Sources:
Bremner DA, Hepatology 2012, Bremner DA, PLoS One, 2015, Torok N, Free Radic Biol Med, 2012. Torok N, Gastroenterology, 2015; Thannickal V, Science Trans Med, 2014; Gray SP, Circulation, 2013

***A current focus on fibrotic disorders with product candidate setanaxib***

The most advanced product candidate developed by Genkyotex is setanaxib, a NOX1 and NOX4 inhibitor that has shown anti-inflammatory and anti-fibrotic properties in numerous preclinical studies and has demonstrated its efficacy in several animal models of liver, lung, kidney, skin and heart fibrosis. These results have been published in more than 50 leading scientific journals and have led the Company to identify fibrotic processes—which are estimated to contribute to approximately 45% of deaths in the industrialized world—as a very important therapeutic target. The Company has thus identified fibrotic disorders in the liver, and subsequently in other organs, as priority targets for its product candidate setanaxib.

In the liver, there are a number of fibrotic disorders of potential interest to the Company, including primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC) and nonalcoholic steatohepatitis (NASH).

*Primary biliary cholangitis (PBC)*

PBC is a chronic orphan autoimmune disease that overwhelmingly affects women (90%) and causes the progressive destruction of the intrahepatic bile ducts. This process creates an accumulation of bile

acids in the bile ducts and liver, triggering progressive inflammatory and fibrotic processes. If left untreated, PBC induces cirrhosis of the liver, severe liver failure and the need for liver transplantation within seven to ten years.

To date, there is no medication that can cure PBC, although the generic drug, ursodeoxycholic acid (UDCA), is able to slow progression of the disease in 60% to 70% of patients. Furthermore, UDCA does not improve the quality of life of patients with PBC, who suffer from itching (pruritus) and extreme fatigue. More recently, Ocaliva® (obeticholic acid or OCA), by Intercept Pharmaceuticals, has been approved in the United States and several European countries for the treatment of PBC in patients who do not respond sufficiently to UDCA. This drug slows the progression of the disease in these patients, but it aggravates itching in some of them (Pate J, BMJ Open Gastroenterol. 2019 Feb 1; 6(1)). A significant need thus exists to develop new therapies for this disease that can delay the onset of cirrhosis and avoid liver transplantation, as well as improve patients' quality of life with drugs that are well tolerated.

While it is difficult to estimate the size of the PBC market, given that there is only one non-generic drug currently commercially available (Ocaliva®), the Company believes that the PBC market, based on the prevalence of this orphan disease and the cost of marketing Ocaliva®, generates revenues of between US$1.5 billion and US$2 billion.

In addition to the therapeutic and commercial potential, demonstrating its clinical efficacy in PBC would extend the evaluation of setanaxib to other fibrotic liver disorders, such as PSC and NASH, as well as to other fibrotic disorders of organs such as the kidneys and lungs, and even to some types of cancer.

*Chronic kidney disease (CKD)*

Chronic kidney disease (CKD) is a major health problem as a result of an aging population, but also, and especially, because of the global diabetes pandemic. A variety of mechanisms including hypertension, diabetes and various immunological and toxic stresses induce the activation of NOX enzymes and the generation of ROS, leading to a loss of functional nephrons as well as chronic inflammation of the renal parenchyma. This inhibits tissue repair and leads to fibrosis development in these compartments and ultimately to a deterioration in kidney function. The inhibition of NOX enzymes in chronic kidney disease represents a major treatment opportunity in a global context of dramatic and alarming increases in the prevalence of diabetes and cardiovascular disease.

Setanaxib has been shown to have a protective effect in kidney inflammation and fibrosis in several mouse models of chronic kidney disease in type 1 and type 2 diabetes or in genetically altered conditions (You YH, et al. Metabolomics reveals a key role for fumarate in mediating the effects of NADPH Oxidase 4 in diabetic kidney disease; *J Am Soc Nephrol.* 2016 Feb; 27(2):466-81. Gorin Y, et al. Targeting NADPH oxidase with a novel dual Nox1/Nox4 inhibitor attenuates renal pathology in type 1 diabetes; *Am J Physiol Renal Physiol.* 2015 Jun 1; 308(11):F1276-87. Jha JC, et al. Genetic targeting or pharmacologic inhibition of NADPH oxidase nox4 provides renoprotection in long-term diabetic nephropathy; *J Am Soc Nephrol*. 2014 Jun; 25(6):1237-54).

*Fibrotic lung diseases*

The Company also believes that developing a treatment that inhibits NOX, whose role is now clearly established in the onset and development of fibrotic lung diseases, particularly idiopathic pulmonary fibrosis (IPF), should be a priority. As with PBC, there is currently no drug that can cure idiopathic pulmonary fibrosis, although some medications may slow the disease's progression. Pharmacological inhibition of NOX1 and NOX4 with setanaxib has shown a direct effect on scar tissue production in

several mouse models of pulmonary fibrosis, suggesting the possibility of an effective treatment alternative for patients with pulmonary fibrosis. (Hecker L, et al. Reversal of persistent fibrosis in aging by targeting Nox4-Nrf2 redox imbalance. *Sci Transl Med*. 2014).

To date, a total of around 280 subjects have been exposed to setanaxib in the following clinical trials:

- Five Phase 1 clinical trials led by the Company, which showed setanaxib to have a very good safety and pharmacokinetics profile. These trials were completed in 2019 and were conducted in a total of 132 healthy subjects (of whom 120 subjects exposed to setanaxib).
- A Phase 2 trial of diabetic kidney disease or DKD (type 1 diabetes and kidney disease) completed in 2015 included 136 patients (including 68 patients exposed to setanaxib). Although this trial did not achieve its primary efficacy endpoint, it did enable the Company to demonstrate a statistically significant effect on several predefined secondary efficacy endpoints.
- In late June 2017, the Company initiated a Phase 2 trial in PBC at 62 centers spanning nine countries in Europe, North America and Israel and involving 111 patients (including 74 patients exposed to setanaxib). The interim results of this trial for 92 patients who completed six weeks of treatment were made public in November 2018. The final results were announced in May 2019.

  A Phase 2 trial in diabetic kidney disease (DKD) initiated in 2017 by the Baker Institute in Melbourne, Australia. This study of 142 patients in 10 centers in Australia and three centers in New Zealand, for which investigators have obtained an extension authorization, is in the recruitment phase. With the agreement of Genkyotex, an application for extension to two European countries (Germany and Denmark) has also been filed. As of the date of this Universal Registration Document, patient randomization is ongoing and 24 patients have already completed the full 48-week treatment without any report of a safety issue.

The Company filed an INN application with the WHO for the NOX therapeutic class under the name “naxib,” which was accepted in March 2019. At the same time, the Company also proposed the trade name “setanaxib” for GKT831 and after the open period for comment that ended on June 14, 2019, this name was officially accepted and thus became the common name of GKT831.

***Identification of NOX1 inhibitors that could lead to a product candidate with analgesic and anti-inflammatory effects for peripheral, topical and central indications***

The Company's second, preclinical program aims to develop NOX1 inhibitors to treat inflammation and pain-related disorders. It is now accepted that NOX1 plays a role in inducing pain mechanisms through the activation of the TRPV1 channel and promotes cell proliferation. It also participates in inflammatory processes, since NOX1 is highly expressed in macrophages, the white blood cells that penetrate tissues in many inflammatory conditions.

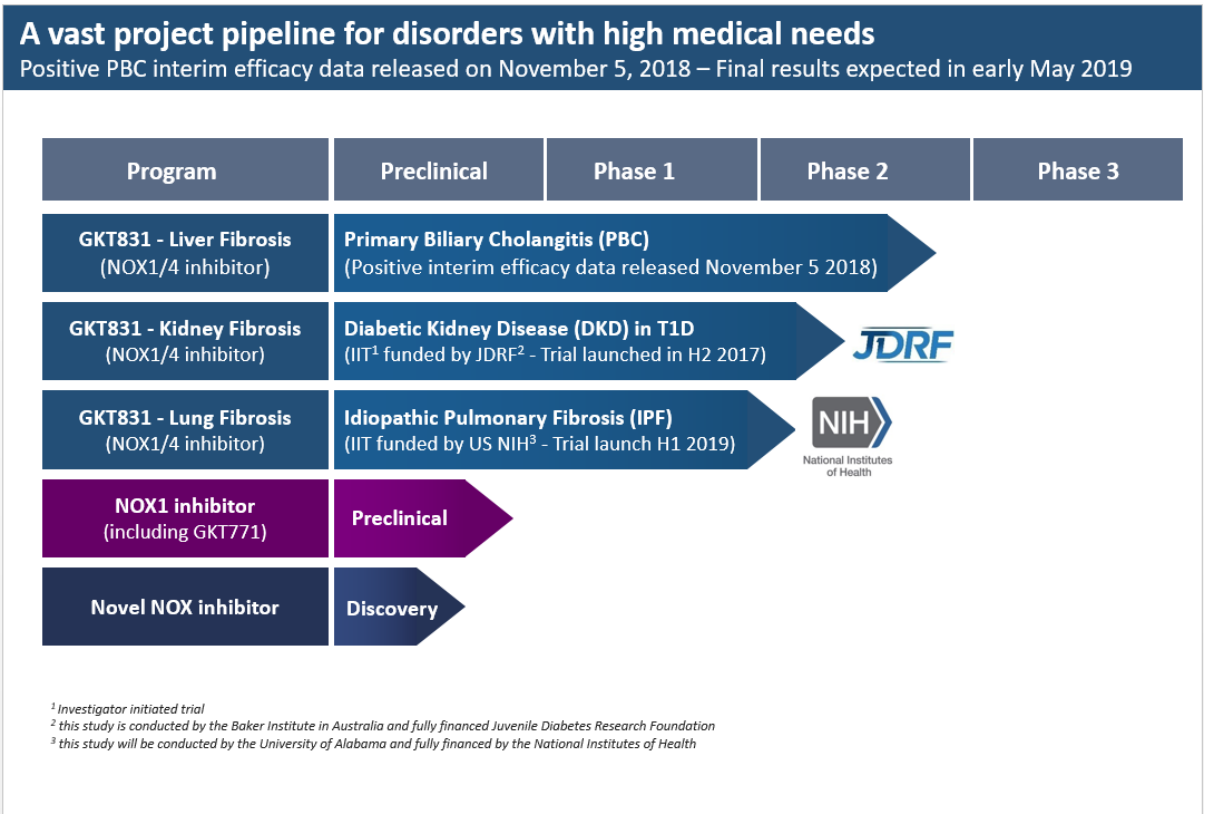
These three processes are major components in a high number of rheumatic disorders and inflammatory skin diseases, as well as in several types of inflammatory pain and in brain disorders such as Parkinson's disease.

The Company is therefore interested in identifying NOX1 inhibitors that could be used in peripheral diseases such as certain epithelial cancers or in the treatment of chronic inflammatory pain. Genkyotex is also interested in identifying and developing NOX1 inhibitors for topical cutaneous, ophthalmic or intra-articular applications, and in molecules that could cross the blood-brain barrier for the treatment of brain disorders such as Parkinson's disease.

This preclinical program includes GKT771, a selective NOX1 inhibitor with anti-inflammatory, anti-angiogenic and analgesic effects (see Section 5.8 below).

***Status of the clinical and preclinical development of Genkyotex's product candidates***

The table below summarizes the progress of the clinical and preclinical development of Genkyotex's product candidates.



### 5.1.1. Competitive advantages

Genkyotex considers itself to have the following competitive advantages:

- **The Company has unique NOX expertise, bolstered by its position as first entrant in the field.** Genkyotex is the first company to bring an NADPH oxidase inhibitor to the clinical stage. Founded by scientists who discovered and characterized the majority of NOX enzymes, Genkyotex boasts unrivaled expertise and technological and scientific leadership in this new therapeutic area. Genkyotex is the first company developing NOX enzyme inhibitors to have positioned a product candidate in a clinical setting, and the number of trials carried out by the Company has demonstrated the clinical feasibility of this therapeutic approach. The identification and development of NOX enzyme inhibitors can only be achieved through the creation of a unique platform that meets pharmaceutical industry standards.

- **A positive safety profile and proof of pharmacological activity for setanaxib.** Setanaxib has undergone four Phase 1 clinical trials which have shown a favorable safety profile and have demonstrated its pharmacological activity. The Company also conducted a Phase 2 clinical trial assessing setanaxib in diabetic kidney disease (DKD), which was completed in 2015 and involved 136 patients. Although this trial did not achieve its primary efficacy endpoint, it did enable the Company to demonstrate a statistically significant effect on several predefined secondary efficacy endpoints. In addition, the positive safety profile observed during the Phase 2 trial in DKD paved the way for clinical evaluation of setanaxib in the kidneys, liver and other organs over a longer treatment period and at higher doses. The favorable safety profile of a product candidate is a key factor in fibrotic disorders such as PBC or idiopathic pulmonary fibrosis (IPF). In this regard, this clinical trial was completed in May 2019 and covered 111 patients, 74 of whom were treated with setanaxib and the safety profile was very favorable throughout the study. This trial has shown the significant effects of the product on several circulating parameters, hepatic stiffness, and quality of life of PBC patients.

- **The inhibition of NOX enzymes, and particularly NOX1 and/or NOX4, offers a therapeutic alternative for significant unmet needs.** The NOX therapies developed by the Company offer a therapeutic alternative for several indications and in particular for fibrotic and inflammatory disorders, for which there are currently no approved therapies. This combined anti-fibrosis and anti-inflammatory effect could help target a population of patients at very advanced stages of their illness as well as a population of patients who do not respond or do not respond well to the proposed treatments, which could cover significant needs that are not met today.

- **The Company's technology allows it to target various biological pathways with a single compound**. The NOX technology developed by the Company allows it to effectively target multiple biological pathways with a single compound and a positive safety profile. The Company also has a unique NOX inhibitor selection and identification platform based on its proprietary cell lines expressing the various NOX enzymes in different species, and on the implementation of screening assays to eliminate all molecules that could be identified as false NOX inhibitors.

- **An experienced management team and Board of Directors assisted by a leading Scientific Advisory Board, including some of the world's most highly regarded specialists in the NOX field.** The Chief Executive Officer, the Medical Director, the Chief Financial Officer, the members of the Board of Directors and the four members of the Company's Scientific Advisory Board, professors Karl-Heinz Krause (University of Geneva), Chihiro Yabe (University of Kyoto), Robert A. Clark (University of Texas) and Dave Lambeth (Emory University Medical School, Atlanta) are highly experienced, with complementary expertise in terms of their training and

experience in the pharmaceutical industry. In particular, they boast extensive experience in translational, preclinical and clinical research, regulatory affairs, business development and finance.

### 5.1.2. Strategy

Genkyotex's aim is to develop a new approach in the treatment of various illnesses, the needs of which are not currently met at all or are only partly met. The main elements of its strategy are as follows:

- **Confirm the efficacy of a NOX1 and NOX4 inhibitor with setanaxib for fibrosis and inflammation in a liver disorder.** The Company's main objective is to confirm the efficacy of its most advanced product candidate, setanaxib, a NOX1 and NOX4 inhibitor, in inflammation and liver fibrosis with a study in PBC. To achieve this objective, the Company launched a Phase 2 clinical trial in late June 2017. This trial was conducted in more than 62 centers initiated in the United States, Canada, Germany, Belgium, Great Britain, Italy, Greece, Spain and Israel and concerned 111 patients, 74 of whom were exposed to setanaxib over a period of 24 weeks. Following the Company's announcement in November 2018 that it had met the primary and secondary efficacy endpoints for this trial (based on 92 patients who completed six weeks of treatment), final efficacy results were reported in May 2019 and showed a significant effect of the high dose of setanaxib on the circulating level of alkaline phosphatase (ALP, p=0.002) at week 24 and a significant 19% reduction in the level of Glutamyl Transpeptidases Gamma (GGT, p=0.002) over the overall 24-week treatment period. This effect was not shown to be significant at week 24, the predefined primary efficacy endpoint. This outcome was surprising because statistical significance had been achieved in reducing GGT ($p<0.01$) and ALP ($p<0.001$) at the time of the intermediate analysis conducted in week six. Genkyotex therefore undertook a post-hoc analysis to identify the reasons for the loss of significance in week 24 and to explore further the therapeutic benefits of setanaxib.

  The analysis showed that GGT data that did not follow a normal dose distribution of 400 mg OD at week 24 had caused the loss of statistical significance at week 24. The statistical significance (p=0.02) is thus reached for the main parameter at 400 mg BID at week 24 after correction of the distribution aberrations in the 400 mg OD group. This correction was performed by applying a standard statistical correction method (log-transformation) to minimize the impact of these statistical distribution aberrations.

  This reduction was also accompanied by a significant 22% decrease in hepatic stiffness (p=0.038) suggesting a high-dose anti-fibrosing effect of setanaxib, thus opening other therapeutic pathways for other inflammatory and fibrotic conditions. This positive result in this Phase 2 study can allow the Company to pursue its development in a Phase 3 study in PBC, but also to consider parallel development in other inflammatory and fibrotic liver indications such as NASH or PSC.

- **Confirm the efficacy of setanaxib for fibrosis and inflammation in a kidney disorder.** The Company has entered into an agreement with the Baker Heart and Diabetes Institute in Melbourne, Australia, as the initiating investigator to conduct a 48-week Phase 2 (IIT) clinical trial to evaluate the efficacy and safety of setanaxib in patients with type 1 diabetes and kidney disease (diabetic kidney disease or DKD). This study will be carried out at the Baker Institute as well as in multiple study sites across Australia. This trial is funded by the Australian Juvenile Diabetes Research Foundation (JDRF Australia), which receives designated funding from the Australian Research Council for the Special Research Initiative for Type 1 Juvenile Diabetes, with financial support from the Baker Institute. Patient randomization is underway and in total, recruitment targets 142 patients at 10 centers in Australia and three centers in New Zealand where investigators have obtained extension authorization. As of the date of

this Universal Registration Document, patient randomization is ongoing and 24 patients have already completed the full 48-week treatment without any report of a safety issue. With the agreement of Genkyotex, an application for extension to two European countries (Germany and Denmark) has also been filed.

- **Launch of the investigator-initiated Phase 2 study with setanaxib in idiopathic pulmonary fibrosis (IPF) planned for 2020, and where applicable in the first half year, as soon as the situation linked to COVID-19 permits:** the central component of this program, funded by a US$8.9 million grant from the National Institutes of Health (NIH) to UAB Professor Victor Thannickal, will involve a 24-week Phase 2 study with setanaxib. This randomized, double-blind, placebo-controlled study will assess the safety and efficacy of setanaxib. Setanaxib will be administered to 60 patients treated with the current standard of care (pirfenidone or nintedanib) for an IPF.

- **Promote the Company's NOX platform by conducting further exploratory preclinical research programs**. Genkyotex also plans to continue its NOX exploratory preclinical research programs, mainly in oncology.

## 5.2. NOX INHIBITION: A NEW AND COMPLEX THERAPEUTIC APPROACH

To date, no NOX inhibitor has been approved by a regulatory authority. The Company's objective is to identify and obtain authorization for selective inhibitors of NOX isoforms involved in target disorders, in order to obtain an optimal efficacy and safety profile to treat these specific disorders.

NOX enzymes are highly complex biological systems. The identification and development of selective inhibitors therefore require a highly sophisticated technological platform. Since the creation of Genkyotex in 2006, the Company has been a pioneer in this area, relying initially on the scientific knowledge of its founders, whose research teams discovered and characterized the majority of NOX enzymes.

Preclinical studies conducted with NOX inhibitors generated by Genkyotex seem to confirm the role of NOXs in important biological pathways such as fibrosis, inflammation, angiogenesis and tumor growth. These data were generated in collaboration with renowned academic groups and have been published in leading scientific journals, with more than 50 publications to date (see Section 5.13 of this Universal Registration Document).

The published scientific data suggest in particular that NOX1 and NOX4 isoforms could play a predominant role in the development of inflammatory and fibrotic processes.

### 5.2.1. Genkyotex's proprietary NOX platform

*Assay complexity*

The development of a platform enabling the development of NOX inhibitors is particularly complex. It is currently very difficult, if not impossible, to apply rational drug design to the development of NOX inhibitors, for the following reasons:

- NOXs are six-helix transmembrane proteins and are therefore very difficult to crystallize, a necessary step for the development of a high-definition tridimensional model;
- It is therefore impossible to correctly model the transmembrane structure of NOXs, and extremely difficult to extrapolate the binding format of NADPH;

- The structure of NOXs is unique, therefore we cannot use a similar crystalline structure as a basis (e.g. modeling of 7TM from bacteriorhodopsin).

It is currently not possible to carry out binding studies. The two NOX substrates, molecular oxygen and NADPH, are reduced as they interact with NOX enzymes, and the resulting product no longer has sufficient affinity for the enzyme and is released. To date, it has not been possible to synthesize a radioactive NADPH moiety which is not reduced (e.g. GTPgS which is not hydrolyzed and which remains linked to the subunit of the G protein). Also impossible is the radiolabeling of a ligand of NOXs, as these ligands, apart from those of Genkyotex, do not exist.

The high-throughput screening of molecules is therefore based on a functional test which assesses the inhibitory activity of the candidate molecules on the enzymatic activity of NOXs. These functional tests assess the production of reactive oxygen species (enzymatic products) and the consumption of oxygen and NADPH (enzymatic substrates).

To conduct these enzymatic tests, the Company first had to express each NOX isoform together with its subunits in cells lacking endogenous NOX expression, in order to be certain of the activity measured. Then, it had to express the enzymes at a rather high rate to be able to measure ROS (reactive oxygen species) levels. At the same time, however, high ROS production kills cells. To resolve this conundrum, the Company constitutively expressed all the necessary subunits in the cells, and the catalytic subunit (NOX1-NOX5) was inducibly expressed using tetracycline. In other words, for the chosen isoform to be expressed, cells need to be treated with tetracycline.

The second challenge for the Company was to measure ROS in a robust fashion and with high throughput. ROS are highly reactive species with a very short lifespan. Furthermore, the existing ROS detection probes are not yet specific enough for one ROS and may be subject to artifacts. For this, Genkyotex has created a battery of assays with different probes which can be used at high throughput. The Company also developed probe-independent methods which can be used in low throughput format. These tests assess the consumption of molecular oxygen and NADPH, which are the two natural substrates in NOXs.

*Cell- and membrane-based NADPH oxidase assays*
For each NOX isoform, it is currently possible to measure the inhibition by small molecules of ROS produced by the cells. Accordingly, in order to minimize off-target effects (e.g. inhibition of an enzyme upstream of the NOXs), Genkyotex has developed a membrane assay for each isoform. For this purpose, highly purified membrane preparations were created from each cell line overexpressing the NOX isoforms. These membranes contain the p22 protein and the catalytic subunit (i.e., the NOX isoform). For the NOX1, NOX2 and NOX3 isoforms, the subunits required for their activity have been added. These subunits were produced recombinantly in bacteria and highly purified. To the best of the Company's knowledge, Genkyotex is the only company to have the full NOX battery of assays, including both membrane and cellular systems. The best molecules identified in the membrane assays are also tested in our cells overexpressing the desired isoform. Moreover, as mentioned above, various probes were used, both on the membrane and on entire cells.

Lastly, the candidate molecules for in vivo tests were also tested on cells expressing NOX endogenously and which are related to each of the disorders of interest to the Company.

*Negative controls and counter screening assays*

To eliminate false positives, the Company has also developed a series of tests capable of identifying antioxidants, ROS scavengers and inhibitors of flavoproteins in general. First, to eliminate antioxidants and ROS scavengers, the reduction of DPPH was measured. This molecule is capable of identifying

hydrogen donors, i.e., molecules with antioxidant capacity. The Company has also developed a xanthine oxidase assay and a glucose oxidase assay. These two enzymes are also oxidases that function in a very similar way to NOXs, i.e., production (albeit to a lesser extent) of superoxide and hydrogen peroxide from molecular oxygen. The activity of these two enzymes was measured using the same probes as those used for the NOX assays. This series of tests was therefore used to eliminate molecules acting mainly via an antioxidant mechanism or through general inhibitors of flavoproteins. Other assays allow for the elimination of other sources of artifacts, such as the direct inhibition of enzymes involved in our ROS detection systems.

## 5.3. CLINICAL DEVELOPMENT PLAN FOR SETANAXIB

Genkyotex's most advanced compound is setanaxib, a NOX1 and NOX4 inhibitor. These two NOX isoforms play an important role in the development and maintenance of fibrotic and inflammatory disorders. The inhibition of NOX1 and NOX4 plays a significant role in the initiation, maintenance and progression of many inflammatory and fibrotic disorders. That is because NOX enzymes generate ROS, which is the starting point for activating many metabolic pathways through the oxidation of numerous proteins.

The Company believes that, since NOX enzymes are upstream of the activation of many metabolic pathways, the inhibition of these NOX enzymes with a single small molecule should help to control multifactorial disorders involving multiple cellular components and signaling pathways. In addition, NOX enzymes are only activated during pathological phenomena and are, in general, relatively silent in the absence of disease. Thus, inhibiting these NOX enzymes should not present any safety concerns. As described below, setanaxib has just demonstrated its positive effects in patients with PBC and is undergoing evaluation in diabetic patients (type 1 diabetes) with kidney disease. It is also expected to be evaluated in idiopathic pulmonary fibrosis (IPF) during 2020, as soon as the situation linked to COVID-19 permits.

Following encouraging preclinical and clinical results in which around 280 subjects to date have shown good tolerance for the product, Genkyotex's objective is to expand the assessment of setanaxib in fibrotic disorders for which an optimal study protocol could be carried out.

### 5.3.1. Strategic therapeutic area for setanaxib: Fibrotic disorders

The preclinical studies conducted to date indicate that setanaxib has direct anti-inflammatory and anti-fibrotic effects. Its anti-inflammatory effects include a reduction in the expression of cytokines, chemokines and adhesion molecules and a reduction in the infiltration of inflammatory cells. Its anti-fibrotic effects include a reduction in the activation of myofibroblasts, the main cellular source of extracellular matrix. These anti-fibrotic effects seem to be due to direct action, as they can be reproduced in myofibroblasts cultivated in vitro. These anti-inflammatory and anti-fibrotic properties could be particularly useful in fibrotic disorders in different organs. These disorders are generally due to genetic and environmental factors which cause the parenchymatous cells to suffer, in turn triggering an inflammatory response. The development of fibrosis (i.e., fibrogenesis) then appears as an initially favorable response to cell and tissue damage, but over time, fibrosis contributes to the gradual and often irreversible loss of function of the organs involved. It is estimated that fibrosis contributes to about 45% of deaths in industrialized countries (*Wynn TA, Nature Rev Immunol 2004 Aug; 4(8):583-94; Mehal WZ, Nature Med 2011 May; 17(5):552-3*). However, no anti-fibrotic therapy has been approved to date.

Fibrotic disorders include lung diseases such as idiopathic pulmonary fibrosis, skin conditions such as scleroderma, and liver diseases of viral, metabolic, cholestatic or immunological origin. Fibrosis also

plays a part in renal disorders, such as diabetic kidney disease and focal segmental glomerulosclerosis. Considerable progress has been made in the understanding of fibrogenic mechanisms in recent years. The cellular origin of components of the extracellular matrix, and the biological pathways involved in this process are better understood. It emerges that fibrogenesis represents a highly complex process involving a myriad of mediators and interconnected cell types. It also emerges that certain biological pathways play a central role and have the capacity to modulate the gene networks and proteins involved in fibrogenesis. The activation of NOXs therefore seems to represent a major biological pathway, necessary for the action of multiple fibrogenic pathways.

The preclinical studies completed to date with setanaxib seem to confirm this theory, as they have revealed setanaxib's efficacy potential in hepatic, pulmonary and renal fibrotic disorders. The Company's objective is therefore to assess the therapeutic potential of setanaxib in fibrotic disorders for which there is a significant medical need.

### 5.3.2. Clinical trials completed on setanaxib

The Phase 1 clinical trials conducted in healthy subjects indicated a positive safety profile and good oral bioavailability. These studies also indicated that setanaxib can be administered with meals and is unlikely to induce drug interactions. Finally, the Phase 1 repeated dose study, conducted in the form of a double-blind placebo-controlled study, also provided the first indications of pharmacodynamic activity.

Setanaxib was then assessed in patients with diabetic kidney disease. This international study, conducted in 75 research sites in North America, Europe and Australia, enrolled 155 patients, 136 of whom were randomized and treated with setanaxib or a placebo. The primary efficacy endpoint, a decrease in proteinuria, was not achieved. As described in Section 5.7 below, the lack of efficacy in the primary efficacy endpoint could be linked to several factors, including the short duration of the treatment (12 weeks), an insufficient dose, the already intensive medical treatment of these patients or possibly the lack of induction of NOXs in this population. Setanaxib did, however, achieve a statistically significant reduction in the plasma concentrations of several markers of inflammation and hepatocyte damage (e.g. hs-CRP, GGT).

These results, obtained on those secondary efficacy endpoints predefined in the study protocol, suggest that setanaxib is active in humans. Moreover, the safety profile of setanaxib was shown to be particularly positive, as described in Section 5.7. below. This positive safety profile allows for the assessment of setanaxib at higher doses and over a longer treatment period.

In June 2017, the Company then set up a 24-week Phase 2 clinical trial in nine countries (the United States, Canada, Germany, Belgium, Great Britain, Spain, Israel, Greece, Italy) to evaluate the efficacy and safety of setanaxib in 111 patients – 74 of whom were treated with setanaxib – with primary biliary cholangitis. The treatments currently available have only a moderate effect with a somewhat limited safety profile (induction of itching) and very little positive impact on patients' quality of life.

The primary efficacy endpoint, a decrease in plasma level of Gamma Glutamyl Transpeptidase (GGT), was reached at week 24 for the 400mg BID group after post-hoc analysis and correction of normal aberrations on the 400mg OD group and a significant effect was demonstrated over the entire 24 weeks of treatment with setanaxib (19% reduction, p=0.002). A significant effect of setanaxib on high dose was also shown on plasma levels of alkaline phosphatase (p=0.002), liver hardness (p= 0.038), and patient quality of life, especially for fatigue (p=0.027).

These results show once again that setanaxib is active in humans. In addition, the safety profile of setanaxib on this study also proved particularly favorable, allowing the Company to consider continuing the clinical evaluation of setanaxib.

### 5.3.3. Continuation of the clinical assessment of setanaxib in fibrotic disorders of the liver

Following these encouraging results, the Company's objective is to extend the assessment of setanaxib in fibrotic disorders for which an optimal study protocol could be carried out. Among fibrotic diseases, liver diseases represent favorable therapeutic targets, with setanaxib having generated beneficial effects, including anti-inflammatory and anti-fibrotic, in several preclinical models (see section 5.6.) and in the Phase 2 clinical trial on PBC patients. Recent publications have also confirmed the induction of NOX1 and/or NOX4 in patients suffering from hepatic fibrosis. Moreover, setanaxib is metabolized in the liver and eliminated by the bile ducts, accumulating in the liver tissue at a rate that is three to five times greater than that in other organs. This favorable tissue distribution allows for good exposure of the target tissues while minimizing systemic exposure. Inflammatory and fibrotic disorders of the liver include the following illnesses:

- Chronic cholestatic disorders such as primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC);
- Metabolic disorders such as nonalcoholic steatohepatitis (NASH);
- Viral disorders such as hepatitis B and C virus;
- Autoimmune hepatitis;
- Chronic alcoholic hepatitis.

Inhibition of NOX1 and NOX4 with setanaxib would reduce liver inflammation and fibrosis while being well tolerated, paving the way for further development in PBC as well as for development in secondary areas for the treatment of inflammatory and fibrotic liver disorders such as primary sclerosing cholangitis (PSC) and NASH.

### 5.3.4. Launch of a study in fibrotic disorders and diabetic kidney disease (DKD)

In June 2017, the Company concluded an agreement with the Baker Heart and Diabetes Institute of Melbourne, Australia (the “Baker Institute”) for a 48-week Phase 2 clinical trial, led by the Baker Institute, to evaluate the efficacy and safety of setanaxib in patients with type 1 diabetes and kidney disease (diabetic kidney disease or DKD). This investigator-initiated study will be carried out at the Baker Institute as well as in multiple study sites mainly across Australia. It is to be wholly financed by the Juvenile Diabetes Research Foundation (JDRF Australia), which is a beneficiary of funding from the Australian Research Council Special Research Initiative in Type 1 Juvenile Diabetes.

As part of this agreement (see Note 22.4 Research contract with Baker Heart and Diabetes Institute in Section 20 of the 2018 Registration Document), having collaborated on the preparation of the protocol, the Company is making available the product candidate used in the context of this study and is participating in joint steering committees. The agreement also provides for an independent supervisory committee to be set up.

Diabetic kidney disease (DKD) is a fibrotic disease characterized by progressive deterioration of renal function is related to fibrotic remodeling of glomerulosclerosis and interstitial tissue (interstitial fibrosis) leading to end-stage kidney disease. Setanaxib is a NOX1 and NOX4 enzyme inhibitor that has shown potent anti-fibrotic activity in a broad range of preclinical models, including several DKD models [1-4]. In a previous, short-term Phase 2 trial in patients with type 2 diabetes and kidney disease, setanaxib demonstrated an excellent safety profile and achieved statistically significant reductions in several secondary efficacy endpoints. However, improvements in albuminuria, the study's primary endpoint, were not achieved after 12 weeks of treatment.

The Baker Institute study is a placebo-controlled, double blind, randomized, parallel group Phase 2 trial to evaluate the effect of oral setanaxib on the urine albumin-to-creatinine ratio (UACR) in patients with type 1 diabetes and persistent albuminuria despite treatment with optimal standard of care. The primary endpoint of the study is the difference between the UACR of the various patient groups at the

end of the 48-week treatment period, adjusted for baseline values. Other secondary endpoints used for this study will help to assess the effect of setanaxib on kidney function (estimated glomerular filtration rate (eGFR)). Blood samples are also taken to evaluate kidney damage markers (KIM-1, NGAL) and to conduct metabolic and transcriptomics analyses. Patients are receiving 200 mg of oral setanaxib or placebo twice a day for 48 weeks. As of the date of this Universal Registration Document, patient randomization is ongoing and 23 patients have already completed the full 48-week treatment without any report of a safety issue. A total of 142 patients are expected to participate in this study at approximately ten research centers in Australia.

The principal investigators leading the diabetic kidney disease study decided, with the agreement of Genkyotex, to extend the study to additional centers first in New Zealand where regulatory agreement was obtained in 2019 for three centers, and then in Germany and Denmark. In addition, following positive results regarding the efficacy and safety of setanaxib in the Company's Phase 2 study in primary biliary cholangitis (PBC), the study protocol in diabetic kidney disease was modified to increase the dose to 400 mg twice a day.

In the context of the COVID-19 pandemic, investigators have taken steps to minimize patient visits to the investigation centers in accordance with applicable rules and recommendations. An adequate supply of drugs has been made available to participating centers and patients. Despite the relatively low rate of SARS-CoV-2 infection in Australia, the investigators still cannot exclude a potential slowdown in the recruitment of new patients into the study.

### 5.3.5. Launch of a study in fibrotic lung disorders (IPF)

The investigator-initiated Phase 2 study with setanaxib in idiopathic pulmonary fibrosis (IPF) is expected to be launched shortly. The central component of this program, funded by a US$8.9 million grant from the National Institutes of Health (NIH) to Professor Victor Thannickal of the University of Alabama at Birmingham (UAB), will involve a 24-week Phase 2 study with setanaxib. In this randomized, double-blind, placebo-controlled study, setanaxib will be administered to 60 patients treated with the current standard of care (pirfenidone or nintedanib) for an IPF. The US Food and Drug Administration (FDA) and the Medical Ethics Committee authorized the IPF Phase 2 study protocol at the end of November 2019, paving the way for patients' recruitment that is expected to begin in 2020 and, if permitted by the COVID-19 situation, in the first half of the year.

Idiopathic pulmonary fibrosis is a lung disease with an unknown cause. It is characterized by a progressive and irreversible destruction of the pulmonary parenchyma and an accumulation of fibrotic and scar tissue produced by myofibroblasts. Patients suffer from severe respiratory failure and progressive hypoxemia resulting in a median survival of only three to four years. While two treatments have been approved to date (nintedanib (Ofev®) and pirfenidone (Esbriet®)), their effect seems mainly restricted to limiting the progression of the disease after diagnosis.

Although the cause of idiopathic pulmonary fibrosis is unknown, numerous studies and publications show the significant role that NOX enzymes, and in particular NOX4, may play in maintaining an inflammatory process and in the development of progressive and invasive fibrosis of the lung. Setanaxib is a NOX1 and NOX4 inhibitor that has demonstrated potent anti-fibrotic activity in a preclinical pulmonary fibrosis model and has notably shown an improvement in mouse body condition as well as improved survival (Hecker L, et al. Reversal of persistent fibrosis in aging by targeting Nox4-Nrf2 redox imbalance. *Sci Transl Med*. 2014).

The study to be conducted by the University of Alabama will be a randomized, double-blind, placebo-controlled, parallel group Phase 2 trial to evaluate the effects of oral setanaxib on the circulating level of o,o'-dityrosine, a marker of pulmonary oxidative stress. The other secondary endpoints of the study will be to assess the effect of setanaxib on lung function with the six-minute walk test. Patients will receive 400 mg of oral setanaxib or placebo twice a day for 24 weeks. As of the date of this Universal Registration Document, the Company is finalizing the contractual terms with UAB relating to their

collaboration for this trial. A total of 60 patients are expected to participate in this study involving a university consortium in the United States.

Obtaining positive data in these two disorders (DKD and IPF) will allow, as appropriate, the Company to consider future development in two new inflammatory and fibrotic diseases and thus confirm the role of NOX1 and NOX4 in these disorders.

## 5.4. OVERVIEW OF PBC AND ITS MARKET

### 5.4.1. Overview of primary biliary cholangitis (PBC)

Primary biliary cholangitis (PBC) is a chronic orphan autoimmune disease which affects the liver. If not treated correctly, it can lead to cirrhosis, liver failure and death. PBC overwhelmingly affects women (90%) and ranks as the second most common cause of liver transplants in women in the United States.

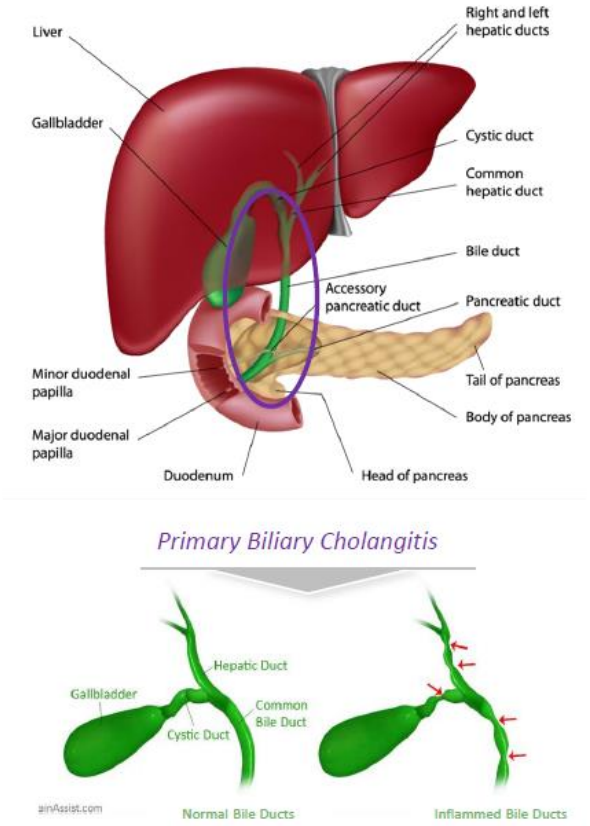
The clinical diagnosis of the illness is based on a combination of clinical signs, biochemical anomalies of the liver related to cholestasis persisting more than six months, and on the presence of antimitochondrial antibodies (AMA). A liver biopsy is sometimes carried out to confirm the diagnosis.

Bile, which contains bile acids, plays a key role in the solubilization of dietary fats. However, these bile acids have detergent properties, making them toxic for cells that have a lipid membrane. In PBC, the progressive autoimmune destruction of the bile ducts causes bile acids to accumulate in the bile ducts and in the liver, causing cell damage and a chronic inflammatory response. An attempt to repair the tissue is then triggered in the form of hepatic fibrosis.

The first symptoms of PBC typically appear between the ages of 30 and 65, with a higher incidence above the age of 50. The progression of the illness varies considerably from patient to patient, with the average survival rate of patients treated varying from 7.5 years if the symptoms of the illness are observed at diagnosis to 16 years if the symptoms are not identified at diagnosis.

However, in the long term, this fibrosing response causes a gradual decrease in liver function and raises blood pressure in the portal venous system, which brings blood to the liver (portal hypertension). This liver failure reduces the synthetic capacity of the liver, which can cause a reduction in coagulation factors, resulting in a hemorrhagic tendency, and/or in plasma proteins, which results in peripheral and intra-abdominal edema (ascites). This liver failure also causes the retention of neurotoxic substances, which can lead to hepatic encephalopathy. Portal hypertension leads to the appearance of esophageal varices, which are the cause of severe digestive hemorrhages. A liver transplant is ultimately needed to prevent death from the condition.

Patients suffering from PBC also have a significantly higher incidence of hepatocellular carcinoma, a particularly aggressive form of cancer. PBC is often connected to other autoimmune diseases, such as Sjögren's syndrome, scleroderma, Raynaud's disease and CREST syndrome.




Although some people suffering from primary biliary cholangitis remain symptom-free for several years after their diagnosis, others may observe some signs and experience certain symptoms.

The first common symptoms are as follows:

- Fatigue;
- Pruritus (itching);
- Xerostomia and xerophthalmia (dry eyes and mouth).

Subsequent signs and symptoms may include:

- Pain in the upper right portion of the abdomen;
- Musculoskeletal pain;
- Jaundice;
- Ascites;
- Cutaneous fat deposits around the eyes and eyelids, or in the creases of the palms, soles of the feet, elbows or knees (xanthelasma);
- Osteoporosis that can lead to bone fractures;
- Higher blood fats;
- Diarrhea (steatorrhea);
- Thyroid problems.

### 5.4.2. Primary biliary cholangitis (PBC) market

Primary biliary cholangitis (PBC) is a chronic orphan disease characterized by an inflammation and progressive destruction of the interlobular bile ducts, with prevalence in Europe, the United States and Japan estimated at between 1.91 and 40.2 per 100,000 inhabitants (Boonstra K et al. *Epidemiology*

*of primary sclerosing cholangitis and primary biliary cirrhosis: a systematic review. J Hepatol. 2012 May; 56(5):1181-8*). This variability is due to the small size of series published.

It does, however, appear that the disease is becoming more prevalent over time. A growing incidence has been noted in Europe, the United States and Japan. This is probably due to a better understanding of the disease and the routine use of new diagnostic tools, such as the detection of antimitochondrial antibodies.

There is a considerable medical need to address this illness, for which only two drugs have been approved:

- Ursodeoxycholic acid (UDCA), approved specifically for the treatment of PBC, is marketed in the form of a generic drug under the name Ursodiol. It is a bile acid present in small quantities in the human body and whose mechanism of action, in therapeutic doses, is to dilute bile acids more detergent than itself that are present in the liver. Long-term treatment using UDCA improves biochemical liver tests, slows down histological progression and extends survival without liver transplant. Monotherapy using UDCA seems to be sufficient for many patients. However, the survival rate without transplant of patients treated using UDCA remains significantly lower than that of a matching control population based on age and gender. Studies have also shown that between 40% and 50% of patients suffering from PBC do not respond properly to UDCA in monotherapy and therefore remain, despite the treatment, exposed to a high risk of liver failure with the only alternative being a liver transplant. The dosage of the drug, with several daily doses having to be administered, ultimately relieves therapeutic observance problems for certain patients.

- In May 2016, obeticholic acid (OCA), developed by Intercept Pharmaceuticals, obtained an accelerated marketing authorization for the US market from the FDA as an orphan drug for the treatment of PBC, in combination with UDCA, for adults with an insufficient response to UDCA or as monotherapy for patients who did not tolerate UDCA. In December 2016, it also received conditional marketing authorization (MA) from the EMA for the European Union for the treatment of PBC. This drug was first marketed under the name Ocaliva by Intercept Pharmaceuticals, not long after its authorization by the FDA in the United States. The same company also announced the launch of sales in Europe starting in January 2017. The annual cost of treatment per patient is approximately US$70,000 in the United States (Cassidy et al. Nat Rev Drug Discov. 2016), and Intercept Pharmaceuticals reported sales of Ocaliva® totaling US$187.5 million for the financial year ended December 31, 2019 (of which US$62 million outside the United States). In accordance with the post-marketing requirements of the accelerated authorization procedure in the United States and the conditional marketing authorization received from the EMA, Intercept Pharmaceuticals is currently conducting a confirmatory Phase 4 clinical trial of Ocaliva® for PBC (Cobalt trial currently at recruitment stage) to confirm and characterize the clinical benefits of the drug with a view to its final authorization. Cymabay conducted a Phase 3 trial with its PPAR-delta agonist, seladelpar, but the trial was suspended by Cymabay in November 2019 due to safety reports, and several biotechnology and pharmaceutical companies are currently conducting Phase 2 trials with several new generations of FXR agonists.

As a result, there is an ongoing need for new therapeutic options in PBC, as is the case for patients suffering from primary sclerosing cholangitis (PSC).

### 5.4.3. Key players and molecules under development for PBC

A sample of the main products currently under development for PBC is as follows:

| Companies | Molecule | Mechanism of action | Clinical/marketing stage |
|---|---|---|---|
| Intercept Pharmaceuticals | Ocaliva® | FXR agonist | Marketed |
| CymaBay | Seladelpar | PPAR agonistδ | Phase 3 (clinical trial suspended due to safety signals) |
| EA Pharma Ltd | E6011 | Anti-fractalkine | Phase 2 |
| Enanta Pharmaceuticals | EEDP-305 | FXR agonist | Phase 2 |
| Genfit | Elafibranor | PPARα agonist | Phase 2 |
| Gilead Sciences | GS-9674 | FXR agonist | Phase 2 |
| GlaxoSmithKline | GSK233067 | IBAT inhibitor | Phase 2 |
| Novartis | LJN452 | FXR agonist | Phase 2 |
| Fast Forward | FFP104 | Anti-CD40 | Phase 1/2 |

## 5.5. OVERVIEW OF NASH AND ITS MARKET

Genkyotex believes that setanaxib also has the potential to directly target fibrogenic processes in patients with another liver disease, namely, nonalcoholic steatohepatitis (NASH). Although there has been no plan or authorization to date for any decision to launch or draft a timetable for the launch of such a trial, this indication could be the subject of a future clinical trial with setanaxib.

### 5.5.1. NASH

Nonalcoholic steatohepatitis (NASH), the hepatic component of metabolic syndrome, covers a variety of illnesses ranging from simple steatosis of the liver to NASH with or without cirrhosis, as well as hepatocellular carcinoma.

The obesity and type 2 diabetes pandemic, together with improvements in the treatment of chronic viral hepatitis, have caused NASH to become the main factor in chronic liver disease, making it the most common cause of liver transplants in 2016 (*Banini BA, et al. Abstract #46. Presented at the American College of Gastroenterology Annual Scientific Meeting; Oct. 14-19, 2016; Las Vegas, NV, USA*).

More generally, liver cirrhosis is the sixth most common cause of death in developed countries and the ninth in developing countries (*Lim YS1, Kim WR. The global impact of hepatic fibrosis and end-stage liver disease; ClinLiver Dis.2008 Nov; 12(4):733-46*).

For reasons that are not yet fully understood, in patients suffering from NASH, steatosis and other factors such as resistance to insulin result in chronic inflammation of the liver and can cause progressive fibrosis and cirrhosis. These pathological processes can cause liver failure and possibly death.

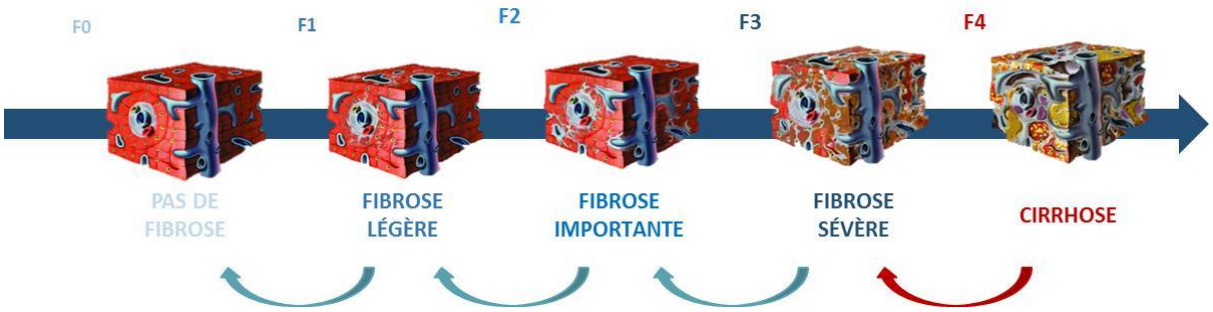
To date, no drug has been approved for the treatment of NASH. The medical need is therefore considerable. However, various therapeutic agents are used off-label, such as vitamin E (an antioxidant), insulin sensitizers (such as metformin), hypolipemiant agents (such as gemfibrozil) and pentoxifylline. Changes in lifestyle, including change of diet and exercise to reduce body weight, and the concurrent treatment of diabetes and dyslipidemia are commonly accepted components of the

standard treatment, but their efficacy has not been convincingly demonstrated in NASH. Histologically, NASH is defined as the presence of hepatic steatosis and inflammation with hepatocyte damage (ballooning), with or without fibrosis. Normally, NASH causes few or no symptoms during the early stages. It is therefore a relatively silent disease until the onset of liver failure, hepatocellular carcinoma or the development of portal hypertension. Although the presence of simple hepatic steatosis has little impact on mortality of hepatic cause, it does trigger inflammatory and fibrotic processes. It is the presence of hepatic fibrosis that reduces the survival rate of NASH patients.

Hence the importance of identifying new therapeutic strategies to prevent, slow down or reverse hepatic fibrosis. However, most treatments available primarily target the mechanisms responsible for hepatic steatosis.

In theory, the elimination of steatosis should, over time, induce a regression in fibrotic processes. However, fibrogenesis is a complex process, and its causes go far beyond simple steatosis. The presence of a resistance to insulin, the activation of the renin-angiotensin system, the exposure of hepatocytes to bacterial products of enteric origin, and genetic factors also play a part in fibrogenic processes. Moreover, patients presenting an advanced stage of fibrosis (F2–F3 (significant to severe fibrosis)) have a risk of developing serious liver complications, particularly cirrhosis and hepatocellular carcinoma.

**Different stages in the development of fibrosis**




It is therefore important to develop new drugs capable of targeting these fibrotic processes directly and effectively. Such therapies could be used as a first-line treatment, or in conjunction with drugs targeting the metabolic causes of NASH.

Genkyotex believes that setanaxib has the potential to directly target fibrogenic processes in patients with NASH.

### 5.5.2. The NASH market

There are currently no treatments for NASH on the market, so medical prescriptions are based on drugs with no proven clinical efficacy in patients suffering from NASH and are therefore used off-label. In most cases, these are drugs prescribed to control type 2 diabetes or hypercholesterolemia.

Against the backdrop of an increasing number of diabetes cases, patients suffering from hypertension and increasing obesity, the prevalence of NASH is expected to rise sharply in the next 10 years. New therapeutic solutions that are specifically approved for this indication are also expected to arrive on the market. These include several Phase 3 studies that are currently underway or completed, such as Intercept Pharmaceuticals' obeticholic acid and Genfit's PPARα/δ agonist, as well as Gilead's Ask-1 inhibitor and Allergan's CCR2/CCR5 antagonist. The increased prevalence of this disorder in

connection with the arrival on the market of therapies specially approved for NASH suggests a strong increase in the market.

Although it is difficult to estimate the size of the NASH market in the absence of an approved drug to date, on the basis of several studies, the prevalence of the illness (estimated at between 3% and 12% in the United States according to sources (source: NIH, Spengler and Loomba, Mayo Clin Proc)) and the estimated price for the potential marketing of drugs, this global market has been valued at between US$30 billion and US$40 billion per year.

A sample of the main product candidates currently under development for NASH is listed in the table below:

| **Companies** | **Molecule** | **Mechanism of action** | **Clinical stage** |
|---|---|---|---|
| Intercept | OCA (REGEN) | FXR agonist | In the process of registration |
| Allergan (Tobira) | Cenicriviroc | Antagonist CCR2 / CCR5 | 3 |
| Conatus | Emricasan | Caspase inhibitor | Failed in phase 2b |
| Genfit | Elafibranor | PPAR agonist | 3 |
| Gilead | Selonsertib | Ask-1 inhibitor | Failed in phase 3 |
| Galmed | Aramchol | Bile acid conjugate | 3/4 |
| Gilead | GS-0976 (NDI-010976) | ACC inhibitor | 2 |
| Inventiva Pharma | Lanifibranor (IVA337) | PPAR agonist | 2b |
| Madrigal | Resmetirom (MGL-3196) | THRβ agonist | 3 |
| Novartis | Tropifexor | FXR agonist | 2 |
| Novo Nordisk | Liraglutide/Semaglutide | GLP-1 agonist | 2 |
| Viking Therapeutics | VK2809 | THRβ agonist | 2 |
| Galecto | GB1211 | Galectin-3 antagonist | (Failed in phase 2) Phase 1 |
| Galectin | Belapectin | Galectin-3 antagonist | 2b/3 (June 2020) |
| Immuron | IMM-124E | Anti-LPS mechanism | 2 |
| Akero Therapeutics | AKR-001 | Fibroblast Growth Factor 21 | 2 |
| Albireo Pharma | Elobixibat | Ileal bile acid transporter inhibitor | 2 |
| AstraZeneca | Cotadutide | Dual GLP-1/glucagon agonist | 2 |
| Bristo-Myers Squibb | BMS-986036 (PEG-FGF21) | Fibroblast Growth Factor 21 | 2b |
| Can-Fite BioPharma | Namodenoson | Adenosine A3 receptor agonist | 2 |

| Companies | Molecule | Mechanism of action | Clinical stage |
|---|---|---|---|
| Eli Lilly and Co. | Tirzepatide (LY3298176) | GIP and GLP-1 receptor agonist | 2 |
| Enanta Pharmaceuticals | EDP-305 | FXR agonist | 2 |
| MediCinova | MN-001 (Tipelukast) | Leukotriene (LT) receptor antagonist | 2 |
| NGM Biopharmaceuticals | Aldafermin (NGM282) | FGF19 | 2b |
| Pfizer | PF_06835919 | Ketohexokinase inhibitor | 2 |
| Pfizer | PF_06865571 & PF_05221304 | DGAT2 inhibitor<br>ACC inhibitor | 2 |

**Table 1: Key players and molecules under development for NASH**

## 5.6. PRECLINICAL CHARACTERISTICS AND RESULTS FOR SETANAXIB

### 5.6.1. Stages of development

#### 5.6.1.1. High-throughput screening of 150,000 molecules and identification of the chemical series

In 2006, Genkyotex launched a high-throughput screening campaign on a library of 150,000 molecules. This screening in miniaturized NOX assays helped to identify positive molecules based on a Z score, before launching a molecule optimization program for a period of around 18 months.

The positive molecules were tested again at Genkyotex in membrane assays on NOX1 and NOX4, and only the reconfirmed molecules were then tested at several concentrations to determine an $IC_{50}$. In order to eliminate potential false positives and particularly antioxidant potential, positive molecules were tested in a xanthine oxidase assay.

Several chemical series were identified and the pyrazolopyridine series that setanaxib comes from was selected as the basis for optimization. This chemical series showed promising affinity with NOX at micromolar levels and also showed a good relationship between the chemical structure and activity (Structure Activity Relationship, or SAR) on NOXs and promising ADME (Absorption, Distribution, Metabolism, Elimination) properties.

**i. Optimization of the chemical series and identification of setanaxib**

During the 18 months of optimization of the chemical series, over 700 molecules were synthesized, allowing for the identification of GKT000239, GKT901 and setanaxib. This optimization helped to considerably improve the affinity of molecules for NOXs, from an affinity of around 10 micromolar to less than 100 nM for the best molecules. A better understanding of the SAR also enabled an improvement in the ADME properties of the molecules tested and in the pharmacokinetics of the molecules and therefore their efficacy in vivo.

During the optimization period, the synthesized molecules were tested in all of the NOX assays developed by Genkyotex (NOX1, NOX2, NOX3, NOX4 and NOX5) to establish their complete selectivity profile and to only develop the most selective molecules for NOX1 and NOX4.

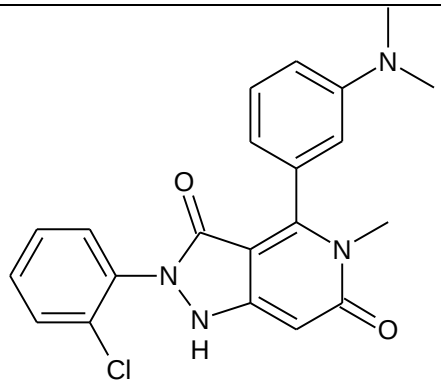
At the end of the 18-month optimization period, three potential preclinical candidates were tested in a preliminary toxicity study in rats and in genotoxicity studies to only select the molecule presenting the best safety profile.

All this information contributed to setanaxib's selection as a preclinical candidate, thereby demonstrating Genkyotex's ability to conduct high-throughput screening, followed by an optimization campaign to the standards of the pharmaceutical industry.

### ii. Physico-chemical characteristics of setanaxib

Setanaxib is a small organic molecule with low molecular weight (394.85 g/mol) from the pyrazolopyridine dione family. Setanaxib is the most successful molecule from this chemical class and was the first NOX inhibitor administered to humans.

The chemical structure of setanaxib is shown in the table below:

| | | |
|---|---|---|
|  | Chemical formula: | $C_{21}H_{19}ClN_4O_2$ |
| | Molecular weight: | 394.85 g/mol |
| | Chemical name: | 2-(2-chlorophenyl)-4-[3-(dimethylamino)phenyl]-5-methyl-1*H*-pyrazolo[4,3-*c*]pyridine-3,6(*2H*,*5H*)-dione |

The physico-chemical characteristics of setanaxib are summarized in the table below:

| Parameters | Characteristics |
|---|---|
| Lipinski's rule | Compliance with rules (<5 hydrogen bond donor, <10 hydrogen bond acceptor, MW<500 daltons, log P<5) |
| Appearance | Pale yellow powder |
| Hygroscopicity | Non-hygroscopic polymorph |
| Solubility in water | Moderate water solubility at pH 7 (0.3 mg/mL), water solubility at pH 1.0 (30 mg/mL), soluble in methanol, ethanol and acetonitrile |
| Large-scale synthesis | GMP batch up to 60 kg |
| Stability | Stability data validated for over 36 months |

### iii. Pharmacology of setanaxib

This molecule is a preferential inhibitor of NOX1 and NOX4 isoforms. Indeed, setanaxib shows an affinity in isolated and purified membrane assays of 90 mM for NOX4 and 150 mM for NOX1, compared with an affinity in the region of 350 mM for NOX3 and NOX5 and over 2 µM for NOX2. Setanaxib has also been tested in cellular assays in cells overexpressing each NOX isoform. These have shown an $IC_{50}$ in the order of 150 nM on NOX4, of around 210 nM for NOX1, in the region of 500 nM for NOX3 and NOX5 and finally of over 2 µM for NOX2. The table below summarizes the inhibitory constant (Ki) of setanaxib on human NOX enzymes.

| NOX isoform | Ki (µM) | Study No. |
|---|---|---|
| NOX1 | 0.150 ± 0.02 | GSN000050 |
| NOX2 | 2.13 ± 0.21 | GSN000006 |
| NOX3 | 0.36 ± 0.15 | GSN000264 |
| NOX4 | 0.09 ± 0.01 | GSN000005 |
| NOX5 | 0.325 ± 0.04 | GSN000023 |

**Figure 1: Affinity (Ki) of setanaxib on isolated human NOX enzymes**

To demonstrate that setanaxib selectively inhibits the production of ROS via NOXs, setanaxib was tested in two Phase I assays, also producing ROS by other enzymatic methods. These consist of xanthine oxidase and glucose oxidase assays. In the xanthine oxidase assay, setanaxib was found inactive with a Ki of over 100 µM, while setanaxib inhibits glucose oxidase with a Ki of 1.7 µM, demonstrating its excellent selectivity for NOXs, compared to other oxidases. It is, however, important to note that setanaxib is a weak electron donor (antioxidant activity) as it reduces DPPH (1,1-Diphenyl-2-picryl-hydrazyl) with an $IC_{50}$ of 20 µM, in other words, at a significantly lower inhibition constant than that of its NOX-inhibitory activity.

Two metabolites that are very similar structurally to setanaxib were identified, synthesized and subjected to the same pharmacological tests as setanaxib in order to establish their pharmacology. This involved GKT137184, corresponding to a Phase 1 N-monodemethylation, and GKT137185, corresponding to an N-didemethylation. These two metabolites therefore display a strictly similar activity, affinity and selectivity profile to that of setanaxib, hence also contributing to the activity of setanaxib.

Setanaxib is a specific inhibitor of NOXs, as it displayed virtually no affinity on a vast panel of other enzymes, kinases and receptors.

As mentioned above, it was important to verify that setanaxib did not affect the phagocytic function linked to NOX2. Setanaxib (25 µM and 100 µM) does not affect the potential of isolated human phagocytes stimulated by phorbol ester and does not reduce their ability to destroy the *Staphylococcus aureus* bacteria in vitro. Nor does setanaxib administered over a period of 25 days at a dose of 100 mg/kg/d affect mice's capacity to successfully kill these *Staphylococcus aureus* and to effectively reduce the inflammation they induce *in vivo*.

**iv. Mechanism of action: in vitro and in vivo data of setanaxib**

***i.Effect of setanaxib on inflammation and hepatic fibrosis, steatosis and cholestasis models***

*Effect of setanaxib on a hepatic fibrosis model induced by a toxic agent*

To induce hepatic fibrosis, C57BL/6J male mice received repeated intraperitoneal injections of the toxic agent carbon tetrachloride (CCL4) over a six-week period. This study was published in the Journal of Hepatology by Professor David Brenner's group at the University of California, San Diego.

In an initial study, mice with a mutated SOD (superoxide dismutase) gene and control mice received injections of CCL4 or a harmless vehicle. The theory was that this specific mutation of SOD, present in

a small proportion of patients suffering from amyotrophic lateral sclerosis, induced a physical interaction between SOD and NOX1 and induces the production of ROS by NOX1. This model therefore offered a good experimental system for testing a NOX1 inhibitor. After six weeks of repeated CCL4 injections, acute liver inflammation associated with fibrosis was observed. As expected, the level of inflammation and fibrosis was significantly higher in mice with the mutant form of SOD. Setanaxib at a dose of 60 mg/kg per day by oral means for the final three weeks of induction of the liver disorder (therapeutic mode) significantly reduced hepatocellular damage as well as inflammation and hepatic fibrosis. It is important to note that setanaxib also reduced inflammation and fibrosis in the normal mice exposed to CCL4 (Figure 2).

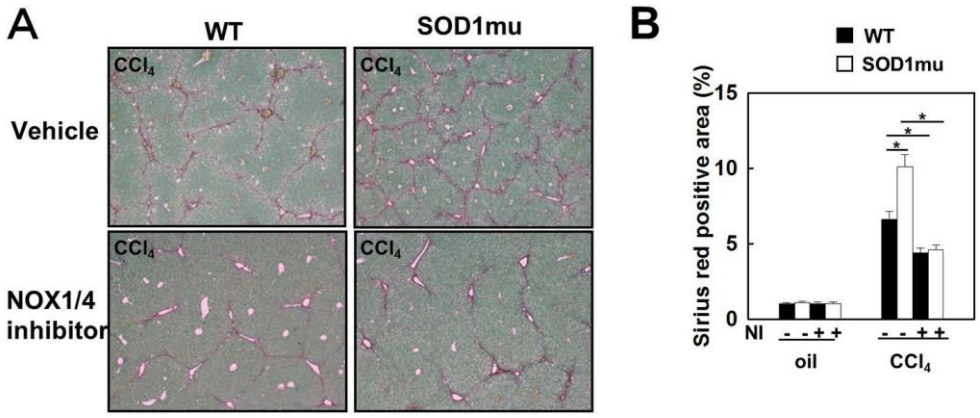



**Figure 2: Effect of setanaxib (NOX1/4 inhibitor) on fibrosis deposition in a mouse model with hepatic fibrosis induced by repeated injections of CCL4**

Mechanistic research was also conducted in vitro. The main fibrogenic mechanism is the activation of hepatic stellate cells (HSC) by TGF-β and angiotensin 2, to induce the transdifferentiation of these HSC in active myofibroblasts. The co-treatment of these cells with 20 µM of setanaxib prevented the induction of fibrogenic and pro-inflammatory genes.

A second study, also conducted by Professor Brenner and his colleagues, provided a clearer definition of the respective roles of NOX1 and NOX4 in this model. Mice presenting a deletion of NOX1 (NOX1 KO) or NOX4 (NOX4 KO) genes and control mice were given repeated injections of CCL4 for six weeks. As expected, the control mice showed a significant elevation of transaminases and an increase in hepatic fibrosis markers, both in terms of expression of the genes involved in fibrotic pathways and in fibrosis quantification. The severity of this inflammatory and fibrotic phenomenon was significantly reduced in both the NOX1 KO and NOX4 KO mice, suggesting an individual role for each of these two NOX isoforms in the induction of inflammatory and fibrotic processes in hepatic disorders. This probably explains setanaxib's marked efficacy in a vast series of inflammation and hepatic fibrosis models (Figure 3).

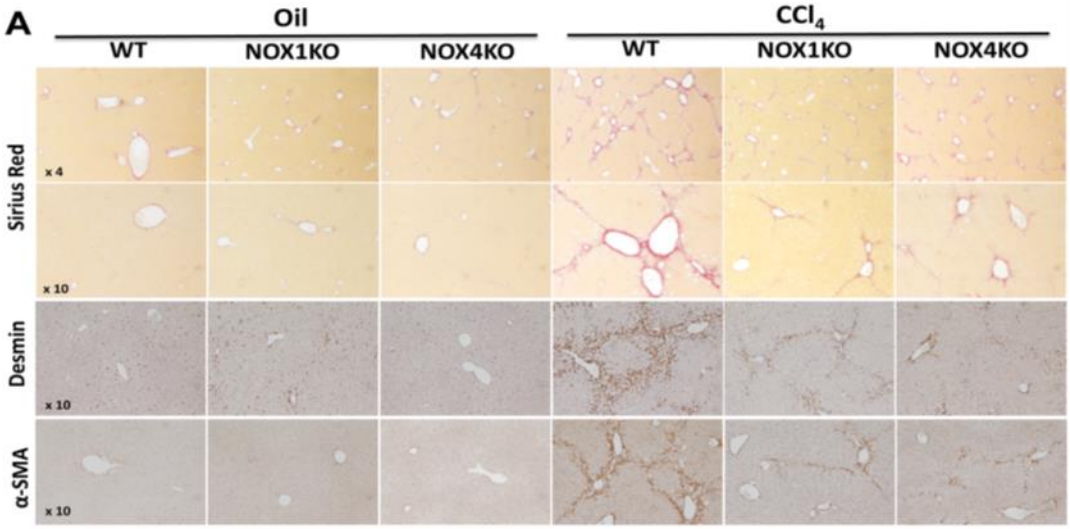



**Figure 3: Beneficial effect of the loss of NOX1 and NOX4 on various fibrosis markers in a mouse model with hepatic fibrosis induced by repeated injections of CCL4**

Besides TGF-β and angiotensin 2, multiple pro-inflammatory and fibrogenic signaling pathways had been described. As a result, HSCs were stimulated with ligands inducing the TLR4, Hedgehog and PDGF pathways. Specific reporter genes were used to assess the activation of these biological pathways. setanaxib was able to block these pro-inflammatory and fibrogenic pathways.

Viewed collectively, these results illustrate the capacity of setanaxib to simultaneously block multiple pathogenic biological pathways and validate its NOX1/4 selectivity profile.

*Effect of setanaxib in a steatosis and hepatic fibrosis model induced by a high-calorie diet*

In an initial study conducted by Professor Natalie Torok's group at the University of California, Davis, C57BL/6J male mice were fed a high-calorie diet for between 12 and 20 weeks to induce hepatic steatosis and secondary inflammation and fibrosis. These mice were treated therapeutically with 60 mg/kg per day of setanaxib orally, or with an inactive vehicle, for six weeks. To confirm the pharmacological approach with a genetic approach, a lineage of mice was produced to eliminate the NOX4 gene in hepatocytes (NOX4 $^{hepKO}$).

Controlled mice receiving the high-calorie diet showed a significant increase in hepatic enzymes and the expression of genes involved in inflammatory and fibrogenic pathways. These phenomena were accompanied by an increase in the number of inflammatory cells recruited in the liver, an increased proportion of hepatocytes that had initiated a programmed cell death process and an increase in the quantity of collagen found in the liver tissue. In contrast, in the NOX4 $^{hepKO}$ mice and in mice treated with setanaxib, it was possible to observe a significant reduction in transaminases, severe tissue inflammation and cell death, as well as a significant reduction of collagen deposits in the liver (Figure 4).

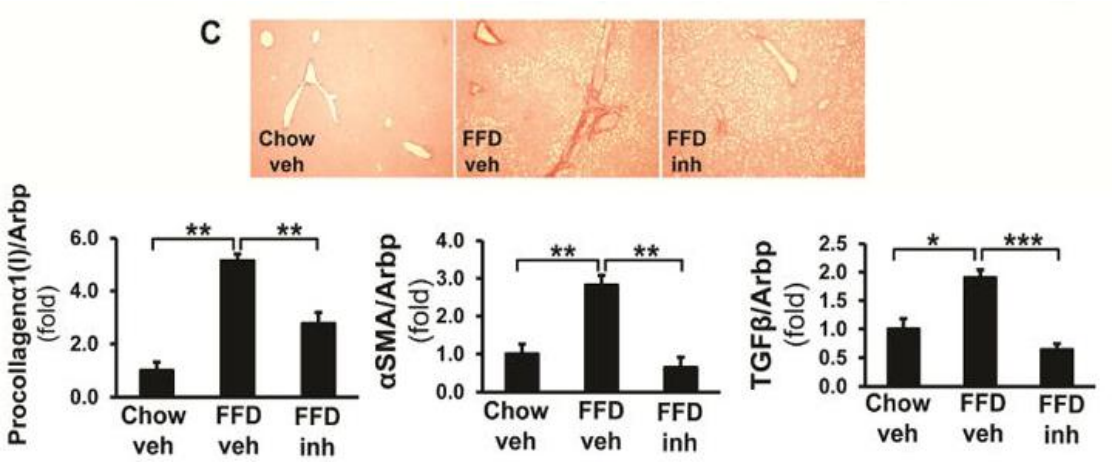



**Figure 4: Effect of setanaxib on collagen deposits and expression of pro-fibrogenic genes in a mouse model with NASH induced by a high-calorie diet**

Tissue analysis for protein expression involved in the signaling pathways linked to stress and cell death reveals that the specific deletion of NOX4 in hepatocytes will prevent the activation and phosphorylation of many kinases and proteins involved in the induction of cell death.

In the end, the mice put on a high-calorie diet presented lower tolerance to glucose and lower sensitivity to insulin. These two anomalies were also significantly reduced in the NOX4 $^{hepKO}$ mice and in the mice treated with setanaxib, suggesting that NOX4 could play an important role in the onset of inflammation and hepatic fibrosis, and in insulin resistance.

A histological analysis also demonstrates that setanaxib does not seem to have any effect on steatosis, despite its considerable anti-inflammatory and anti-fibrotic effect. The mechanism of action of setanaxib therefore seems to be a direct effect on inflammation and fibrogenesis, as it is observed in HSC. This differs from the majority of product candidates under development for NASH, most of which seem to primarily reduce steatosis and the associated lipotoxicity. Setanaxib could therefore hold differentiated and especially useful therapeutic potential in patients presenting a more advanced form of NASH and established fibrosis. It is therefore also logical to suppose that setanaxib could be used to achieve powerful therapeutic effects in a large number of patients if it were used in conjunction with a metabolic approach such as PPAR or FXR agonists or even oral anti-diabetic drugs.

*Effect of setanaxib on a hepatic fibrosis model induced by hepatic cholestasis*

To assess the therapeutic potential of setanaxib in inflammatory and fibrotic disorders of cholestatic origin, the effect of setanaxib was assessed by Professor Natalie Torok's group at the University of California, Davis, in a bile duct ligation model.

C57BL/6 mice underwent complete bile duct ligation to induce cholestasis. As described above, intrahepatic accumulation of bile acids causes inflammation of the bile ducts and hepatocytes. These inflammatory processes, in turn, activate fibrogenic signaling pathways in HSC, leading to the accumulation of collagen in liver tissue. Two additional groups of animals were treated with a daily oral dose of setanaxib (60 mg/kg), either preventively following the ligation of the bile ducts and over the three weeks of the experiment, or therapeutically over the last 15 days of the experiment. Irrespective of whether this was carried out preventively or therapeutically, treatment with setanaxib significantly reduced the plasma level of hepatic enzymes and bilirubin. On a local basis, it was possible to observe a significant decrease in the number of hepatocytes in cell death phase, collagen deposits and expression of fibrogenic genes in the liver tissue (Figure 5).

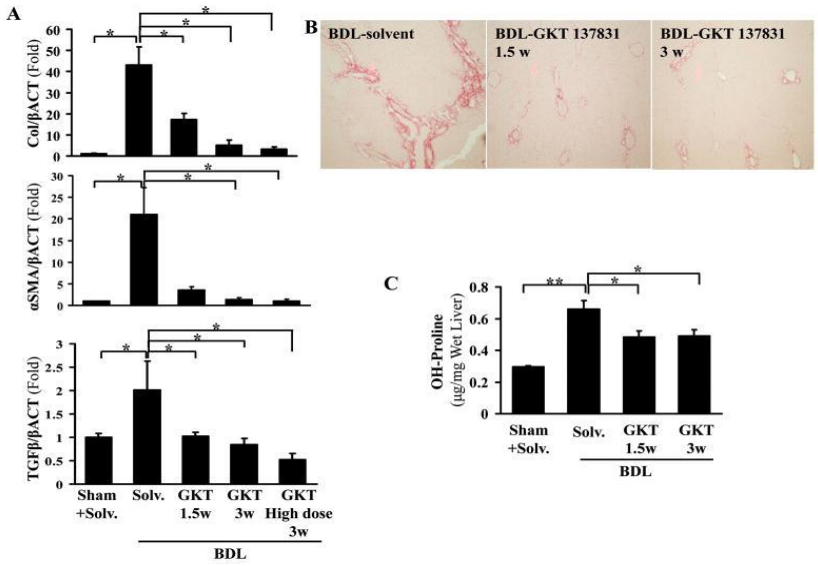



**Figure 5: Effect of setanaxib on collagen deposits and the expression of pro-fibrogenic genes in a mouse model with hepatic cholestasis induced by bile duct ligation**

To confirm the role of NOX4 in the induction of hepatocyte cell death and in HSC activation, hepatocytes and HSC were treated with Fas ligand in order to induce cell death. HSCs were spontaneously activated to acquire a fibrotic phenotype and the activation of genes involved in signaling pathways linked to fibrosis. Treatment with setanaxib at the concentration of 20 µM significantly reduces the death of hepatocytes and the activation of the genes involved in the activation of HSC, confirming the important role of NOX1 and NOX4 in the development of fibrosis in cholestatic disorders.

Taken together, the results of this study seem to suggest that treatment with setanaxib provides significant hepatocyte protection and reduces the activation of HSCs in primary and secondary cholestatic disorders of the liver.

***ii.Effect of setanaxib on inflammation of the kidney and renal fibrosis models***

*Effect of setanaxib in a renal fibrosis model induced by diabetes in ApoE mice*

Many detailed findings suggest that NOXs, in particular NOX1 and NOX4 (but also perhaps NOX5), play an important role in the development of diabetic complications and, in particular, in diabetic kidney disease and arteriosclerosis. The Australian group led by Professors Mark Cooper and Karin Jandeleit-Dahm at the Baker IDI Institute of Melbourne therefore systematically tested the respective roles of NOX1, NOX2 and NOX4 in these vascular and renal diabetic complications. It is important to note that diabetic kidney disease is a progressive fibrotic illness.

In order to induce these renal and vascular complications, mice deficient in alipoprotein E ($ApoE^{-/-}$) are made diabetic using an injection of streptozotocin a few days after birth. After 20 weeks of diabetes, these diabetic $ApoE^{-/-}$ mice develop severe proteinuria, accompanied by glomerulosclerosis as well as renal inflammation and fibrosis. In this study, setanaxib was administered orally on a preventive basis at the dose of 60 mg/kg per day. The results indicate that setanaxib significantly reduces proteinuria, as well as inflammation and fibrogenesis markers (Figure 6).

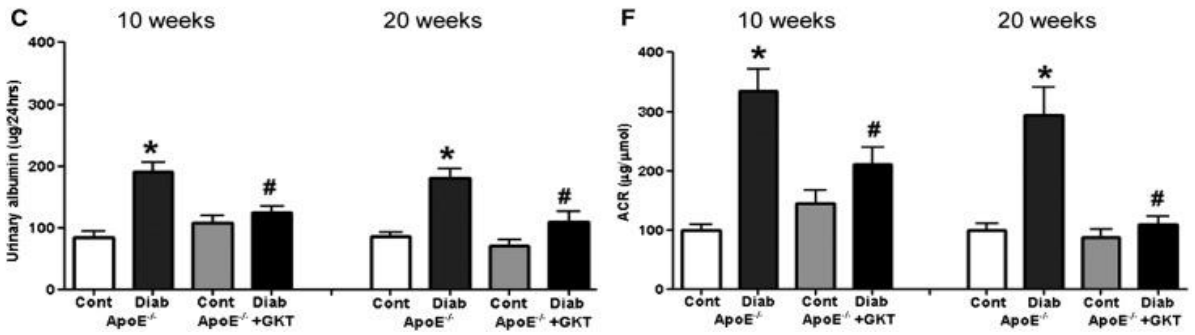



**Figure 6: Effect of setanaxib on the level of urinary albumin after 10 and 20 weeks of diabetes induced by streptozotocin in ApoE$^{-}$/$_{-}$ mice**

Histological observations have confirmed the protective effect of setanaxib on the renal architecture by preventing the loss of the number of glomeruli in the renal cortex. Specific markings were used to show a significant decrease in proliferation markers, inflammatory markers and fibrosis markers confirmed by quantitative analysis.

In this same study, the extent of arteriosclerotic plaques, fibrotic and inflammatory vascular markers and the infiltration of inflammatory cells were also significantly revealed by setanaxib treatment. It is important to note that mice deficient in NOX1 were protected from vascular complications, while mice deficient in NOX4 were protected from renal complications.

These results illustrate the ability of these genetic systems to clarify the specific role of NOX isoforms in specific disorders and, therefore, to validate the specific selectivity profile for relevant inhibitors. The renal results were published in the *Journal of the American Society of Nephrology* and the vascular findings were published in *Circulation*, the top-ranked publications in each of these therapeutic areas. An independent editorial was published in Circulation to illustrate the importance of these results.

In a second study, animals were left for 30 weeks with diabetes to induce a more severe phenotype in the control animals. Setanaxib was administered therapeutically this time for 10 weeks, from week 20 to week 30. The same observations and the same positive results were found with setanaxib.

Podocytes play a major role in the modulation of glomerular filtration, and their destruction causes leakage of macromolecules, including plasma proteins in urine. Freshly isolated human podocytes were cultured with TGF-β, a growth factor activating signaling pathways of cell proliferation and fibrosis. Treatment of these cells with 10 µM of setanaxib blocked the production of ROS by these cells but also blocked the activation of many genes involved in cell proliferation and in fibrosis.

*Effect of setanaxib in a renal fibrosis model in OVE26 mice*

To study the effect of setanaxib in a second diabetic kidney disease model, Professor Hanna Abboud's group at the University of San Antonio used OVE26 mice. These are transgenic mice with type 1 diabetes from birth, which present rapidly progressing proteinuria associated with severe nephropathy. After 24 weeks of diabetes, control mice present a very high level of proteinuria, coupled with renal hypertrophy. Additional markers show a marked increase in the number of inflammatory cells in the cortex and medulla and an increase in fibrosis markers. Two additional groups of animals received an oral dose of 20 mg/kg and 40 mg/kg of setanaxib per day therapeutically for four weeks, from week 20 to week 24. Treatment with setanaxib significantly reduces proteinuria and renal hypertrophy (Figure 7).

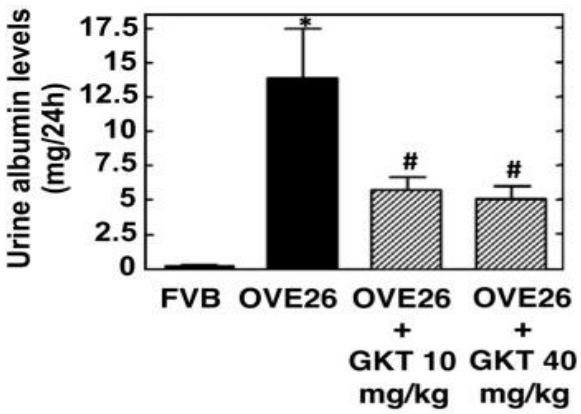



**Figure 7: Effect of setanaxib on the level of urinary albumin after 24 weeks of type 1 diabetes in OVE26 mice**

These improvements are associated with a significant reduction in the infiltration of inflammatory cells in renal tissue and a clear reduction in the level of renal fibrosis. This second study supports the theory that setanaxib has therapeutic potential in renal disorders associated with diabetes.

*Effect of setanaxib in a renal fibrosis model in Akita mice*

In this third diabetic kidney disease model, Professor Kumar Sharma's group at the University of California, San Diego, used Akita mice. These mice present a mutation on the Ins2 insulin gene inducing the development of insulin-dependent diabetes from birth. At the age of 28 weeks, the control mice developed exactly the same symptoms and the same characteristics as the OVE26 mice. Additional markers also revealed a significant increase in tissue hypoxia and an increase in the number of cells undergoing programmed cell death. Separately, preliminary studies conducted in patients with diabetic kidney disease indicated the existence of a mitochondrial dysfunction in the kidney, and Krebs cycle anomalies in particular. These anomalies include the inhibition of the fumarate hydratase enzyme, which processes fumarate. Recently, it was reported that fumarate could play an important role in fibrosis, in epigenetic modifications and in tumorigenesis. This inhibition leads to the accumulation of fumarate in urine, which is a relevant biomarker.

Two groups of mice also received therapeutic treatment for 16 weeks with setanaxib at doses of 30 mg/kg and 60 mg/kg per day. As was the case in the OVE26 mice, mice treated with setanaxib showed a significant improvement in kidney damage and in the level of inflammation and renal fibrosis. Also observed was a significant reduction in the level of hypoxia in the kidney, associated with a reduction in the number of kidney cells undergoing programmed cell death. To a remarkable extent, setanaxib also corrected the metabolic anomalies in renal tissue and tended to normalize urinary fumarate (Figure 8).

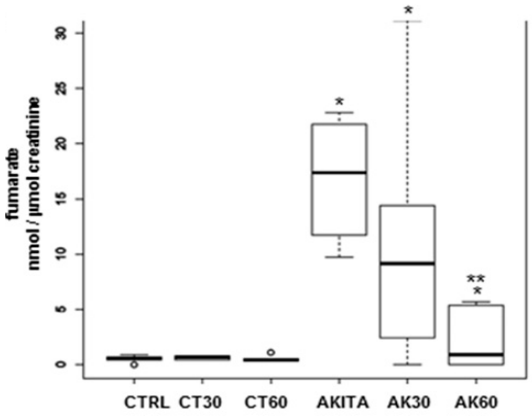


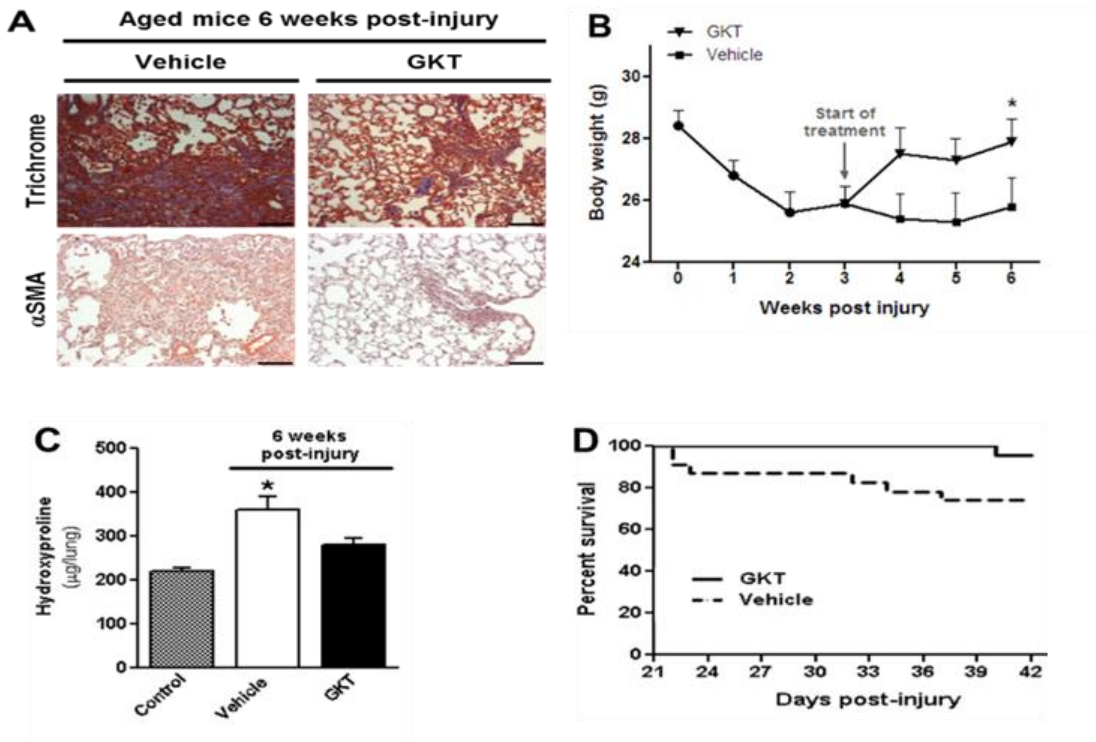

**Figure 8: Effect of setanaxib on the level of urinary fumarate after 28 weeks of type 1 diabetes in Akita mice**

*Effect of setanaxib in a pulmonary fibrosis model in mice treated with bleomycin*

There is now considerable evidence to suggest that NOX, and especially NOX4, plays an essential role in the development of idiopathic pulmonary fibrosis. Professor Victor Thannickal's group at the University of Alabama at Birmingham (UAB) in the United States was able to demonstrate that patients with pulmonary fibrosis had high NOX4 scoring in the biopsy of their fibrosed lungs.

This scientific group developed a mouse model of irreversible pulmonary fibrosis with the intrapulmonary instillation of bleomycin in aged mice, and was thus able to test the effect of setanaxib at a dose of 40 mg/kg three weeks after inducing the disease. These 18-month-old mice have an impaired ability to regenerate fibrosis processes, unlike young two-month-old mice. Three weeks of treatment with setanaxib produced a very significant decrease in the number of fibrosis markers in the lungs of mice instilled with bleomycin. In fact, the histological scoring of the lungs of these mice showed a significant decrease in the surface area marked with Masson's trichrome and $\alpha$-SMA, both markers of myofibroblast accumulation responsible for the deposition of collagen fibers. The assay to determine the level of hydroxyproline, a component of collagen fibers, in the lungs showed restoration nearing the level of the control animals after treatment with setanaxib.

Professor Thannickal's group was also able to show that treatment with setanaxib had a positive effect on the long-term survival rate of the mice compared to placebo-treated animals.




These results therefore suggest that treatment with setanaxib in a persistent pulmonary fibrosis model plays a key role in the prevention, as well as in the reversibility, of this established fibrosis.

**v. Preclinical toxicological data**

The toxicological profile of setanaxib was assessed through an extensive panel of regulatory tests in rats and dogs. In rats, setanaxib was tested over a maximum period of 26 weeks and up to a dose of 1000 mg/kg a day. The compound was extremely well tolerated in rats, which showed no clinical signs, resulting in a NOAEL (no observed adverse effect level) of 1000 mg/kg/day.

Moreover, setanaxib was tested over a similar period of 26 weeks in dogs at the maximum dose of 500 mg/kg/day. The NOAEL allocated to this study was 150 mg/kg/day.

All the observations reported for this treatment were at very high doses and are summarized in the table below.

| Type of changes | 28-day study | | 13-week study | | 26-week study | |
|---|---|---|---|---|---|---|
| | 300 mg/kg/d | 1000mg/kg/d | 100mg/kg/d | 750/500 mg/kg/d | 150mg/kg/d | 500/300 mg/kg/d |
| ECG alteration | | X | | | | X (*) |
| TSH↑; T4↓ | | X | | X | | X |
| Follicular cell hypertrophy | X | X | | X | | |
| Red blood cells ↓ | | X | | X | | X |
| Bone marrow toxicity | | | | | | X (**) |

(*) Only in weeks 1 and 4 (500 mg/kg/d), no signal in weeks 8, 13 and 26.
(**) Non-regenerative anemia in a female (week 13).

A new study in dogs at 50 mg/kg/day, 150 mg/kg/day and 300 mg/kg/day for up to 39 weeks showed no clinical signs, no alterations in biochemical or hematologic data, and no organ alterations. The NOAEL allocated to this study was 300mg/kg/day.

Two reproductive toxicity studies were also conducted in rabbits (300 mg/kg/day, 100 mg/kg/day, 300 mg/kg/day) and in rats (100 mg/kg/day, 300 mg/kg/day, 1000 mg/kg/day) during the embryogenesis period. Neither of these studies demonstrated embryo-fetal toxicity from setanaxib.

It should also be noted that setanaxib was not shown to be positive in any GLP (Good Laboratory Practice) studies of genotoxicity, mutagenicity or cytotoxicity. Lastly, no neurological or respiratory symptoms were observed during regulatory studies on the central nervous system (CNS) and on respiratory function.

## 5.7. SETANAXIB – CLINICAL RESULTS

### 5.7.1. Setanaxib – Phase 1 studies in healthy volunteers (safety and pharmacokinetics)

Five Phase 1 clinical trials have been conducted to date in healthy subjects. The aim of these studies was to assess the safety and pharmacokinetics of the compound after a single dose and repeated doses, to assess the effect of the compound on the CYP3A4 cytochrome, to assess the effect of diet and micronization on the pharmacokinetics of setanaxib and to compare capsule and tablet pharmacokinetics. All these studies were conducted in male subjects.

In terms of the compound's safety, these five studies involved 132 healthy volunteers 120 of whom were exposed to setanaxib. During the repeated dose study, the healthy subjects received up to 900 mg of the compound per day for 10 days. None of the five Phase 1 studies identified events linked to the administration of the compound, irrespective of the dose administered, in terms of biochemical or hematological and cardiac parameters; this demonstrates a very good tolerance to setanaxib.

The pharmacokinetic properties of the compound were consistent for each of the studies carried out. Oral absorption of the compound is rapid and the Cmax is achieved between 1 and 2 hours after administration. The exposure is proportional to the dose up to 900 mg per day and slightly less above 900 mg per day. The molecule's half-life is typically between 10 and 20 hours after repeated administration and between 6 and 11 hours after a single administration. Most of the compound is generally eliminated 12 hours after administration, explaining its lack of accumulation over time, substantiating the compound's good safety profile. GKT138184, which is the primary active metabolite of setanaxib, presents similar pharmacokinetic characteristics as those of the parent molecule, and its exposure is 60 to 100 times less than for setanaxib.

During the drug interaction study, setanaxib was administered with midazolam, which is a substrate of the CYP3A4 cytochrome. The exposure of midazolam increased by 38% and that of its primary metabolite by around 40%. Since the ratio between midazolam and its metabolite is not modified by setanaxib, it is not possible to either conclude or rule out that the increase in midazolam is due to an inhibition of CYP3A4. Setanaxib is therefore classified as a weak inhibitor of CYP3A4.

In the course of the study of interaction with meals, healthy subjects received a single dose of 300 mg of setanaxib. The subjects had either fasted or had received a high-fat meal. The findings showed an increase in the serum exposure of setanaxib and its metabolite (AUC fasted: 38,200 h.ng/mL; AUC fed:

47,600 h.ng/mL) and an increase in their half-life (T1/2 fasted: 17 hours; T1/2 fed: 29 hours) in subjects who received a meal.

In the pharmacokinetic study with the aim of comparing the product as a capsule or as a tablet, healthy volunteers received a single dose of 400 mg of setanaxib either as 4 100 mg capsules or a single 400 mg tablet. The volunteer cohort which received the tablet was either fasting or had received a standard food ration. There were no significant differences between the two pharmaceutical forms of setanaxib at the Cmax, AUC or half-life levels. However, there was a slight decrease in serum exposure of setanaxib and its metabolite in volunteers who received the tablet with a standard food ration. However, Tmax was observed later suggesting slower absorption of the tablet in the presence of a meal and less variability between subjects was also observed. Although the objective of the study was not to demonstrate formal bioequivalence, the study shows that there are no major differences between the form used so far in the various clinical trials (100 mg capsules) and the evolution of the pharmaceutical form that the company wishes to use in the future (400 mg tablets).

Particular focus was placed on the primary toxicity signals observed during toxicity studies in dogs, particularly modifications of ECG tracings, the plasma concentration of thyroid hormones and the levels of red blood cells and reticulocytes. No modification of the values concerning these parameters could be observed or attributed to the treatment with setanaxib in any of the Phase 1 studies, irrespective of the doses administered.

### 5.7.2. Setanaxib – Phase 2 safety and efficacy study in a population of patients suffering from diabetic nephropathy

Following the four Phase 1 clinical trials conducted on healthy subjects, an initial Phase 2 clinical trial was conducted to assess the safety, pharmacokinetic and pharmacodynamic properties, as well as the efficacy of setanaxib in patients with diabetic kidney disease.

These were type 2 diabetes patients who developed macroalbuminuria despite optimal medical treatment.

Scientific literature suggests that NOX1 and NOX4 play an important role in the development of many diabetic complications, including renal, cardiovascular and ophthalmic conditions. Based on these publications, the Juvenile Diabetes Research Foundation (JDRF) awarded a research grant allowing several renowned academic groups to assess the efficacy of setanaxib in diabetic complications models.

These preclinical data, published in leading scientific publications, seem to confirm the therapeutic potential of NOX1 and NOX4 inhibitors (and of setanaxib in particular) in the treatment of diabetic complications (You YH, et al. Metabolomics reveals a key role for fumarate in mediating the effects of NADPH Oxidase 4 in diabetic kidney disease; *J Am Soc Nephrol.* 2016 Feb; 27(2):466-81. Gorin Y, et al. Targeting NADPH oxidase with a novel dual Nox1/Nox4 inhibitor attenuates renal pathology in type 1 diabetes; *Am J Physiol Renal Physiol.* 2015 Jun 1; 308(11):F1276-87. Jha JC, et al. Genetic targeting or pharmacologic inhibition of NADPH oxidase nox4 provides renoprotection in long-term diabetic nephropathy; *J Am Soc Nephrol*. 2014 Jun; 25(6):1237-54).

Diabetic kidney disease is a chronic progressive fibrotic disorder, with glomerulosclerosis and the development of interstitial fibrosis playing a dominant role in the progression of the illness and specifically the decline in renal function. However, these phenomena are slow, and it is not possible to assess the impact of an anti-fibrotic therapy through a short clinical trial.

The aim of this initial Phase 2 (GSN000200) clinical trial was to characterize the safety and pharmacokinetics of setanaxib in this population of patients and to assess the therapeutic efficacy of

setanaxib in early markers of glomerular complaints, such as albuminuria. The toxicological data available at the time was sufficient to support a treatment period of no longer than 12 weeks. This clinical trial GSN000200 was a randomized, double-blind, placebo-controlled multicentric study conducted on parallel groups. Setanaxib or placebo were administered after a run-in period of four weeks during which antihypertensive treatments (diuretic, anticalcic, β-blockers) were adjusted and those prescribed for diabetic kidney disease (inhibitors of the angiotensin-converting enzyme, angiotensin receptor blockers) were optimized up to the maximal dose tolerated, then kept unchanged during the treatment period. The eligibility of patients to enter this run-in period was assessed during a preliminary selection period of up to four weeks.

In total, 155 subjects were enrolled in 75 research sites. The study was carried out in six countries (the United States, Canada, Czech Republic, Poland, Germany and Australia). A total of 136 subjects were still eligible at the end of the run-in period and could be randomized and distributed evenly between the two treatment arms: setanaxib and placebo.

Patients self-administered 100 mg of setanaxib orally morning and night (200 mg per day) or placebo for the first six weeks of the treatment, then 200 mg morning and night (400 mg per day) for the following six weeks. All patients were then monitored for 30 days after the treatment period. The patient retention rate was very high, with 125 patients reaching the end of the full treatment period.

The trial did not achieve its primary efficacy endpoint. No difference was detected between setanaxib and placebo on proteinuria (urinary albumin to creatinine ratio, UACR) after 12 weeks of treatment. Nor did setanaxib have any impact on other measurements of renal function, such as serum creatinine and the estimated glomerular filtration rate.

However, setanaxib did achieve a statistically significant effect on several secondary efficacy endpoints that were predefined in the protocol. It was decided to assess the anti-inflammatory effect of setanaxib, considering its preclinical anti-inflammatory effects, as well as the hepatocellular injury markers. Considering that the subjects included had type 2 diabetes, they may have had some degree of nonalcoholic fatty liver disease (NAFLD). Setanaxib caused a statistically significant decrease in the GGT liver enzyme and in C-reactive protein (“hs-CRP”), an inflammation marker produced in the liver. There was also a clear but non-significant reduction in other serum markers such as serum amyloid A protein, interleukin 6 (IL-6) and plasminogen activator inhibitor-1 (PAI-1), as well as a reduction in triglycerides.

A positive trend for setanaxib was also observed in diabetic peripheral neuropathy assessed with the VAS 100 mm scale, and in erectile dysfunction assessed with the IIEF (International Index of Erectile Function) questionnaire. However, these trends were not statistically significant.

During this trial, setanaxib at a dose of up to 400 mg per day was well tolerated. The number of adverse events (“AE”) was low, with less than 50% of patients reporting at least one AE during the study. Out of a total of 68 patients treated with setanaxib, most of the emerging AEs were low in severity, unrelated to the treatment and quickly resolved. The most common AEs were related to respiratory tract infections. Other one-off AEs were reported by one or two of the patients treated. The fixed dose escalation after six weeks of treatment did not have any impact on the number of AEs emerging. A slight, clinically insignificant increase in diastolic and systolic arterial pressure was observed in patients treated with setanaxib in comparison to those under placebo. These variations remained within the normal range and were not associated with any clinically significant increase in arterial pressure requiring medical intervention. The incidence of adverse effects was noticeably more frequent in patients receiving placebo (119 cases in the placebo group versus 69 in the setanaxib group), i.e., a 42% decrease. If the adverse effects are categorized by degree of severity, a decrease of 12%, 68% and 93% is observed respectively for side effects of mild, moderate and severe severity

(p <0.001). The side effects reported in these patients reflect the natural history of their disease. The effect of setanaxib on the incidence of adverse effects may reflect a decrease in the severity of these diabetic complications.

Lastly, in this Phase 2 study, the safety signals observed in the preliminary toxicology studies in animals have not been confirmed. In particular, no signals affecting thyroid, liver, bone marrow or cardiac conduction were observed.

Although this clinical trial did demonstrate the very good safety profile and pharmacodynamic activity of setanaxib, it was important to analyze the potential reasons for the lack of activity in the primary efficacy endpoint (albuminuria). There are several possible reasons:

- The duration of treatment: compounds acting on intrarenal hemodynamics and in particular on filtration pressure (such as angiotensin II converting enzyme inhibitors, angiotensin II receptor antagonists and endothelin receptor antagonists), generally achieve a reduction in albuminuria within 12 weeks. However, there were no precedents on which to inform the necessary treatment duration for compounds acting on renal fibrosis and inflammation. It is therefore possible that a treatment of more than 12 weeks may have been needed to demonstrate a nephroprotective effect.
- The dose: the selection of doses for this clinical trial (100 mg 2x/day for six weeks, followed by 200 mg 2x/day for six weeks) was based on several elements. Above all, it was important to ensure exposure of the subjects at levels matching the exposure needed for maximal efficacy in animal models. A 20 mg/kg dose seemed sufficient in mice. However, the data obtained since then suggest that a dose of 60 mg/kg is required in some studies to achieve maximal efficacy. This is apparent, for example, in the STAM model, which is a model of NASH. In addition, a population pharmacokinetic model was developed, based on PK data obtained in Phase 1 and Phase 2 clinical trials. These data indicate that a significant proportion of patients would not have been sufficiently exposed with the doses chosen, particularly during the first six weeks of treatment when the dose was 100 mg 2x/day.

Importantly, the good safety profile observed during the Phase II trial in diabetic kidney disease does support the evaluation of setanaxib over a longer treatment period with higher doses in diseases of the kidney, liver and other organs.

### 5.7.3. Setanaxib – Phase 2 clinical trial on primary biliary cholangitis (PBC)

Toward the end of the second half of 2017, Genkyotex initiated a double-blind placebo-controlled Phase 2 study to assess the efficacy and safety of setanaxib in patients with primary biliary cholangitis (PBC), a chronic orphan autoimmune disease and a gateway to fibrotic liver diseases. The therapies currently available to treat PBC have only a limited effect on the progression of the disease, with somewhat limited safety (presence of itching). Hence there is a strong medical need in a significant market for effective molecules that primarily target hepatic inflammation and fibrosis, and that are also well tolerated. Setanaxib's inhibition of NOX1 and NOX4 enzymes, preferentially targeting inflammation and fibrosis, makes PBC a potential entry point for fibrotic disorders with this product candidate setanaxib.

The Phase 2 clinical trial conducted by Genkyotex in patients with diabetic kidney disease revealed a good safety profile, characterized the pharmacokinetic properties of setanaxib, and generated encouraging pharmacodynamics data. As described above, these clinical results brought to light elements that should be taken into account to increase the chances of success of subsequent clinical trials.

The design of this second clinical trial in PBC took these factors into account and was developed to maximize the chances of therapeutic success by using all available preclinical and clinical data.

In this trial, the duration of the treatment was extended to 24 weeks, far exceeding the treatment duration generally used in this type of clinical trial (i.e., 12 weeks). The maximum dose is 400 mg 2x/day for 24 weeks. It is also important to note that setanaxib is eliminated by the bile ducts, which allows for maximum exposure specifically where it is desirable. These preclinical data obtained in rats with radioactive setanaxib revealed tissue concentrations three to five times higher in the liver compared with other organs such as the kidney.

The PBC clinical trial allows for significant and prolonged drug exposure in the target organ. Furthermore, the primary efficacy endpoint is GGT (gamma glutamyl transpeptidase), a liver enzyme that is elevated in cases of hepatic inflammation and/or cholestasis. In the Phase 2 clinical trial conducted, setanaxib produced a significant reduction in GGT.

The main objective of this clinical trial was to assess the efficacy of setanaxib administered for 24 weeks compared to a placebo. Two doses were evaluated to guide dose selection for the following clinical trials (400mg 1 x/day and 400mg 2 x/day). The effectiveness of setanaxib was assessed on the basis of its effects on markers of the following criteria:

1. Cholestasis and bile duct damage: ALP, GGT (primary efficacy endpoint)
2. Hepatic hardness measured by Fibroscan®: Hepatic hardness is a non-invasive measurement of hepatic fibrosis
3. Hepatocytic suffering: transaminases such as ALT, AST, GGT)
4. Quality of life: PBC40 questionnaire
5. Pruritus (itching): similar visual score
6. Hepatocytic apoptosis (CK-18)
7. Immunological activation: IgM immunoglobulin, IL-13, IL-4, IP-10, IFNg, IL-12p70)

The study targeted a total enrollment of 102 patients (in three groups). Patients are included in the study based on the following major criteria:

- Primary biliary cholangitis diagnosis defined by the presence of at least two of the following three criteria: (i) history of high alkaline phosphatase, (ii) positive antimitochondrial antibodies, (iii) a liver biopsy with a histological diagnosis of primary biliary cholangitis;
- Alkaline phosphatase level ≥ 1.5x the upper limit of normal (ULN);
- Plasma GGT value above normal;
- Treatment with ursodeoxycholic acid for at least six months and with a stable dose for at least three months;
- Absence of liver decompensation or cirrhosis;
- Coagulation disorders;
- A history of liver transplant or a MELD score of over 15;
- ALT transaminase more than five times normal.

Lastly, 111 patients were randomized and entered the study in nine countries in North America, Europe and Israel, and patient enrollment was completed on September 25, 2018.

Genkyotex initiated the study at the end of the second quarter of 2017, with the objective of obtaining preliminary results in the fall of 2018 and final results in the first half of 2019.

Patients self-administered oral doses of 400mg of setanaxib in the morning (400mg per day), 400mg morning and evening (800mg per day), or placebo for 24 weeks. All patients were monitored for 28 days after the treatment period with very good patient retention because only 4% of patients left the study before the end of the treatment period.

Interim results of the study were published in November 2018 and covered 92 patients who had completed their first six weeks of treatment. The analysis focused on the primary efficacy endpoint, i.e., the change in the Gamma GT (GGT) blood level at week six compared to basal values. This analysis also examined several secondary efficacy markers, including markers of bile duct lesions (GGT, ALP), liver lesions (ALT, AST, bilirubin) and inflammation markers such as hs-CRP. Finally, the safety and tolerance profile of setanaxib was also evaluated during this interim analysis.

This showed that treatment with 400 mg setanaxib twice daily significantly decreased the circulating GGT level (-23%, $p<0.01$) after six weeks of administration. The same observation was also made for the circulating ALP level (-17%, $p<0.001$).

The Drug Safety Review Committee also issued a very positive opinion on the study and did not make any specific recommendations that would limit the dose or duration of treatment.

The final results of the study were reported by the Company in May 2019. After 24 weeks of treatment, the 19% reduction in the circulating GGT level to 400 mg twice a day did not achieve statistical significance. However, the assessment of repeated measurements over the 24 weeks of treatment—a secondary efficacy endpoint provided for in the statistical analysis plan—showed a statistically significant effect of the 400 mg setanaxib twice daily ( $p=0.002$).

These favorable results are consistent with the statistically significant decrease in GGT and ALP observed in the interim analysis conducted after six weeks of treatment, the results of which were announced in November 2018. The reasons for the loss of statistical significance in week 24 were thus explored in the context of predefined post-hoc analyses in a statistical analysis plan.

The post-hoc analysis showed that GGT data did not follow a normal distribution in the group treated with the 400 mg dose once a day. The initial statistical analysis plan required verification of the normal distribution of GGT data before applying the statistical test. When all of the test groups were evaluated, the distribution of GGT data passed normality test.

However, the post-hoc statistical analysis indicated that this was not the case for the group treated with 400 mg once a day. Although limited to the 400 mg group once a day, this non-normal distribution had an adverse effect on the comparisons of each of the two groups treated with placebo. The data structure for each group is taken into account in the statistical model which is then used for these comparisons.

When this distribution aberration in the 400 mg group once a day is corrected by different methods (non-parametric statistical tests or logarithmic transformation), the value is greatly improved, including a statistical significance reached after logarithmic transformation ($p=0.02$) for the 400 mg group twice a day compared to the placebo.
It appears, therefore, that the main reason for the lack of statistical significance in week 24 is related to a non-normal distribution of GGT data in one of the groups.

Taken as a whole, the results obtained for GGT and ALP show that setanaxib attenuates cholestatic disease (i.e., related to the accumulation of toxic bile acids). This result is interesting since setanaxib does not alter the metabolism of bile acids (i.e., it has no anti-cholestatic effect). This is in contrast to approved products (UDCA, Ocaliva) and products under development (elafibranor, seladelpar).

In this regard, the Company considers that the effect of setanaxib on ALP and GGT very likely reflects its anti-inflammatory effect. The effect on these cholestasis markers is, however, less significant than those obtained by Ocaliva (25-30% reduction of ALP) or PPAR agonists such as elafibranor or seladelpar (40-50% reduction of ALP). These comparisons are important since ALP is the most widely used endpoint in Phase 2 and is part of the composite efficacy endpoint used in Phase 3.

However, it is interesting to obtain an effect by a new and different mechanism, which suggests that this effect will be additive when setanaxib is used with these anti-cholestatic products.

It should also be noted that the phase 3 clinical trial of seladelpar was suspended at the end of November 2019 due to signs of hepatic toxicity.

In PBC, the unaddressed medical need is beyond the markers of cholestasis for which effective treatments are now available (UDCA, Ocaliva®, bezafibrate). However, there continues to be a medical need to address the progression of hepatic fibrosis and its impact on quality of life, in particular for fatigue, the most prevalent symptom in patients with PBC.

As a result, a major objective of the clinical trial was to assess the effect of setanaxib on hepatic fibrosis. This effect was assessed by measuring hepatic stiffness, a non-invasive indicator of hepatic fibrosis. There is an excellent correlation between hepatic stiffness and the histological fibrosis score ("F Score"). Remarkably, the 400 mg setanaxib twice a day induced a 22% decrease in hepatic stiffness in patients with hepatic stiffness equal to or greater than 9.6 kPa ($p$ =0.038 compared to the placebo). This subgroup analysis was part of the protocol and statistical analysis plan. Hepatic stiffness of 9.6 kPa or more corresponds to an F score of F3 or F4. These scores indicate advanced liver fibrosis and are a very significant risk factor for the progression of these patients to cirrhosis, liver transplant, or death. It is therefore a population at risk. Interestingly, in these patients at risk setanaxib at 400 mg twice a day also leads to very significant decreases in GGT and ALP (respectively -32% and -24%).

In addition, setanaxib at 400 mg twice a day also leads to a significant improvement in quality of life, for fatigue in particular ($p$ =0.023). This is a remarkable result, since no drug has shown a favorable effect on quality of life.

Lastly, during this trial, setanaxib at a dose of up to 800 mg per day was particularly well tolerated. The number of adverse events was 121 for the placebo group, 119 for the 400 mg a day group, and only 100 for the setanaxib 400 mg twice a day group.

#### 5.7.4. Potential Phase 3 clinical program in PBC and other indications

After the publication of these positive results obtained during the Phase 2 study with setanaxib in PBC, interactions with the FDA and EMA are in progress to obtain their scientific opinions on further clinical development.

Given that this is an orphan disease, accelerated registration after completion of the Phase 3 program may be considered, as was the case recently for Intercept Pharmaceuticals' Ocaliva®. However, it is important to note that setanaxib has a different mechanism of action than those of Ocaliva® or ursodiol. It is therefore doubtful that the regulatory agencies will approve an identical Phase 3 program based on the same registration criteria.

Should this situation arise, the beneficial effect of setanaxib on histological criteria such as inflammation, biliary damage and fibrosis may need to be demonstrated. This research, if necessary,

could be carried out as part of the Phase 3 study or in a dedicated clinical trial allowing for the inclusion of a specific patient population for these investigations.

For the development of setanaxib in liver disorders, the safety of setanaxib in patients with liver failure would also need to be demonstrated. This trial is currently planned on 36 subjects in Child-Pugh stages A (12 subjects), B (12 subjects) and C (12 subjects). The pharmacokinetic and safety data obtained in these patients will be useful when it comes to planning the pivotal Phase 3 study.

The Company may also consider developing the product candidate setanaxib in PSC where patients have severe and currently untreated liver inflammation and fibrosis.

The Company is considering testing setanaxib in NASH and notably in combination studies with generic molecules.

## 5.8. EXPLORATORY RESEARCH PROGRAMS

NOX enzymes also play an important role in oncology, particularly in potential resistance to anti-cancer treatments due to the presence of a fibrotic stroma around tumors as well as in certain diseases of the central nervous system such as Parkinson's disease. Genkyotex therefore continues to seek non-dilutive financing opportunities to support the preclinical development of product candidates in these therapeutic areas.

### 5.8.1. NOX inhibition in disorders of the central nervous system

There is increasing evidence that the generation of ROS by NOXs is involved in many disorders of the central nervous system. It has been documented that NOX2 could potentially play a vital role in psychiatric disorders, such as schizophrenia, and in certain types of epilepsy, multiple sclerosis and neurodegenerative diseases such as Alzheimer's disease, Creutzfeldt-Jakob disease, amyotrophic lateral sclerosis and Parkinson's disease (*Nayernia Z, Jaquet V, Krause KH, 2014. New insights on NOX enzymes in the central nervous system. Antioxid Redox Signal.; 20:2815-37*).

When it comes to these neurodegenerative diseases, some studies find that NOX2 could play a key role in inflammation of the microglia and in neuronal cell death (*Lelli A, Gervais A, Colin C, Chéret C, Ruiz de Almodovar C, Carmeliet P, Krause KH, Boillée S, Mallat M, 2013*. *The NADPH oxidase Nox2 regulates VEGFR1/CSF-1R-mediated microglial chemotaxis and promotes early postnatal infiltration of phagocytes in the subventricular zone of the mouse cerebral cortex. Glia. 61:1542-55*).

For Parkinson's disease, several studies have demonstrated the key role played by NOX1 in dopaminergic neurons (*Cristóvão AC, Guhathakurta S, Bok E, Je G, Yoo SD, Choi DH, Kim YS., 2012*. *NADPH oxidase 1 mediates α-synucleinopathy in Parkinson's disease. J Neurosci. 32:14465-77*) in various mouse models of Parkinson's, as the pharmacological or genetic inhibition of NOX1 inhibits the degeneration of dopaminergic neurons induced by toxins such as paraquat, 6-OHDA and MPTP (*Zhang F et al., CNS Neurosci Ther, 2014*).

As a priority, Genkyotex is assessing the therapeutic potential of NOX inhibitors in Parkinson's disease.

### 5.8.2. NOX inhibition in oncology

NOXs are a key component in the response to cellular stress. Cancer cells are affected by many forms of stress, including hypoxia, genome instability, increased metabolic demand, immune surveillance, change in environment during metastasis and the effect of anticancer treatments.

As a result, scientific literature suggests that NOXs could play a role in the multiple stages of tumor growth (*Meitzler JL et al., Antioxid Redox Signal, 2014*):

- DNA oxidation inducing genetic mutations facilitating tumorigenesis
- Proliferation of cancer cells
- Switches in energy metabolism (e.g. Warburg effect)
- Tumor angiogenesis
- Stromal growth
- Mesenchymal-epithelial transition in the context of metastasis
- Emergence of secondary mutations causing resistance to anticancer therapies.

In cancer, cellular stresses include hypoxia (lack of oxygen), genomic instability, attacks by the immune system, and anticancer treatments. NOX enzymes are proteins whose genes are among the most commonly induced in many types of human tumors. Cancer cells also induce NOX expression in the cells that make up the tumor microenvironment. In this tumor microenvironment, NOX enzymes help to establish favorable conditions for the growth and local or remote spread of malignant tumors. For example, NOX enzymes participate in the induction of neo-vessels that are essential for tumor growth (i.e., tumor angiogenesis). In addition, growth factors produced by tumor cells, such as TGF-β, induce NOXs in fibroblasts present in the tumor microenvironment. These cancer-associated fibroblasts form a fibrous capsule in the tumor periphery. This fibrotic capsule—also called the "tumor stroma"—isolates and protects cancer cells from the immune cells that would detect and kill them. This effect is especially harmful in the context of anticancer immunotherapies that are designed to activate precisely those protective immune cells. Such immunotherapeutic treatments, e.g. anti-PD-1, anti-PDL1 and anti-CTLA4 antibodies, as well as therapeutic anticancer vaccines represent the most significant therapeutic advance in the fight against cancer. Unfortunately, these treatments are only effective in 20% to 30% of patients (depending on the type of cancer). It is commonly understood that the presence of tumor stroma, limiting the infiltration of immune cells into the tumor, represents a major obstacle to the efficacy of immunotherapeutic treatments.

Thanks to academic partnerships, Genkyotex is exploring the potential of selective NOX inhibitors to target key compounds of the tumor's microenvironment, namely angiogenesis and tumor stroma. It has recently been shown that setanaxib can attenuate the proliferation and migration of fibroblasts and reduce the expression of pro-fibrotic markers in prostate cancers associated with a densely fibrotic stroma *(Sampson N et al., Int J Cancer, 2018)*.

A study conducted by Dr. Natalie Sampson et al. at the Medical University of Innsbruck, the results of which were published in the International Journal of Cancer (https://doi.org/10.1002/ijc.31316), showed that in a preclinical model of prostate cancer, setanaxib, an inhibitor of NOX1 and NOX4, has been effective in targeting cancer-associated fibroblasts (CAF) and has halted the tumorigenic effect of the tumoral microenvironment.

CAFs are an essential component of the tumor-associated stromal microenvironment, which is a major driver of prostate cancer progression and an independent predictor of disease prognosis.

CAFs are largely driven by cancer-derived cytokines, such as transforming growth factor-β (TGFβ1), which fuels cancer cell proliferation and migration.

The results of this study showed that stromal areas with clusters of intense NOX4 staining were localized adjacent to tumor foci with abundant TGFβ1 expression. In vitro, setanaxib significantly reduced TGFβ1-induced expression of CAF markers at both the mRNA and protein levels.

Additionally, setanaxib halted the proliferation and migration of prostate cancer cells. Collectively, these data demonstrated that setanaxib efficiently disrupts the TGFβ1-NOX4 signaling axis underlying reciprocal epithelial-stromal cell crosstalk, fibroblast activation and stromal-driven tumor cell-promoting properties.

The Company considers that these studies highlight the central role of NOX4 in driving CAF activation in prostate cancer. Moreover, the results demonstrate that setanaxib halts the tumor-promoting properties of CAFs, further supporting the Company's focus on the therapeutic potential of NOX enzyme inhibitors in oncology.

This new data follows previous preclinical results published in mid-2017, showing that setanaxib can effectively target CAFs and delay tumor growth in head and neck cancers. In fact, a second group has reported similar results in other types of cancers, such as oral-pharyngeal and colorectal cancers (*Hanley CJ et al, J Natl Cancer Inst, 2018*).

Professor Gareth Thomas and his team have demonstrated that NOX4 is significantly induced in many human cancers and is involved in the activation of cancer-associated fibroblasts. In several in vitro and in vivo models, genetic or pharmacological inhibition of NOX4 has been shown to deactivate cancer-associated fibroblasts and delay tumor growth (Figure 9).

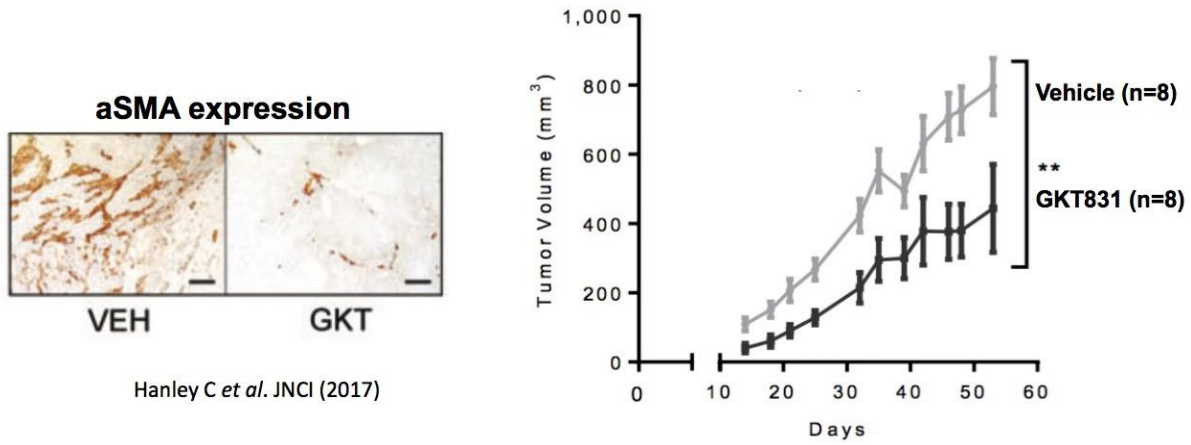



**Figure 9: Effect of setanaxib on aSMA expression (a cancer-associated fibroblast activation marker) and tumor growth in a mouse model of oropharyngeal cancer (5PT)**

The role of NOX4 in CAFs activation shares many similarities with its role in the activation of myofibroblasts, a key characteristic of fibrogenesis in many fibrotic diseases. Consequently, strategies to deactivate cancer-associated fibroblasts are being actively sought.

Setanaxib has also demonstrated potent anti-fibrotic activity in multiple preclinical models of liver, lung, skin and renal fibrosis.

## 5.9. ORGANIZATION OF THE COMPANY

As of the date of this Universal Registration Document, Genkyotex employs nine people, including six employees dedicated to research and development. There are five managers in the team, including three in executive management positions. These employees currently include one medical doctor and three PhDs in sciences.

## 5.10. SCIENTIFIC ADVISORY BOARD

Genkyotex has a Scientific Advisory Board made up of the three scientists who founded Genkyotex Suisse in 2006, as well as Professor Dave Lambeth. The Company's Scientific Advisory Board meets regularly to discuss all matters relating to the design of clinical studies as well as the establishment and review of clinical data. The members of the Scientific Advisory Board are:

**Karl-Heinz Krause**, medical doctor, professor of medicine at the faculty of medicine at the University of Geneva and honorary professor at Beijing Hospital, China. From 1982 to 1989, he trained in internal medicine and infectious diseases at the hospitals of Munich, Geneva and Iowa. Highly active in research on inflammation, since 1998 he has focused his research on mechanisms linked to aging and treatments of age-related illnesses, focusing specifically on the role of the NADPH oxidase family as an important pathological source in the production of oxidative stress. He is a member of the Swiss Academy of Medical Sciences and the American Society for Clinical Investigation. Dr. Krause is one of the founders of Genkyotex.

**Chihiro Yabe**, PhD in Science, medical doctor, professor of pharmacology at the University of Medicine of Kyoto in Japan. In addition to conducting research on diabetes since 2000, she has specialized in research into NOX enzymes. Professor Yabe is an advisor to the Japanese Pharmacological Society, the Japan Diabetes Society and the Japanese Society of Clinical Pharmacology and Therapeutics. Dr. Yabe is one of the founders of Genkyotex.

**Robert A. Clark**, medical doctor, professor of medicine at the University of Texas at San Antonio, USA. Professor Clark has led many fundamental studies and programs in translational medicine on inflammatory response mechanisms and on the understanding of human phagocyte cells. His group was one of the main contributors to the study of production mechanisms of ROS by NOX2 and in studying the role of NOX2 mutations in the onset of CGD (Chronic Granulomatous Disease). He has recently focused his attention on understanding the function and role of NOXs in aging and neurodegeneration. Dr. Clark is one of the founders of Genkyotex.

**Dave Lambeth**, PhD in science, medical doctor, professor at the laboratory of pathology and biochemistry at Emory University in Atlanta, USA. In the 1980s, his research group at Emory University contributed considerably to the understanding of phagocyte NADPH and its method of regulation. His group then became the first to identify the first non-phagocyte NOX, NOX1, in 1999. He went on to make considerable contributions to the discovery of other NOXs and to the understanding of their regulation mechanism.

## 5.11. ORGANIZATION OF OPERATIONS

The Company's registered office is located in Archamps, France.

The Group has nine employees based at the Group's premises in Plan-les-Ouates, Switzerland and Archamps, France.

## 5.12. MULTIPLE PEER-REVIEWED SCIENTIFIC PUBLICATIONS

On the basis of the scientific research conducted by its staff or in collaboration with external scientists, the Company has been able to use leading scientific literature to make its technology known. Below is a list of the main scientific publications used by the Company to validate its scientific and medical approach:

1. Tumoral NOX4 recruits M2 tumor-associated macrophages via ROS/PI3K signaling-dependent various cytokine production to promote NSCLC growth. Zhang J, Li H, Wu Q, Chen Y, Deng Y, Yang Z, Zhang L, Liu B. Redox Biol. 2019 Feb 6;22:10111

2. The Nox1/Nox4 inhibitor attenuates acute lung injury induced by ischemia-reperfusion in mice. Cui Y, Wang Y, Li G, Ma W, Zhou XS, Wang J, Liu B. PLoS One. 2018 Dec 20;13(12):e0209444

3. Nox1/4 dual inhibitor GKT137831 attenuates hypertensive cardiac remodelling associating with the inhibition of ADAM17-dependent proinflammatory cytokines-induced signalling pathways in the rats with abdominal artery constriction. Zeng SY, Yang L, Yan QJ, Gao L, Lu HQ, Yan PK. Biomed Pharmacother. 2019 Jan;109:1907-1914

4. Nox4 Promotes Neural Stem/Precursor Cell Proliferation and Neurogenesis in the Hippocampus and Restores Memory Function Following Trimethyltin-Induced Injury. Yoshikawa Y, Ago T, Kuroda J, Wakisaka Y, Tachibana M, Komori M, Shibahara T, Nakashima H, Nakashima K, Kitazono T. Neuroscience. 2019 Feb 1;398:193-205

5. Nociceptive behavior induced by chemotherapeutic paclitaxel and beneficial role of antioxidative pathways. Miao H, Xu J, Xu D, Ma X, Zhao X, Liu L. Physiol Res. 2018 Oct 23

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Tsiropoulou S, Da Silva RNO, Cao Z, Graham D, McMaster C, Burchmore RJ, Hartley RC, Bulleid N, Montezano AC, Touyz RM. Hypertension. 2018 Jul;72(1):235-246

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## 5.13. EXPERTISE IN PRECLINICAL RESEARCH AND DEVELOPMENT

With setanaxib, the Company has, to date, developed one drug candidate from the stage of discovery to entry in Phase 2. The preclinical and clinical research and development steps completed for this first project constitute expertise applicable to new projects.

In particular, the Company has established a network of consultants and subcontractors enabling it to manage and perform all the successive stages in the development of new product candidates: design and production of candidates, development of processes, development of analytical methods, regulatory expertise, animal pharmacology studies, conduct of toxicological studies, pharmacokinetics, formulation, traceability, quality assurance, etc.

A significant portion of the Company's activities is outsourced to contract research organizations (CRO), which are in particular responsible for carrying out clinical trials, producing compounds and conducting toxicology studies. Above all, this operational model enables Genkyotex to maintain control over its intellectual property, as the consultants and CRO used are not themselves granted any rights over this intellectual property.

## 5.14. CLINICAL DEVELOPMENT EXPERTISE

An experienced team devoted to clinical development is based at the Group's premises in Plan-les-Ouates, Switzerland and Archamps, France. The clinical team works closely with consultants who are experts in regulatory affairs, pharmacokinetics and statistical methods.

The team in charge of clinical development manages all the activities involved in preparation, implementation, management of subcontractors and analysis of the data from Genkyotex's clinical trials (drafting of the research brochure, establishment of a clinical protocol, requests for scientific advice from regulatory agencies, setup of the clinical trial, monitoring of the clinical trial, selection of a CRO, patient recruitment, management of interactions between the different parties involved, etc.), analysis of data, and preparation of regulatory reports presenting results.

## 5.15. INVESTMENTS

### 5.15.1. Main investments made during the last two financial years

On February 28, 2017, the Company's shareholders approved the resolutions to make the merger with Genkyotex Suisse SA official in accordance with the contribution agreement signed on December 22, 2016. Genkyotex Suisse SA was contributed on the basis of a real value of €120 million. This in-kind contribution was paid through the issue of ordinary shares in the Company.

On September 28, 2017, the Company acquired 100% of the shares of Genkyotex Innovation SAS from Genkyotex Suisse SA for €2,467 thousand. This company was merged on November 30, 2017 with retroactive effect for accounting and tax purposes at January 1, 2017.

It is also noted that the Company has devoted a major part of its resources to the research and development of its product candidates. These research costs are systematically recognized in expenses (see Note 3.1 in Section 18.1.1.1. of the Universal Registration Document) and are therefore not shown in this section.

The Company did not make any significant investments during the 2019 financial year.

Main investments since the last financial year:

No significant investments have been made since January 1, 2020.

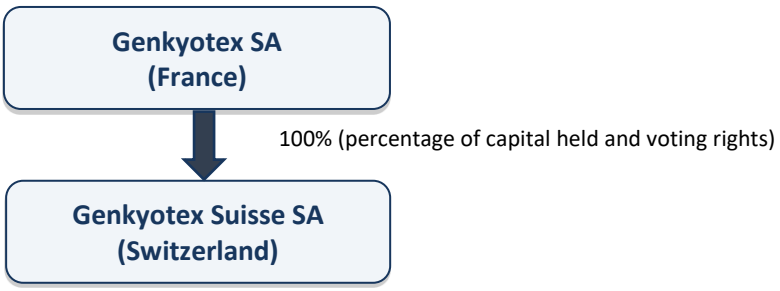
### 5.15.2. Main investments planned

The Company is not planning, for the moment, to make significant investments in the foreseeable future for which the Company management bodies have made firm commitments. It will continue, in the future, to devote a major part of its resources to the research and development of its product candidates.

# SECTION 6. ORGANIZATIONAL STRUCTURE

## 6.1 BRIEF DESCRIPTION OF THE GROUP

This is Genkyotex Group's legal structure as of the date of the Universal Registration Document:




## 6.2 LIST OF SIGNIFICANT SUBSIDIARIES

- **Genkyotex SA**: parent company of the Group, based in Saint-Julien-en-Genevois in France.

- **Genkyotex Suisse SA**: a company established in 2006, located in Plan-les-Ouates (Geneva) in Switzerland. The company conducts screening campaigns to identify the NADPH oxidase inhibitor molecules.

Note that in 2017, Genkyotex Innovation SAS, a research center specializing in preclinical studies and Phase 1 and 2 clinical trials on NADPH oxidase inhibitor molecules, was merged with and into Genkyotex SA.

During financial year 2019, the Company did not:

- Acquire significant stakes in companies with headquarters in France,
- Take control of such companies;
- Dispose of such stakes.

# SECTION 7. ANALYSIS OF FINANCIAL POSITION AND RESULTS

Readers are advised to read the information regarding the financial position and results of the Company and its subsidiary together with the full Universal Registration Document and in particular the consolidated financial statements prepared in accordance with IFRS—as adopted by the European Union—for the financial year ended December 31, 2019. Note that the information below is drawn from the consolidated financial statements presented in Section 18.1 of this Universal Registration Document.

## 7.1 FINANCIAL POSITION

### 7.1.1. Changes in the issuer's results of operation

#### 7.1.1.1. Revenue

Given the stage of development of its drug candidates, the Group does not generate any sales.

#### 7.1.1.2. Revenue from contracts with customers

The Company recognized revenues of €750 thousand during financial year 2018 in connection with the extension of the license transfer agreement (right of use) signed in June 2018 with the Serum Institute of India Pvt. Ltd. (SIIL). In accordance with the terms of the agreement, which provides for milestone payments based on stages of progress, no payment was received as such in 2019.

#### 7.1.1.3. Operating expenses by purpose

***Current operating expenses***

*Research and development expenses*

Research expenses are systematically recognized as expenses.

Due to the risks and uncertainties linked to regulatory authorizations and to the research and development process, the six immobilization criteria according to IAS 38, were considered unfulfilled before obtaining marketing authorization (“MA”) on the drugs market. Accordingly, internal development expenses incurred before obtaining MA, mainly consisting of expenses on clinical studies, are reported as expenses.

The breakdown of research and development expenses during the financial years presented is as follows:

| RESEARCH AND DEVELOPMENT<br>(Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Raw materials and consumables | (83) | (139) |
| Studies and research | (3,158) | (6,096) |
| Personnel expenses (including post-employment benefits) | (1,361) | (1,473) |
| Lease expenses | (18) | (121) |
| Licenses and intellectual property costs | (722) | (531) |
| Depreciation, amortization and impairment | (581) | (586) |
| Share-based payments | (258) | (296) |
| Amortization of rights of use | (98) | - |
| Other | (26) | (40) |
| **Research and development expenses** | **(6,305)** | **(9,282)** |
| Research tax credit | 899 | 893 |
| Subsidies | - | - |
| **Subsidies** | **899** | **893** |
| **Net research and development expenses** | **(5,406)** | **(8,389)** |

In 2019, Research and development expenses consisted mainly of:

- Study expenses of €3,158 thousand (down €2,938 thousand from 2018, mainly reflecting the costs incurred in Phase 2 clinical trials for the setanaxib (GKT831) product indicated for PBC patients, as well as preclinical work in progress on the GKT771 compound);
- Research personnel expenses of €1,361 thousand (down €112 thousand from 2018);
- A share-based payment charge corresponding to stock options awards for employees for €258 thousand (compared to €296 thousand in 2018); and
- Capital depreciation expense of €581 thousand (unchanged from 2018) consisting primarily of the amortization of the license agreement with SIIL, a contract valued in the context of the acquisition in 2017 of the French company Genkyotex SA (formerly Genticel), a company acquired for accounting purposes.

Note that in 2019 the decrease in lease expenses was offset by the use of a new expense line item, the amortization of rights of use. This expense transfer corresponds to the introduction, effective January 1, 2019, of IFRS 16.

Research tax credit income—which remained unchanged—amounted to €899 thousand in 2019 compared with €893 thousand in 2018.

### *General and administrative expenses*

The breakdown of general and administrative expenses during the financial years presented is as follows:

| GENERAL AND ADMINISTRATIVE EXPENSES<br>(Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Travel and incidental expenses | (208) | (325) |
| Fees | (889) | (1,199) |
| Insurance | (35) | (94) |
| Marketing and sales expenditure | (89) | (124) |
| Taxes and duties | (29) | (12) |
| Personnel expenses (including post-employment benefits) | (450) | (643) |
| Attendance fees/Compensation for the activity | (49) | (60) |
| Share-based payments | (226) | (216) |
| Amortization of rights of use | (33) | - |

| | | |
|---|---|---|
| Other | (153) | (163) |
| **General and administrative expenses** | **(2,160)** | **(2,836)** |

General and administrative expenses consist mainly of:

- External legal and advisory fees of €889 thousand (compared with €1,199 thousand in 2018), corresponding mainly to legal (€0.4 million), accounting and audit (€0.3 million), communication (€0.1 million) and listing costs (€0.1 million) associated with a listed company. This also includes special consulting expenses related to the Company's business sector;
- Administrative and financial personnel expenses of €450 thousand in 2019 (down €193 thousand from 2018); and
- Share-based payment expense for €226 thousand (compared with €216K thousand in 2018).

#### 7.1.1.4. Financial income (expenses)

| **FINANCIAL INCOME (EXPENSES), NET (Amounts in € thousands)** | **12/31/2019** | **12/31/2018** |
|---|---|---|
| Cost of bonds issued | (156) | (1,152) |
| Derivative liabilities (fair value) | 64 | - |
| Other financial expenses | (7) | (11) |
| Other financial income | - | 3 |
| Exchange (losses) and gains | 320 | 173 |
| **Financial income (expenses)** | **222** | **(987)** |

The financial income in 2019 and 2018 included essentially net exchange gains from changes in the CHF/EUR exchange rate in the intercompany accounts of Genkyotex Suisse SA with Genkyotex SA and the cost of bonds.

#### 7.1.1.5. Corporate taxes

The Group did not have a corporate tax charge in financial years 2019 and 2018.

As of December 31, 2019, the Group had tax loss carryforwards totaling:

- €91,859 thousand in France;
  The carryforward of tax losses in France is capped at 50% of the taxable profits for the year. This limitation is applicable to the portion of profits exceeding €1 million. The outstanding amount of the tax losses may be carried forward to subsequent financial years, under the same conditions without any time limit.
  The tax rate currently applicable to Genkyotex SA is the rate in force in France, i.e., 28%. This rate will gradually decrease from 2018 onward until it reaches 25% from 2022.

- €60,385 thousand (CHF 67,175 thousand) in Switzerland, broken down as follows:
  - €5,257 thousand (CHF 5,706 thousand) originating in 2019 and expiring in 2027;
  - €9,941 thousand (CHF 10,790 thousand) originating in 2018 and expiring in 2026;
  - €3,478 thousand (CHF 3,775 thousand) originating in 2017 and expiring in 2025;
  - €11,848 thousand (CHF 12,860 thousand) originating in 2015 and expiring in 2023;
  - €14,285 thousand (CHF 15,505 thousand) originating in 2014 and expiring in 2022;
  - €12,416 thousand (CHF 13,476 thousand) originating in 2013 and expiring in 2021;
  - €4,665 thousand (CHF 5,063 thousand) originating in 2012 and expiring in 2020.

The tax rate on applicable income for Genkyotex Suisse SA is the rate that is currently applicable in the Swiss Canton of Geneva (24%).

Deferred tax assets are recorded as tax losses which may be carried forward when it is probable that the Company will have future taxable earnings against which these cumulative tax loss carryforwards may be used. In accordance with this principle, no deferred tax assets are recorded in the Company's financial statements that exceed deferred tax liabilities.

#### 7.1.1.6. Earnings per share

| EARNINGS PER SHARE | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Weighted average number of shares outstanding for the financial periods presented (1) | 8,146,178 | 7,807,515 |
| Net profit/(loss) for the period attributable to owners of the parent company (in € thousands) | (7,203) | (11,417) |
| **Basic earnings per share (€/share) (1)** | **(0.88)** | **(1.46)** |
| **Diluted earnings per share (€/share) (1)** | **(0.88)** | **(1.46)** |

*(1) Following the approval of the Extraordinary Shareholders' Meeting of January 24, 2019, the Board of Directors of the Company meeting on the same day decided to implement the reverse stock split, by exchanging 10 existing shares for one new share, which was carried out on March 29, 2019. The weighted average number of shares in 2018 was thus divided by 10, and the share loss shown above in 2018 was thus adjusted to take account of this reverse stock split.*

#### 7.1.1.7. Non-current assets

| NON-CURRENT ASSETS (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Intangible assets | 9,086 | 9,653 |
| Property, plant and equipment | 154 | 31 |
| Non-current financial assets | 29 | 45 |
| **Total non-current assets** | **9,270** | **9,729** |

Intangible assets consist of the SIIL agreement, whose value was measured as part of the acquisition in 2017 of the French company Genkyotex SA (formerly Genticel), a company acquired for accounting purposes. The estimated fair value of the SIIL contract and extensions was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence. The fair value of this contract was estimated at €10,697 thousand and is amortized on a straight-line basis over the life of the business plan used for the initial measurement of the contract's value (i.e., 2017-2035, corresponding to the life of the patent licensed to SIIL).

Property, plant and equipment mainly comprises laboratory equipment and instruments.

Non-current financial assets consist of the cash reserve linked to the liquidity contract and deposits.

#### 7.1.1.8. Current assets

| CURRENT ASSETS<br>(Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Other receivables | 1,500 | 2,156 |
| Cash and cash equivalents | 2,417 | 10,309 |
| **Total current assets** | **3,917** | **12,465** |

Other receivables mainly include:

- Research tax credit receivables (€899 thousand in 2019 compared with €893 thousand in 2018), which were repaid or are due to be repaid in the next financial year;
- Deductible VAT and VAT credits for a total of €229 thousand in 2019 (compared with €359 thousand in 2018);
- Credit notes receivable, advances and down payments for €75 thousand in 2019 (compared with €612 thousand in 2018), mainly relating to the down payments made to the contract research organization (CRO) in charge of the studies. The decrease in installments is related to the development stage of the Phase II PBC study.
- Prepaid expenses relating to current expenses.

Cash and cash equivalents consist of bank accounts and short-term investments with original maturities of less than three months.

#### 7.1.1.9. Shareholders' equity

| SHAREHOLDERS' EQUITY<br>(Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Capital | 8,683 | 7,935 |
| Non-voting shares | - | - |
| Additional paid-in capital | 126,118 | 124,183 |
| Currency translation reserve | (2,732) | (2,361) |
| Other comprehensive income | (697) | (514) |
| Reserves – Group share | (114,332) | (103,383) |
| Income (loss) – Group share | (7,203) | (11,417) |
| **Shareholders' equity, Group share** | **9,836** | **14,442** |
| Non-controlling interests | - | - |
| **Total shareholders' equity** | **9,836** | **14,442** |

The share capital as of December 31, 2019 totaled €8,683,449 and is divided into 8,683,449 ordinary shares fully subscribed and paid up for a par value of €1.00.

The change in shareholders' equity during the 2019 financial year mainly reflects:

- The effect of the conversion of convertible bonds issued for Yorkville in 2019 for €2,710 thousand;
- The loss for financial year 2019 in the amount of -€7,203 thousand.

Please refer to the statement of changes in shareholders' equity presented in the financial statements prepared in accordance with IFRS as adopted by the European Union, for the financial year ended December 31, 2019 in Section 18 of this Universal Registration Document.

#### 7.1.1.10. Non-current liabilities

| NON-CURRENT LIABILITIES (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Employee benefit obligations | 1,348 | 996 |
| Non-current financial liabilities | 17 | - |
| **Total non-current liabilities** | **1,364** | **996** |

Employee benefit obligations comprise the defined benefit obligation under Pillar 2 of the Swiss pension system and the provision for retirement benefits for employees under the French system. The increase in commitments stems mainly from the decrease in the discount rate in Switzerland from 0.85% in 2018 to 0.20% in 2019.

Non-current financial liabilities for financial year 2019 comprised the non-current portion of debt linked to lease payment obligations.

Refer to Section 8 of this Universal Registration Document for more information on the Group's sources of funds.

#### 7.1.1.11. Current liabilities

| CURRENT LIABILITIES (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Current financial liabilities | 848 | 3,641 |
| Derivative liabilities | 64 | - |
| Trade and related payables | 562 | 2,114 |
| Other current liabilities | 512 | 903 |
| **Total current liabilities** | **1,986** | **6,757** |

Current financial liabilities mainly include the current share of the bond.

Refer to Section 8 of this Universal Registration Document for more information on the Group's sources of funds.

### 7.1.2 The issuer's likely future development and its activities in the field of R&D

See section 5 of this Universal Registration Document.

## 7.2 OPERATING RESULTS

### 7.2.1. Income (loss) of the Company Genkyotex SA

Genkyotex SA's statutory income statement is set out as follows:

| GENKYOTEX SA<br>(Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Operating income | 3,446 | 7,229 |
| *o/w revenue* | *3,443* | *6,456* |
| Operating expenses | (16,319) | (8,385) |
| Operating income | (12,873) | (1,156) |
| Financial income (expenses) | (111,640) | 288 |
| Non-recurring income (expenses) | (290) | (20) |
| Corporate taxes | 899 | 893 |
| **Net profit/(loss)** | **(123,904)** | **5** |

Operating income amounted to €3,446 thousand in 2019 compared with €7,229 thousand in 2018, a decrease of €3,783 thousand. This mainly reflects:

- a €3,013 thousand decrease in revenue. In 2019 and 2018, revenue was generated exclusively with the subsidiary Genkyotex Suisse SA;
- In 2018, as part of the extension of the license transfer agreement with the Serum Institute of India (SIIL) for the Vaxiclase platform signed in June 2018, the Company recognized revenues in the amount of €750 thousand. In accordance with the terms of the agreement, which provides for development milestone payments, no payment was made in 2019.

Operating expenses amounted to €16,319 thousand in 2019, compared with €8,385 thousand in 2018, an increase of €7,934 thousand, mainly due to a provision recognized on the claims of Genkyotex Suisse for €11,230 thousand. This position is offset by the decrease in study purchases for €3,026 thousand.

Operating income thus reflected a net loss of -€12,873 thousand at December 31, 2019 compared with a net loss of -€1,156 thousand at December 31, 2018.

Financial income amounted to -€111,640 thousand at December 31, 2019 compared with €288 thousand at December 31, 2018. In 2019, it essentially consisted of a provision on the Genkyotex Suisse securities in the amount of €111,632 thousand. In 2018, it primarily consisted of the capital gain on the redemption of the capital bond subscribed by the Company for €331 thousand.

Non-recurring income was -€290 thousand at December 31, 2019 and is primarily made up of fee invoices for the previous financial year as well as the loss from treasury share buybacks.

After taking into account a research tax credit of -€899 thousand, the Company reported a net loss of -€123,904 thousand at December 31, 2019 compared to a profit of +€5 thousand at December 31, 2018.

### 7.2.2. Activities of subsidiaries

As of December 31, 2019, the only subsidiary of Genkyotex SA is Genkyotex Suisse SA, whose statutory financial statements are presented as follows:

| **GENKYOTEX SUISSE SA (Amounts in € thousands*)** | **12/31/2019** | **12/31/2018** |
|---|---|---|
| Operating income | 286 | 14 |
| *o/w revenue* | *280* | - |
| Operating expenses | (5,719) | (9,626) |
| Operating income | (5,433) | (9,612) |
| Financial income (expenses) | 304 | 279 |
| Non-recurring income (expenses) | - | - |
| Corporate taxes | - | (10) |
| **Net profit/(loss)** | **(5,130)** | **(9,343)** |

** Converted at the average EUR/CHF exchange rate for the period.*

Genkyotex Suisse SA's operating expenses were -€5,719 thousand at December 31, 2019 compared with -€9,626 thousand at December 31, 2018. This represents a decrease of €3,907 thousand (-€4,117 thousand at constant exchange rates), mainly due to:

- a reduction in the general and administrative costs of €3,139 thousand (-€3,259 thousand at constant exchange rates) related to reinvoicing by Genkyotex SA;
- a decrease of €406 thousand (-€452 thousand at constant exchange rates) in personnel expenses.

Financial income amounted to €304 thousand at December 31, 2019 compared with €279 thousand at December 31, 2018.

As of December 31, 2019 and December 31, 2018, it mainly consisted of foreign exchange gains for €315 thousand and €173 thousand, respectively.

The result was a net loss of -€5,130 thousand at December 31, 2019 compared with -€9,343 thousand at December 31, 2018.

# SECTION 8. CAPITAL RESOURCES

## 8.1. INFORMATION ABOUT THE ISSUER'S CAPITAL RESOURCES

### 8.1.1. Financing by equity capital

The following table summarizes, in terms of value, the main capital increases of Genkyotex SA (formerly Genticel SA) until the date of this Universal Registration Document:

| Period | Gross amount raised in € thousands | Transactions |
|---|---|---|
| **2001** | **49** | Contribution by founders |
| **2003 - 2008** | **3,163** | Capital increase |
| **2008 - 2010** | **516** | Capital increase (P1 preferred shares) |
| **2013** | **8,357** | Capital increase (P3 and P5 preferred shares) |
| **2014** | **3,246** | Exercise of share subscription warrants (BSA) Closing 2 |
| **2014** | **34,670** | IPO |
| **2014** | **2,452** | Capital increase (conversion of convertible bonds March 7, 2014) |
| **2015 - 2016** | **408** | Exercise of founders' warrants (BSPCE) |
| **2017** | **120,000** | Capital increase of 62,279,951 new shares at a subscription price of €1.9268 per share as payment for the in-kind contribution of Genkyotex Suisse SA shares |
| **2018** | **1,750** | Conversion of convertible bonds to Yorkville shares (2018 contract) |
| **2019** | **1,650** | Conversion of convertible bonds to Yorkville shares (2018 contract) |
| **2019** | **800** | Conversion of convertible bonds to Yorkville shares (2019 contract) |
| **2020** | **800** | Conversion of convertible bonds to Yorkville shares (2019 contract) |
| **2020** | **4,944** | Capital increase with shareholders' pre-emptive rights maintained |
| **Total** | **182,805** | |

As of the date of this Universal Registration Document, all bonds convertible into shares held by Yorkville under the issuance contract established on August 19, 2019 for a total nominal amount of €1,600 thousand have been converted through the issuance of 855,782 new shares with a unit value €1.00.

### 8.1.2. Financing through repayable advances

The Company has received several repayable advances which have all been repaid as of the date of this Universal Registration Document.

On January 11, 2013, Genkyotex SA (formerly Genticel SA) obtained from OSEO a repayable advance of up to €849 thousand to “extend the Phase 1 clinical studies of the ProCervix (GTL001) project.”

Following confirmation of completion of the program and after obtaining the statement of expenditure incurred on the project financed by OSEO, the repayable advance was reduced to €812 thousand to take into account the fact that actual expenditure was less than projected. This advance was repaid in quarterly installments between 2014 and 2019.

As of December 31, 2019, the debt had been fully repaid.

#### 8.1.3. Financing through the research tax credit

The Company has benefited from research tax credits since it was founded.

- The research tax credit ("CIR") declared for financial year 2017 (€558 thousand) was repaid in financial year 2018.
- The CIR declared for financial year 2018 (€893 thousand) was repaid in October 2019.
- The Company declared a CIR of €899 thousand for financial year 2019, for which it received the repayment in April 2020.

#### 8.1.4. Financing by issuing convertible bonds

The Company has entered into an agreement with Yorkville Advisors Global LP ("**Yorkville**"), the management company of a US investment fund, YA II PN, Ltd., covering the 12-month extension of the conversion period for the €1.6 million of convertible bonds issued in August 2018 and still held by Yorkville. To this end, on August 19, 2019, Genkyotex bought from Yorkville the balance of €1.6 million of bonds convertible into shares maturing on August 20, 2019 ("**2019 OCA**") that it still held, then immediately issued to a fund managed by Yorkville new convertible bonds, equivalent to that of the existing 2019 OCA, i.e., €1.6 million maturing on August 20, 2020 (the "**2020 OCA**").

The key features of the 2020 OCAs were:

- Nominal unit value equal to ten thousand euro (€10,000). Each 2020 OCA will be issued at a subscription price per 2020 OCA equal to 100% of its nominal unit value, a total nominal amount of one million six hundred thousand euro (€1,600,000).
- The 2020 OCAs (i) are freely assignable or transferable by the investor to any of its affiliates and (ii) may not be transferred to any other third party without the prior written consent of the Company.
- The 2020 OCAs are not listed or admitted to trading on the regulated markets of Euronext Paris or Euronext Brussels or on any other financial market. Each 2020 OCA expires twelve (12) months from its issue (the "**Maturity Date**"). In the event that a 2020 OCA is not converted before the Maturity Date, the Company is obliged to reimburse the outstanding amount in cash.
- The 2020 OCAs do not bear any interest. However, in the event of the occurrence of a Default, each 2020 OCA outstanding will bear interest at the rate of 15% per year from the date of the Default and until (i) the date on which the Default is resolved, or (ii) the date on which the 2020 OCA has been fully converted and/or repaid, if the Default has not yet been resolved.
- The number of new shares issued by the Company for the benefit of each 2020 OCA holder when converting one or more 2020 OCAs corresponds to the amount of the conversion divided by the applicable Conversion Price. The "**Conversion Price**" is equal to 92% of the weighted average share price quoted on Euronext (as reported by Bloomberg) (the "**Average Prices**") on the five (5) consecutive stock exchange sessions up to the trading session immediately before the conversion date.

The remaining outstanding 2020 OCAs were converted into new Company shares on January 15, 2020. As of the date of the Universal Registration Document, all of the 2020 OCAs held by Yorkville under the contract established on August 19, 2019 have thus been converted into new Company shares.

## 8.2. THE ISSUER'S CASH FLOWS

The following information is derived from the 2019 annual consolidated financial statements included in the Company's annual financial report as of December 31, 2019 appended to this Universal Registration Document.

### 8.2.1. Cash flows from operating activities

Cash consumed in operating activities amounted to -€7,588 thousand for the financial year ended December 31, 2019 versus -€8,866 thousand for the financial year ended December 31, 2018. Cash consumption mainly reflects the Company's research activities.

### 8.2.2. Cash flows from investing activities

Cash generated by investing activities amounted to -€1 thousand for the financial year ended December 31, 2019 versus €3,279 thousand for the financial year ended December 31, 2018.

Cash flows generated in 2018 primarily relate to the redemption of the capital bond subscribed by the Company for €3,283 thousand.

### 8.2.3. Cash flows from financing activities

Cash flows from financing activities for the years presented are as follows:

| CASH FLOWS FROM FINANCING ACTIVITIES (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Reduction in right-of-use financial debt (IFRS 16) | (130) | - |
| Gross financial interest paid | (5) | - |
| Repayment of advances | (118) | (291) |
| Capital increase expenses | (27) | - |
| Bond issuance | - | 4,658 |
| Issuance of share subscription warrants (BSA) | - | 242 |
| **Cash flows from financing activities** | **(281)** | **4,609** |

## 8.3. BORROWING REQUIREMENTS AND FUNDING STRUCTURE OF THE ISSUER

Information on the financing of the Group's activities is provided in Section 8.1 “Information about the issuer's capital resources” of this Universal Registration Document.

## 8.4. POSSIBLE RESTRICTIONS ON THE USE OF THE ISSUER'S CAPITAL RESOURCES

None.

## 8.5. SOURCES OF FUNDS FOR ANTICIPATED CASH FLOWS

As of the date of this Universal Registration Document, the Company has sufficient cash resources to carry out its operations until early 2021 (see Section 3.2.1 Liquidity Risk in this Universal Registration Document).

# SECTION 9. REGULATORY ENVIRONMENT

Research and development, preclinical testing, clinical studies, facilities, as well as the manufacturing and marketing of the Company's drug candidates are and will continue to be subject to complex legal and regulatory provisions defined by various public authorities in France, Europe, In the United States and other countries around the world. The European Medicines Agency ("**EMA**"), the US Food and Drug Administration ("**FDA**"), the *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (French agency for the safety of drugs and healthcare products) ("**ANSM**") and the equivalent regulatory authorities in other countries impose significant constraints for the development (including clinical trials), manufacturing and marketing of products such as those developed by the Company.

In the event of non-compliance with these regulations, the regulatory authorities may impose fines, seize or withdraw products from the market, or suspend, in part or in full, their production. They may also withdraw marketing authorizations previously granted or refuse applications submitted by the Company for authorizations and may take legal action. These regulatory constraints are important in assessing whether an active ingredient can eventually become a drug, as well as in assessing the time and investments needed for such development.

Although there are differences from country to country, the development of therapeutic products for human use must meet certain common regulatory requirements across developed countries. To obtain market authorization for a product, it is generally necessary to provide evidence of its efficacy and safety, as well as detailed information on its composition and manufacturing process. This involves conducting important laboratory tests, preclinical pharmaceutical developments and clinical trials. The development of a new drug, from basic research to market, thus involves five steps: (i) research, (ii) preclinical development, (iii) human clinical trials, (iv) marketing authorization, and (v) marketing and sale.

## 9.1 PRECLINICAL DEVELOPMENT

Preclinical studies include laboratory assessment of the purity and stability of the active pharmaceutical ingredient and the formulated product, as well as tolerance assessment studies (toxicology studies), activity and behavior of the drug candidate in vitro and in animal studies (in vivo) before clinical trials can be initiated in humans. The conduct of preclinical studies is subject to legal and regulatory provisions, as well as good laboratory practices ("GLP"). All preclinical trial results are submitted to the regulatory authorities in conjunction with the request for initiation of clinical trials.

## 9.2 CLINICAL TRIALS IN HUMANS

Clinical studies are commonly conducted in three phases (Phase I, II and III), usually sequentially, but can also be conducted jointly, including in different indications or different therapeutic combinations. Each phase must achieve the necessary objectives and conditions for the well-being of patients before the start of a new phase. Trials—sometimes referred to as Phase IV trials—may also be conducted after the initial market authorization. Such trials are intended to obtain more information on the treatment of patients in the targeted therapeutic indication. In some cases, the competent regulatory body may require a Phase IV clinical trial as a condition of approval.

Clinical trials can be conducted in the United States, Europe, or the rest of the world provided that they have been authorized by the regulatory authorities and by the independent ethics committees

of each of these countries. Regulatory authorities may oppose clinical study protocols proposed by companies that request testing, suspending or requiring significant changes.

In most countries, clinical trials must comply with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human use ("ICH") standards of Good Clinical Practice.

In addition, Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of individuals with regard to the processing of personal data and the free movement of such data (GDPR), which became effective on May 25, 2018, significantly enhances the rights of citizens by giving them more control over their personal data. In particular, French national law was brought into conformity with the GDPR by updating Law No. 78-17 of January 6, 1978 on information technology, data files and civil liberties (Law No. 2018-493 of June 20, 2018 and Rewriting Order No. 2018-1125 of December 12, 2018).

In accordance with the Information Technology Act and Freedoms, personal data collected during clinical trials are reported to France's Data Protection Authority — *Commission Nationale Informatique et Liberté* ("CNIL"). Patients have a right to access and rectify such data. Lastly, patients should be kept informed of the conduct of clinical trials and overall research results on a regular basis.

The conduct of clinical trials must therefore comply with complex regulations throughout the various phases of the process which are based on the principle of informed consent of the patients to whom the product(s) is to be administered. Information on the purpose, methodology and duration of the research, as well as expected benefits, constraints and foreseeable risks due to the administration of the products communicated is summarized in a written document submitted to patients prior to their participation in the research.

### 9.2.1 Authorization of clinical trials

#### 9.2.1.1 In the European Union (EU)

The current European regulatory framework is derived from the European Directive 2001/20/EC on the conduct of clinical trials which was intended to harmonize the regulatory framework governing clinical trials by introducing common rules for the control and authorization of trials within The European Union; Member States, however, have transposed it and applied the provisions differently.

Accordingly, the European regulation on clinical trials of medicinal products for human use was therefore reviewed and replaced by Regulation (EU) No. 536/2014 of April 16, 2014, repealing Directive 2001/20/EC, adopted on April 16, 2014 and published in the Official Journal of the European Union on May 27, 2014. This regulation, which is directly applicable in all EU Member States, lays down the following points in particular:

- Submission of a single authorization application through the portal associated with the EU database, including a common part jointly assessed by all EU members, and a national part covering the ethical and operational aspects of the test evaluated by each EU Member State independently. A single decision covering all aspects of the application will thus be issued by each of the Member States concerned;

- Increased transparency with regard to clinical trials authorized in the EU: The EU database will be a source of public information, without prejudice to the protection of personal data, the protection of confidential commercial information and the protection of confidential communication between Member countries and of the supervision of clinical trials by Member States. Public information will include, for drugs under development, clinical trial authorization, general trial information, and a summary of the final results.

Although this regulation came into force on June 16, 2014, it will only apply six months after confirmation that the IT portal and database provided for in this regulation are fully operational. This is not the case to date, although it is currently estimated that this regulation would be implemented in 2020. As a result, the aforementioned Directive 2001/20/EC on clinical trials continues to apply.

Under the current rules, a clinical trial can only begin after it has been authorized in each of the Member States in which it is to be conducted by two separate authorities: the competent national authority (NCA) and one or more Ethics Committees (EC). Similarly, all suspected unexpected serious adverse reactions (SUSARs) to an experimental drug occurring during the clinical trial should be reported to the NCAs and the ECs of the Member State in which they occurred.

#### 9.2.1.2 In the United States

In the United States, an application for a new clinical trial, known as Investigational New Drug ("**IND**") application, must be submitted to the FDA and must be accepted before clinical trials in humans can begin. A trial can only start if it has obtained approval from the FDA and from an ethics committee, the Institutional Review Board (IRB).

This application concerns early scientific data and the pharmaceutical documents, preclinical and clinical data (if any), including the clinical protocol. In the absence of FDA objection, the IND application becomes effective 30 days from receipt by the FDA. This time frame is intended to allow the FDA to examine the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during or after this 30-day period, the FDA may request the suspension of clinical trials, whether planned or in progress, and request additional information. Such temporary suspension is maintained until the FDA has obtained the clarification it requires.

In addition to the requirements of an IND request, an independent ethics committee, or IRB, representing each institution participating in the clinical trial, must review and approve the plan for any clinical trial prior to the start of the trial at that institution, and the IRB must conduct a permanent review and reapprove the study at least once a year. The IRB is required to review and approve, among other things, the study protocol and information on informed consent that has to be given to the study subjects. An IRB must act in accordance with FDA regulations. An IRB may suspend or cancel the authorization of a clinical trial, if the clinical trial is not performed in accordance with the IRB requirements or if the drug candidate has been associated with unexpected serious effects on patients.

The main objectives of the FDA when examining an IND are to ensure patient safety and the respect of patient rights and to ensure the adequacy of the quality of the research to enable an assessment of the safety, purity and effectiveness of the compound. The decision to stop the development of a compound may be made by a health authority body such as the FDA, an IRB or ethics committee, or by the Company for a variety of reasons. In addition, some trials are supervised by an independent group of qualified experts organized by the trial sponsor, known as the data monitoring board or

committee. This group authorizes or does not allow the continuation of a trial at designated checkpoints on the basis of the group's unique access to available study data. Development may be suspended or interrupted during any phase of clinical trials if it is determined that participants or patients are exposed to an unacceptable health risk. The Company may suspend or discontinue development for any other reason based on the Company's evolving objectives and/or competitive environment.

## 9.3 MARKETING AUTHORIZATION

Medical products may only be marketed once A Marketing Authorization ("MA") is obtained, issued by the competent European or national authorities—the EMA or the ANSM—or the FDA for the United States.

Pharmaceutical laboratories submit an application with these authorities for MA or NDA (New Drug Application)/BLA (Biologics License Application) for the United States which will be evaluated according to scientific criteria of quality, safety and efficacy. This application is written in a standardized format: The Common Technical Document (CTD) format. This format is used in Europe, the United States and Japan. The MA file describes both the manufacture of the active substance, the manufacture of the finished product, non-clinical and clinical studies.

In the European Economic Area (EEA), which is still composed of the 27 Member States of the European Union and Norway, Iceland and Liechtenstein, as well as the United Kingdom which left the European Union on January 31, 2020, but where the European Union's pharmaceutical legislation continues to apply until December 31, 2020, marketing authorizations may be granted either at European level (European MA) or at national level (national MA).

A drug may be withdrawn from the market either directly by the laboratory or at the request of health authorities when a serious problem arises, including safety or non-compliance with manufacturing rules.

### 9.3.1. In the European Union (EU)

The European MA is delivered centrally by the European Commission in accordance with the centralized procedure, on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), and is valid throughout the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology drugs, orphan drugs, and drugs containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The centralized procedure is optional for products containing a new active substance that has not yet been authorized in the EEA or for products that constitute a significant therapeutic, scientific or technical innovation or that are in the interest of public health in the European Union.

National MAs are issued at national level by the competent authorities of the EEA Member States and are valid in their territory only. National MAs may be issued for products that do not fall within the mandatory scope of the centralized procedure.
In accordance with the procedures described above, the EMA or the competent authority of the EEA Member State must, before granting an MA, assess the benefit-to-risk ratio of the product on the basis of scientific criteria of quality, safe use and efficacy.

Similarly, according to Regulation (EC) No. 1901/2006, all AM applications for new drugs must include the results of studies as described in a pediatric investigation plan (PIP) agreed to by the EMA and the applicant, unless the drug is exempted from it under a deferral or waiver. Before the EMA can begin to assess a European MA application, it must ensure that the applicant has completed the proposed PIP. The applicant and the EMA may, if warranted, agree to amend the PIP to facilitate its validation. Amendments are not always possible; they may—still at this stage—require the applicant to withdraw its MA application and conduct additional, clinical and non-clinical studies according to the authorized PIP.

### 9.3.2. In the United States

In the United States, the FDA regulates the marketing and sale of drugs under the Federal Food, Drugs and Cosmetics Act (FDCA), the Public Health Service Act (PHSA) and their implementing regulations. Biological agents are also subject to other federal, state and local laws and regulations. Obtaining authorizations and complying with federal, state, local and foreign laws and regulations requires considerable investment in time and financial resources. Any incident of non-compliance with U.S. regulations during the drug development process, authorization process or after the authorization obtained may expose the applicant and/or sponsor to various administrative and judicial penalties, including: clinical suspension, FDA refusal to authorize applications, withdrawal of authorization, delays in imports/exports, warning letters and other binding letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusal to award public contracts, restitution, profit-taking, or investigations and sentencing to civil or criminal penalties at the initiative of the FDA and the Department of Justice or other government agencies.

In short, clinical trials, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import and export, marketing, among others, the Company's drug candidates are governed by numerous regulatory texts written by government authorities applicable in the United States and other countries. In the United States, the FDA governs pharmaceutical products in accordance with the provisions of the FDCA. The steps to be taken before obtaining a marketing authorization for a drug in the United States are generally as follows:

1. Conducting laboratory pre-clinical trials, animal studies and formulation studies in accordance with FDA Good Laboratory Practice (GLP) regulations;
2. Submission of an IND application to the FDA for a first clinical trial in the United States in humans, which must be accepted before the start of that trial — and then maintained for the following clinical trials;
3. Authorization by an Independent Institutional Review Board (IRB), representing each clinical site, prior to the start of each clinical trial;
4. Conducting adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for each indication, and conducted in accordance with Good Clinical Practices (GCP);
5. Preparation and submission of an NDA to the FDA;
6. FDA acceptance, review and approval of the NDA, with possible review by an Advisory Board;
7. Performance by the FDA of an inspection of manufacturing facilities in which the product or components of the product are manufactured; the purpose of this inspection is to assess their compliance with current good manufacturing practices (cGMP);
8. Performance by the FDA of audits of clinical trial sites to ensure compliance with GCP and clinical data integrity;

9. Applicant's commitment to comply with any post-MA requirements, including a Risk Evaluation and Mitigation Strategies (REMS) program and to conduct post-MA studies required by the FDA.

The authorization process requires a lot of time, effort and financial resources, without any guarantee that the authorization will be granted in a timely manner, or at all.

### 9.3.3. Waivers from common registration procedures

Some waivers allowing the faster marketing and sale of medicinal products exist in parallel with the usual procedure described above.

In the EU, these are:

- The conditional MA: valid for one year only instead of five. It is granted only if the drug meets unmet medical needs, and if the public health benefits outweigh the risk of uncertainty due to incomplete drug evaluation. The issuance of a conditional MA is subject to the finalization of clinical trials and/or the completion of new trials to confirm the drug's benefits/risks.

- The accelerated assessment: the evaluation procedure is accelerated (150 days instead of 210 days) when a drug is of major interest to public health and a therapeutic innovation. The PRIME Project (Priority Medicines), an EMA initiative launched in 2015, also allows for early identification (from Phase II /III) of medicines eligible for the accelerated procedure and enhanced support through scientific advice and dialog throughout development.

- The exceptional circumstances MA: an MA can be granted exceptionally, subject to re-evaluation each year, when the drug evaluation documents cannot be submitted fully at the outset, for example when a therapeutic indication corresponds to too few patients, or the collection of the necessary information would be unethical.

- The temporary authorization for use (ATU): this is the possibility for a Member State to use a medicinal product which does not yet have MA in the country, for the treatment of serious or rare diseases for which adequate treatment does not yet exist. In France, a temporary authorization for use may be granted by the ANSM for a specific patient (nominative ATU), or for a group of patients (cohort ATU).

In the United States, the FDA is authorized to give certain drugs a designation that leads to an accelerated procedure or support, if they are intended to address an unmet medical need in the treatment of a disease or to treat serious or life-threatening conditions:

- “Accelerated Approval” procedure: intended to bring to market promising products for the treatment of serious conditions based on preliminary evidence prior to formal demonstration of patient benefits. The FDA can rely on an effect, substitution outcome, or any other outcome that has reasonable chances of being predictive of clinical benefit, not on a well-defined clinical endpoint. Thus, a surrogate endpoint (or marker) is a result obtained in a laboratory or physical sign that is not, in itself, a direct measure of the patient's sensations, body functions or survival, but that can be used to predict therapeutic benefit. The MA that is granted can be considered as interim approval with written commitment to complete clinical

studies that demonstrate real benefit for the patient. This procedure corresponds to the so-called “conditional MA” procedure in Europe.

- “Priority Review” procedure: used for drugs that treat serious conditions and present major therapeutic advances or provide treatment for a disease in which there is no suitable therapy. This procedure means that the time it takes the FDA to review an application is reduced to six months (instead of 10). Priority Review corresponds to the so-called “accelerated assessment in Europe” procedure.

- “Fast track” designation: the FDA may grant “Fast Track” designation to a product if the latter is intended—either alone or in combination with other drugs—to treat a serious or life-threatening illness or condition, and it demonstrates the potential to address unmet medical needs related to that illness or condition. If “Fast Track” designation is granted to a drug, the sponsors will likely have many exchanges with the FDA. In addition, the FDA may review certain sections of the NDA of a fast-tracked drug on an ongoing basis before the file is submitted in full. A “Fast Track” designation does not necessarily lead to the “Priority Review” or “Accelerated Approval” procedure.

- “Breakthrough Therapy” designation: The FDA may assign a “Breakthrough Therapy” designation to a drug if the latter is intended to treat a serious condition and if preliminary clinical evidence demonstrates that the product may demonstrate substantial improvement over other therapies on clinically significant endpoint(s). This designation provides the same benefits as the “Fast Track” designation, but it also provides extensive support from the FDA to facilitate the development and organizational commitment of the agency to that end.

If further research or experiments shows that a product presents risks while it is marketed, the FDA may require its immediate withdrawal. In addition, the FDA may withdraw marketing authorization for other reasons, especially if post-authorization studies are not diligently conducted.

## 9.4 POST-AUTHORIZATION REGULATION

### 9.4.1. Post-authorization in the EU

#### 9.4.1.1. Pharmacovigilance system requirements

The holder of an MA issued by the competent European authorities must establish and maintain a system of pharmacovigilance and appoint a Qualified Person Responsible for Pharmacovigilance (“QPPV”). The QPPV's main obligations include promptly reporting suspected serious adverse reactions and submitting Periodic Safety Update Reports (PSURs).

Any new MA application must include a Risk Management Plan (RMP) describing the risk management system that the Company will implement and which sets out measures to prevent or minimize risks associated with the drug. The regulatory authorities may also make the MA conditional on the performance of specific obligations. These risk mitigation measures or post-authorization obligations may include, among other things, enhanced security monitoring, more frequent submission of PSURs or conduct of additional clinical trials or post-authorization safety studies. The RMPs and the PSURs are regularly made available to third parties who request it, subject to being redacted.

#### 9.4.1.2. Regulatory requirements for advertising

Any advertising or promotion of a drug must comply with the authorized summary of its characteristics and, therefore, any promotion of unauthorized features is prohibited. The EU prohibits the direct advertising of prescription drugs to consumers. Although the general principles on advertising and drug promotion are established by EU directives, the details are governed by the rules of each Member State and may differ from country to country.

If the Company does not comply with applicable foreign regulatory requirements, it could be subject, among other things, to fines, suspensions or withdrawals of regulatory approvals, drug recalls, drug seizures, restrictions of use and criminal prosecution.

#### 9.4.1.3. Drug coverage, pricing, and reimbursement

In the EU, pricing and reimbursement systems vary widely from country to country. Some countries provide that drugs can only be marketed after a reimbursement price has been agreed. Some countries may require additional studies comparing the cost-effectiveness of a drug candidate with current therapies or for the evaluation of medical technologies, in order to obtain approval of reimbursement or pricing. For example, the EU offers its Member States the possibility of restricting the range of medicines for which their national health insurance system provides for reimbursement and controlling the price of medicines for human use. EU Member States may agree on a specific price for a drug or adopt, instead, a system of direct or indirect control of the profitability of the company putting the drug on the market. Other Member States allow companies to set the price of medicines themselves, but monitor and control the quantity of prescriptions and give instructions to physicians to limit the requirements.

Recently, many EU countries have increased the amount of drug discounts, and these efforts could continue as countries attempt to manage their healthcare spending. In particular, given the severe fiscal crises and the debt situation of many EU countries. Downward pressure on healthcare costs in general, including prescription drugs, has become considerable. As a result, increasingly high barriers are created when new drugs are put on the market. Changes to the political, economic and regulatory situation can further complicate the negotiation of prices. This price negotiation can continue after the reimbursement has been obtained. The reference prices used by various EU Member States and parallel trade, i.e., the arbitrage between low and high-priced Member States, can further reduce prices. There is no guarantee that a country that has price control procedures or imposes limits on the reimbursement of pharmaceutical products will apply advantageous agreements on the reimbursement and price of any product, if approved in that country.

### 9.4.2. Post-approval in the United States

Biologic products manufactured or distributed under FDA authorizations are subject to the FDA's general and permanent regulations, including, but not limited to, record keeping, periodic reporting, sampling and distribution requirements. advertising and promotion and reporting of negative experiences with the product. After approval, most changes to the approved drug, such as the addition of new indications or other label claims, are subject to FDA review and approval. There are also ongoing annual user fee payment requirements for any marketed product and any facility in which

the product is manufactured, as well as a processing fee for any additional application with clinical data.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved products must register their institutions with the FDA and government agencies and are subject to unexpected periodic inspections by the FDA and these public agencies to verify compliance with GMP requirements. Changes to the manufacturing process are strictly regulated and often require prior approval from the FDA prior to implementation. FDA regulations also require the review and rectification of any deviation from GMP requirements, and impose reporting and documentation requirements for the sponsor and any third-party manufacturer which the sponsor may choose to use. As a result, manufacturers must continue to devote time, funds, and efforts in production and quality control to maintain their GMP compliance level.

Once an authorization has been granted, the FDA may withdraw it if compliance with regulatory requirements and standards is not maintained or if problems arise after the product is released. Late discovery of previously unknown problems with a product, such as adverse reactions of unexpected severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in the revision of the approved label to add new safety information, such as the obligation to conduct post-market clinical studies or trials to assess new safety risks or the imposition of distribution or other restrictions under a REMS program.

Other potential consequences include:

- Restrictions on the marketing or manufacturing of the product, the suspension of the authorization, or the total withdrawal of the product from the market or product recalls;
- Fines, warning letters or suspension of clinical trials after approval;
- The FDA's refusal to approve pending applications or additions to approved BLAs, or the suspension or revocation of product license approvals;
- The seizure or detention of the product, or the non-authorization of the import or export of the products; and
- Injunctions or the imposition of civil or criminal fines.

The FDA strictly regulates the marketing, labeling, advertising and promotion of products put on the market. Promotion of products may only be performed for approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce laws and regulations prohibiting the promotion of unauthorized uses. The promotion of products sold by prescription may only be made for approved indications and in accordance with the provisions of the approved labeling. However, companies can also communicate truthful and non-misleading information that is consistent with the labeling. A company that is deemed to have improperly promoted unauthorized uses may incur significant liability.

In addition, the distribution of prescription pharmaceuticals is governed by the Prescription Drug Marketing Act (the "**PDMA**"), its implementing regulations, and the Drug Supply Chain Security Act (the "**DSCA**") which govern the distribution and monitoring of regulated prescription drug samples at the federal level and set the minimum requirements for the states' regulations for drug distribution. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCA imposes requirements to ensure responsible distribution and to identify and remove counterfeit and other illicit products from the market.

#### 9.4.2.1 Healthcare laws and regulations in the United States

Healthcare providers and third-party payers play an essential role in the recommendation and prescription of biologic products that are authorized for marketing. Arrangements with suppliers, consultants, third-party payers and customers are governed by laws and regulations generally applicable to the fight against fraud and abuse, corruption, false allegations, laws on transparency and confidentiality of patient data and other health care laws and regulations that may restrict business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The U.S. Anti-Kickback Statute, which specifically prohibits individuals and entities from claiming, offering, paying, receiving or providing compensation, directly or indirectly, in cash or in kind, knowingly and deliberately, to induce or reward the presentation of a person for, or the purchase, order or recommendation of, any property or service, for which a payment can be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- The U.S. laws to combat false civil and criminal allegations, including the Civil False Claims Act, and civil fines laws, prohibiting individuals or entities, among other things, from deliberately making or causing to be made false claims to the federal government, fictitious or fraudulent or deliberately preparing or causing to be prepared, using or causing to be used a fraudulent record or statement to avoid, reduce or conceal an obligation to pay money to the federal government;

- The U.S. 1996 Health Insurance Portability and Accountability Act ("HIPAA"), which creates additional federal criminal laws prohibiting, among other things, the deliberate execution or attempted execution of a scheme to defraud a healthcare benefit program or the making of false statements regarding healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which imposes obligations on covered entities and their business associates, including mandatory contractual terms, the preservation of the confidentiality, security and transmission of individually identifiable health information.

- Federal transparency requirements known as the Federal Physician Payments Sunshine Act, under The Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act (the "ACA"), which requires certain manufacturers of drugs, medical devices, biologics and medical supplies report annually to the Centers for Medicare & Medicaid Services (the "CMS"), within the United States Department of Health and Human Services, information on payments and other transfers of value made by that entity to physicians and teaching hospitals, and any ownership or investment interests held by physicians and their immediate family members; and

- Similar state and foreign laws and regulations—such as the states' anti-corruption and false claims acts—that may apply to healthcare items or services reimbursed by third-party non-governmental payers, including private insurers.

Some state laws require pharmaceutical companies to comply with the voluntary compliance guidelines of the pharmaceutical industry and the relevant compliance guide issued by the federal government, in addition to requiring manufacturers to report payment information to physicians and other healthcare providers or marketing expenses. Some state laws require the reporting of information on prices of drugs and biologics, and certain state and local laws require registration of pharmaceutical sales representatives. State and foreign laws also govern the confidentiality and security of health information under certain circumstances, and many of these laws differ significantly from each other and often are not invalidated by HIPAA, making compliance efforts difficult.

Failure to comply with these laws or other applicable government regulations may result in heavy penalties such as civil, criminal and administrative penalties, damages, fines, reimbursement, imprisonment, potential exclusion from government-funded health care programs such as Medicare and Medicaid, additional monitoring and reporting requirements, and contractual damages, reputational damage, reduced profits and future gains, and reduced operations.

#### 9.4.2.2. Pharmaceutical coverage, price and reimbursement

In the United States, patients with prescribed treatments and providers supplying prescribed services generally rely on third parties to reimburse all or part of the associated healthcare costs. There is considerable uncertainty about the status of coverage and reimbursement of products approved by the FDA and other government agencies. Therefore, even if a drug candidate is approved, sales of the product will depend in part on the extent to which third-party payers, including government health programs in the United States such as Medicare and Medicaid, commercial medical insurance companies and managed care organizations, ensure product coverage and establish sufficient reimbursement levels for the product. The process of determining the coverage of a product by a payer may differ from the pricing process or the reimbursement rate that the payer will pay for the product after coverage is approved. Third-party payers increasingly challenge the prices charged, checking medical necessity, studying the cost-effectiveness of drugs and medical services, and imposing controls to manage costs. Third-party payers may limit coverage to specific products on an approved list, also known as a formulary, which may not include all products approved for a particular indication.

In order to ensure the coverage and reimbursement of any drug that can be approved for sale, a company may need to conduct cost-effective drug studies to demonstrate the medical necessity and cost-effectiveness of the drug, in addition to the costs required to obtain FDA clearance and other comparable marketing costs. However, drug candidates may not be considered medically necessary or cost-effective. A third-party payer's decision not to cover a drug candidate could reduce its use by the physician once the drug has been approved and have a significant adverse effect on sales, results of operations and the financial position. In addition, a payer's decision to cover a product does not imply that an appropriate reimbursement rate will be approved. Moreover, a payer's decision to cover a product does not guarantee that other payers will also cover and reimburse the product, and the level of coverage and reimbursement may differ significantly from one payer to another.

Reducing healthcare costs has also become a priority for federal, state and foreign governments, and drug prices are particularly targeted in this context. Governments show great interest in implementing cost reduction programs, including price controls, restrictions on reimbursements, and generic substitution obligations. The adoption of price control and cost reduction measures and the adoption of more restrictive policies in jurisdictions in which controls and measures are already in place could further limit a company's revenue from the sale of any approved product. Third-party coverage policies and reimbursement rates may change at any time. Although favorable coverage and reimbursement status is obtained for one or more products for which a company or its employees

obtain marketing authorization, less favorable coverage policies and reimbursement rates can be applied in the future.

## SECTION 10. TREND INFORMATION

Information on trends can be found in Section 5, “Business overview” of this Universal Registration Document.

**Update on Genkyotex's business and cash flow as of March 31, 2020 (excerpts from the press release for the fourth quarter of 2020 published on April 23, 2020)**

Genkyotex (…) today reported cash and cash equivalents of €5.6 million as of March 31, 2020. This amount does not include the French research tax credit of €0.9 million which was received by the Company in April 2020. The existing cash and cash equivalents provide cash runway to end of February 2021.

**The COVID-19 update**

In the context of the COVID-19 pandemic, the Company is following the guidelines and recommendations in order to protect its employees and subcontractors. The Company has also implemented strategies to mitigate the impact of the global shutdown on its business and operations. The Company has asked its employees in France and Switzerland to work from home and organize meetings and events virtually as much as possible. To date, the Company is only anticipating a limited impact on its operations, including the planned discussions with regulatory authorities, the conducting of clinical trials as well as interactions with the scientific community and other stakeholders. The Company will continue to monitor the possible impact of COVID-19 on the conducting of clinical trials and discussions with health authorities and, depending on the evolution of the pandemics and of its material impact on such trials and discussions, will report to the markets on any such material impact.

The Company has made progress in its key activities, in particular in the end-of-phase 2 discussions with regulators with a view to a phase 3 study in Primary biliary cholangitis (PBC), and the conducting of the phase 1 study with setanaxib as described in the clinical highlights section below. The launch of the phase 2 trial in the IPF is still expected in 2020 and could occur in the first semester despite the COVID-19 situation.

**Clinical developments**

- End-of-phase 2 discussions with regulators for PBC: an end-of-phase 2 meeting with the US Food and Drug Administration (FDA) is planned for April, as previously indicated. In line with FDA’s remote work guidelines, the meeting will take place via conference call. The Company also plans to submit its final briefing document to the European Medicines Agency (EMA) in Q2 2020, as expected.

- IPF phase 2 trial: as previously reported, the U.S. Food and Drug Administration (FDA) and the relevant Institutional Review Board (IRB) have approved the protocol of the Phase 2 IPF trial, allowing the initiation of patient enrollment. The launch of the study is still expected in 2020 and could occur in the first semester despite the COVID-19 situation. The trial is fully funded by a US$8.9 million grant awarded by the U.S. National Institutes of Health (NIH). The study is being led by Professor Victor Thannickal from the University of Alabama in Birmingham and includes a consortium of five investigational centers of excellence in the United States. The study will evaluate the safety and efficacy of setanaxib in 60 IPF patients receiving standard of care theraphy (pirfenidone or nintanib).

- Enrolled patients will be treated with setanaxib or a matching placebo for 24 weeks. Efficacy endpoints include changes in plasma o,o'-dityrosine, a biomarker based on the mechanism of action of setanaxib, as well as standard clinical outcomes that include the 6-minute walking test and forced vital capacity (FVC). Plasma levels of collagen fragments will also be assessed. The safety and tolerance of setanaxib will also be assessed. The trial size, design, and endpoints are adequate to support the initiation of a phase 3 program should there be a positive outcome.

- DKD phase 2 trial: following positive efficacy and safety results of the Company's Phase 2 trial of setanaxib in primary biliary cholangitis (PBC), the DKD trial protocol was amended to increase the dose to 400 mg BID. To date, 23 patients have already completed the full 48-week treatment and no safety signals have been identified. The DKD trial is being conducted primarily in Australia, with work ongoing to activate centers in New Zealand, Denmark and Germany. In the context of the COVID-19 pandemic, investigators have taken steps to minimize patient visits to investigation centers in accordance with applicable rules and recommendations. Adequate drug supplies have been made available to the participating centers and patients. Despite the relatively low rate of SARS-CoV-2 infection in Australia, investigators cannot exclude a potential slowdown in new patient enrollment in the study.

- Phase 1 study with setanaxib at high doses: the Company plans to conduct an additional phase 1 study to investigate the pharmacokinetics, potential for drug interactios, and safety profile of setanaxib at doses up to 1,600 mg. The study protocol was submitted to local and national regulators and the study it is still expected to start in H1 2020.

**Financial highlights**

On March 31, 2020, Genkyotex's cash and cash equivalents totaled €5.6 million vs. €2.4 million on December 31, 2019. This includes the €4.9 million rights issue completed in February 2020, but does not include the French research tax credit of €0.9 million which was received by the Company in April.

Despite the COVID-19 situation, the Company still expects its current resources to support anticipated operations until the end of February 2021, taking into account the facts and assumptions detailed in Note 2.1 “Going concern” of the December 31, 2019 consolidated financial statements. The Company will continue to inform the market of the potential impacts of COVID-19 on its operations.

## SECTION 11. PROFIT FORECASTS OR ESTIMATES

The Company does not provide forecasts or estimates of profits.

# SECTION 12. ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND SENIOR MANAGEMENT

## 12.1. EXECUTIVES AND DIRECTORS

### 12.1.1. Composition of the Board of Directors and senior management

As of the Date of the Universal Registration Document, the Board of Directors and senior management comprised the following members:

| Name | Office/Function | Date of first appointment | Expiration date of term |
|---|---|---|---|
| Claudio Nessi | Chairman of the Board of Directors<br><br>Member of the Appointments and Compensation Committee | CGSM 2/28/2017 | OGSM called to approve the financial statements for the year ended 12/31/2019 |
| Ilias (Elias) Papatheodorou | Director and Chief Executive Officer | CGSM 2/28/2017 | OGSM called to approve the financial statements for the year ended 12/31/2019 |
| Eclosion2 SA represented by Jesús Martin-Garcia | Director<br><br>Member of the Audit Committee | CGSM 2/28/2017 | OGSM called to approve the financial statements for the year ended 12/31/2019 |
| Andera Partners represented by Gilles Nobécourt | Director<br><br>Chair of the Appointments and Compensation Committee | CGSM 7/31/2008 | OGSM called to approve the financial statements for the year ended 12/31/2019 |
| Catherine Moukheibir | Independent Director<br><br>Chair of the Audit Committee<br><br>Member of the Appointments and Compensation Committee | CGSM 2/28/2017 | OGSM called to approve the financial statements for the year ended 12/31/2019 |
| Mary Tanner | Independent Director<br><br>Member of the Audit Committee | Ratification by CGSM 6/11/2015 | OGSM called to approve the financial statements for the year ended 12/31/2019 |
| Stéphane Verdood | Observer | CGSM 2/28/2017 | OGSM called to approve the financial statements for the year ended 12/31/2019 |

| Name | Office/Function | Date of first appointment | Expiration date of term |
|---|---|---|---|
| Joseph McCracken | Observer | CGSM 2/28/2017 | OGSM called to approve the financial statements for the year ended 12/31/2019 |

For the purposes of their corporate duties, the members of the Board of Directors and senior management are domiciled at the Company's registered office.

As of the date of the Universal Registration Document, the other corporate duties and functions performed by the members of the Board of Directors and senior management are:

### 12.1.2. Other current corporate duties outside the Group

| Name | Office/Function | Company/Entity |
|---|---|---|
| **Claudio Nessi** | | |
| | Director | Avitide Ltd |
| | *Managing partner* | NeoMed Management |
| | *Managing Director* | Omega Funds in Boston |
| | Director | Anaconda Biotech in Barcelona |
| **Ilias (Elias) Papatheodorou** | - | - |
| **Jesús Martin-Garcia** | Chairman & CEO | GeNeuro SA |
| | Shareholder and Managing Director | Eclosion2 SA |
| | Chairman of the Board of Directors | Value Management Group |
| | Director | DepGen SA |
| | Member of the Board | Union des Associations Patronales Genevoises (UAPG) |
| | Chairman | Association des Industries Genevoises des Sciences de la Vie (AIGSV) |
| **Gilles Nobécourt** | Director | COMPLIX |
| | Director | INOTREM |
| | Director | COMPLEXA, Inc |
| | Director | Crescendo Biologics Ltd |
| **Catherine Moukheibir** | Chairman of the Board and Chief Executive Officer | MedDay |
| | Member of the Board of Directors and Chair of the Audit Committee | Orphazyme |
| | Member of the Board of Directors and Chair of the Audit Committee | Ironwood |
| **Mary Tanner** | Senior Managing Director | EVOLUTION Life Science Partners |
| | Member of the Board of Directors | Lineagen, Inc. |
| | Member of the Board of Deans | Yale Blavatnik Fund |
| | Member of the Advisory Board | New York Biotech Development Effort |
| | Member of the Advisory Board | Yale School of Management |

Expired offices (held in the past five years):

| Name | Office/Function | Company/Entity |
|---|---|---|
| **Claudio Nessi** | Director | Creabilis S.A. |
| | Director | Endosense S.A. |
| | Director | Arsanis Ltd |
| **Ilias (Elias) Papatheodorou** | Chairman of the Board of Directors | Priaxon |
| **Jesús Martin-Garcia** | Executive | Fondation Eclosion |
| | Chairman of the Board of Directors | ArisGen SA |
| | Director | Melcure |
| **Gilles Nobécourt** | Director | Innociné |
| | Director | Gamamabs Pharma |
| | Director | Covagen |
| | Director | GlycoVaxyn |
| | Managing Director | Andera Partners |
| | Director | Fondation Ophtalmologique Adolphe de Rothschild |
| | Member of the Executive Committee | PARVULUS |
| **Catherine Moukheibir** | Member of the Board of Directors and the Audit Committee | Cerenis |
| | Member of the Board of Directors and Chair of the Audit Committee | Zealand pharma |
| | Member of the Board of Directors and the Audit Committee | Ablynx NV |
| | Member of the Executive Committee | Innate Pharma |
| | Chairman of the Board of Directors | Creabilis |
| **Mary Tanner** | Director | Evotec |
| | Director | PanGenX |
| | Member of the Board of Deans | Yale School of Medicine |
| | Member of the Advisory Board | Yale School of Management |

Biographies of the Chairman of the Board of Directors, the Chief Executive Officer and Directors:

**Claudio Nessi – Chairman of the Board of Directors, a Swiss citizen, born in 1968**

Claudio Nessi has 18 years' experience in venture capital, investing in healthcare both in Europe and the US. He has been an investor and board member of multiple life science companies, including Axovan AG, Kuros Biosciences AG, Endosense SA, PregLem SA and Creabilis Ltd. He currently serves on the Board of Directors of Arsanis Ltd., Avitide Ltd. and Anaconda Biomed in Barcelona.

Claudio Nessi joined NeoMed Management in 2001 before becoming a partner in 2004, and he heads NeoMed's operations in Switzerland. He has also been a partner of Omega Funds in Boston since 2016. He has academic research experience in molecular biology from the Max Planck Institute and the University of Connecticut and has published articles in leading scientific journals.

Claudio Nessi holds an MBA from Erasmus University, the Netherlands, and a PhD in genetics from the University of Pavia, Italy.

**Ilias (Elias) Papatheodorou – Director and Chief Executive Officer, a Greek citizen, born in 1969**

Ilias (Elias) brings with him more than 20 years of experience with private and public biotechnology companies, as well as with multinationals (Philip Morris International, The Coca-Cola Company). At Covagen AG, he was instrumental in the closing of a CHF 46 million second round of financing and the subsequent acquisition of Covagen by Janssen Pharmaceuticals, a Johnson & Johnson Group company.

Ilias (Elias) has solid experience in raising capital, business development and license negotiation.

**Jesús Martin-Garcia representing Eclosion2 SA – Director, a Swiss citizen, born in 1962**

Jesús began his career in 1983 at the World Economic Foundation, then in 1989 joined McKinsey & Co, where he directed studies in the pharmaceutical and food industries.

Beginning in 1993, he became an entrepreneur by creating, investing in, and managing numerous start-ups in Switzerland and the United States. He was the co-founder of LeShop in 1996, a company that became the e-commerce leader in Switzerland and was sold to Migros. He was also an initial equity investor and participated in the development of other start-ups, such as Silverwire and VTX, for over a decade.

In 2003, he founded Eclosion, a public-private partnership, to transform potentially disruptive academic discoveries in the area of life science into medications. This original structure was instrumental in the launch of GeNeuro; Jesús took the helm in 2006 and is now its Chairman and Chief Executive Officer.

Jesús Martin-Garcia holds a degree in economics and in law from the University of Geneva. He also holds an MBA from Harvard Business School. He serves on the boards of biotech companies and industrial and management associations.

**Gilles Nobécourt representing Andera Partners, Director, a French citizen, born in 1957**

Gilles joined Edmond de Rothschild Investment Partners (EdRIP – now Andera Partners) in 2002.

He was advisor to the French Minister for Industry and Research, then advisor to the Prime Minister's Cabinet Office, before joining the United Nations High Commission for Refugees as Field Director in Africa and Latin America. He then joined Rhône-Poulenc Group and Rhône-Poulenc Rorer (Aventis), where he was Vice President of Global Operations at RPR Gencell, RPR's biotechnology division based in San Francisco, USA, then General Manager of a commercial subsidiary in Mexico until 2000. Prior to joining EdRIP (now Andera Partners), Gilles worked at Russell Reynolds Associates as a consultant to pharmaceutical and biotechnology companies.

Gilles is a graduate of the Paris Institute for Political Sciences (Sciences Po Paris). He holds a Master's degree in applied economics and a certificate from Stanford University's Graduate School of Business.

He is a Director of Complix, Complexa, Genkyotex, Inotrem and Crescendo Biologics Ltd.

**Catherine Moukheibir, Director, a Lebanese, British and American citizen, born in 1959**

Catherine Moukheibir has over 25 years of experience in finance, including 20 years in the biotechnology industry, holding multiple leadership roles and board roles. Catherine Moukheibir is currently CEO of Medday Pharma, having previously been a member of the Executive Board of Innate Pharma (from 2011 to 2016). Prior to joining Innate, she was CFO of Movetis, a Belgian biotech company (from 2008 to 2010), for which she led the IPO on Euronext Brussels and then the acquisition

by Shire. Previously, she was Director of Capital Markets at Zeltia (from 2001 to 2007), a Spanish biopharma and consumer chemicals company, where she steered its financial strategy. Before joining Zeltia, she was Executive Director of Investment Banking at Salomon Smith Barney and Morgan Stanley. Catherine Moukheibir is also a Non-Executive Director of Kymab, Ironwood and Orphazyme.

She has an MBA from Yale University.

**Mary Tanner, Director, a US citizen, born in 1951**

Mary Tanner is co-founder and Senior Managing Director at the consulting firm Life Sciences Partners LLC, specializing in strategic and financial advice for companies operating in the life sciences and healthcare industries. She is also a Member of the Advisory Board of the Yale School of Management. Based in New York, Mary has held various positions at world-class investment banks such as Lehman Brothers Inc., Bear Stearns & Co. and Peter J. Solomon.

Mary Tanner has over 25 years' experience in health-related industries. She has developed strong expertise in the pharmaceutical, biotechnology, diagnostic, medical devices and healthcare sectors.

She is a member of the Board of Directors of Lineagen Inc., a molecular diagnostics company.

She has a BA from Harvard University and speaks fluent French.

**Stéphane Verdood, Observer, a Belgian citizen, born in 1961**

Stéphane is a founding partner of Vesalius Biocapital. Since 2007, he has invested in more than 25 biotech companies. Prior to founding Vesalius Biocapital, Stéphane was a consultant for growth-stage companies. He was a founder and managing partner at Value4Growth, a specialized life science consulting firm, supporting start-ups in all aspects of company formation, product strategy and fundraising. He began his career with Arthur Andersen as an information technology auditor. After having led the mergers and acquisitions division of Arthur Andersen in Belgium from 1989 to 1995, he founded and led Arthur Andersen's business consulting division in Belgium and Luxembourg. He served on the European Board of Partners of Arthur Andersen. Stéphane has an MBA and a degree in commercial engineering from the Catholic University of Leuven (Belgium).

**Joseph McCracken, Observer, a US citizen, born in 1953**

Dr. McCracken has more than 25 years of experience in business development roles at biotechnology and pharmaceutical companies. Most recently, he was Global Head of Business Development & Licensing at Roche Pharma, where he was responsible for Roche Pharma's global in-licensing and out-licensing activities. Prior to joining Roche Pharma, Dr. McCracken held the position of Vice President, Business Development at Genentech for more than 9 years. He was also at one time Director of Business Development and Representative Director of Genentech Ltd., Genentech's wholly owned subsidiary in Japan. He has also held the positions of Vice President of Technology Licensing and Alliances at Aventis, and Vice President of Worldwide Business and Technology Development at Rhône-Poulenc Rorer SA.

Dr. McCracken holds a Bachelor of Science in microbiology, a Master of Science in pharmacology and a Doctorate of Veterinary Medicine from Ohio State University.

### 12.1.3 Statements relating to members of management and directors

In the past five years, none of the members of the Board of Directors and the general management of the Company:

- Has been the subject of a conviction for fraud, an incrimination or official public sanction imposed thereon by statutory or regulatory authorities;
- Has been involved in bankruptcy, receivership or liquidation as a senior executive or corporate officer;
- Has been prevented by a court from acting as a member of a management or supervisory administrative body or from being involved in the management or conduct of the affairs of an issuer.

## 12.2. POTENTIAL CONFLICTS OF INTEREST IN THE COMPANY'S ADMINISTRATIVE, MANAGEMENT, SUPERVISORY BODIES AND SENIOR MANAGEMENT

There is no family relationship between the persons referred to above.

Mr. Papatheodorou and Ms. Mary Tanner are direct and/or indirect shareholders of the Company and/or holders of securities giving access to the Company's share capital.

Mr. Martin-Garcia and Mr. Nobécourt each represent the management company managing the Company's shareholder funds, respectively Eclosion2 and Andera Partners (formerly EdRIP).

Mr. Nessi is managing partner of NeoMed Management, a management company that manages some of the Company's shareholder funds.

An existing related party agreement is described in Section 14.2 of the Universal Registration Document.

To the knowledge of the Company, and subject to the relationships described above and the personal interests related to the agreement presented in Section 14.2 of the Universal Registration Document, there is no current or potential conflict of interest between the duties toward the Company, and the private interests and/or other duties of persons who make up the administrative and management bodies of the Company.

# SECTION 13. COMPENSATION AND BENEFITS

## 13.1. COMPENSATION, BENEFITS IN KIND, OPTIONS AND FREE SHARES GRANTED TO CORPORATE OFFICERS

### 13.1.1. Compensation in financial years 2019 and 2018

The following tables show the compensation and other benefits due and/or paid to corporate officers in office in the financial years 2019 or 2018.

**Table 1: Summary of compensation, options and shares granted to each executive corporate officer**

| Summary of compensation, options and shares allocated to each executive corporate officer | | |
|---|---|---|
| | **Financial year 2018** | **Financial year 2019** |
| **Elias (Ilias) Papatheodorou – Chief Executive Officer** | | |
| Compensation for the financial year *(detailed in Table 2)* | CHF 348,466 | CHF 266,200 |
| Value of multi-year variable compensation awarded during the financial year | - CHF | - CHF |
| Value of options granted during the financial year *(detailed in Table 4)* | €260,413 (or CHF 300,777) | €232,490 (or CHF 258,622) |
| Value of free shares granted during the financial year *(detailed in Table 6)* | - CHF | - CHF |
| **Total** | **CHF 649,243** | ***CHF 524,822*** |
| ***TOTAL equivalent in euros** (for information purposes only, based on the average exchange rates of the financial years in question)* | ***€562,115*** | ***€471,792*** |

**Table 2: Summary of compensation granted to executive corporate officers**

The following tables show the compensation due to executive corporate officers for the financial years ended December 31, 2019 and December 31, 2018 and the compensation received by them during those financial years.

| Summary of compensation granted to executive corporate officers | | | | |
|---|---|---|---|---|
| | **Financial year 2018** | | **Financial year 2019** | |
| | **Amount due (1)** | **Amount paid (2)** | **Amount due (1)** | **Amount paid (2)** |
| **Elias (Ilias) Papatheodorou – Chief Executive Officer (3)** | | | | |
| Base (fixed) compensation | CHF 244,861 | CHF 244,861 | CHF 244,094 | CHF 244,094 |
| Annual variable compensation | CHF 79,860 | CHF 96,250 | - CHF | CHF 79,860 |
| Multi-year variable compensation | - CHF | - CHF | - CHF | - CHF |
| Exceptional compensation | - CHF | - CHF | - CHF | - CHF |
| Attendance fees/Compensation for the activity | - CHF | - CHF | - CHF | - CHF |
| Benefits in kind | CHF 23,745 | CHF 23,745 | CHF 22,106 | CHF 22,106 |
| **TOTAL** | CHF 348,466 | CHF 364,856 | **CHF 266,200** | **CHF 346,060** |
| ***TOTAL equivalent in euros** (for information purposes only, based on the average exchange rates of the financial years in question)* | **€301,702** | **€315,893** | ***€239,302*** | ***€311,093*** |

*(1) For the financial year.*
*(2) During the financial year.*

**Table 3: Attendance fees/compensation for the activity and other compensation received by non-executive corporate officers**

| Attendance fees/compensation for the activity and other compensation received by non-executive corporate officers | | | |
|---|---|---|---|
| **Non-executive corporate officers** | | **Amounts paid in FY 2018** | **Amounts paid in FY 2019** |
| **Claudio Nessi – Chairman of the Board of Directors** | Attendance fees/compensation for the activity | -€ | -€ |
| | Other compensation | -€ | -€ |
| **Andera Partners (formerly Edmond de Rothschild Investment Partners) represented by Gilles Nobécourt** | Attendance fees/compensation for the activity | -€ | -€ |
| | Other compensation | -€ | -€ |
| **Eclosion SA represented by Jesús Martin-Garcia** | Attendance fees/compensation for the activity | -€ | -€ |
| | Other compensation | -€ | -€ |
| **Mary Tanner** | Attendance fees/compensation for the activity | €30,000 | €24,546 |
| | Other compensation | -€ | -€ |
| **Catherine Moukheibir** | Attendance fees/compensation for the activity | €30,000 | €24,546 |
| | Other compensation | -€ | -€ |

**Table 4: Share subscription warrants (BSAs) or Founders' share subscription warrants (BPCEs) awarded to each executive corporate officer by the Company or any company in its Group during the financial years ended December 31, 2018 and 2019**

During the financial years ended December 31, 2018 and December 31, 2019, no share subscription options were allocated to a corporate officer of the Company for directorships and positions held within the Company.

However, Mr. Papatheodorou, Chief Executive Officer of the Company, having a contract of employment with the subsidiary Genkyotex Suisse SA, received from the Board of Directors:

- On January 9, 2018, 583,616 stock subscription options at the exercise price of €1.67 as an employee;
- On March 21, 2019, 607,220 stock subscription options at the exercise price of €0.91 as an employee.

**Table 5: Share subscription warrants (BSAs) or Founders' share subscription warrants (BSPCEs) exercised by each executive corporate officer during the financial years ended December 31, 2018 and 2019**

None

**Table 6: Free shares allocated to executive corporate officers during the financial years ended December 31, 2018 and 2019**

None

**Table 7: Allocated free shares now available for each executive corporate officer during the financial years ended December 31, 2018 and 2019**

None

**Table 8: History of allocations of share subscription warrants (BSAs) or founders' share subscription warrants (BSPCEs) to executive corporate officers**

See the tables in Section 19.1.4 of the Universal Registration Document.

**Table 9: Share subscription options or founders' share subscription warrants (BSPCEs) granted to the top 10 employees who are not corporate officers and warrants exercised by the latter**

| OPTIONS GRANTED TO THE TOP TEN EMPLOYEES WHO ARE NOT CORPORATE OFFICERS AND OPTIONS EXERCISED BY THEM IN 2019 | Total number of options allocated/shares subscribed or purchased | Weighted average subscription price per share | No. and date of plan |
|---|---|---|---|
| Options granted, during the period, by the issuer and any company included in the scope of option allocation, to the ten employees of the issuer and of any company included in this scope with the highest number of options thus granted (aggregate numbers) | 1,130,153 (1) | €1.67 (1) | Options 01/09/2018 |
| | 20,000 (2) | €1.49 (2) | Options 09/26/2018 |
| | 1,336,380 (3) | €0.91 (3) | Options 03/21/2019 |
| Options held on the issuer and the companies referred to above, exercised during the year by the ten employees of the issuer and of these companies with the highest number of OPTIONS thus exercised (aggregate numbers) | - | - | Options 01/09/2018 |
| | | - | Options 09/26/2018 |
| | | - | Options 03/21/2019 |

(1) Prior to the 1-for-10 reverse stock split, which took effect on March 29, 2019. Upon exercise, 10 options will allow 1 new share to be subscribed at a price of €16.70.

(2) Prior to the 1-for-10 reverse stock split, which took effect on March 29, 2019. Upon exercise, 10 options will allow 1 new share to be subscribed at a price of €14.90.

(3) Prior to the 1-for-10 reverse stock split, which took effect on March 29, 2019. Upon exercise, 10 options will allow 1 new share to be subscribed at a price of €9.10.

**Table 10: History of allocations of free shares**

None.

**Table 11:**

Breakdown of compensation terms and other benefits granted to executive corporate officers:

| Executive corporate officers | Employment contract | | Supplemental pension plan | | Allowances and benefits due or likely to be due upon termination or change of function | | Indemnities under a non-compete clause | |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| **Ilias (Elias) Papatheodorou – Chief Executive Officer** | X (1) | | X (2) | | | X | X (3) | |
| *Start date of term of office:* | Date appointed: February 28, 2017 | | | | | | | |
| *End date of term of office:* | At the close of the General Shareholders' Meeting called to approve the financial statements for the financial year ending December 31, 2019 | | | | | | | |
| **Claudio Nessi – Chairman of the Board of Directors** | | X | | X | | X | | X |
| *Start date of term of office:* | Date appointed: February 28, 2017 | | | | | | | |
| *End date of term of office:* | At the close of the General Shareholders' Meeting called to approve the financial statements for the financial year ending December 31, 2019 | | | | | | | |

*(1) Elias (Ilias) Papatheodorou's employment contract was signed with Genkyotex Suisse SA.*
*(2) In accordance with the Swiss system, employees receive old-age insurance and pension benefits consisting of two components: a minimum pension from the government (AVC, 1st pillar) and a mandatory occupational pension plan (LPP, 2nd pillar).*
*(3) The employment contract provides non-compete compensation equal to 100% of base annual pay and benefits (CHF 250,000 in 2017).*

### 13.1.2. Compensation policy for corporate officers

The French Sapin II law of December 9, 2016 established new regulations relating to voting at General Shareholders' Meetings on the compensation of executive corporate officers of companies whose shares are listed for trading on Euronext Paris.

These regulations were amended by Law No. 2019-486 known as the "Pacte" Law of May 22, 2019 and by Order No. 2019-1234 of November 27, 2019 and by Decree No. 2019-1235 of November 27, 2019.

There are two types of voting:

- A first *ex ante* vote of the General Shareholders' Meeting on the compensation policy for the Chairman of the Board of Directors, the Chief Executive Officer and members of the Board of Directors of Genkyotex as corporate officers (Article L. 225-37-2 of the French Commercial Code). The corporate officers compensation policy describes all the components of the fixed and variable compensation of corporate officers, and explains the decision-making process followed to determine, review and implement this policy. The *ex ante* vote on the compensation policy applicable to each of the Company's corporate officers will be submitted for vote on a yearly basis;
- A second *ex post* vote of the general meeting of shareholders on (i) a draft resolution on the information referred to in Article L. 225-37-3-I of the French Commercial Code (information on the corporate officers' compensation taken as a whole for the financial year ended), and (ii) on separate draft resolutions for each corporate officer concerned, on the fixed, variable and exceptional components of total compensation and benefits of any kind paid to such corporate officer during the financial year ended or awarded for that same year (Article L. 225-100 of the French Commercial Code).

### *13.1.2.1 Compensation policy for corporate officers*

This report on compensation policies for corporate officers was adopted on February 24, 2020 by the Board of Directors. It describes, in accordance with Article L. 225-37-2 of the French Commercial Code, all components of fixed and variable compensation of corporate officers and explains the decision-making process followed to determine, revise and implement the Company's compensation policy.

The report will be subject to shareholder approval during the Annual General Shareholders' Meeting on June 10, 2020, as part of its 8th and 9th resolutions.

The Company believes that, given its size and stage of development, its compensation policy helps to strengthen the motivation and loyalty of corporate officers while promoting the alignment of the interests of the latter with those of shareholders and with the Company's social interest, especially compared to its competitors. The Board of Directors ensures that the compensation policy is adapted to the strategy and competitive environment in which the Company operates.

The Company strives to have a transparent and controlled compensation policy that creates a balance between the interests of shareholders, managers, and the company in line with the compensation and employment conditions of employees.

When the Company changed its governance structure, the Board of Directors decided that the Chairman and CEO functions would not be compensated at this stage.

At a meeting on February 24, 2020, the Board of Directors decided to renew the compensation policy for its executive corporate officers for financial year 2020.

As a result, the Chairman will not receive compensation for activity on the Board of Directors, annual or multi-annual variable compensation, nor benefit from any severance arrangements. However, depending on how the Company's business progresses, the Board of Directors, on the recommendation of the Appointments and Compensation Committee, could review the compensation policy and include a performance-based compensation plan and/or stock option plan. Approval by the General Shareholders' Meeting will be required for any changes to the Chairman's compensation policy.

The Chief Executive Officer will also not be granted any fixed or variable compensation as a corporate officer for 2020. The Chief Executive Officer may, however, receive stock options and/or performance shares. However, depending on how the Company's business progresses, the Board of Directors, on the recommendation of the Appointments and Compensation Committee, could review the compensation policy and include benefits in kind and variable compensation which would be based on performance criteria. In this case, approval by the General Shareholders' Meeting will be required for any modification of the Chief Executive Officer's compensation policy.

Among the members of the Board of Directors, only independent directors will be awarded compensation for activity on the Board. In particular, the amount of such compensation takes into account their attendance and the amount of time they spend on their duties. In addition, members of the Board of Directors may, where appropriate, be awarded exceptional compensation for the performance of casual missions or mandates that do not fall within the normal exercise of the remit of directors. The exceptional compensation is subject to the regulated agreement procedure, i.e. the prior authorization of the Board of Directors.

All compensation arrangements will be voted on by the Board of Directors based on a proposal by the Appointments and Compensation Committee, which takes into consideration the level and difficulties of the responsibilities, the field of activity and industry practices.

The Company does not offer severance arrangements or supplemental pension plans for corporate duties.

None of the corporate officers concerned receive the compensation or benefits of any kind mentioned in Articles L. 225-37-2 and R. 225-29-1 of the French Commercial Code for their corporate duties.

The compensation policy in force in the Company automatically applies to newly appointed officers and to those whose term of office has been renewed.

In a situation that indicates or may indicate a conflict of interest between the social interest and the direct or indirect personal interest of a director or the interest of the shareholder or group of shareholders such director represents, the director concerned must inform the Board of Directors upon becoming aware of such situation and refrain from voting or participating in the proceedings and, if the situation cannot be remedied, resign.

#### *13.1.2.2 Compensation and benefits of corporate officers for financial year 2019*

The Company considers that the compensation and benefits awarded and paid to corporate officers for financial year 2019 are in accordance with its compensation policy. According to the Company, its compensation policy has allowed the interests of corporate officers to be aligned with those of shareholders and with the company's social interest, while allowing the Company to continue its growth momentum.

*Compensation and benefits of Claudio Nessi, Chairman of the Board of Directors, for the 2019 financial year*

Claudio Nessi was appointed Chairman of the Board of Directors on February 28, 2017. He was not paid or allocated compensation or benefits of any kind for the financial year 2019 due to his position as Chairman of the Board of Directors.

In accordance with Article L. 225-100 of the French Commercial Code, the Company will submit the above-mentioned items related to Claudio Nessi for financial year 2019 to the shareholders (Resolution 6 submitted to shareholders at the Annual General Shareholders' Meeting to be held on June 10, 2020).

*Compensation and benefits of Elias (Ilias) Papatheodorou, Chief Executive Officer, for the financial year 2019*

Elias (Ilias) Papatheodorou was appointed Chief Executive Officer on February 28, 2017. He was not paid or allocated compensation or benefits of any kind for the 2019 financial year due to his position as Chief Executive Officer of the Company.

However, Ilias (Elias) Papatheodorou receives compensation under an employment contract that predates his functions as a corporate officer at the Company and ties him to the Genkyotex Suisse SA subsidiary as the Chief Executive Officer of that subsidiary. For information, two stock option plans were implemented in early 2018 and March 2019 respectively for the benefit of all Genkyotex employee staff; as Mr. Papatheodorou holds a contract of employment within the Genkyotex Suisse

SA subsidiary, he received 583,616 stock options under the first plan and 607,220 stock options for the second plan, as an employee. The characteristics of these plans are specified in Section 19.1.4.2 of the Universal Registration Document.

In accordance with Article L. 225-100 of the French Commercial Code, the Company will submit the above-mentioned items related to Elias (Ilias) Papatheodorou for financial year 2019 to the shareholders (Resolution 7 submitted to shareholders at the Annual General Shareholders' Meeting to be held on June 10, 2020).

*Compensation of members of the Board of Directors, for financial year 2019*

In accordance with the decision of the Board of Directors of February 28, 2019 ruling on the allocation of attendance fees set by the Combined General Shareholders' Meeting of February 28, 2017, only independent directors were awarded compensation for activity on the Board in financial year 2019.

Thus, Catherine Moukheibir and Mary Tanner each received a gross payment of €24,546 for their participation as independent members of the Board. In particular, the amount of such compensation takes into account their attendance and the time they have devoted to their duties.

### *13.1.2.3 Equity ratio between the level of compensation of the Chairman of the Board of Directors and the Chief Executive Officer and the average and median compensation of the Company's employees*

This presentation is made in accordance with Article L. 225-37-3 subsection 6 and 7 of the French Commercial Code. It states:

(a) The level of compensation of the Chairman of the Board of Directors and the Chief Executive Officer of the Company compared to the average compensation on a full-time equivalent basis of the Company's employees (excluding corporate officers);
(b) The level of compensation of the Chairman of the Board of Directors and the Chief Executive Officer of the Company compared to the median compensation on a full-time equivalent basis to the Company's employees (excluding corporate officers);
(c) The annual changes to compensation, the Company's performance, the average compensation on a full-time equivalent basis for employees of the Company, other than officers, and the ratios referred to in paragraphs (a) and (b) above over the five most recent financial years.

As indicated in paragraph 13.1.2.2 above, Claudio Nessi, Chairman of the Board of Directors, has not received any compensation or benefit of any kind from the Company (i) for financial year 2019, and (ii) for the last five financial years ended. Each of the equity ratios, as defined in Article L. 225-37-3 of the French Commercial Code referred to above, is therefore zero for Claudio Nessi.

For the Chief Executive Officer of the Company, the equity ratios as defined in Article L. 225-37-3 subsection 6 and 7 of the French Commercial Code and their development over the five most recent financial years are as follows:

(a) Equity ratios between the compensation of the Chief Executive Officer or Chairman of the Management Board (2015/2016) and the average and median compensation of employees of the Company (excluding corporate officers)

| | Financial year 2015 | Financial year 2016 | Financial year 2017 | Financial year 2018 | Financial year 2019 |
|---|---|---|---|---|---|
| **Chief Executive Officer or Chairman of the Management Board (2015/2016)** | **Benedikt Timmerman** | **Benedikt Timmerman** | **Elias (Ilias) Papatheodorou** | **Elias (Ilias) Papatheodorou** | **Elias (Ilias) Papatheodorou** |
| Ratio with the average compensation paid to employees | 3.73 | 3.19 | 1.92 | 2.96 | 2.63 |
| Ratio with median compensation paid to employees | 5.60 | 4.69 | 2.23 | 3.51 | 3.21 |

(b) Comparison table of the CEO's compensation for the Company's performance and the average compensation of the Company's employees (other than officers)

| | Change 2014/2015 | Change 2015/2016 | Change 2016/2017 | Change 2017/2018 | Change 2018/2019 |
|---|---|---|---|---|---|
| **Chief Executive Officer or Chairman of the Management Board (2015/2016)** | **Benedikt Timmerman** | **Benedikt Timmerman** | **Elias (Ilias) Papatheodorou** | **Elias (Ilias) Papatheodorou** | **Elias (Ilias) Papatheodorou** |
| Annual compensation paid to the Chief Executive Officer | 3.8% | -8.0% | -1.3% | 40.4% | -1.5% |
| Performance of the | 3.3% | -35.1% | 244.2% | -59.1% | -28.8% |

| | | | | | |
|---|---|---|---|---|---|
| Company*: Operating profit/(loss) | | | | | |
| Performance of the Company*: Net income Group share | 2.3% | -35.3% | 256.0% | -55.7% | -36.9% |
| Average compensation paid to employees | 13.1% | 7.9% | 64.1% | -9.0% | 10.9% |
| Equity ratio on average compensation paid | -8.3% | -14.7% | -39.8% | 54.4% | -11.2% |

*it is recalled that Genkyotex is a clinical-stage biopharmaceutical company specializing in the discovery and development of therapeutic molecules and that since the beginning of its operations, the Company has posted operating losses. Such losses reflect both the significance of the expenses incurred in research and development and, in particular depending on the funds raised or obtained, the weakness of its income. The Company foresees that such losses will continue over the next few years, at least until the marketing and sale of its drug candidates, because of the significant investments required for research, development, manufacture, quality control and distribution of its drug candidates, preclinical and clinical trials, administrative activities, and activities linked to the development of intellectual property, as well as license agreements for new drug candidates and for the acquisition of new technologies that may become necessary, as the case may be.

In the current state of its development and as long as it is not able, as the case may be, to market its drug candidates, the Company considers that the financial indicators mentioned in the table above are hardly representative of the Company's performance. It also considers that in the absence of easily identifiable and market-recognized performance indicators (since the success of clinical trials is random in nature and the ability to raise the funds needed for its development is linked to both the success of these trials and market conditions) it is unable to indicate other relevant indicators for an annual comparison.

**Comments**:

Financial year 2016/2017: appointment of Elias (Ilias) Papatheodorou as Chief Executive Officer of the Company on February 28, 2017 – annualized fixed compensation of Elias (Ilias) Papatheodorou.

## 13.2. TOTAL AMOUNTS SET ASIDE TO PROVIDE PENSION, RETIREMENT OR SIMILAR BENEFITS

The amounts set aside or recorded by the Company or its subsidiaries for pension payments, retirement packages or other benefits to directors and executives relate only to the legally required retirement packages for French employees and the intra-company mandatory defined benefit plan for Swiss employees. They are calculated on the same basis as for the Group's other employees.

## 13.3. SHARE SUBSCRIPTION OR PURCHASE OPTIONS; WARRANTS AND FOUNDERS' WARRANTS

The terms and conditions of each BSA, BSPCE and stock option plan are disclosed in detail in Section 19.1.4 of the Universal Registration Document.

## 13.4. SUMMARY OF TRANSACTIONS BY EXECUTIVES AND THE PERSONS MENTIONED IN ARTICLE L. 621-18-2 OF THE FRENCH MONETARY AND FINANCIAL CODE INVOLVING COMPANY SECURITIES IN THE FINANCIAL YEAR ENDED

| Person concerned | Type of transaction | Date of transaction | Number of securities | Amount of transaction |
|---|---|---|---|---|
| None | | | | |

# SECTION 14. BOARD PRACTICES

## 14.1. COMPANY MANAGEMENT

When the Company changed its governance and management structure via Shareholder vote at the General Shareholders' Meeting on February 28, 2017, a decision was made to separate the functions of Chairman of the Board of Directors and Chief Executive Officer.

In fact, the Chairman of the Board of Directors organizes and directs the work of the Board, and reports on this work to the General Shareholders' Meeting. The Chairman oversees the proper functioning of the Company's bodies and ensures, in particular, that directors are capable of fulfilling their duties. The Chairman chairs Board meetings, but in the event of a tie, does not cast the deciding vote within the Board.

The Chairman of the Board of Directors ensures ongoing dialog and discussion between the Board of Directors and the management team, especially with regards to implementing the strategy and reviewing the Company's key projects. The Chairman also ensures that the Board's specialized committees are operating well and have open and productive lines of communication with the Board of Directors.

The Chief Executive Officer is responsible for the Company's management and is not limited in any particular way by the Board of Directors.

Changes are described in Section 12 “Administrative, management and supervisory bodies and senior management” and in Section 19.2 “Articles of incorporation and bylaws” of this Universal Registration Document.

## 14.2. CONTRACTS BINDING CORPORATE OFFICERS AND THE GROUP

Ilias (Elias) Papatheodorou, appointed Chief Executive Officer of the Company on February 28, 2017, has an employment contract with Genkyotex Suisse SA as its Chief Executive Officer.

There are no other contracts binding a corporate officer to the Company or to any company of the Group.

## 14.3. BOARD OF DIRECTORS AND SPECIALIZED COMMITTEES – CORPORATE GOVERNANCE

Developments regarding the composition of the Board of Directors and information about its members are presented in Section 12 “Administrative, management and supervisory bodies and senior management” and Section 19.2 “Articles of incorporation and bylaws” of this Universal Registration Document.

The members of the Board of Directors may be compensated for their activity and the total amount of this compensation is distributed among them based on attendance records at Board meetings and their participation in specialized committees.

To date, only the independent members of the Board of Directors receive compensation for their activity (e.g. attendance fees).

New internal rules and procedures were adopted by the Board of Directors at its meeting of February 28, 2017.

The internal rules and procedures specify the rules of conduct and the obligations of its members. Board members separately undertake to maintain their independence of analysis, judgment and action, and to actively participate in the work of the Board. They inform the Board of any conflicts of interest that may involve them. Moreover, the internal rules and procedures reaffirm the current regulations on the communication and use of inside information and specify that its members must refrain from trading in Company shares when they have inside information. All members of the Board of Directors are also obligated to declare to the Company and to the AMF (French Financial Markets Authority) any direct or indirect trading they do in Company shares.

The Board of Directors believes that Ms. Catherine Moukheibir and Ms. Mary Tanner are two independent members in terms of the independence criteria defined by the Corporate Governance Code for small and medium enterprises as updated in September 2016 by MiddleNext and approved as a standard code by the AMF, to the extent that Ms. Catherine Moukheibir and Ms. Mary Tanner:

- Are not and have not been in the past five years employees or executive corporate officers of the Company or of a company in its group;
- Do not have and have not had in the past two years a significant business relationship with the Company or its group (as customer, supplier, competitor, service provider, creditor, banker, etc.);
- Are not major shareholders of the Company or do not hold a significant percentage of voting rights;
- Have no close or family relationship with any corporate officer or major shareholder; and
- Have not been auditors of the Company in the past six years.

The number of Board of Directors meetings reflects the various events in the life of the Company. Thus, the Board meets at least four (4) times per year, but does not meet more frequently than Company events justify.

In the financial year ended December 31, 2019, the Board of Directors met 15 times, and the average attendance rate of directors was 93.94%.

The Board of Directors also has two specialized committees: an Audit Committee and an Appointments and Compensation Committee.

The Audit Committee monitors issues relating to the preparation and verification of accounting and financial information and, for that purpose, has the following main duties:

- Monitor the process of preparing financial information and, as appropriate, make recommendations to guarantee its integrity;
- Monitor the effectiveness of internal control and risk management systems, and, as appropriate, internal audits of procedures relating to the preparation and processing of accounting and financial information, without undermining its independence;
- Oversee the Statutory Auditors' review of the annual financial statements and consolidated financial statements;
- Issue a recommendation regarding the appointment of Statutory Auditors by the General Shareholders' Meeting and issue a recommendation to the Board of Directors when the term of office of the Statutory Auditor(s) comes up for renewal;

- Ensure that the Statutory Auditors carry out their assignment and take into consideration the findings and conclusions of the French audit control board (Haut conseil du commissariat aux comptes – H3C) following their audits;
- Ensure that the Statutory Auditors meet the independence requirements; take any necessary measures as needed;
- Approve the provision of non-audit services by the Statutory Auditors (Article L.822-11-2 of the French Commercial Code);
- Report on a regular basis to the Board of Directors regarding the progress of its assignments and on the results of the statutory audit, how it contributed to the integrity of financial information and the role it played in that process. The Audit Committee immediately reports any problems encountered;
- Review the Company's procedures for receiving, storing and processing complaints concerning internal accounting and control, audit-related issues as well as documents sent by employees anonymously and confidentially that may call into question accounting or auditing practices.
- In general, offer all appropriate advice and recommendations in the above-mentioned areas.

The Audit Committee is composed of: Catherine Moukheibir (Chair of the Audit Committee), the company Eclosion2 SA represented by Jesús Martin-Garcia, and Mary Tanner.

The Appointments and Compensation Committee's tasks are:

- Regarding appointments:
  - Submit recommendations to the Board of Directors for the Chief Executive Officer and Deputy Chief Executive Officers, when appropriate, the composition of the Board of Directors and its committees;
  - Propose to the Board of Directors on an annual basis a list of directors who qualify as “independent member” in terms of the criteria defined in the MiddleNext Code;
  - Prepare a list of individuals who can be recommended as Chief Executive Officer, Deputy Chief Executive Officer or Director;
  - Prepare a list of directors who can be recommended as a member of a Board of Directors committee.

- Regarding compensation:
  - Review the key objectives proposed by the Chief Executive Officer and their Deputy Chief Executive Officers, when appropriate, in terms of compensation for non-corporate-officer executives of the Company and the Group, including free share plans and share subscription or purchase options;
  - Review the compensation of non-corporate-officer executives, including free share plans and share subscription or purchase options, pension and insurance plans and benefits in kind;
  - Submit recommendations and proposals to the Board of Directors regarding:
    - the compensation, pension and insurance plans, benefits in kind, and other monetary rights, including in the case of cessation of business, for the Chief Executive Officer and Deputy Chief Executive Officers, if any. The Appointments and Compensation Committee proposes compensation amounts and structures and, in particular, the rules for setting the variable portion taking into account the Company's strategy, objectives and results as well as market practices, and

- free share plans, share subscription or purchase options and any other similar incentive mechanisms and, in particular, allocations by name to the Chief Executive Officer and to Deputy Chief Executive Officers, if any;

- Review the total compensation for their activity and the system for allocating it among the members of the Board of Directors, as well as the conditions for the reimbursement of any expenses incurred by Board members;
- Prepare and submit reports, if any, specified by the rules of procedure of the Appointments and Compensation Committee; and
- Submit any other recommendations that may be requested of it by the Board of Directors or the Chief Executive Officer regarding compensation.

The Appointments and Compensation Committee is composed of the company Andera Partners (formerly Edmond de Rothschild Investment Partners), represented by Gilles Nobécourt (Chair of the Appointments and Compensation Committee), Catherine Moukheibir and Claudio Nessi.

As of December 31, 2019, the Board of Directors has two women, representing 33.33% of the Board members.

The Company applies the exemption defined in Article L. 225-18-1 of the French Commercial Code, which states that when the Board of Directors comprises at most eight members, the difference between the number of men and women directors may not exceed two.

The Board of Directors also has two observers, namely, Stéphane Verdood and Joseph McCracken. Observers are invited to Board of Directors meetings on the same terms as the Board members and have the same right to receive information prior to the meetings on the same terms and conditions as the Board members. They attend Board meetings in an advisory capacity only (see Section 19.2.2 of this Universal Registration Document for the statutory provisions concerning observers).

## 14.4. STATEMENT REGARDING CORPORATE GOVERNANCE

The Company has designated the Corporate Governance Code for small and medium enterprises as updated in September 2016 by MiddleNext (the "**MiddleNext Code**") as standard code.

The Company intends to comply with all the recommendations of the Corporate Governance Code for small and medium enterprises. The table below lists out the various recommendations from this Code and specifies whether the Company complies with the recommendation or not.

| MiddleNext Corporate Governance Code Recommendations | Compliance | Non-compliance |
|---|---|---|
| "**Supervisory**" **power** | | |
| R1 - Board member ethics | X | |
| R2 - Conflicts of interest* | X | |
| R3 - Composition of the board – Presence of independent members | X | |
| R4 - Information on board members | X | |
| R5 - Structure of board meetings and committees | X | |
| R6 - Committee setup | X | |
| R7 - Implementation of Board internal rules and procedures | X | |
| R8 - Independence of each board member | X | |
| R9 - Board member terms of office | X | |
| R10 - Board member compensation | X | |

| MiddleNext Corporate Governance Code Recommendations | Compliance | Non-compliance |
|---|---|---|
| R11 - Implementation of a mechanism for assessing the Board's performance | | X (1) |
| R12 - "Shareholder" relations* | X | |
| **Executive power** | | |
| R13 - Definition and transparency of compensation for executive corporate officers | | X (2) |
| R14 - "Executive" succession planning * | X (3) | |
| R15 - Combined employment contract and corporate mandate | X (4) | |
| R16 - Severance pay | X | |
| R17 - Supplementary retirement plans | X | |
| R18 - Stock options and free share awards | | X (5) |
| R19 - Review of key areas of concern* | X | |

** New recommendations shown in the version of the code of corporate governance published by MiddleNext in September 2016 compared to the version published by MiddleNext in December 2009.*

(1) Since 2019, Board members are invited by the Chairman to speak about Board practices and the preparation of its work, once a year.

(2) The mandates of the Company's executive corporate officers (Chairman of the Board of Directors and CEO) are not compensated at this stage.

(3) The Board does not consider that it is in a situation of dependency vis-à-vis one of its members. Furthermore, the roles of Chairman and Chief Executive Officer are separate.

(4) No executive corporate officer of the Company may carry out an employment contract and a corporate office within the same Company at the same time; however, Mr. Ilias (Elias) Papatheodorou holds an employment contract with Genkyotex Suisse SA, which was signed prior to his appointment as Chief Executive Officer of the Company.

(5) During the financial year ended December 31, 2018, a stock options plan was set up for the benefit of all Group employees; this plan does not attach performance conditions to the exercising of these options. As the holder of an employment contract with the subsidiary Genkyotex Suisse SA, Mr. Papatheodorou received 583,616 stock options in his capacity as an employee of the 1,179,934 options allocated to all employees in 2018 (prior to the Company's 1-for-10 reverse stock split, which took effect on March 29, 2019). In addition, he will be required to retain at least two thirds of the shares resulting from the exercise of options thus allocated until the end of his corporate office within the Company. The Company does not allocate stock options and free shares to executive corporate officers at the time of their departure.

## 14.5. INTERNAL CONTROL

As of the date of the Universal Registration Document, the Company has the following internal control procedures in place:

**Organization of the accounting and finance department**

The accounting function is outsourced under the supervision of the Chief Financial and Administrative Officer. The Company is diligent in maintaining a separation between the preparation and supervision of its financial statements and uses independent experts to measure complex accounting items (pension obligations, value of shareholders' equity instruments) and/or relies on subjective assumptions.
Payroll and review of tax issues are entrusted to chartered accountants.
The financial statements, prepared in accordance with French standards and IFRS, as adopted in the European Union, produced with the assistance of an independent audit firm, are submitted to the Company's co-auditors.

**Budget process**

The Company prepares an annual projected spending budget per project, taking into account actual spending, revenue adjustments and expenses remaining to be incurred. These factors are reviewed on a regular basis at Board meetings.

**Delegation of powers**

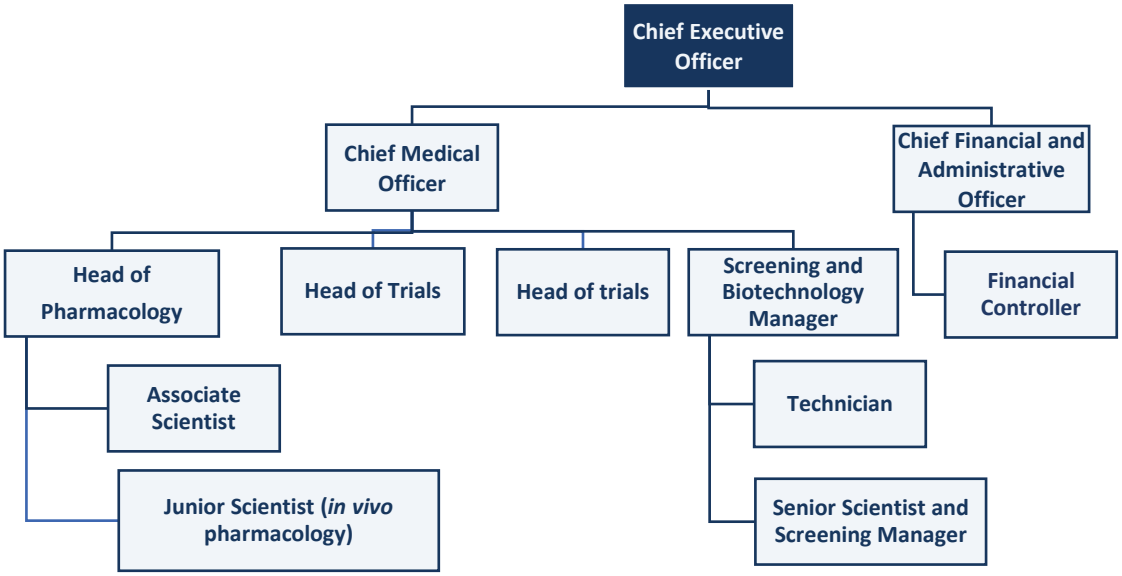
The Company has put in place a procedure for delegating powers, including signing powers for the payment of invoices and the placing of purchase orders.

# SECTION 15. EMPLOYEES

## 15.1. WORKFORCE

### 15.1.1. Operational organizational chart

As of the date of the Universal Registration Document, the Group's operational organizational chart appears as follows:




### 15.1.2. Number and breakdown of employees

At the close of the stated financial periods, the breakdown of the workforce was as follows:

| Breakdown by activity | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Research & Development | 9 | 10 |
| Administrative employees | 3 | 3 |
| **TOTAL** | **12** | **13** |

As of the date of the Universal Registration Document, the Group has 12 employees.

## 15.2. SHAREHOLDINGS AND STOCK OPTIONS

A detailed description of the terms and conditions of each of the BSAs, BPCEs and stock options plans is provided in Section 19.1.4 “Securities, convertible, exchangeable or with warrants attached” and 16.1 “Shareholders with an interest exceeding 5% in the share capital or voting rights” of the Universal Registration Document.

## 15.3. ARRANGEMENTS FOR EMPLOYEE SHAREHOLDING IN THE CAPITAL

In accordance with Article L. 225-102 of the French Commercial Code, the Company states that no employee savings plan has been implemented for the employees of the Company.

Refer to Section 16.1 “Shareholders with an interest exceeding 5% in the share capital or voting rights” of the Universal Registration Document.

# SECTION 16. MAJOR SHAREHOLDERS

## 16.1. SHAREHOLDERS WITH AN INTEREST EXCEEDING 5% IN THE SHARE CAPITAL OR VOTING RIGHTS

### 16.1.1. Shareholding structure and voting rights

As of the date of this Universal Registration Document, to the best of the Company's knowledge, the breakdown of the shareholder base was as follows:

| Shareholders | As of the date of this Universal Registration Document | | | |
|---|---|---|---|---|
| | On a non-diluted basis | | On a diluted basis (1) | |
| | Number of shares | % of capital and voting rights (2) | Number of shares | % of capital and voting rights (2) |
| Andera Partners (3) (formerly EdRIP) | 3,001,692 | 25.99% | 3,001,692 | 25.23% |
| Eclosion2 SA | 1,393,285 | 12.06% | 1,393,285 | 11.71% |
| Vesalius Biocapital II SA, SICAR | 1,087,568 | 9.42% | 1,087,568 | 9.14% |
| NeoMed Innovation V L.P. | 940,589 | 8.14% | 940,589 | 7.91% |
| Wellington | 482,967 | 4.18% | 482,967 | 4.06% |
| N5 Investment AS | 67,633 | 0.59% | 67,633 | 0.57% |
| Management & Employees | 434,730 | 3.76% | 678,233 | 5.70% |
| Other investors | 4,134,857 | 35.80% | 4,238,066 | 35.63% |
| Treasury stock (4) | 5,241 | 0.05% | 5,241 | 0.04% |
| **Total** | **11,548,562** | **100.00%** | **11,895,274** | **100.00%** |

(1) Taking into account (i) 972,826 share warrants (BSA) and the 2,494,416 stock options issued and allocated by the Company as of the date of this Universal Registration Document, exercisable or otherwise, giving respectively the right to the subscription of 97,280 and 249,432 new shares of the Company.

(2) Theoretical voting rights. All shares have the same voting rights, except treasury shares.

(3) Biodiscovery 2 fund, Biodiscovery 3 fund, Partenariat et Innovation 2 and Partenariat et Innovation 3, represented by Andera Partners.

(4) Shares held as of April 24, 2020 under the liquidity contract signed with Kepler on April 23, 2018.

## 16.2. EXISTENCE OF VOTING RIGHTS

None.

## 16.3 CONTROL OF THE COMPANY BY MAJOR SHAREHOLDERS

In the meaning of Article L. 233-3 of the French Commercial Code, no controlling shareholder of the Company existed as of the date of the Universal Registration Document.

The Company did not make any arrangement to protect against abusive exercise of control of the Company.

To the Company's knowledge, there is no concerted action among its shareholders.

## 16.4. AGREEMENTS THAT MAY TRIGGER A CHANGE OF CONTROL

To the Company's knowledge, there is no agreement which, if implemented, could trigger a change in control of the Company.

# SECTION 17. RELATED-PARTY TRANSACTIONS

## 17.1. INTRA-GROUP TRANSACTIONS

As of the date of the Universal Registration Document, the following agreements are in effect within the Group:

- **Cash management agreement** signed on April 1, 2012 between Genkyotex Suisse SA and Genkyotex Innovation SAS. This agreement was transferred to Genkyotex SA for fiscal year 2017 as part of the merger of Genkyotex Innovation SAS with Genkyotex SA. This agreement allows either company's cash advances to be used as working capital to support its current operations and defines the payment terms.

- **Research and development services agreement** signed on December 29, 2017 between Genkyotex Suisse SA (beneficiary) and Genkyotex SA (service provider), with retroactive effect from January 1, 2017. This agreement sets out the payment terms for research and development assignments performed by Genkyotex SA for the benefit of Genkyotex Suisse SA based on the cost-plus method.

- **Service agreement** signed on January 31, 2018 between Genkyotex Suisse SA (service provider) and Genkyotex SA (beneficiary), with retroactive effect from March 1, 2017. This agreement sets out the terms and conditions of the services rendered by Genkyotex Suisse SA for the benefit of Genkyotex SA based on the cost-plus method.

## 17.2. SIGNIFICANT AGREEMENTS WITH RELATED PARTIES

At the General Shareholder's Meeting of February 28, 2017, the Company's shareholders approved the change to the Company's management and governance structure and adopted a one-tier board structure. All the functions of the members of the Supervisory Board and the members of the Management Board were terminated at the close of that General Shareholders' Meeting.

It should also be noted that no new agreement was signed with corporate officers between January 1, 2019 and the date of the Universal Registration Document. Mr. Papatheodorou, the Company's Chief Executive Officer, has an employment contract with the Company's Swiss subsidiary, Genkyotex Suisse SA.

## 17.3. STATUTORY AUDITORS' SPECIAL REPORTS ON THE REGULATED AGREEMENTS

### 17.3.1. Statutory auditors' Special Report on regulated agreements established for the year ended December 31, 2019

KPMG Audit
51 rue de Saint-Cyr
CS 60409
69338 Lyon Cedex 9
France

sygnatures
8, chemin de la Terrasse
BP 45122
31512 Toulouse Cedex 5

**Genkyotex S.A.**

Siège social : 218, avenue Marie Curie
Forum 2 Archamps Technopole
74166 Saint-Julien-en-Genevois
Capital social : €.11 548 562

**Statutory auditors' special report on regulated agreements**

General Meeting of Shareholders to approve the financial statements for the year ended 31 December 2019

To the annual general meeting of Genkyotex S.A.,

As Statutory Auditors of your company, we present to you our report on regulated agreements.

It is our duty to report to you, based on the information provided to us, the key features and benefits to the Company, of the agreements of which we have been informed or of which we have identified during our assignment, without being required to form an opinion as to their usefulness or appropriateness or to search for undisclosed agreements.

According to the provisions of Article R.225-31 of the French Commercial Code, it is your duty to assess the benefits of entering into these agreements when they are submitted for your approval.

It is also our duty, where appropriate, to inform you of the information referred to in article R.225-31 of the French Commercial Code relating to the continuation, in the period under review, of agreements approved by General Shareholders' Meetings in previous years.

We carried out the investigations that we considered necessary to comply with the professional guidelines issued by the Compagnie nationale des commissaires aux comptes in respect of this assignment.

AGREEMENTS SUBMITTED FOR THE APPROVAL OF THE GENERAL SHAREHOLDERS' MEETING

We inform you that we have not been advised of any agreement authorised and concluded in the period of review to be submitted for the approval of the general shareholders' meeting in accordance with the provisions of article L.225-38 of the French Commercial Code.

AGREEMENTS PREVIOUSLY APPROVED BY THE GENERAL SHAREHOLDERS' MEETING

We inform you that we have not been advised of any agreement approved by a General Shareholders' Meeting, whose execution would have continued during the past year.

The Statutory Auditors
French original signed by

| | |
|---|---|
| Lyon, on the 23 April 2020 | Toulouse, on the 23 April 2020 |
| KPMG Audit | Sygnatures S.A.S. |
| *Département de KPMG S.A.* | |
| Stéphane Devin | Laure Mulin |
| *Partner* | *Associée* |

### 17.3.2. Statutory Auditors' Special Report on regulated agreements established for the financial year ended December 31, 2018

«

**GENKYOTEX**

LIMITED COMPANY (*SOCIÉTÉ ANONYME*) WITH SHARE CAPITAL OF €7,934,762.10

Registered office:
218 avenue Marie Curie – Forum 2 Archamps Technopole
74166 Saint-Julien-en-Genevois Cedex, France

## STATUTORY AUDITORS' SPECIAL REPORT ON REGULATED AGREEMENTS AND COMMITMENTS

**General Shareholders' Meeting to approve the financial statements for the year ended December 31, 2018**

_____

*This is a free translation into English of the Statutory Auditors' special report on regulated agreements and commitments issued in French and is provided solely for the convenience of English speaking readers. This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France. It should be understood that the agreements and commitments reported on are only those provided by the French Commercial Code and that the report does not apply to related party agreements described in IAS 24 or other equivalent accounting standards.*

_____

To the Shareholders,

As Statutory Auditors of your company, we present to you our report on related-party agreements and commitments.

It is our duty to report to you, based on the information provided to us, the key features of and benefits to the Company, of the agreements and commitments of which we have been informed or which we have identified during our assignment, without being required to form an opinion as to their usefulness or appropriateness or to search for undisclosed agreements and commitments.

According to the provisions of Article R. 225-31 of the French Commercial Code, it is your duty to assess the benefits of entering into these agreements and commitments when they are submitted for your approval.

It is also our duty, where appropriate, to inform you of the information referred to in Article R. 225-31 of the French Commercial Code relating to the continuation, in the period under review, of agreements and commitments approved by General Shareholders' Meetings in previous years.

We carried out the investigations that we considered necessary to comply with the professional guidelines issued by the Compagnie Nationale des Commissaires aux Comptes (French institute of auditors) in respect of this assignment.

## 1. Agreements and commitments submitted for the approval of the General Shareholders' Meeting

We inform you that we have not been advised of any agreement or commitment authorized and concluded in the period of review to be submitted for the approval of the General Shareholders' Meeting in accordance with the provisions of Article L. 225-38 of the French Commercial Code.

## 2. Agreements and commitments previously approved by the General Shareholders' Meeting

We inform you that we have not been informed of any agreements or commitments approved by a General Shareholders' Meeting in previous years that were still in force in the past year.

*Neuilly-sur-Seine and Toulouse, France, April 15, 2019*
*The Statutory Auditors*
*French original signed by*

| | |
|---|---|
| **Grant Thornton**<br>**French Member of Grant Thornton International** | **Sygnatures** |
| **Samuel Clochard**<br>Partner | **Laure Mulin**<br>Partner |

"

## 17.4. PROCEDURE FOR EVALUATING CURRENT AND REGULATED AGREEMENTS

In accordance with Article L. 225-39 paragraph 2 of the French Commercial Code, as amended by Law No. 2019-486 of May 22, 2019 on business growth and transformation (known as the "Pacte" Law), the Board of Directors is required to establish a procedure to regularly assess whether agreements relating to current operations and concluded under normal conditions fulfill these conditions.

On the recommendation of the Audit Committee, the Board of Directors adopted at its meeting on April 23, 2020 an internal charter on regulated agreements and commitments and on the procedure for evaluating current agreements concluded under normal conditions.

The purpose of this charter is to recall the regulatory framework applicable to regulated agreements and commitments, as well as to establish a procedure to distinguish between the agreements concluded directly or through an intermediary between the Company and the persons referred to in Article L. 225-38 of the French Commercial Code, those subject to the ordinary law of prior authorizations of the Board of Directors and those likely to be qualified as current within the meaning of Article L.225-39 of the French Commercial Code and which must be subject to regular assessment to ensure that the agreements satisfy the conditions for this category.

# SECTION 18. FINANCIAL INFORMATION CONCERNING THE ISSUER'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES

## 18.1. HISTORICAL FINANCIAL INFORMATION

### 18.1.1. Consolidated financial statements and Statutory Auditors' Report

**18.1.1.1 Consolidated financial statements prepared in accordance with IFRS for the financial year ended December 31, 2019**

#### CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| Consolidated Statement of Financial Position (in € thousands) | Notes | 12/31/2019 | 12/31/2018 |
|---|---|---|---|
| **ASSETS** | | | |
| Intangible assets | 3.1 | 9,086 | 9,653 |
| Property, plant and equipment | 3.2 | 154 | 31 |
| Non-current financial assets | 4 | 29 | 45 |
| **Total non-current assets** | | **9,270** | **9,729** |
| Other receivables | 5 | 1,500 | 2,157 |
| Cash and cash equivalents | 6 | 2,417 | 10,309 |
| **Total current assets** | | **3,917** | **12,466** |
| **Total assets** | | **13,186** | **22,195** |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | | |
| **Shareholders' equity** | | | |
| Capital | 7 | 8,683 | 7,935 |
| Additional paid-in capital | | 126,118 | 124,183 |
| Currency translation reserve | | (2,732) | (2,361) |
| Other comprehensive income | | (697) | (514) |
| Accumulated deficit attributable to owners of the parent | | (114,332) | (103,383) |
| Net income attributable to shareholders of the parent | | (7,203) | (11,417) |
| **Equity attributable to owners of the parent** | | **9,836** | **14,442** |
| Non-controlling interests | | - | - |
| **Total equity** | | **9,836** | **14,442** |
| Employee benefit obligations | 10 | 1,348 | 996 |
| Non-current financial liabilities | 9 | 17 | - |
| **Total non-current liabilities** | | **1,364** | **996** |
| Current financial liabilities | 9 | 848 | 3,641 |
| Derivative liabilities | 9 | 64 | - |
| Trade payables | | 562 | 2,214 |
| Other current liabilities | 12 | 512 | 903 |
| **Total current liabilities** | | **1,986** | **6,757** |

| | | |
|---|---|---|
| **Total liabilities and shareholders' equity** | **13,186** | **22,195** |

## CONSOLIDATED INCOME STATEMENT

| Consolidated income statement (in € thousands) | Notes | 12/31/2019<br>12 months | 12/31/2018<br>12 months |
|---|---|---|---|
| Revenue | | - | - |
| Cost of sales | | - | - |
| **Gross margin** | | **-** | **-** |
| Revenue from contracts with customers | 14 | - | 750 |
| Net research and development expenses | | | |
| Research and development expenses | 15.1 | (6,305) | (9,282) |
| Subsidies | 15.1 | 899 | 893 |
| General and administrative expenses | 15.2 | (2,160) | (2,836) |
| Other income | | 142 | 44 |
| **Operating profit/(loss)** | | **(7,425)** | **(10,430)** |
| Financial expenses | 17 | (190) | (1,185) |
| Financial income | 17 | 412 | 197 |
| **Profit/(loss) before tax** | | **(7,203)** | **(11,417)** |
| Income taxes | 18 | - | - |
| **Net profit/(loss) for the period** | | **(7,203)** | **(11,417)** |
| *Portion attributable to shareholders of the parent* | | (7,203) | (11,417) |
| *Non-controlling interests* | | - | - |

| | | 12/31/2019 | 12/31/2018 |
|---|---|---|---|
| **Basic earnings per share (€/share) for the financial periods presented (1)** | 19 | **(0.88)** | **(1.46)** |
| **Diluted earnings per share (€/share) for the financial periods presented (1)** | 19 | **(0.88)** | **(1.46)** |

*(1) On January 24, 2019, the Company's Board of Directors decided to carry out the reverse stock split by exchanging 10 existing shares for 1 new share, approved by the Company's shareholders at the Extraordinary General Shareholders' Meeting of January 24, 2019 (see Note 19). The weighted average number of shares was thus divided by 10. In accordance with IAS 33, the earnings per share presented for the financial year ended December 31, 2018 have been retrospectively adjusted.*

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

| Consolidated Statement of Comprehensive Income (in € thousands) | 12/31/2019 12 months | 12/31/2018 12 months |
|---|---|---|
| **Net profit/(loss) for the period** | **(7,203)** | **(11,417)** |
| Actuarial gains and losses | (183) | (198) |
| Tax effect | - | - |
| **Other items of comprehensive income that will not be reclassified subsequently to profit or loss** | **(183)** | **(198)** |
| Translation differences | (370) | (103) |
| **Other items of comprehensive income that will be reclassified subsequently to profit or loss** | **(370)** | **(103)** |
| **Comprehensive income** | **(7,757)** | **(11,719)** |
| *Portion attributable to shareholders of the parent* | *(7,757)* | *(11,719)* |
| *Non-controlling interests* | - | - |

## CHANGE IN CONSOLIDATED EQUITY

| Change in Consolidated Equity | | *Genkyotex SA capital* | Capital – ordinary shares | Additional paid-in capital | Accumulated deficit and income (loss) attributable to owners of the parent | Treasury shares | Currency translation reserve | Other comprehensive income | Equity attributable to owners of the parent | Non-controlling interests | Total equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | *Number of shares* | *In € thousands* | | | | | | | | |
| **As of December 31, 2017** | | *77,850,006* | **7,785** | **162,015** | **(143,558)** | **(132)** | **(2,258)** | **(316)** | **23,535** | **-** | **23,535** |
| Net income at December 31, 2018 | | | - | - | (11,417) | - | - | - | (11,417) | - | (11,417) |
| Other comprehensive income | | | - | - | - | - | (103) | (198) | (301) | - | (301) |
| **Comprehensive income** | | | **-** | **-** | **(11,417)** | **-** | **(103)** | **(198)** | **(11,719)** | **-** | **(11,719)** |
| Clearance of the accumulated loss carried forward | | | - | (39,572) | 39,572 | - | - | - | - | - | - |
| Conversion of convertible bonds | | *1,497,615* | 150 | 1,740 | - | - | - | - | 1,890 | - | 1,890 |
| Issuance of BSAs on bonds | | | - | - | 242 | - | - | - | 242 | - | 242 |
| Treasury shares | | | - | - | - | (19) | - | - | (19) | - | (19) |
| Share-based payments | 8.4 | | - | - | 512 | - | - | - | 512 | - | 512 |
| **As of December 31, 2018** | | *79,347,621* | **7,935** | **124,183** | **(114,649)** | **(152)** | **(2,361)** | **(514)** | **14,442** | **-** | **14,442** |
| Net income at December 31, 2019 | | | - | - | (7,203) | - | - | - | (7,203) | - | (7,203) |
| Other comprehensive income | | | - | - | - | - | (370) | (183) | (554) | - | (554) |
| **Comprehensive income** | | | **-** | **-** | **(7,203)** | **-** | **(370)** | **(183)** | **(7,757)** | **-** | **(7,757)** |
| Conversion of convertible bonds | | *748,687* | 749 | 1,961 | - | - | - | - | 2,710 | - | 2,710 |
| Effect of the 10-for-1 reverse stock split | | *(71,412,859)* | - | - | - | - | - | - | - | - | - |
| Capital increase expenses | | | - | (27) | - | - | - | - | (27) | - | (27) |
| Treasury shares | | | - | - | - | (15) | - | - | (15) | - | (15) |
| Share-based payments | 8.4 | | - | - | 483 | - | - | - | 483 | - | 483 |
| **As of December 31, 2019** | | *8,683,449* | **8,683** | **126,118** | **(121,369)** | **(167)** | **(2,732)** | **(697)** | **9,836** | **-** | **9,836** |

## CONSOLIDATED CASH FLOW STATEMENT

| Consolidated Cash Flow Statement<br>Amounts in € thousands | Notes | 12/31/2019<br>12 months | 12/31/2018<br>12 months |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| **Net profit/(loss) for the period** | | **(7,203)** | **(11,417)** |
| (-) Elimination of depreciation of intangible assets | 3.1 | (567) | (567) |
| (-) Elimination of depreciation of property, plant and equipment | 3.2 | (147) | (24) |
| (-) Unrealized foreign exchange gains or losses | | 325 | - |
| (-) Provisions for pension commitments | 10 | (123) | 59 |
| (-) Costs related to share-based payments | 8.3 | (483) | (512) |
| (-) Fair value of bond loans | 9.2 | - | (742) |
| (-) Fair value of the capitalization contract | | - | 3 |
| (-) Interest expenses | | (5) | - |
| (-) Accretion of repayable advances | 9.1 | (1) | (7) |
| **Self-financing capacity before cost of net financial debt and taxes** | | **(6,201)** | **(9,627)** |
| (-) Change in working capital requirement | | 1,386 | (679) |
| **Taxes paid** | | **-** | **81** |
| **Cash flows from operating activities** | | **(7,588)** | **(8,866)** |
| **Cash flows from investing activities** | | | |
| Acquisition of property, plant and equipment | 3.2 | (1) | (3) |
| Winding down of investments classified as current and non-current financial assets | | - | 3,283 |
| **Cash flows from investing activities** | | **(1)** | **3,279** |
| **Cash flows from financing activities** | | | |
| Reduction of financial debt relating to the right of use (IFRS 16) | 9.3 | (130) | - |
| Gross financial interest paid | | (5) | - |
| Repayment of advances | 9.1 | (118) | (291) |
| Capital increase expenses | | (27) | - |
| Bond issuance | 9.2 | - | 4,658 |
| Share subscription warrant (BSA) issuance | 9.2 | - | 242 |
| **Cash flows from financing activities** | | **(281)** | **4,609** |
| Impact of fluctuations in exchange rates | | (11) | (69) |
| **Increase/(decrease) in cash & cash equivalents** | | **(7,881)** | **(1,048)** |
| Cash & cash equivalents – start of the period | 6 | 10,297 | 11,345 |
| Cash & cash equivalents – end of the period | 6 | 2,416 | 10,297 |
| **Increase/(decrease) in cash & cash equivalents** | | **(7,881)** | **(1,048)** |

| **Cash and cash equivalents<br>(including short-term borrowings)** | **Notes** | **12/31/2019** | **12/31/2018** |
|---|---|---|---|
| Cash and cash equivalents | 6 | 2,417 | 10,309 |
| Short-term borrowings | | (0) | (13) |
| **Cash & cash equivalents – end of the period<br>(including short-term borrowings)** | | **2,416** | **10,297** |

## BREAKDOWN OF CHANGE IN WORKING CAPITAL REQUIREMENT (WCR)

| Breakdown of change in working capital requirement (WCR) (amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Trade and related receivables | - | - |
| Other receivables | (656) | 305 |
| Trade payables | 1,652 | (902) |
| Social security payables | 358 | (99) |
| Tax payables | 16 | 25 |
| Other current liabilities | 17 | (9) |
| **Total change** | **1,386** | **(679)** |

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

*(Unless otherwise stated, the amounts referred to in these notes are in thousands of euro, except for the data relating to shares. Some amounts may be rounded up or down in order to calculate the financial information in the consolidated financial statements. Consequently, the totals in some tables may not correspond exactly to the sum of the preceding figures.)*

### Note 1: Activity and significant events

The information below forms the notes to the consolidated financial statements prepared in accordance with IFRS as of December 31, 2019.

The consolidated financial statements for Genkyotex SA were adopted by the Board of Directors on February 24, 2020 and authorized for publication.

### 1.1 THE COMPANY AND ITS BUSINESS

Founded in October 2001, Genkyotex is a French limited company (*société anonyme*) with the following corporate purpose in France and abroad: research, study, development, manufacturing and distribution of medicines and drug and health products in the field of human and animal health.

The Company's therapeutic approach is primarily based on the selective inhibition of NOX enzymes which amplify many pathological processes such as fibroses, inflammation, the perception of pain, the development of cancer and neurodegeneration.

Genkyotex SA has been listed on the Euronext market in Paris and Brussels since April 8, 2014.
Registered office: 218 avenue Marie Curie – Forum 2 Archamps Technopole,
74166 Saint-Julien-en-Genevois Cedex, France
Trade and Companies Register: 439 489 022 RCS de Thonon les Bains.

Genkyotex SA is hereinafter referred to as the "Company." The group formed by Genkyotex SA and Genkyotex Suisse SA is hereinafter referred to as the "Group."

### 1.2 SIGNIFICANT EVENTS OF THE YEAR

January 2019:

- The Company announced that shareholders approved the 1-for-10 reverse stock split commencing February 27, 2019 and taking effect on March 29, 2019 (delisting the existing shares and listing the new shares).
- Genkyotex announced that the final results of its Phase 2 study on GKT831 in patients with primary biliary cholangitis (PBC) will be published in spring 2019.

February 2019:

- Genkyotex announced that a university partner, Professor Gareth Thomas of the University of Southampton, has been awarded a second Cancer Research UK grant to further develop NOX research in oncology.

March 2019:

- Announcement by Genkyotex of the end of the 24-week treatment period for its Phase 2 clinical study with GKT831 in PBC.

April 2019:

- Genkyotex presented the interim results of its Phase 2 trial of GKT831 in PBC at the 2019 EASL International Liver Congress: all patients have completed the treatment; favorable safety profile for GKT831, there were no patient dropouts or treatment interruptions.

June 2019:

- Genkyotex presented the final results of its Phase 2 study in PBC, which show that the anti-fibrotic candidate drug GKT831 demonstrated statistically significant improvements in GGT and ALP over the full treatment period.

July 2019

- The Company announced the publication in the *Clinics and Research in Hepatology and Gastroenterology* journal of the results of studies showing that its anti-fibrosis drug, GKT831, reduces the complications of portal hypertension and demonstrates the therapeutic potential of GKT831 in patients with advanced fibrosis of the liver.
- Genkyotex announced that the FDA in the United States has approved its Phase 2 trial of GKT831 in pulmonary fibrosis. The Company had previously announced that the National Institutes of Health (NIH) in the United States had awarded a grant of $8.9 million to Professor Victor Thannickal of the University of Alabama at Birmingham (UAB) to finance a multi-year research program evaluating the role of NOX enzymes in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in scarring (fibrosis) of the lungs.
- The World Health Organization (WHO) recognized GKT831 as the first representative of the NOX inhibitor therapeutic class. WHO recommended setanaxib as the international nonproprietary name (INN) for GKT831. The new stem “naxib” approved by WHO refers to the mechanism of action (NANADPH oXidase inhIBitors). The NOX inhibitor therapeutic class has significant potential in fibrotic and inflammatory disorders, neurodegenerative diseases and oncology.
- The Company announced favorable results from the post-hoc analysis of the Phase 2 trial in PCB.

August 2019

- The Company signed an agreement with Yorkville Advisors Global—the management company of a US investment fund—covering a 12-month extension of the conversion period for the remaining €1.6 million of convertible bonds still held by Yorkville. To this end, on August 19, 2019, Genkyotex bought back from Yorkville the remaining €1.6 million of convertible bonds maturing on August 20, 2019 that Yorkville still held, and then immediately issued new convertible bonds—maturing on August 20, 2020— to Yorkville, for an amount equal to that of the existing OCAs. See Note 9.2.

December 2019:

- The company announced the extension of the Phase 2 study in diabetic nephropathy funded by the Juvenile Diabetes Research Foundation (JDRF) in Europe and New Zealand. Note that 13 patients included in the diabetic kidney disease study completed the full 48-week treatment, without any reported safety concerns.
- The US Food and Drug Administration (FDA) and the US Medical Ethics Committee have authorized the IPF Phase 2 study protocol, paving the way for the recruitment of new patients. This study is fully funded by a USD 8.9 million grant from the National Institutes of Health (NIH).

## 2.1 PRINCIPLES USED TO PREPARE THE FINANCIAL STATEMENTS

### Statement of compliance

The Company prepared its consolidated financial statements in accordance with IFRS (International Financial Reporting Standards) as published by the International Accounting Standards Board (IASB) and adopted by the European Union as of the date the financial statements were prepared.

This reference framework, available on the European Commission website, incorporates the international accounting standards (IAS and IFRS) and the interpretations of the Interpretations Committees (IFRS Interpretations Committee, or IFRS IC, and the Standing Interpretations Committee, or SIC).

The accounting principles, methods and options adopted by the Company are described below. In some cases, IFRS allow a choice between the application of a benchmark treatment and another approved treatment.

### Principles used in the preparation of the financial statements

The Company's consolidated financial statements have been prepared in accordance with the historical cost principle, with the exception of financial instruments measured at their fair value.

### Going concern

The Company focuses on inventing and developing new treatments. The loss-making position over the reference periods is not unusual for a company at this stage of development.

The Company has managed to finance its operations to date primarily through successive capital fund-raising or convertible bonds.

As of the reporting date, the Board of Directors considers that the Company will be able to meet its financing needs for anticipated operations until February 2021 on the basis of the following:

- the level of net consolidated cash and cash equivalents (including current bank overdrafts) as of December 31, 2019, which amounted to €2,417 thousand;
- the estimated receipt of the 2019 research tax credit for an amount of €899 thousand;
- forecasts of the cash required by the Company's operations in 2020 and early 2021;
- the conversion of the entire convertible bond to shares in January 2020, with a balance of €800 thousand at December 31, 2019 (see Notes 9.2 and 25);
- the capital increase of €4.9 million in February 2020 (see Note 25).

The going-concern principle was adopted by the Board of Directors for the approval of these financial statements, with the Group having, in view of the above data and assumptions, the necessary means to finance its activities for at least 12 months after the reporting date.

Beyond its liquidity horizon of February 2021, the Company will need additional funds. Measures are already being implemented by Management to seek additional funding.
This could include raising additional funding from current investors, new investors and/or the conclusion of strategic partnerships or transactions. The success of these transactions may depend, among other things, on attaining development milestones, achieving favorable clinical outcomes and/or achieving commercial success.

**Accounting methods**

The accounting principles used are the same as those used to prepare the annual IFRS consolidated financial statements for the financial year ended December 31, 2018, except where applying the following new standards, amendments to standards and interpretations adopted by the European Union which had to be applied by the Group as of January 1, 2019:

- IFRS 16 – Leases, published on January 13, 2016. This standard aligns the treatment of operating leases with that of finance leases (i.e., recognition in the balance sheet of a liability in respect of future lease payments and of a right of use);
- IFRIC 23 – Uncertainty over Income Tax Treatments, published on June 7, 2017;
- Amendments to IAS 19 – Plan Amendment, Curtailment or Settlement, published on February 7, 2018;
- Improvements to IFRS Standards 2015-2017 Cycle, published on December 12, 2017; and
- Amendments to IFRS 9 – Financial Instruments, published on October 12, 2017.

With the exception of IFRS 16, these new texts adopted by the European Union do not have a significant impact on the Group's financial statements.

IFRS 16 was published in January 2016. It replaces IAS 17 Leases, IFRIC 4 Determining Whether an Arrangement Contains a Lease, SIC-15 Operating Leases – Incentives and SIC-27 Evaluating the Substance of Transactions in the Legal Form of a Lease. IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to use a single accounting model to recognize all leases in the balance sheet similar to that used to recognize finance leases in accordance with IAS 17. The standard includes two accounting exemptions for lessees (leases for “low-value” assets and short-term leases of less than 12 months). On the effective date of a lease, the lessee registers a liability for lease payments (i.e., the rental liability) and an asset representing the right to use the underlying assets during the term of the lease (i.e., the right-of-use asset). Lessees are required to recognize separately the interest cost for the lease liability and the depreciation expense for the right-of-use asset. The change to the presentation of charges for operating leases results in a corresponding increase in cash flows associated with operating activities and a decrease in cash flows associated with financing activities.

In accordance with the new standard, the Group has determined the term of the lease agreement, including the option for extension or termination agreed by the lessee. These options were appraised at the start of a lease agreement and required the management's judgment. The measurement of the lease liability at the present value of the remaining non-cancellable lease payments uses an appropriate discount rate in accordance with IFRS 16. The discount rate corresponds to the interest rate implicit in the lease or, if that cannot be determined, the incremental borrowing rate on the lease start date. The incremental borrowing rate may have a significant impact on the net present value of the right-of-use asset and the liability for the recognized leases, which requires judgment.

Lessees reassess the liability of the lease if certain events occur (for example, a change in the term of the lease, an amendment to future lease payments resulting from a change in the index or interest rate used to determine these payments). The lessee generally recognizes the amount of the reassessment of the lease liability as an adjustment in the right-of-use asset.

*Transition to IFRS 16*

The Group decided to adopt IFRS 16 by applying the modified retrospective approach to contracts previously recognized as leases. Consequently, the leases will only be recognized in the balance sheet as of January 1, 2019 and the comparative information will not be restated.

These liabilities are measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of January 1, 2019. The right-of-use asset is measured at an amount equal to the lease liability, adjusted by the amount of any advance payments or provisions relating to this lease that were recorded in the statement of the financial position immediately before the date of initial application.

In accordance with IFRS 16, the Company applies the following principles:

- application of a single discount rate to assets with similar characteristics; and
- use of the exemption proposed by the standard on leases that expire within 12 months of the transition date.

The Company excludes the initial direct costs of measuring right-of-use assets as of the date of the initial application.

Applying this standard from January 1, 2019 resulted in an increase of €253 thousand in the Company's financial liabilities and an increase of €262 thousand in its property, plant and equipment (see Notes 3.2 and 9.3). The weighted average incremental borrowing rate applied by the Company to lease liabilities, recognized in the consolidated financial statements as of January 1, 2019, was 2%.

The reconciliation of lease liabilities recognized as of January 1, 2019 to non-cancelable lease commitments disclosed as of December 31, 2018 breaks down as follows:

| **Reconciliation of off-balance sheet commitments as of December 31, 2018 and recognition of rights of use as of January 1, 2019** | **Amounts (in € thousands)** |
|---|---|
| Off-balance sheet commitments on commercial leases and finance leases as of December 31, 2018 | 268 |
| Leases previously restated in accordance with IAS 17 | - |
| Leases exempt under IFRS 16 | - |
| Discounted according to the period of time used by IFRS 16 | (6) |
| Difference in periods of time used by off-balance sheet commitments and IFRS 16 | - |
| **Total rights of use as of January 1, 2019** | **263** |

The table below shows the impact of the application of IFRS 16 on the consolidated income statement as of December 31, 2019:

| Consolidated income statement (Amounts in € thousands) | As of December 31, 2019 | | |
|---|---|---|---|
| | **Reported** | **Impact of IFRS 16** | **Excluding IFRS 16** |
| Revenue | - | - | - |
| Cost of sales | - | - | - |
| **Gross margin** | **-** | **-** | **-** |
| Revenue from contracts with customers | - | - | - |
| Research and development expenses | (5,184) | (2) | (5,186) |
| General and administrative expenses | (2,382) | (1) | (2,383) |
| Other income | 142 | - | 142 |
| **Operating profit/(loss)** | **(7,424)** | **(3)** | **(7,427)** |
| Financial expenses | (190) | 4 | (187) |

| | | | |
|---|---|---|---|
| Financial income | 412 | - | 412 |
| **Profit/(loss) before tax** | **(7,203)** | **1** | **(7,202)** |
| Tax | - | - | - |
| **Net profit/(loss)** | **(7,203)** | **1** | **(7,202)** |

IFRS 16 affects the consolidated statements of consolidated cash flow for the financial year ended December 31, 2019. Lease-related disbursements are classified under the heading “Cash flows from financing activities,” rather than “Cash flows from operating activities.” The table below shows the impact of the application of IFRS 16 on the interim consolidated statements of consolidated cash flow:

| | 12-month financial year ended December 31, 2019 | | |
|---|---|---|---|
| **Consolidated Cash Flow Statement (in € thousands)** | **Reported** | **Impact of IFRS 16** | **Excluding IFRS 16** |
| Cash flows from operating activities | (7,263) | (131) | (7,394) |
| Cash flows from investing activities | (1) | - | (1) |
| Cash flows from financing activities | (281) | 131 | (150) |
| Impact of fluctuations in exchange rates | (336) | - | (336) |
| **Increase/(decrease) in cash & cash equivalents** | **(7,880)** | **-** | **(7,880)** |
| Cash & cash equivalents – start of the period | 10,297 | | 10,297 |
| Cash & cash equivalents – end of the period | 2,416 | | 2,416 |
| **Increase/(decrease) in cash & cash equivalents** | **(7,880)** | | **(7,880)** |

## 2.2 SCOPE AND METHODS OF CONSOLIDATION

### Scope

According to IFRS 10, subsidiaries are all the entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The subsidiaries are consolidated by the full consolidation method as from the date on which the Group acquires control. They are deconsolidated as of the date on which control ceases to be exercised.

In connection with the merger of Genkyotex SA and Genkyotex Suisse SA which took place on February 28, 2017, Genkyotex Suisse SA was considered the buyer from an accounting standpoint in light of IFRS 10. These financial statements have thus been prepared in keeping with the IFRS consolidated financial statements of Genkyotex Suisse SA.

The scope of consolidation is as follows:

| | 12/31/2019 | | 12/31/2018 | |
|---|---|---|---|---|
| | Percent interest | Percent control | Percent interest | Percent control |
| GENKYOTEX SA | Parent company (from a legal standpoint) | | | |
| GENKYOTEX SUISSE SA | 100.00% | 100.00% | 100.00% | 100.00% |

### 2.3 Reporting currency

The Group's financial statements are prepared in euros (EUR).

### 2.4 Conversion method

#### *2.4.1 Recognition of foreign currency transactions*

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates as of the date this transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currency are converted into functional currency at the exchange rate on the closing date.

Differences resulting from the settlement or conversion of monetary items are recognized as income.

#### 2.4.2 Conversion of financial statements of companies whose functional currency is not the euro

The financial statements of companies whose operating currency is not the euro (EUR) are converted as follows:

- Statement of financial position items are converted using the closing rate for the year;
- Income statement items are converted at the average exchange rate for the period.

The exchange differences arising on conversion for consolidation are recognized in the “currency translation reserve”.

The exchange rates used to prepare the consolidated financial statements are as follows:

| EXCHANGE RATE (for 1 EUR) | 12/31/2019 | | 12/31/2018 | |
|---|---|---|---|---|
| | Average rate | Closing rate | Average rate | Closing rate |
| Swiss franc (CHF) | 1.1124 | 1.0854 | 1.1550 | 1.1269 |

**2.5 Use of judgments and estimates**

To prepare the financial statements in accordance with IFRS, the Group has made judgments and estimates that could affect the amounts presented under assets and liabilities as of the reporting date, and the amounts disclosed under income and expenses for the period.

Such estimates are made by the Group's management based on the assumption of business continuity and on the information available at the time. These estimates are ongoing and are based on past experience as well as various other factors judged to be reasonable and form the basis for assessment of the carrying amount of assets and liabilities. The estimates may be revised if the circumstances on which they are based change or as a result of new information. Actual results may differ significantly from these estimates if the assumptions or conditions change.

The significant estimates or judgments made by the Group relate to the following in particular:

- Valuation of share subscription options and non-voting shares allocated to employees, executives and external service providers:
    - The fair value measurement of share-based payments is based on the Black & Scholes option valuation model, which makes assumptions about complex and subjective variables. These variables notably include the value of the shares, the expected volatility of the share price over the lifetime of the instrument, and the present and future behavior of the holders of those instruments. There is a high inherent risk of subjectivity when using an option valuation model to measure the fair value of share-based payments in accordance with IFRS 2.
    - The valuation assumptions adopted are disclosed in Note 8.

- Defined benefit plans:
    - Defined benefit plans are reported in the balance sheet based on an actuarial valuation of the obligations at period-end, less the fair value of the plan's assets. This valuation is determined by using the projected unit credit method while taking into account the workforce turnover rate, mortality probability and actuarial assumptions based on management estimates.
    - The valuation assumptions adopted are disclosed in Note 10.

- Initial valuation and during impairment tests subsequent to the license agreement signed with SIIL (for use of the Vaxiclase platform) and extensions to the contract:
    - The estimated fair value of the SIIL contract and extensions is calculated based on the discounted cash flow (DCF) method, adjusted for the likelihood of some impact on a business plan extending to 2035. In doing so, the Company's management used estimates to determine:

- future flows for the period until 2035, corresponding to the life of the patent underlying the license sold to SIIL;
- the probability of success of the various stages of clinical development;
- the discount rate.

- The valuation assumptions adopted are disclosed in Note 3.1.

## 3.1 INTANGIBLE ASSETS

### Accounting principles

**Research and development expenses**

Research and development costs are recognized as expenses when they are incurred. Costs incurred on development projects are recognized as intangible assets when the following criteria are fulfilled:

- it is technically feasible to complete the intangible asset so that it will be available for use or sale;
- management intends to complete the intangible asset and use or sell it;
- it is possible to use or sell the intangible asset;
- it can be demonstrated that the intangible asset will likely generate economic benefits in the future;
- adequate technical, financial and other resources necessary to complete the development and to use or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

Regarding the expenses incurred for developing a medicinal product and due to the risks and uncertainties inherent in the R&D process and in obtaining regulatory authorizations, the six criteria for capitalizing expenses are considered fulfilled only when the medicinal product has received marketing authorization.

Consequently, internal development expenses are recognized in the income statement when incurred.

**SIIL contract (for use of the Vaxiclase platform) and extensions to this contract**

As part of the valuation of the assets and liabilities assumed from Genkyotex SA, the Company carried out a provisional valuation of the SIIL contract and extensions to this contract as of February 28, 2017.

Genkyotex SA signed a license agreement with the company for its Vaxiclase technology as part of the development by SIIL of acellular and multivalent vaccines containing antigens for whooping cough. In return for access to and use of the Vaxiclase platform in the authorized indication, the Company could receive up to US$57 million in initial payments and development and sales milestone payments based on criteria defined in the terms and conditions of the agreement, as well as royalties as a percentage of net sales.

As a result of signing the license agreement extension for the Vaxiclase platform with Serum Institute of India Pvt. Ltd. (SIIL) in June 2018, the agreement provides for:

- An initial payment of €750 thousand (recognized during the first half of 2018);
- Milestone payments for emerging markets for up to US$57 million;
- Milestone payments for industrialized countries for up to €100 million.

The Company is also eligible to receive “single-digit percentage” royalties on sales.

The estimated fair value of the SIIL contract and extensions was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence. The main valuation assumptions are as follows:

- The business plan for the period until 2035, corresponding to the life of the patent licensed to SIIL (disregarding a terminal value).
- The probability of success of the various stages of clinical development (based on a study conducted by Biomedtracker in 2016 who undertook a retrospective analysis of the probability of success of the various stages of clinical development in 9,985 trials between 2006 and 2015):

| | **Probability of success of each phase** | **Overall probability of success** |
|---|---|---|
| POC (1) | 100% | 100% |
| Phase 1 | 70% | 70% |
| Phase 2 | 43% | 30% |
| Phase 3 | 73% | 22% |
| Commercial success | 89% | 19% |

(1): Proof of concept already achieved

- The discount rate of 14.2%, based particularly on a risk premium of the French equity market, an average beta originating from a sample of French biotechnology companies listed on Euronext and a risk premium specific to the Company.

**Software**

Software license acquisition costs are posted to assets based on the costs incurred to acquire and bring the software concerned online.

**Other intangible assets**

In application of the IAS 38 criteria, intangible assets acquired are recognized under assets at their acquisition cost.

**Amortization charge and duration**

When an asset has a finite useful life, depreciation is calculated using the straight-line method to spread the cost over the estimated useful life, specifically:

| **Items** | **Amortization period** |
|---|---|
| Software | 1 year – straight line |
| SIIL contract and extensions | 19 years – straight line (2017-2035 business plan corresponding to the life of the patent underlying the license sold to SIIL) |

The amortization charge for intangible assets is recognized in the income statement as:

- "General and administrative expenses" for amortization charges related to accounting software;
- "Research and development expenses" for the amortization expense relating to the SIIL contract and extensions and the software used by the laboratory.

| **INTANGIBLE ASSETS (Amounts in € thousands)** | **Software** | **SIIL contract and extensions** | **Total** |
|---|---|---|---|
| **GROSS VALUE** | | | |
| **Statement of financial position at December 31, 2017** | **17** | **10,697** | **10,714** |
| Acquisition | **-** | **-** | **-** |
| Disposal | **(1)** | **-** | **(1)** |
| Transfer | **-** | **-** | **-** |
| Currency translation effects | **1** | **-** | **1** |
| **Statement of financial position at December 31, 2018** | **16** | **10,697** | **10,713** |
| Acquisition | - | - | - |
| Disposal | - | - | - |
| Transfer | - | - | - |
| Currency translation effects | 1 | - | 1 |
| **Statement of financial position at December 31, 2019** | **17** | **10,697** | **10,714** |
| **CUMULATIVE AMORTIZATION** | | | |
| **Statement of financial position at December 31, 2017** | **17** | **476** | **493** |
| Increase | - | 567 | 567 |
| Decrease | (1) | - | (1) |
| Currency translation effects | 1 | - | 1 |
| **Statement of financial position at December 31, 2018** | **16** | **1,043** | **1,060** |
| Increase | - | 567 | 567 |
| Decrease | - | - | - |
| Currency translation effects | 1 | - | 1 |
| **Statement of financial position at December 31, 2019** | **17** | **1,611** | **1,628** |
| **NET BOOK VALUE** | | | |
| **As of December 31, 2017** | **-** | **10,221** | **10,221** |
| **As of December 31, 2018** | **-** | **9,653** | **9,653** |
| **As of December 31, 2019** | **-** | **9,086** | **9,086** |

### 3.2 PROPERTY, PLANT AND EQUIPMENT

#### Accounting principles

Property, plant and equipment are valued at their acquisition cost. Asset items are depreciated according to the actual useful life of the asset.
The following amortization periods and methods are used:

| Items | Amortization period |
|---|---|
| Furniture and computer equipment | 3 to 5 years – straight line |
| Laboratory equipment | 5 to 8 years – straight line |
| General fixtures and fittings | 8 to 10 years – straight line |

The amortization charge for property, plant and equipment is recognized in the income statement as:

- "General and administrative expenses" for depreciation of general facilities, fixtures and fittings, computer and office equipment;
- "Research and development expenses" for laboratory equipment and other laboratory assets.

| PROPERTY, PLANT AND EQUIPMENT (Amounts in € thousands) | Equipment and tooling | Office equipment, computer equipment, furniture | Buildings (right of use) | Total | Of which right of use |
|---|---|---|---|---|---|
| **GROSS VALUE** | | | | | |
| **Statement of financial position at December 31, 2017** | **521** | **93** | **-** | **614** | - |
| Acquisition | 2 | 1 | - | **3** | - |
| Disposal | - | - | - | **-** | - |
| Transfer | - | - | - | **-** | - |
| Currency translation effects | 15 | 3 | - | **18** | - |
| **Statement of financial position at December 31, 2018** | **538** | **98** | **-** | **636** | **-** |
| Impact of the initial application of IFRS 16 | - | - | 262 | **262** | 262 |
| Acquisition | - | 1 | - | **1** | - |
| Disposal | - | - | - | **-** | - |
| Transfer | - | - | - | **-** | - |
| Currency translation effects | 15 | 3 | 10 | **29** | 10 |
| **Statement of financial position at December 31, 2019** | **553** | **102** | **272** | **927** | **272** |
| **CUMULATIVE AMORTIZATION** | | | | | |
| **Statement of financial position at December 31, 2017** | 470 | 93 | - | **563** | - |
| Increase | 23 | 1 | - | **24** | - |
| Decrease | - | - | - | **-** | - |
| Currency translation effects | 14 | 3 | - | **17** | - |
| **Statement of financial position at December 31, 2018** | **508** | **97** | **-** | **605** | **-** |
| Impact of the first-time application of IFRS 16 | - | - | 131 | 131 | 131 |
| Increase | 15 | 1 | - | 16 | - |
| Decrease | - | - | - | - | - |
| Currency translation effects | 15 | 3 | 3 | 21 | 3 |
| **Statement of financial position at December 31, 2019** | **538** | **101** | **134** | **772** | **134** |
| **NET BOOK VALUE** | | | | | |
| **As of December 31, 2017** | **51** | **1** | **-** | **51** | **-** |
| **As of December 31, 2018** | **30** | **1** | **-** | **31** | **-** |
| **As of December 31, 2019** | **15** | **1** | **138** | **154** | **138** |

As part of the first-time application of IFRS 16, the Company opted for the simplified retrospective approach and used practical simplification measures in accordance with IFRS 16.C10 (see Note 2.1, "Transition to IFRS 16").

### 3.3 IMPAIRMENT IN VALUE OF INTANGIBLE ASSETS AND PROPERTY, PLANT AND EQUIPMENT

**Accounting principles**

Assets with an indefinite useful life or which have not yet been depreciated are subject to an annual impairment test.

Assets in the process of being depreciated are subject to an impairment test when an internal or external index indicates that they may have lost value.

Impairment is recognized when the net carrying amount of an asset exceeds its recoverable value. The recoverable value of an asset is its fair value less selling costs, or its value-in-use, whichever is higher.

During the reference periods, the Company has only had depreciable assets.

For the purposes of the impairment test, the Company has updated the valuation model for the license agreement signed with SIIL (for use of the Vaxiclase platform) and expansions to the agreement as of December 31, 2019. This impairment test did not highlight any loss of value as of December 31, 2019. The main assumptions used for the test are:

| Assumptions | 2019 | 2018 |
|---|---|---|
| Discount rate | 14.2% | 16% |
| Probability of successful development phases | 2016 Biomedtracker study | 2016 Biomedtracker study |
| Forecast periods | 2020-2035 | 2019-2035 |

The sensitivity of the assumptions used in the valuation model is as follows:

- A 1-point increase in the discount rate would not generate an impairment;
- A 2.5-point decrease in the probability of success of different phases would not generate an impairment;
- A 10% deterioration in the business plan would not generate an impairment;
- A one-year delay in the development phases of a project would not generate an impairment.

### Accounting principles

The Group's financial assets are made up of:

- loans and receivables initially reported at fair value and subsequently evaluated at amortized cost, using the effective interest rate method. Collateral deposits are non-derivative financial assets with fixed or determinable payments that are not quoted on an active market.
- financial assets at fair value through profit or loss. These represent assets held for trading purposes. They are measured at their fair value, and changes in fair value are reported through profit or loss. Some assets can also voluntarily be classified in this category. This category includes the capital bond. These assets fall under category 1, defined by IAS 7.

Financial assets having a term of maturity of over one year are classified under “Non-current financial assets”.

| NON-CURRENT FINANCIAL ASSETS<br>(Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Liquidity contract | 14 | 30 |
| Guarantees | 15 | 15 |
| **Total non-current financial assets** | **29** | **45** |

### Accounting principles

**Research tax credit**

Research tax credits are granted to the Group's French companies by the French State as an incentive to conduct technical and scientific research. Companies with expenses that meet the eligibility criteria receive a tax credit that can be used to pay the corporate income tax due in the year in which it is granted, as well as in the following three financial years or, as the case may be, any surplus tax paid can be reimbursed.
In the absence of taxable income, and in view of the Company's beneficiary company community SME status, the CIR receivable from the French State is paid in the year following the year for which it is granted.
The research tax credit is recorded in assets for the year it was granted that corresponds to the year during which eligible expenses giving rise to a tax credit were incurred.
The research tax credit is presented in the income statement under subsidies in “Research and development expenses”.

**Competitiveness and Employment Tax Credit (CICE)**

The tax credit for competitiveness and employment (crédit d'impôt pour la compétitivité et l'emploi or “CICE”) is a French tax credit benefiting the Group's French companies. The Group uses this tax credit through its research and development effort.
In view of the beneficiary companies' community SME status, the CICE may be repaid in the year following that in which it was granted.
For financial year 2018, the CICE tax credit was reported as a reduction of personnel costs in the income statement.
This tax credit has been replaced by reductions in payroll charges as from January 1, 2019.

**Subsidies**

Subsidies received are reported as soon as the corresponding receivable becomes certain, taking into consideration the conditions specified when the subsidy was granted.

| OTHER RECEIVABLES (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Research tax credit (1) | 899 | 893 |
| Value Added Tax | 229 | 359 |
| Social security receivables | 16 | 114 |
| Outstanding receivables, advances and installments (2) | 75 | 612 |
| Pre-paid expenses (3) | 151 | 133 |
| Other | 131 | 44 |
| **Total other receivables** | **1,500** | **2,157** |

**(1) Research tax credit ("CIR")**

- 2019 CIR: €899 thousand, with repayment planned in 2020
- 2018 CIR: €893 thousand, repaid in October 2019.

**(2) Amounts receivable, advances and installments paid** primarily involve installments paid to the Contract Research Organization (CRO) responsible for studies.

**(3) Prepaid expenses** are related to the day-to-day activity of the Group and mainly concern fees.

## Note 6: Cash and cash equivalents

### Accounting principles

Cash and cash equivalents recognized in the balance sheet include cash at banks, cash at hand and short-term deposits with an initial maturity of less than three months.

Cash equivalents are held for trading purposes, are easily convertible into a known amount of cash and exposed to negligible risk that they will change in value. They are measured at fair value and any changes in value are recorded as financial income. These assets fall under category 1, defined by IFRS 7.

For cash flow statement purposes, net cash consists of cash and cash equivalents as defined above.

| CASH AND CASH EQUIVALENTS<br>(Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Bank accounts | 2,417 | 10,309 |
| **Total cash and cash equivalents** | **2,417** | **10,309** |

### Accounting principles

Ancillary costs directly attributable to the issuance of shares or stock options are reported, net of tax, as a deduction from equity.

**Liquidity contract**
The portion of the contract invested in the Company's treasury shares is reported as a deduction from Company equity at acquisition cost.
The income from the sale of these treasury shares is also reported directly in equity.
The cash reserve for the liquidity contract is shown under “Non-current financial assets”.

| | Pro forma – effect of reverse stock split (10 existing shares for one new share) (1) | | At the end of the financial periods presented | |
|---|---|---|---|---|
| **SHARE CAPITAL** | **12/31/2019** | **12/31/2018** | **12/31/2019** | **12/31/2018** |
| Share capital (in € thousands) | 8,683 | 7,935 | 8,683 | 7,935 |
| Number of shares | 8,683,449 | 7,934,762 | 8,683,449 | 79,347,621 |
| o/w ordinary shares | 8,683,449 | 7,934,762 | 8,683,449 | 79,347,621 |
| Par value of shares (in euro) | €1.00 | €1.00 | €1.00 | €0.10 |

(1) Following the Board of Directors' decision on January 24, 2019 to carry out a 1-for-10 reverse stock split, the Company's share capital will be divided into 7,934,762 shares starting from March 29, 2019.

Genkyotex SA's share capital is made up of fully subscribed and paid-up ordinary shares.

The number of Company shares excludes share subscription warrants (“BSAs”) and founders' warrants (“BSPCEs”) granted to certain investors and to certain natural persons, whether or not employees of the Group, that have not yet been exercised.

During financial year 2019, 245 bonds were converted for a total of 748,687 new shares with a unit value of €1.00, creating a €749 thousand capital increase plus an issue premium of €1,701 thousand.

**Capital management**
The Group's policy is to maintain a sufficient capital base in order to preserve the confidence of investors and creditors and to support the Company's future growth.

Following the Company's IPO on the regulated Euronext market in Paris and Brussels, the Company signed a liquidity contract on April 18, 2014, in order to limit intra-day volatility in the Company's share price. For this purpose, the Company had initially entrusted €200 thousand to Oddo Corporate Finance so that it could carry out purchase and sale transactions on the Company's shares. The contract was transferred to Kepler Cheuvreux on May 7, 2018.

As of December 31, 2019—under the contract—7,789 treasury shares were removed from equity and €14 thousand in cash was entered as non-current financial assets.

**Dividends**

The Company paid no dividend in the financial periods presented.

## Note 8: Share-based payments

### Accounting principles

In accordance with the IFRS 2 standard, the cost of transactions settled in equity instruments is reported under expenses for the period in which the rights to benefit from the share capital equity instruments are acquired, as counterpart to a capital increase.
The Group has applied IFRS 2 to all the equity instruments granted to employees, members of the Board of Directors and to external service providers such as consultants.
The fair value of the warrants granted to employees is measured via the Black-Scholes option valuation model. The same applies to the options granted to other natural persons supplying similar services, as their market value is not determinable.
All methods used in measuring the fair value of such options are disclosed below:

- The share price used is equal to the stock market price or to the investor subscription price or by reference to internal valuations;
- The risk-free rate is based on the average lifetime of the instruments;
- Volatility is calculated with reference to a sample of listed companies in the biotechnology sector, as of the date the instruments are subscribed and over a period equal to the lifetime of the option.

### 8.1 Share subscription warrants ("BSAs")

The following table summarizes the option plans issued and the assumptions adopted for IFRS 2 valuation:

| | | Plan features | | | Assumptions | | |
|---|---|---|---|---|---|---|---|
| **Type** | **Grant date** | **Number of warrants granted (1)** | **Maturity date** | **Adjusted exercise price (2)** | **Volatility** | **Risk-free rate** | **Total initial IFRS 2 valuation (€ thousands) (Black&Scholes)** |
| **BSA 02/2010** | 02/04/2010 | **155,200** | 10 years | €30.00 | 55.14% | 3.58% | **258** |
| **BSA 12/2013** | 12/20/2013 | **116,000** | 10 years | €40.00 | 54.27% | 2.09% | **221** |
| **BSA 09/2014** | 09/12/2014 | **35,000** | 10 years | €57.90 | 50.03% | 0.50% | **72** |

(1) After the reverse stock split (see Notes 7 and 25) at the beginning of 2019, the parity is 10 BSAs issued before 2019 for 1 new share.

(2) The exercise price was adjusted to take the reverse split into account.

Changes in the number of warrants outstanding

| Number of options outstanding | | | | | | |
|---|---|---|---|---|---|---|
| **Type** | **Grant date** | **12/31/2018** | **Issued** | **Exercised** | **Lapsed** | **12/31/2019** |
| **BSA** 02/2010 | 02/04/2010 | 155,200 | - | - | - | 155,200 |
| **BSA** 12/2013 | 12/20/2013 | 116,000 | - | - | - | 116,000 |
| **BSA** 09/2014 | 09/12/2014 | 35,000 | - | - | - | 35,000 |
| **TOTAL** | | **306,200** | **-** | **-** | **-** | **306,200** |

**8.2 Share subscription options**

The following table summarizes the option plans issued and the assumptions adopted for IFRS 2 valuation:

| | | Plan features | | | Assumptions | | |
|---|---|---|---|---|---|---|---|
| **Type** | **Grant date** | **Number of warrants granted (1)** | **Exercise period** | **Adjusted exercise price (2)** | **Volatility** | **Risk-free rate** | **Total initial IFRS 2 valuation (€ thousands) (Black&Scholes)** |
| **Stock option** 01/2018 | 01/09/2018 | **1,159,934** | 10 years | €16.70 | 60.68% | 0.00% | **1,096** |
| **Stock option** 10/2018 | 10/11/2018 | **20,000** | 10 years | €14.90 | 56.86% | 0.11% | **13** |
| **Stock option** 03/2019 | 03/21/2019 | **1,336,380** | 10 years | €9.10 | 56.80% | -0.27% | **604** |

(1) After the reverse stock split (see Notes 7 and 25) at the beginning of 2019, the exchange ratio was 10 stock options issued before 2019 for 1 new share.

(2) The exercise price was adjusted to take the reverse split into account.

The vesting period is one quarter per year over four years.

Changes in the number of outstanding options

| Number of warrants outstanding | | | | | | |
|---|---|---|---|---|---|---|
| **Type** | **Grant date** | **12/31/2018** | **Issued** | **Exercised** | **Lapsed** | **12/31/2019** |
| **Stock option** 01/2018 | 01/09/2018 | 1,145,153 | - | - | (15,000) | 1,130,153 |
| **Stock option** 10/2018 | 10/11/2018 | 20,000 | - | - | - | 20,000 |
| **Stock option** 03/2019 | 03/21/2019 | - | 1,336,380 | - | - | 1,336,380 |
| **TOTAL** | | **1,165,153** | **1,336,380** | **-** | **(15,000)** | **2,486,533** |

### 8.4 Breakdown of charges recognized in accordance with IFRS 2 during the periods presented

| Type | Grant date | 2019 cost | 2018 cost |
|---|---|---|---|
| **Stock option** $_{01/2018}$ | 01/09/2018 | 250 | 511 |
| **Stock option** $_{10/2018}$ | 10/11/2018 | 6 | 1 |
| **Stock option** $_{03/2019}$ | 03/21/2019 | 228 | - |
| **TOTAL** | | **483** | **512** |

## Note 9: Interest-bearing loans and borrowings

### Accounting principles

Unless otherwise indicated, loans and borrowings are reported at amortized cost, calculated using the effective interest rate (EIR) method, in accordance with IFRS 9.
The portion of financial debts due within one year is presented as "Current financial debt".

| CURRENT AND NON-CURRENT FINANCIAL LIABILITIES (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Repayable advances | - | - |
| Debt related to lease payment obligations (IFRS 16) (1) | 17 | - |
| **Non-current financial liabilities** | **17** | **-** |
| Repayable advances | - | 118 |
| Debt related to lease payment obligations (IFRS 16) (1) | 122 | - |
| Bonds | 725 | 3,510 |
| Derivative liabilities | 64 | |
| Short-term borrowings | - | 13 |
| **Current financial liabilities** | **912** | **3,641** |
| **Total financial debts** | **928** | **3,641** |

(1) See Note 2.1, paragraph "Transition to IFRS 16"

### Reconciliation of redemption value to book value

| RECONCILIATION OF REDEMPTION VALUE TO BOOK VALUE (Amounts in € thousands) | Repayment value 12/31/2019 | Amortized cost | Fair value | Book value | |
|---|---|---|---|---|---|
| | | | | 12/31/2019 | 12/31/2018 |
| Repayable advances | - | - | - | - | 118 |
| Debt related to lease payment obligations (IFRS 16) | 139 | - | - | 139 | - |
| Bonds | 800 | - | (75) | 725 | 3,510 |
| Derivative liabilities | 64 | - | - | 64 | - |
| Short-term borrowings | - | - | - | - | 13 |
| **Total financial debts** | **1,003** | **-** | **(75)** | **928** | **3,641** |

**Breakdown of financial debt by maturity, in repayment value**

| CURRENT AND NON-CURRENT FINANCIAL LIABILITIES BY MATURITY, IN REPAYMENT VALUE (Amounts in € thousands) | 12/31/2019 | | | |
|---|---|---|---|---|
| | Gross amount | Maturing in less than 1 year | 1 to 5 years | More than 5 years |
| Repayable advances | - | - | - | - |
| Debt related to lease payment obligations (IFRS 16) | 139 | 122 | 16 | - |
| Bonds | 800 | 800 | - | - |
| Derivative liabilities | 64 | 64 | - | - |
| Short-term borrowings | - | - | - | - |
| **Total financial debts** | **1,003** | **987** | **16** | **-** |
| *Current financial liabilities* | *987* | | | |
| *Non-current financial liabilities* | *16* | | | |

**9.1 Repayable advances**

**Accounting principles**

The Group benefits from a certain amount of public aid, in the form of conditional subsidies and advances. They are reported in accordance with IAS 20. These advances are granted at below market interest and measured at amortized cost, in accordance with IFRS 9:

- The interest rate advantage is measured by using a discount rate corresponding to a market rate on the date the aid is granted. The amount resulting from the interest rate advantage obtained when the repayable interest-free advance is granted is considered to be a subsidy recorded under income in the statement of comprehensive income.
- The financial cost of the repayable advances, calculated at the market interest rate, is then recorded under financial expenses.

In the event of failure of the project, the abandonment of the receivable is recorded under subsidies.

| CHANGE IN REPAYABLE ADVANCES AND SUBSIDIES (Amounts in € thousands) | OSEO 3 - ProCervix (GTL001) | Total |
|---|---|---|
| **As of December 31, 2017** | **402** | **402** |
| Cash inflow | - | - |
| Repayment | (291) | (291) |
| Subsidies | - | - |
| Financial expenses | 7 | 7 |
| **As of December 31, 2018** | **118** | **118** |
| Cash inflow | - | - |
| Repayment | (118) | (118) |
| Subsidies | - | - |
| Financial expenses | 1 | 1 |
| **As of December 31, 2019** | **-** | **-** |

**Breakdown of repayable advances by maturity, in repayment value**

| BREAKDOWN OF REPAYABLE ADVANCES BY MATURITY, IN REPAYMENT VALUE (Amounts in € thousands) | OSEO 3 - ProCervix (GTL001) | Total |
|---|---|---|
| **As of December 31, 2019** | **-** | **-** |
| Maturing in less than 1 year | - | - |
| Maturing in 1 to 5 years | - | - |
| Maturing in more than 5 years | - | - |

**OSEO Innovation repayable advance – OSEO 3**

On January 11, 2013, Genkyotex SA (formerly Genticel SA) obtained from OSEO an interest-free repayable advance to "extend the Phase I clinical studies of the ProCervix (GTL001) project" for a total of €849 thousand.

Following confirmation of completion of the program and after obtaining the statement of expenditure incurred on the project financed by OSEO, the repayable advance was reduced to take into account the fact that actual expenditure was less than projected. The aid was thus reduced to €812 thousand, and an amendment was signed on September 5, 2014, to change the repayment dates.

The Company repaid this advance as follows:

- Quarterly from September 30, 2014 to June 30, 2015: €19 thousand
- Quarterly from September 30, 2015 to June 30, 2016: €29 thousand
- Quarterly from September 30, 2016 to June 30, 2017: €38 thousand
- Quarterly from September 30, 2017 to June 30, 2018: €57 thousand
- Quarterly from September 30, 2018 to March 31, 2019: €60 thousand
- The balance on June 30, 2019: €60 thousand

The last repayment was made at the beginning of July 2019. Thus, the repayable OSEO Innovation – OSEO 3 advance was fully repaid as of December 31, 2019.

### 9.2 Bonds

**Accounting principles**

Financial instruments (BSAs and bond conversion options) undergo specific analysis.

When these financial instruments provide for exchanging a set number of shares versus a set amount of cash, they are considered as equity instruments according to IAS 32.

When the analysis conducted concludes that it is impossible to consider these instruments as equity and that the variable is financial, they are then considered derivative liabilities falling under the scope of IFRS 9. They are then recognized as derivative liabilities at fair value as of the issue date, with the fair value being determined by applying the Black & Scholes valuation model. Changes in this fair value are recorded in financial income and expenses. These liabilities fall under category 3, defined by IFRS 7.

| CHANGE IN BONDS (Amounts in € thousands) | 2018 YORKVILLE OCABSA | 2019 YORKVILLE OCABSA | TOTAL |
|---|---|---|---|
| **As of December 31, 2017** | **-** | **-** | **-** |
| Cash inflow | 4,900 | - | 4,900 |
| Issuance of share subscription warrants (BSA) | (242) | - | (242) |
| Fair value as of date of issue | 742 | - | 742 |
| Repayment | - | - | - |
| Conversion | (1,890) | - | (1,890) |
| **As of December 31, 2018** | **3,510** | **-** | **3,510** |
| Debt issuances | - | 1,600 | 1,600 |
| Derivative liabilities | | (128) | (128) |
| Amortized cost of debt | | 53 | 53 |
| Debt extinction | (1,600) | - | (1,600) |
| Conversion | (1,910) | (800) | (2,710) |
| **As of December 31, 2019** | **-** | **725** | **725** |

**Breakdown of bonds by maturity, in repayment value**

| BREAKDOWN OF BONDS BY MATURITY, IN REPAYMENT VALUE (Amounts in € thousands) | 2018 YORKVILLE OCABSA | 2019 YORKVILLE OCABSA |
|---|---|---|
| **As of December 31, 2019** | **-** | **800** |
| Maturing in less than 1 year | - | 800 |
| Maturing in 1 to 5 years | - | - |
| Maturing in more than 5 years | - | - |

**9.2.1 Convertible bonds with share subscription warrants ("2018 YORKVILLE OCABSAs") issued to YA II PN Ltd ("Yorkville") on August 20, 2018.**

On August 20, 2018, the Company signed a convertible bonds with stock acquisition rights ("2018 YORKVILLE OCABSA") agreement with YA II PN Ltd ("Yorkville") to potentially raise up to €7.5 million, at the Company's discretion.

The loan comprises two tranches:

- A first tranche of 500 OCAs for a nominal amount of €5 million (as of the signature date);
- A second €2.5 million tranche consisting of 250 OCAs became null and void on November 23, 2018.

The OCAs have the following features:

- Par value: €10,000
- Subscription price: 98% of par
- Commitment fees: 6% of par value
- Maturity: 12 months
- No interest
- Conversion methods: N = Vn / P where
    - N corresponds to the number of shares that can be subscribed
    - Vn corresponds to the par (nominal) value of the bond
    - P corresponds to 92% of the average share price for the five trading days before the conversion request.

If the OCAs are not converted before the maturity date, they are refundable in cash.

The BSAs have the following features:

- Maturity: 5 years
- Exercise price: 115% of the average share price for the five trading days before the tranche is issued.

The Company incurred €410 thousand in fees setting up the bond, including €300 thousand in commitment fees. These fees were recognized in expenses.

<u>2018 YORKVILLE OCABSA valuation</u>

The OCAs were recorded at fair value as of the issue date in accordance with the provisions of IFRS 9.

As of the issue date, the Company has recorded:

- OCAs amounting to €5,400 thousand, or 108% of their par value;
- a €1,152 thousand financial expense (day one loss, see Note 17) in view of the fact that the holder of OCAs may request payment by exercising their conversion option at any time, especially starting from the issue date of same. This expense corresponds to the difference between 98% of the issue price and the fair value of the OCAs amounting to €500 thousand, the commitment fee amounting to €300 thousand, other fees amounting to €110 thousand and the BSA discount amounting to €242 thousand (see below).

The BSAs issued are recognized at fair value through equity on the issue date in accordance with IAS 32.

| BSA YA II PN Ltd ("YORKVILLE") | Tranche 1 |
|---|---|
| | On issuance 08/20/2018 |
| Number of BSAs (before reverse stock split) | 666,312 |
| Maximum number of shares available for subscription (1) | 66,631 |
| Exercise price (1) | €18.76 |
| Expected term | 2.5 years |
| Volatility | 43.71% |
| Risk-free rate | -0.56% |
| **Value of the equity instrument (in € thousands)** | **242** |

(1) After taking into account the 1-for-10 reverse stock split of the Company's shares, effective March 29, 2019.

Conversions in financial year 2019

In financial year 2019, Yorkville converted 165 2018 YORKVILLE OCABSA bonds in accordance with the following terms and conditions:

| Conversion date | Number of bonds | Amounts (in €) | Conversion price | Number of shares issued | Issuance premium |
|---|---|---|---|---|---|
| **Total converted in 2018** | **175** | **€1,750,000** | | **149,762 (1)** | **1,600,239** |
| 04/02/2019 | 10 | €100,000 | €7.949 | 12,580 | 87,420 |
| 04/04/2019 | 10 | €100,000 | €7.949 | 12,580 | 87,420 |
| 04/08/2019 | 20 | €200,000 | €7.901 | 25,313 | 174,687 |
| 04/15/2019 | 30 | €300,000 | €7.989 | 37,551 | 262,449 |
| 04/30/2019 | 25 | €250,000 | €8.359 | 29,907 | 220,093 |
| 06/06/2019 | 30 | €300,000 | €3.339 | 89,846 | 210,154 |
| 07/29/2019 | 10 | €100,000 | €3.7230 | 26,860 | 73,140 |
| 07/31/2019 | 30 | €300,000 | €3.9430 | 76,084 | 223,916 |
| **Total converted in 2019** | **165** | **€1,650,000** | | **310,721** | **1,339,279** |

(1) After taking into account the 1-for-10 reverse stock split of the Company's shares, effective March 29, 2019.

In August 2019, the Company signed an agreement with Yorkville Advisors Global—the management company of a US investment fund—covering a 12-month extension of the conversion period for the remaining €1.6 million of convertible bonds still held by Yorkville.

To this end, on August 19, 2019, Genkyotex bought back from Yorkville, the remaining €1.6 million of convertible bonds maturing on August 20, 2019 that Yorkville still held, and then immediately issued to Yorkville 160 convertible bonds for a total nominal amount of €1.6 million (see Note 9.2.2), by offsetting this against the €1.6 million debt corresponding to the Investor's prior sale to the Company of 160 2018 OCAs, issued on August 20, 2018.

In accordance with IFRS 9, the redemption of the debt was considered by the Company to be a debt extinction.

As of December 31, 2019, 666,312 BSAs (giving the right to subscribe 66,631 shares) were outstanding.

### 9.2.2 Bonds convertible into shares ("2019 YORKVILLE OCAs") issued to YA II PN Ltd ("YORKVILLE") on August 19, 2019

The main features of the 2019 YORKVILLE OCAs issued August 19, 2019 are:

- The nominal unit value of the OCAs is equal to ten thousand euro (€10,000). Each OCA will be issued at a subscription price per OCA equal to 100% of its nominal unit value, a total nominal amount of one million six hundred thousand euro (€1,600,000).
- The OCAs (i) are freely assignable or transferable by the Investor to any of its affiliates and (ii) may not be transferred to any other third party without the prior written consent of the Company.
- The OCAs will not be listed or admitted to trading on the regulated markets of Euronext Paris or Euronext Brussels or on any other financial market. Each OCA expires twelve (12) months from its issue (the "Maturity date"). In the event that an OCA is not converted before the Maturity date, the Company is obliged to repay the outstanding amount in cash.
- The OCAs do not bear any interest. However, in the event of the occurrence of a Default (2), each OCA outstanding will bear interest at the rate of 15% per year from the date of the Default and up to (i) the date on which the Default is resolved, or (ii) the date on which the OCA has been fully converted and/or repaid, if the Default has not yet been resolved.
- The number of new shares issued by the Company for the benefit of each OCA holder when converting one or more OCAs corresponds to the amount of the conversion divided by the applicable Conversion Price. The "Conversion Price" is equal to 92% of the weighted average share price quoted on Euronext (as reported by Bloomberg) (the "Average Prices") on the five (5) consecutive stock exchange sessions up to the trading session immediately before the conversion date.

Valuation

Debt is assessed using the amortized cost method in accordance with IFRS 9. The Company incurred €103 thousand of charges directly attributable to the issuance of the debt.

The conversion option is recognized under derivative liabilities and is valued at fair value in a Monte-Carlo model, with recognition of changes in this fair value through profit or loss.

At the date of issue, the value of the derivative liability was €128 thousand or 8% of the total nominal amount of €1,600 thousand. As of December 31, 2019, the derivative liability was €64 thousand or 8% of the residual nominal amount of €800 thousand.

Conversions in financial year 2019

| Conversion date | Number of bonds | Amounts (in €) | Conversion price | Number of shares issued | Issuance premium |
|---|---|---|---|---|---|
| 11/04/2019 | 20 | €200,000 | €1.7850 | 112,044 | 87,955 |
| 11/27/2019 | 10 | €100,000 | €1.8440 | 54,229 | 45,769 |
| 11/29/2019 | 10 | €100,000 | €1.8920 | 52,854 | 47,146 |
| 12/13/2019 | 20 | €200,000 | €1.8460 | 108,342 | 91,657 |
| 12/30/2019 | 20 | €200,000 | €1.8100 | 110,497 | 89,503 |
| **Total converted in 2019** | **80** | **€800,000** | | **437,966** | **362,029** |

As of December 31, 2019, 80 2019 OCAs were outstanding.

They were fully converted on January 14 and 15, 2020 see Note 25.

**9.3 Debt related to lease payment obligations**

| CHANGES IN FINANCIAL DEBT – LEASE LIABILITIES (Amounts in € thousands) | Financial debt (lease liabilities) |
|---|---|
| **As of December 31, 2018** | **-** |
| Impact of the initial application of IFRS 16 | 263 |
| (+) Leases concluded during the period | - |
| (-) Reduction in the financial debt relating to rights of use (IFRS 16) | (121) |
| (-) Advance payment | (9) |
| Exchange rate | 6 |
| **As of December 31, 2019** | **139** |

Breakdown of financial debt by maturity, in repayment value

| BREAKDOWN OF FINANCIAL DEBT BY MATURITY, IN REPAYMENT VALUE (Amounts in € thousands) | Financial debt (lease liabilities) |
|---|---|
| **As of December 31, 2019** | **139** |
| Maturing in less than 1 year | 122 |
| Maturing in 1 to 5 years | 16 |
| Maturing in more than 5 years | - |

### Accounting principles

The Group provides retirement, death and disability benefits to its employees in line with local customs and requirements through pension payments by social security bodies, which are funded by Group and employee contributions (defined contribution plan) in Switzerland and France, the two countries where the Group operates.
The Group also provides retirement, death and disability benefits to its Swiss and French employees through the following defined-benefit plans:

- For Swiss employees, Genkyotex Suisse SA's compulsory company-wide defined-benefit plan through a program that is funded through employer (50%) and employee (50%) contributions. This company-specific plan has been in place since Genkyotex Suisse SA was founded, and all Swiss employees of this company are beneficiaries of the plan. On retirement, the plan participant will receive his/her accumulated savings, which consist of all contributions paid in by the employer and the employee (net of any withdrawals) and the interest granted on those savings, which are fixed, according to the law for the compulsory part and at the discretion of the Council of the Foundation for the optional part. At retirement age, the plan participant will be entitled to choose between a lump sum payment or an annuity, or a combination of the two.
- Employees of the Group's French companies are entitled to a retirement lump sum payment at the time of retirement.

Pension plans, similar compensation and other employee benefits that qualify as defined benefit plans (in which the Group guarantees an amount or defined level of benefits) are reported in the balance sheet based on an actuarial valuation of the obligations at period end, minus the fair value of the plan's assets.
This valuation is determined by using the projected unit credit method, taking into account staff turnover and mortality probability. Any actuarial differences are reported in equity under “Other comprehensive income.”
The Group's payments into defined contribution plans are reported under expenses on the income statement for the period to which they relate. Retirement expenses (cost of services rendered and interest expense) are presented in operating income (loss).

| **EMPLOYEE BENEFIT OBLIGATIONS (Amounts in € thousands)** | **12/31/2019** | **12/31/2018** |
|---|---|---|
| Swiss employees | 1,335 | 991 |
| French employees | 13 | 5 |
| **Employee benefit obligations** | **1,348** | **996** |

**10.1 SWISS EMPLOYEES**

The defined benefit obligation related to the 2nd pillar of the Swiss pension system is assessed using the following assumptions:

| ACTUARIAL ASSUMPTIONS | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Age at retirement | Voluntary retirement 64 years of age for women/65 years of age for men | |
| Discount rate | 0.20% | 0.85% |
| Mortality table | LPP 2015 generation | LPP 2015 generation |
| Salary revaluation rate | 1.00% | 1.00% |
| Retirement pension inflation rate | 0.50% | 0.50% |
| Deposit rate on savings accounts | 1.00% | 0.85% |
| Turnover rate | 10.00% | 10.00% |

*Mortality rate*

Assumptions regarding future mortality are based on advice, statistics publications and experience. The weighted average duration of the retirement obligation is as follows:

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| The weighted average duration of the retirement obligation | 26.00 | 29.40 |

Changes to the retirement obligation and the fair value of retirement benefit plan assets are as follows:

| Amounts in € thousands | Defined benefit plan obligation | Fair value of plan assets | Employee benefit obligations |
|---|---|---|---|
| **December 31, 2017** | **1,771** | **(952)** | **819** |
| Service costs | 249 | - | **249** |
| Interest expense | 13 | (8) | **5** |
| Employee contribution | - | (157) | **(157)** |
| **Subtotal included in the income statement** | **262** | **(165)** | **97** |
| **Amounts paid/received** | **(83)** | **83** | **-** |
| Return on assets (excluding interest expenses) | - | (3) | **(3)** |
| Actuarial gains and losses related to changes in financial assumptions | (46) | - | **(46)** |
| Other actuarial gains (losses) | 247 | - | **247** |
| **Subtotal included in other items of comprehensive income** | **201** | **(3)** | **198** |
| **Employer contributions** | **-** | **(157)** | **(157)** |
| **Currency translation effect** | **78** | **(43)** | **35** |
| **December 31, 2018** | **2,228** | **(1,237)** | **991** |
| Service costs | 328 | - | 328 |
| Interest expense | 19 | (11) | 8 |
| Employee contribution | - | (109) | (109) |
| **Subtotal included in the income statement** | **347** | **(120)** | **227** |
| **Amounts paid/received** | **(22)** | **22** | - |
| Return on assets (excluding interest expenses) | - | (2) | (2) |
| Actuarial gains and losses related to changes in demographic assumptions | - | - | - |
| Actuarial gains and losses related to changes in financial assumptions | 172 | - | 172 |
| Other actuarial gains (losses) | 11 | - | 11 |
| Experience effect | - | - | **-** |
| **Subtotal included in other items of comprehensive income** | **182** | **(2)** | **180** |
| **Employer contributions** | - | **(109)** | **(109)** |
| **Currency translation effect** | **98** | **(52)** | **45** |
| **December 31, 2019** | **2,833** | **(1,498)** | **1,335** |

**Sensitivity analysis as of December 31, 2019**

| (Amounts in € thousands) | | Salary revaluation rate | |
|---|---|---|---|
| Sensitivity analysis | 0.50% | **Assumptions: 1%** | 1.50% |
| Retirement obligation | 2,779 | **2,883** | 2,890 |
| | | **Discount rate** | |
| Sensitivity analysis | -0.30% | **Assumptions: 0.85%** | 0.70% |
| Retirement obligation | 3,235 | **2,833** | 2,496 |
| | | **Pension inflation rate** | |
| Sensitivity analysis | 0.00% | **Assumptions: 0.50%** | 1.00% |
| Retirement obligation | 2,653 | **2,883** | 3,035 |

Group contributions for the 2020 retirement plan are estimated at €116 thousand.

Asset classes from the retirement plan and their respective allocations are as follows:

| Allocation (in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Cash and cash equivalent | 37 | 37 |
| Bonds | 840 | 695 |
| Mortgage loans | 228 | 210 |
| Shares | 259 | 98 |
| Real estate | - | 182 |
| Other investments | 133 | 15 |
| **Total** | **1,498** | **1,237** |

The following table shows estimated benefit payments for the next ten years:

| | |
|---|---|
| 2020 | €116 thousand |
| 2021 | €105 thousand |
| 2022 | €93 thousand |
| 2023 | €82 thousand |
| 2024 | €69 thousand |
| 2025-2029 | €197 thousand |

**10.2 FRENCH EMPLOYEES**

The main actuarial assumptions used to measure retirement packages are as follows:

| ACTUARIAL ASSUMPTIONS | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Age at retirement | Voluntary retirement age between 65 and 67 | |
| Collective bargaining agreement | Pharmaceutical industry | |
| Discount rate (IBOXX Corporates AA) | 0.77% | 1.57% |
| Mortality table | INSEE 2018 | INSEE 2017 |
| Salary revaluation rate | 2.00% | 2.00% |
| Turnover rate | High | High |
| Social security expense ratio | | |
| Managers | 47% | 44%* |
| Non-managers | 47% | 46% |

**excluding managers eligible for withholding tax*

The following shows the change in retirement provisions:

| Amounts in € thousands | Retirement obligation |
|---|---|
| **As of December 31, 2017** | **3** |
| Service costs | 2 |
| Interest expense | 0 |
| Actuarial gains and losses | (1) |
| **As of December 31, 2018** | **5** |
| Service costs | 5 |
| Interest expense | 0 |
| Actuarial gains and losses | 3 |
| **As of December 31, 2019** | **13** |

## Note 11: Provisions

### Accounting principles

Provisions correspond to commitments resulting from litigation and various risks, the outcome and value of which are uncertain, that the Company may face as part of its activities.

A provision is reported when the Company has an obligation to a third party resulting from a past event that is likely to cause an outflow of resources to the benefit of that third party, without a counterpart at least equivalent to it, and future outflows of cash can be reliably estimated. The amount reported in provisions is the estimated expense necessary to extinguish the obligation, discounted if necessary at the end of the period.

## Note 12: Other current liabilities

### Accounting principles

The fair value of current liabilities is equivalent to their carrying amount in the balance sheet, taking into account the extremely short deadlines for payment.

| **OTHER CURRENT LIABILITIES (Amounts in € thousands)** | **12/31/2019** | **12/31/2018** |
|---|---|---|
| Bonus (including social security contributions) | 17 | 372 |
| Payroll & related accounts | 190 | 172 |
| Social security & other welfare programs | 134 | 155 |
| Other taxes and similar | 128 | 144 |
| Other liabilities | 43 | 60 |
| **Other current liabilities** | **512** | **903** |

## Note 13: Financial assets and liabilities and effects on income

### Accounting principles

The Company has established three categories of financial instruments depending on their valuation methods and uses this classification to disclose some of the information required by IFRS 7:

- Level 1: financial instruments listed on an active market;
- Level 2: financial instruments whose valuation methods rely on observable inputs;
- Level 3: financial instruments whose valuation methods rely entirely or partly on unobservable inputs, an unobservable input being defined as one whose measurement relies on assumptions or correlations that are not based on the prices of observable market transactions for a given instrument on the valuation date, nor on observable market data on the valuation date.

The Company's assets and liabilities are measured as follows at the year-end of the financial years presented:

| HEADERS - STATEMENT OF FINANCIAL POSITION (amounts in € thousands) | 12/31/2019 | | Value – statement of financial position under IFRS 9 | | | Financial instrument category |
|---|---|---|---|---|---|---|
| | Value – statement of financial position | Fair value | Fair value through income/(loss) | Fair value through other comprehensive income | Amortized cost | |
| Non-current financial assets | 29 | 29 | | | 29 | Level 1 |
| Other receivables | 1,500 | 1,500 | | | 1,500 | Level 1 |
| Cash and cash equivalents | 2,417 | 2,417 | 2,417 | | | Level 1 |
| **Total assets** | **3,946** | **3,946** | **2,417** | **-** | **1,529** | |
| Non-current financial liabilities | 17 | 17 | | | 17 | Level 1 (right of use) |
| Current financial liabilities | 912 | 912 | 725 | | 186 | Level 1 (repayable advances, debt related to lease obligations) / Level 3 (bonds) |
| Trade payables | 562 | 562 | | | 562 | Level 1 |
| Other current liabilities | 512 | 512 | | | 512 | Level 1 |
| **Total liabilities** | **2,002** | **2,002** | **725** | | **1,277** | |

| HEADERS - STATEMENT OF FINANCIAL POSITION (amounts in € thousands) | 12/31/2018 | | Value – statement of financial position under IFRS 9 | | | Financial instrument category |
|---|---|---|---|---|---|---|
| | Value – statement of financial position | Fair value | Fair value through income/(loss) | Fair value through other comprehensive income | Amortized cost | |
| Non-current financial assets | 45 | 45 | | | 45 | Level 1 |
| Other receivables | 2,157 | 2,157 | | | 2,157 | Level 1 |
| Cash and cash equivalents | 10,309 | 10,309 | 10,309 | | | Level 1 |
| **Total assets** | **12,511** | **12,511** | **10,309** | **-** | **2,201** | |
| Non-current financial liabilities | - | - | - | | | - |
| Current financial liabilities | 3,641 | 3,641 | 3,510 | | 131 | Level 1 (repayable advances)/Level 3 (bond debt) |
| Trade payables | 2,214 | 2,214 | | | 2,214 | Level 1 |
| Other current liabilities | 903 | 903 | | | 903 | Level 1 |
| **Total liabilities** | **6,757** | **6,757** | **3,510** | **-** | **3,247** | |

| IMPACTS - INCOME STATEMENT (Amounts in € thousands) | 12/31/2019 | | 12/31/2018 | |
|---|---|---|---|---|
| | Interest | Change in fair value | Interest | Change in fair value |
| **Assets** | | | | |
| Fair value through income/(loss) | - | - | - | 3 |
| Cash and cash equivalents | - | - | - | - |
| **Liabilities** | | | | - |
| Financial debt at amortized cost (repayable advances) | 1 | - | - | - |
| Financial debt at amortized cost (right of use) | 5 | - | - | - |
| Bond at amortized cost | 156 | - | - | - |
| Derivative liability at fair value through profit or loss | - | (64) | - | - |
| Bonds at fair value through profit or loss | - | - | - | 1,152 |

**Accounting principles**

Application of IFRS 15 has been mandatory since January 1, 2018. This standard overhauls the model used to recognize income, the fundamental principle of which is based on the transfer of control of goods and services to the customer.
The standard sets out a five-step general approach to revenue recognition:

- Step 1: Identify the contract;
- Step 2: Identify the "performance obligations" under the contract. The "performance obligations" serve as a unit of account for the revenue recognition;
- Step 3: Determine the transaction price;
- Step 4: Allocate the transaction price to each "performance obligation";
- Step 5: Recognize the revenue when the "performance obligation" is satisfied, either on a given date or over time.

The standard specifies how to treat licenses and distinguishes two types:

- those which constitute a right to access intellectual property as it will change over the term of the license as a result of future action taken by the licensor. These licenses are known as "dynamic licenses" or "rights to access" and recognition of the associated income is spread over the term of the license; and
- those which constitute a right to use "fixed" intellectual property, as it exists as of the date on which the license is assigned. These licenses are called "static licenses" or "rights of use", and the income related to them is recognized on a given date at the time when control of the license is transferred, unless the royalty exception applies, regardless of the type of license.

Variable consideration is recognized when it is highly probable.
IFRS 15 also provides that the revenue related to intellectual property licenses for which royalties are received should be recognized when the later of the following two events occurs:

- the license is sold or used by the customer (on which the calculation of royalties is based);
- the "performance obligation" to which these royalties have been allocated has been satisfied.

In accordance with IFRS 15, the Group has reviewed the license agreement with the Serum Institute of India Pvt. Ltd. (SIIL) for the Vaxiclase platform. The Group considers that the license covered by the agreement constitutes a right of use (static license).

Considering the above, the Company recognized €750 thousand in revenue during the first half of 2018 for the expanded license transfer signed in June 2018, which constitutes a right to use.

The agreement provides for four types of variable compensation:

- Development milestone payments based on the progress of work undertaken by the customer;
- Commercial milestone payments based on levels of total sales achieved by the customer;
- Milestone payments in the event that the customer grants any sublicenses;
- Royalties.

The development milestone payments set out in the contract will be recognized when they become highly probable. Given that the various phases of the project progress at uncertain rates, the revenue associated with these milestone payments is recognized as of the date the customer achieves these development phases.

The other two types of milestone payments are related to sales and are treated as royalties. They will therefore be recognized as income when the sale is made.

## Note 15: Breakdown of expenses and items by function

### Accounting principles

The Group presents its income statement by function in two categories:

- Research and development;
- General and administrative expenses.

Expenses are broken down on the basis of cost accounting.
The research tax credit and operating grants are presented in subsidies and are deducted for the research and development costs.
Operating grants are recorded, taking into account the rate of corresponding expenses so as to adhere to the principle of matching revenues and expenses, as the case may be.

### 15.1 RESEARCH AND DEVELOPMENT

| RESEARCH AND DEVELOPMENT (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Raw materials and consumables | (83) | (139) |
| Studies and research | (3,158) | (6,096) |
| Personnel expenses | (1,277) | (1,509) |
| Expenses related to retirement obligations | (84) | 36 |
| Lease expenses | (18) | (121) |
| Licenses and intellectual property costs | (722) | (531) |
| Depreciation, amortization and impairment | (581) | (586) |
| Share-based payments | (258) | (296) |
| Other | (26) | (40) |
| Amortization of rights of use | (98) | - |
| **Research and development expenses** | **(6,305)** | **(9,282)** |
| Research tax credit | 899 | 893 |
| Subsidies | - | - |
| **Subsidies** | **899** | **893** |
| **Net research and development expenses** | **(5,406)** | **(8,389)** |

Study and research costs correspond to the costs incurred in connection with the Phase 2 trial of its GKT831 product in PBC and the preclinical work in progress on the GKT771 compound.

Research and development expenses amounted to €5,406 thousand as of December 31, 2019, compared with €8,389 thousand as of December 31, 2018, i.e., a decrease of -€2,983 thousand. This decrease can be explained primarily by a reduction in the study and research costs associated with the end of the Phase 2 trial of its GKT831 product.

### 15.2 GENERAL AND ADMINISTRATIVE EXPENSES

| GENERAL AND ADMINISTRATIVE EXPENSES (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Travel and incidental expenses | (208) | (325) |
| Lease expenses | (1) | (38) |
| Fees | (889) | (1,199) |
| Insurance | (35) | (94) |
| Marketing and sales expenditure | (89) | (124) |
| Taxes and duties | (29) | (12) |
| Personnel expenses | (411) | (666) |
| Expenses related to retirement obligations | (39) | 23 |
| Attendance fees | (49) | (60) |
| Amortization and depreciation | (3) | (6) |
| Share-based payments | (226) | (216) |
| Other | (149) | (119) |
| Amortization of rights of use | (33) | - |
| **General and administrative expenses** | **(2,160)** | **(2,836)** |

General and administrative expenses amounted to €2,160 thousand as of December 31, 2019 compared with €2,836 thousand as of December 31, 2018, i.e., a decrease of €676 thousand. This change can be explained primarily by the following:

- A decrease in travel and mission expenses of €117 thousand,
- A decrease in fees of €310 thousand,
- A reduction of €256 thousand in personnel expenses in relation to changes in components of variable compensation.

## Note 16: Other operating income and expenses

**Accounting principles**

Other operating income and expenses include significant items that may not be considered as inherent to the Group's day-to-day activity due to their nature or non-habitual character.

They may include, in particular:

- costs relating to the merger/acquisition of companies;
- certain restructuring costs;
- other operating income and expenses such as a provision relating to a highly material dispute;
- a capital gain or loss on sale or substantial and unusual depreciation of non-current assets.

The Group did not recognize any other non-current operating income or expenses in financial years 2018 and 2019.

## Note 17: Net financial income (expenses)

### Accounting principles

Net financial income includes:

- Expenses related to the financing of the Company: interest paid and unwinding of repayable advances and financial liabilities.
- Interest income from term deposits and the capital bond.

Gains and losses on currency translation are also reported under financial income (expenses).

| NET FINANCIAL INCOME AND EXPENSES (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Cost of bonds issued | (156) | (1,152) |
| Derivative liabilities (fair value) | 64 | - |
| Other financial expenses | (7) | (11) |
| Other financial income | 0 | 3 |
| Currency gains and losses | 320 | 173 |
| **Net financial income (expenses)** | **222** | **(987)** |

The cost of the bonds is described in Note 9.2.

Gains and losses on currency translation as of December 31, 2019 and December 31, 2018 primarily represent the impact of fluctuations in the CHF/EUR exchange rate on the intragroup accounts of Genkyotex Suisse SA with Genkyotex SA.

## Note 18: Income taxes

### Accounting principles

Taxable assets and liabilities for this and previous financial years are valued at the amount expected to be recovered from or paid to the tax authorities.
The tax rates and tax regulations used to calculate these amounts are those which were adopted or partially adopted at the end of the period.

Deferred taxes are reported using the variable deferral method for all temporary differences existing at the end of the reporting period between the tax base of assets and liabilities and their carrying amount on the balance sheet, as well as on deferrable losses.

The main temporary differences relate to deferrable tax losses.
Deferred tax assets are reported as deferrable tax losses when it is probable that the Company will have future taxable profits to which those unused tax losses could be applied. The measurement of identifiable deferred tax assets requires Management to make estimates about the time period over which the deferred losses will be used up, and about the level of future taxable income, based on the tax strategies adopted.

**Tax rate and tax loss carryforwards**

Genkyotex SA had tax losses in France that can be carried forward indefinitely totaling €91,859 thousand as of December 31, 2019.

The tax rate on applicable income for Genkyotex SA is the rate that is currently applicable in France (28%). This rate will gradually decrease to reach 25% by 2022.

Genkyotex Suisse SA had approximately €60,385 thousand (CHF 67,175 thousand) in tax loss carryforwards as of December 31, 2019, which break down as follows:

- €5,257 thousand (CHF 5,706 thousand) originating in 2019 and expiring in 2027;
- €9,941 thousand (CHF 10,790 thousand) originating in 2018 and expiring in 2026;
- €3,478 thousand (CHF 3,775 thousand) originating in 2017 and expiring in 2025;
- €11,848 thousand (CHF 12,860 thousand) originating in 2015 and expiring in 2023;
- €14,285 thousand (CHF 15,505 thousand) originating in 2014 and expiring in 2022;
- €12,416 thousand (CHF 13,476 thousand) originating in 2013 and expiring in 2021;
- €4,665 thousand (CHF 5,063 thousand) originating in 2012 and expiring in 2020.

The tax rate on applicable income for Genkyotex Suisse SA is the rate that is currently applicable in the Swiss Canton of Geneva (24%).

In accordance with the principles described above, no deferred tax assets have been recognized beyond deferred tax liabilities in the Group's consolidated financial statements as of December 31, 2019. Deferred tax assets are reported as deferrable tax losses, when it is more probable than improbable that the Company will have future taxable profits to which those unused tax losses could be applied.

Additionally, no deferred tax liabilities were reported based on the revaluation of the SIIL contract in view of the exemption under IAS 12.15 in the event of acquisition of assets.

**Reconciliation between theoretical tax and effective tax**

| **TAX PROOF (amounts in € thousands)** | **12/31/2019** | **12/31/2018** |
|---|---|---|
| Net profit/(loss) | (7,203) | (11,417) |
| Income taxes | - | - |
| **Profit/(loss) before tax** | **(7,203)** | **(11,417)** |
| Current tax rate | 24.00% | 24.00% |
| **Theoretical tax at the current rate** | **1,729** | **2,740** |
| Non-taxable items | 105 | (201) |
| Share-based payments | (135) | (143) |
| Non-capitalized tax, adjusted for deferred tax | (1,777) | (2,479) |
| Effect of tax rate differences | 78 | 83 |
| **Income taxes** | **0** | **0** |
| *Effective tax rate* | 0.00% | 0.00% |

The permanent differences include the impact of the research tax credit (non-taxable operating income).

**Nature of deferred taxes**

| NATURE OF DEFERRED TAXES<br>(amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Retirement | 297 | 212 |
| Other | 4 | 27 |
| Loss carryforward in France | 25,717 | 22,023 |
| Loss carryforward in Switzerland | 14,854 | 13,091 |
| **Total items with a deferred tax asset nature** | **40,872** | **35,352** |
| | | |
| SIIL contract | (2,271) | (2,413) |
| **Total items with a deferred tax liability nature** | **(2,271)** | **(2,413)** |
| | | |
| **Total items with a deferred tax nature** | **38,601** | **32,939** |
| Unrecognized deferred tax assets | (38,601) | (32,939) |
| **Deferred taxes, net** | **-** | **-** |

## Note 19: Earnings per share

### Accounting principles

Basic earnings per share are calculated by dividing the net profit attributable to Company shareholders by the weighted average number of the shares outstanding during the period.

Diluted earnings per share are calculated by adjusting the net income attributable to the holders of ordinary shares and the weighted average number of ordinary shares outstanding by the effects of all the dilutive potential ordinary shares.

If, when calculating diluted earnings per share, taking into account instruments giving deferred access to capital (BSA and BSPCE) creates an anti-dilutive effect, those instruments are not taken into account. In this way, diluted earnings per share are identical to basic earnings per share.

| EARNINGS PER SHARE | 12/31/2019 | 12/31/2018 |
|---|---|---|
| | Ordinary shares | Ordinary shares |
| Weighted average number of shares outstanding for the financial periods presented (1) | 8,146,178 | 7,807,515 |
| | | |
| Net profit/(loss) for the period attributable to owners of the parent company (in € thousands) | (7,203) | (11,417) |
| **Basic earnings per share (€/share)** | **(0.88)** | **(1.46)** |
| **Diluted earnings per share (€/share)** | **(0.88)** | **(1.46)** |

*(2) On January 24, 2019, the Company's Board of Directors voted to perform a 1-for-10 reverse stock split, which was approved by the Company's shareholders during the Extraordinary General Shareholders' Meeting on January 24, 2019. The weighted average number of shares was thus divided by 10. In accordance with IAS 33, the earnings per share presented for the financial year ended December 31, 2018 have been retrospectively adjusted.*

## Note 20: Segment information

### Accounting principles

The Group operates in only one business segment, the research and development of pharmaceutical products.

Assets, operating losses as well as research and development fees are located in France and in Switzerland.

## Note 21: Related parties

### 21.1 COMPENSATION DUE TO CORPORATE OFFICERS

Executive compensation breaks down as follows:

| EXECUTIVE COMPENSATION (Amounts in € thousands) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Fixed compensation due | 221 | 212 |
| Variable compensation due | - | 138 |
| Benefits in kind | 20 | 21 |
| Employer contributions to the retirement plan | 29 | 29 |
| Share-based payments | 232 | 260 |
| Attendance fees | 49 | 60 |
| **TOTAL** | **551** | **721** |

No post-employment benefits were granted to members of the Board of Directors or to executives, with the exception of the mandatory defined benefit plan applicable for Swiss employees under the 2nd pillar of the Swiss social security system.

The variable components of compensation were allocated on the basis of performance criteria.
The methods used to calculate the fair value of share-based payments are explained in Note 8.

### 22.1 Guarantee

A bank guarantee for €22 thousand (CHF 24 thousand) was provided to the landlord of the Plan-les-Ouates premises.

### 22.2 Contractual obligations

#### 22.2.1 Licensing agreement with the Institut Pasteur

Genkyotex SA signed a license agreement with the Institut Pasteur that takes effect on January 1, 2018 and replaces the first agreement signed on February 22, 2006.

The new agreement provides for:

- royalties on net proceeds by the Company, categorized by human use and by veterinary use (lack of revenue generated by the Company under the agreement);
- a share in the cost of maintaining the patents: the Institut Pasteur is responsible for obtaining the issuance and assuring the continuing validity of patents. However, the Company will reimburse the Institut Pasteur for all of the direct external expenses incurred by the Institut Pasteur to maintain and extend the patents;
- a royalty in the case of sublicensing (to date, the Company has not signed this type of agreement).

#### 22.2.2 License agreement with Serum Institute of India Pvt. Ltd. (SIIL)

Following the signature of an extension to the license agreement for the Vaxiclase platform with the Serum Institute of India (SIIL) in June 2018, the contract provides for:

- An initial payment of €750 thousand (recognized during the first half of 2018);
- Milestone payments for emerging markets for up to USD 57 million;
- Milestone payments for industrialized countries for up to €100 million.

The Company is also eligible to receive “single-digit percentage” royalties on sales.

#### 22.2.3 Research contract with Baker Heart and Diabetes Institute

On June 28, 2017, the Company announced that the world-class diabetes experts, Professor Mark Cooper, Head of the Department of Diabetes at Monash University, and Professor Jonathan Shaw, Deputy Director of Clinical and Population Health at the Baker Heart and Diabetes Institute in Melbourne, Australia, will direct a Phase 2 clinical trial to assess the efficacy and safety of the Company's flagship product candidate, GKT831, in patients with type 1 diabetes and kidney disease (diabetic nephropathy).

This investigator-initiated study will be conducted at the Baker Institute and in several clinical centers across Australia. It will be funded by the Juvenile Diabetes Research Foundation of Australia (JDRF Australia), a beneficiary of the Australian Research Council fund dedicated to the Special Research Initiative for Type 1 Juvenile Diabetes, with financial support from the Baker Institute. As part of this study, Genkyotex will provide the GKT831 compound compliant with good manufacturing practices (GMP).

Under this contract, the company recorded additional income of €141 thousand at December 31, 2019 versus €44 thousand at December 31, 2018.

### 22.2.4 Other commitments

The first-time application of IFRS 16 as from January 1, 2019 (see Notes 2.1 and 9.3) removes the distinction between finance leases and operating leases. The standard means that the Company's obligation to pay future lease payments must be recognized as a liability and a right of use as an asset.

As a result of the impact of IFRS 16, the current off-balance sheet commitments as of December 31, 2019 are deemed to be immaterial.

## Note 23: Financial risk management and assessment

Genkyotex SA may find itself exposed to various types of financial risk: market risk, credit risk and liquidity risk. When necessary, Genkyotex SA implements simple measures proportional to its size to minimize the potential adverse effects of those risks on its financial performance.
It is Genkyotex SA's policy not to use financial instruments for speculative purposes.

### Interest rate risk

Genkyotex SA is not significantly exposed to interest rate risk, to the extent that:

- its cash and cash equivalents and financial assets include term deposits,
- no variable rate debt has been obtained.

### Credit risk

Credit risk is associated with deposits with banks and financial institutions. For its cash investments, Genkyotex SA uses top-tier financial institutions and therefore does not carry significant credit risk on its cash.

### Foreign exchange risk

The main risks related to the impact of foreign exchange rates are considered insignificant, except for the SIIL contract where some milestone revenue and royalties are denominated in US dollars (see Note 3.1).
The Company, at its present stage of development, does not use hedging instruments to protect its activity from exchange rate fluctuations. However, the Company cannot rule out the possibility that a major increase in its activity will increase its exposure to exchange rate risk. In such a case, the Company would consider adopting an appropriate policy to hedge such risks.

### Equity risk

The Company does not hold equity investments or marketable securities on a regulated market.

### Liquidity risk

As of the reporting date, the Board of Directors considers that the Company will be able to meet its financing needs for anticipated operations until February 2021. Refer to Note 2.1.

## Note 24: Statutory Auditors' fees

| STATUTORY AUDITORS' FEES | Financial year 2019 (12 months) | | Financial year 2018 (12 months) | |
|---|---|---|---|---|
| **(Amounts exc. VAT in € thousand)** | **KPMG** | **SYGNATURES** | **GRANT THORNTON** | **SYGNATURES** |
| For auditing the financial statements | 60 | 60 | 63 | 59 |
| For other services directly related to the duties of the Statutory Auditor | - | - | - | - |
| Services unrelated to the auditing of accounts (1) | - | - | 6 | 6 |
| ***Subtotal*** | **60** | **60** | **69** | **65** |
| Other services | | | | |
| - Tax | - | - | - | - |
| - Other | - | - | - | - |
| ***Subtotal*** | **-** | **-** | **-** | **-** |
| **Total** | **60** | **60** | **69** | **65** |

*(1) In 2018, services other than certifying the financial statements, covering services required by laws and regulations (reports related to the General Shareholders' Meeting) as well as services provided upon Genkyotex's request (review of the 2017 Registration Document).*

## Note 25: Post-balance sheet events

January 2020:

- On January 14 and 15, 2020, Yorkville converted the remaining 80 2019 OCAs outstanding at December 31, 2020. See Note 9.2. Following these conversions, 417,816 new shares were issued. As of the reporting date the Company no longer has a bond.

February 2020:

- The company finalized a capital increase with shareholders' pre-emptive rights maintained in the amount of €4.9 million.

## 18.1.1.2 Report of the Statutory Auditors on the IFRS Consolidated Financial Statements at December 31, 2019

KPMG Audit
51 rue de Saint-Cyr
CS 60409
69338 Lyon Cedex 9
France

sygnatures
8, chemin de la Terrasse
BP 45122 Toulouse Cedex 5

*This is a translation into English of the statutory auditors' report on the financial statements of the Company issued in French and it is provided solely for the convenience of English speaking users.*
*This statutory auditors' report includes information required by European regulation and French law, such as information about the appointment of the statutory auditors or verification of the management report and other documents provided to shareholders.*
*This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.*

**Genkyotex S.A.**

Registered office: 218, avenue Marie Curie, Forum 2 Archamps Technopole 74166 Saint-Julien-en-Genevois
Share capital: €.11.548.562

**Statutory auditors' report on the consolidated financial statements**

For the year ended 31 December 2019

Dear Shareholders

### Opinion

In compliance with the engagement entrusted to us by your annual general meeting, we have audited the accompanying consolidated financial statements of Genkyotex S.A. for the year ended December 31, 2019. These financial statements were approved by the Board of Directors on 24 February 2020 based on the information available at that date and in the evolving context of the health crisis linked to the Covid-19.

In our opinion, the consolidated financial statements give a true and fair view of the assets and liabilities and of the financial position of the Group as at 31 december 2019 and of the results of its operations for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union.

The audit opinion expressed above is consistent with our report to the Audit Committee.

### Basis for Opinion

#### *Audit Framework*

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the *Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements* section of our report.

***Independence***

We conducted our audit engagement in compliance with independence rules applicable to us, for the period from January 1, 2019, to the date of our report and specifically we did not provide any prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No 537/2014 or in the French Code of ethics (code de déontologie) for statutory auditors.

**Justification of Assessments - Key Audit Matters**

In accordance with the requirements of Articles L.823-9 and R.823-7 of the French Commercial Code (code de commerce) relating to the justification of our assessments, we inform you of the key audit matters relating to risks of material misstatement that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period, as well as how we addressed those risks.

These matters were addressed in the context of our audit of the consolidated financial statements as a whole, approved in the context described above, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the consolidated financial statements.

| Assessment of management evaluation of the going concern | |
|---|---|
| **Key Audit Matter** | **Our response** |
| As indicated in Note 2.1 to the consolidated financial statements, Genkyotex S.A. Board of Directors evaluated that the Group will have sufficient financial resources to operate until February 2021.<br><br>At the date the consolidated financial statements were approved, the Board of Directors assessed the going concern principle applied in preparing the financial statements based on the following:<br><br>• the €2.417k outstanding cash and cash equivalents at December 31, 2019;<br><br>• the expected collection of the 2019 research tax credit for €899k ;<br><br>• the operational cash outflows forecasted for 2020 and beginning of 2021 ;<br><br>• the conversion in January 2020 of the remaining convertible bonds which were outstanding for €800k at December 31, 2019;<br><br>• the €4.9m share capital increase which was successfully completed in February 2020.<br><br>We identified the assessment of the Group's ability to continue as a going concern as key audit matter because it is dependent upon management assumptions and judgments and because of the inherent risk involved in forecasting future cash flows. | We assessed management evaluation of the Group's ability to continue as a going concern for the 12 months from the financial statements reporting date.<br><br>Specifically we :<br><br>• understood the process used by management to prepare the cash forecast and estimate future expenses,<br><br>• assessed the key assumptions used by management in the cash forecast with regards to our experience with the Company and management's plans<br><br>• evaluated the impact of the conversion of the remaining outstanding convertible bonds and of the share capital increase which occurred after the reporting date on the cash forecast<br><br>• inquired of management whether they were aware of any other events after the reporting date which could question the Group's ability to continue as a going concern.<br><br>We also assessed whether the going concern disclosure in the footnotes to the consolidated financial statements was appropriate |

| Impairment test of intangible assets | |
|---|---|
| **Key Audit Matter** | **Our response** |
| The reverse acquisition in 2017 of Genticel by Genkyotex Suisse has led to the recognition of a license agreement with SIIL related to the Vaxiclase technology as an intangible asset. The SIIL license intangible asset is amortized over 19 years and its net book value amounts to € 9,086k at December 31, 2019.<br><br>The SIIL license intangible asset is tested for impairment as described in Note 3.3 to the consolidated financial statements. Its recoverable value is determined using the discounted cash flow method. The cash flow forecast rely on a number of assumptions and estimates including likelihood of success of development programs, regulatory approval, market share and discount rate.<br><br>Based on management's assessment, the recoverable value of this intangible asset exceeded its carrying value at December 31, 2019 and they concluded that there was no impairment loss during the financial year.<br><br>We considered that the valuation of the SIIL license intangible asset is a key audit matter due to (i) its significance to the Group's consolidated financial statements, (ii) the judgment involved in the estimates and assumptions used for the impairment testing. | Our approach consisted principally in:<br><br>• understanding the process for developing and approving the estimates and assumptions used by your Group in the preparation of the impairment tests;<br><br>• Assessing the relevance of the valuation model and of the discount rate used, with the support of our financial valuation experts.<br><br>• Reperforming the calculation and sensitivity analysis<br><br>• Critically challenging the assumed revenue assumptions and the likelihood of success of development programs by reference to external market data available and/or reviewing communication between Genkyotex and SIIL<br><br>• Assessing the appropriateness of the information given in Note 3.3 to the consolidated financial statements, especially with regards to the main assumptions and the sensitivity analysis performed. |

**Specific Verifications**

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by laws and regulations of the Group's information given in the management report of the Board of Directors approved on 24 February 2020.

We have no matters to report as to its fair presentation and its consistency with the consolidated financial statements. With regards to the events that occurred and information that became known after the date the financial statements were approved by the Board of Directors relating to the impact of the crisis linked to Covid-19, management informed us that such events and information will be communicated to annual general meeting called to approve the financial statements.

## Report on Other Legal and Regulatory Requirements

### *Appointment of the Statutory Auditors*

We were appointed as statutory auditors of Genkyotex S.A. by the annual general meeting held on 20 December 2013 for Sygnatures and on 13 June 2019 for KPMG S.A.

As at 31 December 2019, Sygnatures was in the 6th year of total uninterrupted engagement and KPMG S.A in the first year, which are the 6th year and first year since securities of the Company were admitted to trading on a regulated market, respectively.

## Responsibilities of Management and Those Charged with Governance for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards as adopted by the European Union and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless it is expected to liquidate the Company or to cease operations.

The Audit Committee is responsible for monitoring the financial reporting process and the effectiveness of internal control and risks management systems and where applicable, its internal audit, regarding the accounting and financial reporting procedures.

The consolidated financial statements were approved by the Board of Directors.

## Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements

*Objectives and audit approach*

Our role is to issue a report on the consolidated financial statements. Our objective is to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As specified in Article L.823-10-1 of the French Commercial Code (code de commerce), our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.

- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the consolidated financial statements.

- Assesses the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the consolidated financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.

- Evaluates the overall presentation of the consolidated financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

- Obtains sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. The statutory auditor is responsible for the direction, supervision and performance of the audit of the consolidated financial statements and for the opinion expressed on these consolidated financial statements.

*Report to the Audit Committee*

We submit a report to the Audit Committee which includes in particular a description of the scope of the audit and the audit program implemented, as well as the results of our audit. We also report, if any, significant deficiencies in internal control regarding the accounting and financial reporting procedures that we have identified.

Our report to the Audit Committee includes the risks of material misstatement that, in our professional judgment, were of most significance in the audit of the consolidated financial statements of the current period and which are therefore the key audit matters, that we are required to describe in this audit report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) N° 537/2014, confirming our independence within the meaning of the rules applicable in France such as they are set in particular by Articles L.822-10 to L.822-14 of the French Commercial Code (code de commerce) and in the French Code of Ethics *(code de déontologie)* for statutory auditors. Where appropriate, we discuss with the Audit Committee the risks that may reasonably be thought to bear on our independence, and the related safeguards.

Lyon, on the 23 April 2020

Toulouse, on the 23 April 2020

The statutory auditors

French original signed by

Stéphane Devin

*Partner*

Laure Mulin

*Partner*

### 18.1.1.3 Consolidated financial statements prepared in accordance with IFRS for the financial year ended December 31, 2018 and Statutory Auditors' report

The following information contained in the 2018 Registration Document registered with the AMF on April 26, 2019, under number R.19-014, is incorporated by reference into the Universal Registration Document:

- the consolidated financial statements prepared in accordance with IFRS for the financial year ended December 31, 2018, presented on pages 157 to 208 of the 2018 Registration Document,
- the Statutory Auditors' report presented on pages 239 to 243 of the 2018 Registration Document.

### 18.1.1.4 Consolidated financial statements prepared in accordance with IFRS for the financial year ended December 31, 2017 and Statutory Auditors' report

The following information contained in the 2017 Registration Document registered with the AMF on April 27, 2018, under number R.18-037, is incorporated by reference into the Universal Registration Document:

- The consolidated financial statements prepared in accordance with IFRS for the financial year ended December 31, 2017, presented on pages 151 to 198 of the 2017 Registration Document.
- The Statutory Auditors' report presented on pages 227 to 233 of the 2017 Registration Document.

### 18.1.2. Change of accounting reference date

None.

### 18.1.3. Accounting standards

The Company's consolidated financial statements for the financial years ended December 31, 2017, December 31, 2018 and December 31, 2019 are in compliance with the International Financial Reporting Standards (IFRS) as published by the International Accounting Standards Board (IASB) and adopted by the European Union as of the date of preparation of the financial statements.

### 18.1.4. Change of accounting framework

The Company does not have a planned change in accounting standards.

### 18.1.5. Historical financial information prepared in accordance with national accounting standards

Historical financial information is prepared in accordance with IFRS. See section 18.1.1.1 of the Universal Registration Document.

### 18.1.6. Consolidated financial statements

See section 18.1.1.1 of the Universal Registration Document.

### 18.1.7. Date of the latest financial information

The latest financial information was prepared on December 31, 2019.

## BALANCE SHEET – ASSETS

| Genkyotex SA<br>Balance sheet - assets in euros | Notes | 31.12.2019<br>Amount | Amort. & depre. Prov. | Net book value | 31.12.2018<br>Net book value |
|---|---|---|---|---|---|
| Subscribed capital not called | | - | - | - | - |
| **Intangible assets** | | | | | |
| Set-up costs | | - | - | - | - |
| Development costs | | - | - | - | - |
| Concessions, patents, similar rights | 3.1 | - | - | - | - |
| Other intangible assets | 3.1 | - | - | - | - |
| **Property, plant and equipment** | | | | | |
| Land | | - | - | - | - |
| Buildings | | - | - | - | - |
| Technical installations, equipment, tools | 3.1 | 143 002 | 129 953 | 13 049 | 20 289 |
| Other property, plant and equipment | 3.1 | 8 519 | 7 189 | 1 330 | 1 167 |
| Fixed assets in progress | 3.1 | - | - | - | - |
| Advances and deposits | | - | - | - | - |
| **Financial assets** | | | | | |
| Other equity investments | 3.2 | 120 000 000 | 111 632 091 | 8 367 909 | 120 000 000 |
| Other financial assets | 3.2 | 45 076 | - | 45 076 | 140 812 |
| **Total fixed assets** | | **120 196 597** | **111 769 233** | **8 427 364** | **120 162 268** |
| **Inventory and work-in-progress** | | | | | |
| Raw materials, supplies | | - | - | - | - |
| Semi-finished and finished products | | - | - | - | - |
| Commodities | | - | - | - | - |
| Advances, deposits on orders | 4.2 | 75 118 | - | 75 118 | 604 184 |
| **Receivables** | | | | | |
| Trade receivables & related accounts | 4.1 & 6 | 9 844 082 | 9 713 105 | 130 977 | 6 456 433 |
| Other receivables | 4.2 | 2 632 596 | 1 517 500 | 1 115 096 | 1 722 361 |
| Subscribed and called capital, not paid up | | - | - | - | - |
| **Miscellaneous** | | | | | |
| Marketable securities | 5 | - | - | - | - |
| Cash and cash equivalents | 5 | 2 140 674 | - | 2 140 674 | 8 402 496 |
| **Accruals** | | | | | |
| Pre-paid expenses | 13 | 52 630 | - | 52 630 | 21 314 |
| **Total assets outstanding** | | **14 745 100** | **11 230 605** | **3 514 495** | **17 206 788** |
| Bond redemption premium | 10.2 | - | - | - | 41 315 |
| Translation adjustment assets | | 8 145 | - | 8 145 | 794 |
| **Total assets** | | **134 949 842** | **122 999 838** | **11 950 004** | **137 411 165** |

## BALANCE SHEET – LIABILITIES

| Genkyotex SA<br>Balance sheet - Liabilities in euros | Notes | 31.12.2019<br>€ | 31.12.2018<br>€ |
|---|---|---|---|
| **Shareholders' equity** | | | |
| Share capital or individual capital | 7 | 8 683 449 | 7 934 762 |
| Additional paid-in capital | 7 | 125 086 476 | 123 393 549 |
| Revaluation costs | | - | - |
| Legal reserve | 7 | 5 451 | 5 451 |
| Statutory or contractual reserves | | - | - |
| Regulated reserves | | - | - |
| Other reserves | | - | - |
| Retained earnings | | 5 036 | - |
| Results for the financial period (profit or loss) | | **(123 904 104)** | **5 036** |
| Investment grants | | | |
| Regulated provisions | | | |
| **Total equity** | | **9 876 308** | **131 338 798** |
| **Other equity** | | | |
| Revenue from equity securities issues | | - | - |
| Conditional advances | 10.1 | - | 119 033 |
| **Total other equity** | | - | **119 033** |
| **Provisions for loss and contingencies** | | | |
| Provisions for loss | 9 | 8 145 | 522 |
| Provisions for contingencies | 9 | - | - |
| **Total provisions** | | **8 145** | **522** |
| **Debts** | | | |
| Convertible bonds | 10.2 | 800 000 | 3 250 000 |
| Other bonds | | - | - |
| Loans and debts to credit institutions | 11 | 150 | 12 860 |
| Borrowing, financial debts Miscellaneous | | - | - |
| Advances and advance payments received on current orders | | - | - |
| Trade and related payables | 11 | 960 319 | 2 336 716 |
| Tax and social security liabilities | 11 | 262 243 | 293 268 |
| Debts on fixed assets and related accounts | | - | - |
| Other liabilities | 11 | 42 839 | 59 591 |
| **Accruals** | | | |
| Deferred income | | - | - |
| **Total debts** | | **2 065 551** | **5 952 434** |
| Translation adjustment liabilities | | - | 378 |
| **Total liabilities** | | **11 950 004** | **137 411 165** |

## INCOME STATEMENT

| Genkyotex SA<br>Income statement in euros | Notes | 12/31/2019<br>12 months | 12/31/2018<br>12 months |
|---|---|---|---|
| **Operating income** | | | |
| Sales of goods | | - | - |
| Production sold | 14 | 3 442 916 | 6 456 433 |
| **Revenue** | | **3 442 916** | **6 456 433** |
| Stored production | | - | - |
| Operating subsidies | 15 | - | - |
| Reversals of depreciation and provisions, expense transfers | 16 | 842 | - |
| Other revenue | 14 | 2 386 | 772 269 |
| **Total operating income** | | **3 446 144** | **7 228 702** |
| **Operating expenses** | | | |
| Purchases of goods | | - | - |
| Change in inventory of goods | | - | - |
| Raw material purchases, other supplies | | 15 833 | 41 641 |
| Changes in raw material inventory and supplies | | - | - |
| Other purchases and external expenses | 17 | 4 533 270 | 7 858 396 |
| Income tax, levies and similar payments | | 22 093 | 11 378 |
| Salaries and wages | | 299 343 | 286 398 |
| Social security costs | | 156 729 | 104 045 |
| **Operating allowance** | | - | - |
| Amortization of fixed assets | | 7 658 | 9 272 |
| Provisions for assets outstanding | | 11 230 605 | - |
| Provisions for loss and contingencies | | - | - |
| Other expenses | | 53 959 | 73 765 |
| **Total operating expenses** | | **16 319 490** | **8 384 895** |
| **Operating income** | | **(12 873 346)** | **(1 156 193)** |
| Financial income | 18 | 41 281 | 345 017 |
| Financial expenses | 18 | 111 681 093 | 56 984 |
| **Financial income (expenses)** | | **(111 639 812)** | **288 033** |
| **Current profit/(loss) before tax** | | **(124 513 158)** | **(868 160)** |
| Non-recurring income | 19 | 5 689 | 27 143 |
| Non-recurring expenses | 19 | 295 319 | 46 839 |
| **Non-recurring income (expenses)** | | **(289 630)** | **(19 696)** |
| Employee profit-sharing | | - | - |
| Income taxes | 20 | (898 683) | (892 892) |
| **Profit or loss for the financial period** | | **(123 904 104)** | **5 036** |

## NOTES TO THE ANNUAL FINANCIAL STATEMENTS

***(Unless indicated otherwise, the amounts mentioned in this note are denominated in euros.)***

### Note 1: Overview of activity and significant events

The information below constitutes the Notes to the annual financial statements for the financial year ended December 31, 2019.

Each of the financial years presented has a duration of 12 months covering the period from January 1 to December 31.

The financial statements as of December 31, 2019, were approved by the Board of Directors on February 24, 2020.

#### 1.1 The Company and its activity

Founded in October 2001, Genkyotex is a French limited company (*société anonyme*) with the following corporate purpose in France and abroad: research, study, development, manufacturing and distribution of medicines and drug and health products in the field of human and animal health.

The Company's therapeutic approach is primarily based on the selective inhibition of NOX enzymes which amplify many pathological processes such as fibroses, inflammation, the perception of pain, the development of cancer and neurodegeneration.

The Company has been listed on the Euronext market in Paris and Brussels since April 8, 2014.

Registered office: 218 avenue Marie Curie – Forum 2 Archamps Technopole,
74166 Saint-Julien-en-Genevois Cedex, France
Trade and Companies Register: 439 489 022 RCS de Thonon les Bains.

#### 1.2 Significant events of the financial year

January 2019:

- The Company announced that shareholders approved the 1-for-10 reverse stock split commencing February 27, 2019 and taking effect on March 29, 2019 (delisting the existing shares and listing the new shares).
- Genkyotex announced that the final results of its Phase 2 study on GKT831 in patients with primary biliary cholangitis (PBC) will be published in spring 2019.

February 2019:

- Genkyotex announced that a university partner, Professor Gareth Thomas of the University of Southampton, has been awarded a second Cancer Research UK grant to further develop NOX research in oncology.

March 2019:

- Announcement by Genkyotex of the end of the 24-week treatment period for its Phase 2 clinical study with GKT831 in PBC.

April 2019:

- Genkyotex presented the interim results of its Phase 2 trial of GKT831 in PBC at the 2019 EASL International Liver Congress: all patients have completed the treatment; favorable safety profile for GKT831, there were no patient dropouts or treatment interruptions.

June 2019:

- Genkyotex presented the final results of its Phase 2 study in PBC, which show that the anti-fibrotic candidate drug GKT831 demonstrated statistically significant improvements in GGT and ALP over the full treatment period.

July 2019

- The Company announced the publication in the *Clinics and Research in Hepatology and Gastroenterology* journal of the results of studies showing that its anti-fibrosis drug, GKT831, reduces the complications of portal hypertension and demonstrates the therapeutic potential of GKT831 in patients with advanced fibrosis of the liver.
- Genkyotex announced that the FDA in the United States has approved its Phase 2 trial of GKT831 in pulmonary fibrosis. The Company had previously announced that the National Institutes of Health (NIH) in the United States had awarded a grant of $8.9 million to Professor Victor Thannickal of the University of Alabama at Birmingham (UAB) to finance a multi-year research program evaluating the role of NOX enzymes in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in scarring (fibrosis) of the lungs.
- The World Health Organization (WHO) recognized GKT831 as the first representative of the NOX inhibitor therapeutic class. WHO recommended setanaxib as the international nonproprietary name (INN) for GKT831. The new stem “naxib” approved by WHO refers to the mechanism of action (NANADPH oXidase inhIBitors). The NOX inhibitor therapeutic class has significant potential in fibrotic and inflammatory disorders, neurodegenerative diseases and oncology.
- The Company announced favorable results from the post-hoc analysis of the Phase 2 trial in PCB.

August 2019

- The Company signed an agreement with Yorkville Advisors Global—the management company of a US investment fund—covering a 12-month extension of the conversion period for the remaining €1.6 million of convertible bonds still held by Yorkville. To this end, on August 19, 2019, Genkyotex bought back from Yorkville the remaining €1.6 million of convertible bonds maturing on August 20, 2019 that Yorkville still held, and then immediately issued new convertible bonds—maturing on August 20, 2020— to Yorkville, for an amount equal to that of the existing OCAs.

December 2019:

- The company announced the extension of the Phase 2 study in diabetic nephropathy funded by the Juvenile Diabetes Research Foundation (JDRF) in Europe and New Zealand. Note that 13 patients included in the diabetic kidney disease study completed the full 48-week treatment, without any reported safety concerns.
- The US Food and Drug Administration (FDA) and the US Medical Ethics Committee have authorized the IPF Phase 2 study protocol, paving the way for the recruitment of new patients. This study is fully funded by a USD 8.9 million grant from the National Institutes of Health (NIH).

## Note 2: Accounting principles, rules and methods

### 2.1 Basis for preparation of the financial statements

The accounting conventions have been adopted in compliance with the principle of prudence and in accordance with the following basic assumptions:

- going concern;
- consistency of accounting methods from one financial period to the next;
- independence of financial years – segregation of accounting periods

and, in accordance with the general rules for the preparation and presentation of annual financial statements under French generally accepted accounting principles, in particular the regulatory provisions in the general accounting plan (ANC rule 2018-01 of April 20, 2018, amending ANC regulation 2016-01 of November 4, 2016 and the regulations issued subsequently by the French Accounting Standards Authority).

The historical cost method has been adopted as the basic method of accounting.

Going concern

The Company focuses on inventing and developing new treatments. The loss-making position over the reference periods is not unusual for a company at this stage of development.

The Company has managed to finance its operations to date primarily through successive capital fund-raising or convertible bonds.

As of the reporting date, the Board of Directors considers that the Company will be able to meet its financing needs for anticipated operations until February 2021 on the basis of the following:

- the level of net cash flow, totaling €2,141 thousand as of December 31, 2019;
- the estimated receipt of the 2019 research tax credit for an amount of €899 thousand;
- forecasts of the cash required by the Company's operations in 2020 and early 2021;

- the conversion of the entire convertible bond to shares in January 2020, with a balance of €800 thousand at December 31, 2019 (see Notes 10.2 and 26);
- the capital increase of €4.9 million in February 2020 (see Note 26).

The going-concern principle was adopted by the Board of Directors for the approval of these financial statements, with the Group having, in view of the above data and assumptions, the necessary means to finance its activities for at least 12 months after the reporting date.

Beyond its liquidity horizon of February 2021, the Company will need additional funds. Measures are already being implemented by Management to seek additional funding.

This could include raising additional funding from current investors, new investors and/or the conclusion of strategic partnerships or transactions. The success of these transactions may depend, among other things, on attaining development milestones, achieving favorable clinical outcomes and/or achieving commercial success.

The main measurement methods used are described below.

**2.2 Intangible assets**

Intangible assets are valued at their acquisition cost or at their production cost.

The following depreciation periods and methods are used:

| Items | Amortization period |
|---|---|
| Software | 1 year – Straight line |
| Patents | Period of validity |

In accordance with the most frequently encountered and accepted industry practices, development work is assigned to expenses due to the risks and uncertainties linked to regulatory authorizations and the development process; the six activation criteria specified in Articles 211-1 to 211-3 of the General Accounting Plan (must be identifiable, controlled by the Company, have future economic benefits, used for longer than one financial year, can be reliably measured) are considered fulfilled only when marketing authorization for products is obtained, and this is not yet the case for the Company.

Expenses incurred in filing, maintaining and protecting “internal” patents developed by the Company are reported in dedicated lines under operating expenses and follow the same accounting principles as development expenses.

**2.3 Property, plant and equipment**

Property, plant and equipment are valued at their acquisition cost (purchase price plus ancillary expenses) or at their production cost.

Asset items are depreciated according to the actual useful duration of the asset.

The following depreciation periods and methods are used:

| Items | Amortization period |
|---|---|
| Fixtures and fittings | 9 years – Straight line |
| Fixtures equipment | 5 years – Straight line |
| Hardware and tools | 5 years – Straight line |
| Office furniture and computer equipment | 3 to 5 years – Straight line |

**2.4 Financial assets**

Equity securities

Equity securities are reported in the balance sheet at the acquisition cost. Their value is reviewed on a yearly basis by referring to their value-in-use.

The value in use of the equity securities of the subsidiary Genkyotex Suisse is assessed on the basis of the valuation method known as risk-adjusted Net Present Value (rNPV). This method is suitable for the biotechnology sector in that it includes the following key parameters: progress of clinical trials/projects, probability of success, future sales estimates and associated risk.

The Company completes this analysis by taking into account the market capitalization of the Company to which the value of intangibles (not recognized in the parent company financial statements) relating to the license agreement with the Serum Institute of India (SIIL) is determined.

When applicable, an impairment is recorded via a provision if the value-in-use becomes less than the acquisition cost.

Loans and receivables

Loans and receivables are measured at their nominal value. These items are impaired via a provision to reduce them to their value-in-use at year-end, if necessary.

Liquidity contract

The cash part (i.e., cash, strictly speaking), is reported in “Other capitalized receivables” and the shares portfolio is reported in “Treasury shares” based on periodic statements of the transactions conducted by the service provider. The gains or losses made from purchasing or selling treasury shares are recorded in non-recurring income (loss). The portfolio is measured at period-end at cost price. A provision for financial impairment is reported if an unrealized loss is identified.

**2.5 Receivables**

Receivables are measured at their nominal value. A provision for impairment is constituted when the inventory value is less than the carrying amount.

Research tax credit

Research tax credits are granted to companies by the French State as an incentive for technical and scientific research. Companies with expenses that meet the eligibility criteria (research expenses in France, or, since January 1, 2005, within the European Union or another State party to the agreement on the European Economic Area, and having entered into a tax agreement with France that contains an administrative assistance clause) receive a tax credit that can be used to pay the corporate income tax due in the year in which it is granted, as well as in the following three financial years or, as the case may be, any surplus tax paid can be reimbursed.

The research tax credit is presented in the income statement under “income taxes”.

The Company has benefited from research tax credits since it was founded.

Competitiveness and Employment Tax Credit (CICE)

The tax credit for competitiveness and employment (crédit d'impôt pour la compétitivité et l'emploi or “CICE”) is a French tax credit benefiting the Group's French companies. The Group uses this tax credit through its research and development effort.

In view of the beneficiary companies' community SME status, the CICE may be repaid in the year following that in which it was granted.

For financial year 2018, the CICE tax credit was reported as a reduction of personnel costs in the income statement.

This tax credit has been replaced by reductions in payroll charges as from January 1, 2019.

Subsidies

Subsidies received are reported as soon as the corresponding receivable becomes certain, taking into consideration the conditions specified when the subsidy was granted.

Operating grants are recorded as operating income, taking into account the rate of corresponding expenses so as to adhere to the principle of matching revenues and expenses, as the case may be.

**2.6 Cash and cash equivalents**

Cash and cash equivalents include the following assets: current accounts at banks, interest-bearing surplus cash accounts and interest-bearing term-deposit accounts immediately accessible, regardless of contractual term.

**2.7 Capital increase expenses**

Capital increase and contribution expenses are posted directly to the issuance and contribution premiums.

**2.8 Provisions for loss and contingencies**

These provisions, recorded in compliance with CRC regulation No. 2000-06, are intended to cover loss and contingencies that could occur due to events in progress or that already took place. The amount of these provisions is quantifiable as regards their purpose, but their realization, due date or amount are uncertain.

The Company recognizes a provision for loss and contingencies when an obligation to a third party exists on the date the accounts are closed for which it is probable or certain that, on the close date,

the obligation will result in a payment to this third party without a counterpart at least equivalent in return, and for which the amount may be reliably estimated.
That reported amount corresponds to the reliable estimate of the cost for eliminating the obligation.

**2.9 Retirement benefits**
The amounts of future payments corresponding to benefits granted to employees are valued according to an actuarial method using assumptions concerning changes in salaries, retirement age and mortality, and are then brought back to their present value.

These commitments are not subject to provisions but are shown in off-balance sheet commitments in Note 22.1.

**2.10 Conditional advances**
Advances received from public bodies to fund the Company's research activities or for regional business development, for which reimbursements are conditional, are presented as liabilities under “Conditional advances”, and their characteristics are detailed in Note 10.1.

**2.11 Bonds**
Loans are measured at their nominal value. Loan issue fees are paid immediately.

For convertible premium bonds, the transaction is recognized in two separate transactions: a bond issue and then a share conversion.

When a loan is issued, the issue premium is recorded in assets and liabilities and is amortized.

When converted into shares, the capital increase is carried out for the amount of the loan excluding premiums plus the amortized amount of the issue premium.

**2.12 Foreign currency transactions**
Income and expenses in foreign currencies are recorded in their equivalent value on the transaction date.

Profit or loss from currency exchange on trade receivables and payables is recorded in operating profit/(loss) in accordance with the new provisions of ANC regulation 2015-05 (Articles 946-65 and 946-66 of the modified French GAAP).

Existing receivables and payables in foreign currencies at year-end are translated at the exchange rate in effect on that date.

The difference resulting from translating payables and receivables into foreign currencies at the latest rate is recorded in the “currency translation adjustments” line item under balance sheet assets and liabilities. Currency translation adjustments – assets are subject to a provision for loss and contingencies for the same amount.

## 3.1 Intangible assets and property, plant and equipment

| GROSS VALUE OF FIXED ASSETS (Amounts in euros) | 12/31/2018 | Acquisitions | Disposals | 12/31/2019 |
|---|---|---|---|---|
| Intangible assets in progress | - | - | - | - |
| **Total intangible assets** | **-** | **-** | **-** | - |
| General plant assets, fixtures, fittings | 143,002 | | - | 143,002 |
| Office equipment, computer equipment, furniture | 7,937 | 582 | - | 8,519 |
| **Total property, plant and equipment** | **150,939** | **582** | **-** | **151,521** |
| **GRAND TOTAL** | **150,939** | **582** | **-** | **151,521** |

| AMORTIZATION, DEPRECIATION & IMPAIRMENT OF FIXED ASSETS (Amounts in euros) | 12/31/2018 | Allocations | Reversals | 12/31/2019 | Net values 12/31/2019 |
|---|---|---|---|---|---|
| Intangible assets in progress | - | - | | - | - |
| **Total intangible assets** | **-** | **-** | **-** | - | - |
| General plant assets, fixtures, fittings | 122,714 | 7,265 | - | 129,979 | 13,023 |
| Office equipment, computer equipment, furniture | 6,770 | 393 | - | 7,163 | 1,356 |
| **Total property, plant and equipment** | **129,484** | **7,658** | **-** | **137,142** | **14,379** |
| **GRAND TOTAL** | **129,484** | **7,658** | **-** | **137,142** | **14,379** |

## 3.2 Financial assets

| GROSS VALUE OF FIXED ASSETS (Amounts in euros) | 12/31/2018 | Acquisitions | Disposals | 12/31/2019 |
|---|---|---|---|---|
| Other equity investments | 120,000,000 | - | - | 120,000,000 |
| Other financial assets | 166,761 | - | 121,685 | 45,076 |
| **Total financial assets** | **120,166,761** | **-** | **121,685** | **120,045,076** |

| AMORTIZATION, DEPRECIATION & IMPAIRMENT OF FIXED ASSETS (Amounts in euros) | 12/31/2018 | Allocations | Reversals | 12/31/2019 | Net values 12/31/2019 |
|---|---|---|---|---|---|
| Other equity investments | - | 111,632,091 | - | 111,632,091 | 8,367,909 |
| Other financial assets | 25,949 | - | 25,949 | - | 45,076 |
| **Total financial assets** | **25,949** | **111,632,091** | **25,949** | **111,632,091** | **8,412.985** |

Other financial assets comprise:

- guarantee deposits paid under simple lease agreements for French premises;
- liquidity contract.

**Equity securities**

- Genkyotex Suisse SA

On February 28, 2017, the Company's shareholders approved the resolutions to make the merger with Genkyotex Suisse SA official in accordance with the contribution agreement signed on December 22, 2016. Genkyotex Suisse SA was contributed based on an actual value of €120,000,000.
As of December 31, 2019, the Company conducted an impairment test (see Note 2.4).

The value in use of the securities was assessed from:

- the risk-adjusted Net Present Value (rNPV), a method used to determine contribution values.
- the company's market capitalization as of December 31, 2019 (€2.18 per share) decreased by the value of intangibles (not recognized in the parent company financial statements) relating to the licensing agreement with SIIL.

The Company applied a value in use of the securities of €8,367,909 as of December 31, 2019. As a result, an impairment of €111,632,091 was recognized.

**Other financial assets**

Other financial assets comprise guarantee deposits paid under simple lease agreements for French locations and the liquidity contract.

- Liquidity contract

Following the Company's IPO on the regulated markets of Euronext Paris and Euronext Brussels, on April 18, 2014 a liquidity contract was signed with Banque Oddo et Cie with a view to limiting intra-day volatility in the Company's share price. For this purpose, the Company entrusted €200 thousand to this establishment so that it can take both buying and selling positions on the Company's shares. The contract was transferred to Kepler Cheuvreux on May 7, 2018.

| ITEMS | 12/31/2019 | Proforma (1) 12/31/2018 | 12/31/2018 |
|---|---|---|---|
| **Initial payment on 4/22/2014** | 200,000 | 200,000 | 200,000 |
| Total realized capital gains or losses from disposals during the period | (121,935) | (43,134) | (43,134) |
| Number of treasury shares: | 7,789 | 9,454 | 94,540 |
| Cost price of treasury shares: | 15,687 | 122,002 | 122,002 |
| Closing price of treasury shares: | 2.180 | 10.16 | 1.02 |
| Cash account “Other capitalized receivables” | 14,389 | 29,622 | 29,622 |
| **Unrealized capital gains or losses 12/31** | **1,293** | **(25,949)** | **(25,949)** |
| **Allocation to or reversal of provision for unrealized capital losses** | **25,949** | **(25,949)** | **(25,949)** |

*(1) Following the Board of Directors' decision on January 24, 2019 to carry out a 1-for-10 reverse stock split, the Company's share capital will be divided into 7,934,762 shares starting from March 29, 2019.*

### 4.1 Trade receivables

| TRADE AND RELATED RECEIVABLES (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Trade and related receivables | 9,844,082 | 6,456,433 |
| **Gross total of trade and related receivables** | **9,844,082** | **6,456,433** |
| Impairment of trade and related receivables | **(9,713,105)** | - |
| **Total impairment of trade and related receivables** | **(9,713,105)** | **-** |
| **Net total of trade and related receivables** | **130,977** | **6,456,433** |

Trade receivables include up to €9,713 thousand in receivables with the Genkyotex Suisse SA subsidiary as of December 31, 2019.

On February 19, 2020, Genkyotex SA and Genkyotex Suisse SA signed an agreement whereby trade receivables, issued under the service delivery contract established in 2017 between the Companies, and representing an amount of €9,713 thousand as of December 31, 2019 are posted behind all current and future receivables for the Company.

As of December 31, 2019, Genkyotex Suisse was unable to honor its commercial debt, the debt has been fully written off.

### 4.2 Details of receivables and breakdown by due date

| STATEMENT OF RECEIVABLES (Amounts in euros) | 12/31/2019 | | |
|---|---|---|---|
| | Gross amount | No more than 1 year | Over 1 year |
| **Of capitalized assets** | | | |
| Other financial assets | 45,076 | - | 45,076 |
| **Total capitalized assets** | **45,076** | - | **45,076** |
| **Of assets outstanding** | | | |
| Trade receivables (1) | 9,844,082 | 9,844,082 | - |
| Government - Research tax credit (2) | 898,683 | 898,683 | - |
| Government - Business competitiveness tax credit | - | - | - |
| Government - Corporate income tax deposit | - | - | - |
| Value Added Tax | 215,686 | 215,686 | - |
| Advances and deposits (3) | 75,118 | 75,118 | - |
| Debtor suppliers | 546 | 546 | - |
| Group (4) | 1,517,500 | 1,517,500 | - |
| Other debtors | 181 | 181 | - |
| **Total assets outstanding** | **12,551,796** | **12,551,796** | **-** |
| Pre-paid expenses | 52,630 | 52,630 | - |
| **Grand total** | **12,649,502** | **12,604,426** | **45,076** |

(1) The customer receivables relating to the subsidiary Genkyotex Suisse SA were written down for impairment for a total amount of €9,713 thousand at December 31, 2019.
(2) In the absence of taxable income, and in view of the Company's community SME status, the Company may request that the Research tax credit ("CIR") be repaid the year after it is recorded. The CIR for 2019 totaled €899 thousand, and repayment is scheduled for 2020.
(3) Advances and installments mainly involve installments paid to CMED, a contract research organization (CRO) in charge of studies and clinical trials.
(4) The "group" receivables relate to the subsidiary Genkyotex Suisse SA and were written down for impairment for a total amount of €1,518 thousand at December 31, 2019.

### Note 5: Net cash flow

The table below shows a breakdown of short-term investments and cash:

| NET CASH FLOW (Amounts in euros) | 12/31/2019 Value in use | 12/31/2018 Value in use |
|---|---|---|
| Bank accounts and cash at hand | 2,140,674 | 8,402,496 |
| Short-term borrowings | (150) | (12,860) |
| **Net cash flow** | **2,140,524** | **8,389,636** |

### Note 6: Breakdown of income receivables

Income receivables break down as follows over the two financial years presented:

| BREAKDOWN OF INCOME RECEIVABLES (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Customers - invoices to be issued | 130,977 | **3,107,004** |
| **Total receivables and related accounts** | **130,977** | **3,107,004** |
| Government - income receivable | - | - |
| **Total tax and social security receivables** | **-** | **-** |
| Interest on current account | - | - |
| **Total other liabilities** | **-** | **-** |
| **Grand total** | **130,977** | **3,107,004** |

### 7.1 Changes in equity

Changes in equity throughout 2019 were as follows:

| GENKYOTEX<br>Changes in equity<br>Amount in € | Capital<br>*Number of shares* | Capital | Issue premiums | Regulated reserve | Legal reserve | Other reserves | Retained earnings | Result | Shareholders' equity |
|---|---|---|---|---|---|---|---|---|---|
| **As of December 31, 2018** | **79,347,621** | **7,934,762** | **123,393,549** | **-** | **5,451** | **-** | **-** | **5,036** | **131,338,798** |
| Allocation of 2018 result | | | | | | | **5,036** | **(5,036)** | **-** |
| Net result 2019 | | | | | | | | **(123,904,104)** | **(123,904,104)** |
| Effect of the reverse stock split (1) | **(71,412,859)** | | | | | | | | **-** |
| Conversion of convertible bonds (2) | **748,687** | **748,687** | **1,692,927** | | | | | | **2,441,614** |
| **As of December 31, 2019** | **8,683,449** | **8,683,449** | **125,086,476** | **-** | **5,451** | **-** | **5,036** | **(123,904,104)** | **9,876,308** |

(1) Following the Board of Directors' decision on January 24, 2019 to carry out a 1-for-10 reverse stock split, the Company's share capital will be divided into 7,934,762 shares starting from March 29, 2019.

(2) During the 2019 financial year, 245 bonds were converted for a total of 748,687 new shares with a unit value of €1.00, creating a €748,687 capital increase plus €1,692,927 in issue premiums.

### 7.2 Composition of share capital and detail by share class

| BREAKDOWN OF SHARE CAPITAL | 12/31/2019 | 12/31/2018 Proforma (1) | 12/31/2018 |
|---|---|---|---|
| Capital (in euros) | 8,683,449 | 7,934,762 | 7,934,762 |
| Number of shares | 8,683,449 | 7,934,762 | 79,347,621 |
| o/w ordinary shares | 8,683,449 | 7,934,762 | 79,347,621 |
| Par value of shares (in euro) | €1.00 | €1.00 | €0.10 |

As of December 31, 2019, the share capital was set at €8,683,449.
It is divided into 8,683,449 fully subscribed and paid-up ordinary shares, each with a par value of €1.00.

This number of shares excludes share subscription warrants ("BSAs") granted to certain investors and to certain natural persons that have not yet been exercised.

(1) Following the Board of Directors' decision on January 24, 2019 to carry out a 1-for-10 reverse stock split, the Company's share capital will be divided into 7,934,762 shares starting from March 29, 2019.

### 7.3 Dividend distribution

The Company paid no dividends in the financial years presented.

## Note 8: Equity instruments

### 8.1 Share subscription warrants

| | | Plan features | | |
|---|---|---|---|---|
| Type | Grant date | Number of warrants granted | Exercise period | Initial exercise price |
| **BSA 10/2008** | 10/24/2008 | **30 800** | 10 years | €30,00 |
| **BSA 02/2010** | 02/14/2010 | **155 200** | 10 years | €30,00 |
| **BSA 12/2013** | 12/20/2013 | **116 000** | 10 years | €40,00 |
| **BSA 09/2014** | 09/12/2014 | **35 000** | 10 years | €57,90 |

(1) After the reverse stock split (see Note 7) at the beginning of 2019, the exchange ratio was 10 BSAs issued before 2019 for 1 new share.
(2) The exercise price was adjusted to take the reverse split into account.

| | | Number of warrants outstanding | | | | | Number of shares available for subscription |
|---|---|---|---|---|---|---|---|
| **Type** | **Grant date** | **12/31/2018** | **Granted** | **Exercised** | **Lapsed** | **12/31/2019** | |
| **BSA 10/2008** | 10/24/2008 | 0 | - | - | - | - | 0 |
| **BSA 02/2010** | 02/04/2010 | 155,200 | - | - | - | 155,200 | 155,200 |
| **BSA 12/2013** | 12/20/2013 | 116,000 | - | - | - | 116,000 | 116,000 |
| **BSA 09/2014** | 09/12/2014 | 35,000 | - | - | - | 35,000 | 35,000 |
| **Total** | | **306,200** | **-** | **-** | **-** | **306,200** | **306,200** |

As part of the first tranche of 500 convertible bonds with stock acquisition rights ("OCABSA") issued to YA II PN Ltd ("Yorkville"), 666,312 BSAs were issued on August 20, 2018 (See Note 10.2).

### 8.2 Stock options

| | | Plan features | | |
|---|---|---|---|---|
| **Type** | **Grant date** | **Number of warrants granted (1)** | **Exercise period** | **Exercise price (2)** |
| **Stock option 01/2018** | 01/09/2018 | **115,993** | 10 years | €1.67 |
| **Stock option 10/2018** | 10/11/2018 | **2,000** | 10 years | €1.49 |
| **Stock option 03/2019** | 03/21/2019 | **133,638** | 10 years | €0.91 |

(1) After the reverse stock split (see Note 7) at the beginning of 2019, the exchange ratio was 10 stock options issued before 2019 for 1 new share.

(2) The exercise price was adjusted to take the reverse split into account.

| | | Number of warrants outstanding | | | | |
|---|---|---|---|---|---|---|
| **Type** | **Grant date** | **12/31/2018** | **Issued** | **Exercised** | **Lapsed** | **12/31/2019** |
| **Stock option 01/2018** | 01/09/2018 | - | 1,145,153 | - | (15,000) | 1,130,153 |
| **Stock option 10/2018** | 10/11/2018 | - | 20,000 | - | - | 20,000 |
| **Stock option 03/2019** | 03/21/2019 | - | 1,336,380 | - | - | 1,336,380 |
| **TOTAL** | | **-** | **2,501,533** | **-** | **(15,000)** | **2,486,533** |

## Note 9: Provisions for loss and contingencies

| PROVISIONS (amount in euros) | 12/31/2019 | | | | |
|---|---|---|---|---|---|
| | **Amount at the beginning of the period** | Allocations | Reversals of needed provisions | Reversals of unneeded provisions | **Amount at the end of the period** |
| Provisions for currency translation losses | 522 | 8,145 | 522 | - | 8,145 |
| **Total provisions for loss and contingencies** | **522** | **8,145** | **522** | **-** | **8,145** |
| Provisions on financial assets | 25,949 | - | 25,949 | - | - |
| **Total impairment provisions** | **25,949** | **-** | **25,949** | **-** | - |
| **Grand total** | **26,471** | **8,145** | **26,471** | **-** | **8,145** |

## Note 10.1: Conditional advances

Conditional advances consist of repayable advances granted by public bodies (OSEO Innovation, now BpiFrance).

The table below shows a breakdown of and changes to conditional advances:

| CHANGE IN REPAYABLE ADVANCES (Amount in euros) | OSEO 3 | Total |
|---|---|---|
| **As of December 31, 2018** | **119,033** | **119,033** |
| (+) Cash inflow | - | - |
| (-) Repayment | (119,033) | (119,033) |
| (+ /-) other movements | - | - |
| **As of December 31, 2019** | - | - |

OSEO Innovation repayable advance – OSEO 3

On January 11, 2013, Genkyotex SA (formerly Genticel SA) obtained from OSEO an interest-free repayable advance "to extend the Phase I clinical studies of the ProCervix (GTL001) project" for a total of €849 thousand.

Following confirmation of completion of the program and after obtaining the statement of expenditure incurred on the project financed by OSEO, the repayable advance was reduced to take into account the fact that actual expenditure was less than projected. The aid was thus reduced to €812 thousand, and an amendment was signed on September 5, 2014, to change the repayment dates.

The Company repaid this advance as follows:

- Quarterly from September 30, 2014 to June 30, 2015: €19 thousand
- Quarterly from September 30, 2015 to June 30, 2016: €29 thousand
- Quarterly from September 30, 2016 to June 30, 2017: €38 thousand
- Quarterly from September 30, 2017 to June 30, 2018: €57 thousand

- Quarterly from September 30, 2018 to March 31, 2019: €60 thousand
- The balance on June 30, 2019: €60 thousand

The last repayment was made at the beginning of July 2019. Thus, the repayable OSEO Innovation – OSEO 3 advance was fully repaid as of December 31, 2019.

**Note 10.2: Bonds**

| CHANGE IN BONDS (Amounts in € thousands) | 2018 YORKVILLE OCABSA | 2019 YORKVILLE OCA |
|---|---|---|
| **As of December 31, 2018** | **3,250,000** | **-** |
| Bond issuance | - | 1,600,000 |
| Repayment | (1,600,000) | - |
| Conversion | (1,650,000) | (800,000) |
| **As of December 31, 2019** | - | **800,000** |

**10.2.1 Convertible bonds with share subscription warrants ("2018 YORKVILLE OCABSAs") issued to YA II PN Ltd ("Yorkville") on August 20, 2018.**

On August 20, 2018, the Company signed a convertible bonds with stock acquisition rights ("OCABSA") agreement with YA II PN Ltd ("Yorkville") to potentially raise up to €7.5 million (in par value), at the Company's discretion.

The loan comprises two tranches:

- A first tranche of 500 OCAs for a nominal amount of €5 million (as of the signature date);
- A second €2.5 million tranche consisting of 250 OCAs became null and void on November 23, 2018.

The OCAs have the following features:

- Par value: €10,000
- Subscription price: 98% of par
- Commitment fees: 6% of par value
- Maturity: 12 months
- No interest (except in the event of default: 15%)
- Conversion methods: N = Vn / P where
    - N corresponds to the number of shares that can be subscribed
    - Vn corresponds to the par (nominal) value of the bond
    - P corresponds to 92% of the average share price for the five trading days before the conversion request.

If the OCAs are not converted before the maturity date, they are refundable in cash.

The BSAs have the following features:

- Maturity: 5 years
- Exercise price: 115% of the average share price for the five trading days before the tranche is issued.

The Company incurred €410 thousand in fees setting up the bond, including €300 thousand in commitment fees. These fees were recognized in expenses.

Conversions in financial year 2019

In financial year 2019, Yorkville converted 165 2018 YORKVILLE OCABSA bonds in accordance with the following terms and conditions:

| Conversion date | Number of bonds | Amounts (in €) | Conversion price | Number of shares issued | Issuance premium |
|---|---|---|---|---|---|
| **Total converted in 2018** | **175** | **€1,750,000** | | **149,762 (1)** | **1,600,239** |
| 04/02/2019 | 10 | €100,000 | €7.949 | 12,580 | 87,420 |
| 04/04/2019 | 10 | €100,000 | €7.949 | 12,580 | 87,420 |
| 04/08/2019 | 20 | €200,000 | €7.901 | 25,313 | 174,687 |
| 04/15/2019 | 30 | €300,000 | €7.989 | 37,551 | 262,449 |
| 04/30/2019 | 25 | €250,000 | €8.359 | 29,907 | 220,093 |
| 06/06/2019 | 30 | €300,000 | €3.339 | 89,846 | 210,154 |
| 07/29/2019 | 10 | €100,000 | €3.7230 | 26,860 | 73,140 |
| 07/31/2019 | 30 | €300,000 | €3.9430 | 76,084 | 223,916 |
| **Total converted in 2019** | **165** | **€1,650,000** | | **310,721** | **1,339,279** |

(1) After taking into account the 1-for-10 reverse stock split of the Company's shares, effective March 29, 2019.

In August 2019, the Company signed an agreement with Yorkville Advisors Global—the management company of a US investment fund—covering a 12-month extension of the conversion period for the remaining €1.6 million of convertible bonds still held by Yorkville.

To this end, on August 19, 2019, Genkyotex bought back from Yorkville, the remaining €1.6 million of convertible bonds maturing on August 20, 2019 that Yorkville still held, and then immediately issued to Yorkville 160 convertible bonds for a total nominal amount of €1.6 million (see Note 10.2.2), by offsetting this against the €1.6 million debt corresponding to the Investor's prior sale to the Company of 160 2018 OCAs, issued on August 20, 2018.

As of December 31, 2019, 666,312 BSAs (giving the right to subscribe 66,631 shares) were outstanding.

**10.2.2 Bonds convertible into shares ("2019 YORKVILLE OCAs") issued to YA II PN Ltd ("YORKVILLE") on August 19, 2019**

The main features of the 2019 YORKVILLE OCAs issued August 19, 2019 are:

- The nominal unit value of the OCAs is equal to ten thousand euro (€10,000). Each OCA will be issued at a subscription price per OCA equal to 100% of its nominal unit value, a total nominal amount of one million six hundred thousand euro (€1,600,000).
- The OCAs (i) are freely assignable or transferable by the Investor to any of its affiliates and (ii) may not be transferred to any other third party without the prior written consent of the Company.
- The OCAs will not be listed or admitted to trading on the regulated markets of Euronext Paris or Euronext Brussels or on any other financial market. Each OCA expires twelve (12) months from its issue (the "Maturity date"). In the event that an OCA is not converted before the Maturity date, the Company is obliged to repay the outstanding amount in cash.
- The OCAs do not bear any interest. However, in the event of the occurrence of a Default (2), each OCA outstanding will bear interest at the rate of 15% per year from the date of the Default and up to (i) the date on which the Default is resolved, or (ii) the date on which the OCA has been fully converted and/or repaid, if the Default has not yet been resolved.
- The number of new shares issued by the Company for the benefit of each OCA holder when converting one or more OCAs corresponds to the amount of the conversion divided by the applicable Conversion Price. The "Conversion Price" is equal to 92% of the weighted average share price quoted on Euronext (as reported by Bloomberg) (the "Average Prices") on the five (5) consecutive stock exchange sessions up to the trading session immediately before the conversion date.

The Company incurred €103 thousand in fees setting up the bond. These fees were recognized in expenses.

Conversions in financial year 2019

| Conversion date | Number of bonds | Amounts (in €) | Conversion price | Number of shares issued | Issuance premium |
|---|---|---|---|---|---|
| 11/04/2019 | 20 | €200,000 | €1.7850 | 112,044 | 87,955 |
| 11/27/2019 | 10 | €100,000 | €1.8440 | 54,229 | 45,769 |
| 11/29/2019 | 10 | €100,000 | €1.8920 | 52,854 | 47,146 |
| 12/13/2019 | 20 | €200,000 | €1.8460 | 108,342 | 91,657 |
| 12/30/2019 | 20 | €200,000 | €1.8100 | 110,497 | 89,503 |
| **Total converted in 2019** | **80** | **€800,000** | | **437,966** | **362,029** |

As of December 31, 2019, 80 2019 OCAs were outstanding.

They were fully converted on January 14 and 15, 2020 see Note 26.

## Note 11: Maturity of debts at year-end

| STATEMENTS OF DEBTS (Amounts in euros) | 12/31/2019 | | | |
|---|---|---|---|---|
| | Gross amount | No more than 1 year | 1 to 5 years | More than 5 years |
| **Financial debt** | | | | |
| Convertible bond | 800,000 | 800,000 | - | - |
| Bond and accrued interest | - | - | - | - |
| Borrowing and debts to credit institutions | 150 | 150 | - | - |
| Interest-bearing loans and miscellaneous borrowings | - | - | - | - |
| **Total financial debts** | **800,150** | **800,150** | - | - |
| **Operating debts** | | | | |
| Trade payables & related accounts | 960,319 | 960,319 | - | - |
| Payroll & related accounts | 22,626 | 22,626 | - | - |
| Social security & other welfare programs | 111,633 | 111,633 | - | - |
| Other taxes, levies and similar payments | 127,984 | 127,984 | - | - |
| Other liabilities | 42,839 | 42,839 | - | - |
| **Total operating liabilities** | **1,265,401** | **1,265,401** | - | - |
| **Grand total** | **2,065,551** | **2,065,551** | - | - |

## Note 12: Breakdown of payables

Payables break down as follows over the present two financial years:

| BREAKDOWN OF PAYABLES<br>(Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Borrowing and debts from credit institutions | - | - |
| Accrued interest payable | 150 | 12,860 |
| **Total bonds** | **150** | **12,860** |
| Trade and related payables | - | - |
| Suppliers - Invoices not received (1) | 367,273 | 1,682,202 |
| **o/w Trade payables and related accounts** | **367,273** | **1,682,202** |
| Tax and social security liabilities | - | - |
| Employees - provision for paid leave | 16,626 | 18,927 |
| Personnel payables | 6,000 | 12,384 |
| Payroll taxes payable | 93,750 | 95,385 |
| Government - payables | 2,943 | 3,374 |
| **Total tax and social security liabilities** | **119,319** | **130,070** |
| Shareholder current accounts | - | - |
| Other liabilities | - | - |
| **Total other liabilities** | **-** | **-** |
| **Grand total** | **486,742** | **1,825,132** |

(1) as of December 31, 2019, the invoices not received mainly consisted of services rendered by PATHEON (a company responsible for the synthesis of the GKT137831 compound) and legal and financial fees relating to the capital increase carried out in January 2020.

## Note 13: Accruals

The amount of prepaid expenses by type are broken down as follows:

| PREPAID EXPENSES<br>(Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Insurance | 6,104 | 13,017 |
| R&D supplier services and consulting | 44,729 | 8,297 |
| Maintenance | 1,797 | - |
| **Total prepaid expenses** | **52,630** | **21,314** |

The amount of prepaid expenses only involves operating expenses. There was no prepaid income as of December 31, 2018 or 2019.

| REVENUE AND OTHER OPERATING INCOME BY GEOGRAPHIC AREA (Amounts in euro) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Switzerland (1) | 3,301,161 | 6,411,944 |
| Australia (2) | 141,755 | 44,489 |
| India | - | - |
| France | - | - |
| **Total revenue by geographic area (#706)** | **3,442,916** | **6,456,433** |
| Switzerland | - | - |
| India (3) | - | 750,000 |
| France | 2,386 | 22,269 |
| **Total other operating income by geographic area (#75)** | **2,386** | **772,269** |

**(1) Research and development services with Genkyotex Suisse SA**

As of December 31, 2019 and December 31, 2018, revenue generated with Switzerland falls under the service and research and development agreement with the Genkyotex Suisse SA subsidiary.

**(2) Research contract with Baker Heart and Diabetes Institute (see Note 22.4)**

The Company recorded €131 thousand in accrued income under this agreement as of December 31, 2019.

**(3) License agreement with Serum Institute of India Pvt. Ltd. (SIIL):**

In February 2015, the Company signed a license agreement with SIIL for its Vaxiclase technology as part of the development by SIIL of acellular and multivalent vaccines containing antigens for whooping cough. In return for access to and use of the Vaxiclase platform in the authorized indication, the Company could receive up to US$57 million in initial payments and development and sales milestone payments based on criteria defined in the terms and conditions of the agreement, as well as royalties as a percentage of net sales.
No revenue was recorded for this contract during 2017.

As a result of signing the license agreement expansion for the Vaxiclase platform with Serum Institute of India Pvt. Ltd. (SIIL) in June 2018, the agreement provides for:

- an initial payment of €750 thousand (recognized during the first half of 2018);
- milestone payments for emerging markets for up to US$57 million;
- milestone payments for industrialized countries for up to €100 million.

The Company is also eligible to receive “single-digit percentage” royalties on sales.

## Note 15: Operating subsidies

For the financial years ended December 31, 2018 and December 31, 2019, the company received no operating grants.

## Note 16: Expense transfers

| EXPENSE TRANSFERS (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Transfers of personnel-related expenses | 842 | - |
| Other | - | - |
| **Total expense transfers** | **842** | **-** |

## Note 17: Other purchases and external expenses

Other purchases and external expenses mostly comprise services rendered by CROs (Contract Research Organizations) for €2,654 thousand in 2019, legal and financial fees, property rentals, communication costs, rebilling services between Genkyotex Suisse SA and Genkyotex SA, and insurance and expenses related to managing intellectual property.

## Note 18: Financial income and expenses

| FINANCIAL INCOME (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Foreign exchange gains | 4,810 | - |
| Interest income (1) | 10,000 | 338,587 |
| Reversal of treasury share impairments | 25,949 | 4,578 |
| Reversal of provision for foreign exchange loss | 522 | 1,852 |
| **Total financial income** | **41,281** | **345,017** |

| FINANCIAL EXPENSES (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Foreign exchange losses | 8,367 | - |
| Bond redemption premium | 32,490 | 30,512 |
| Provision for foreign exchange loss risk | 8,145 | 522 |
| Provision for treasury share impairments | - | 25,949 |
| Provision for impairment of equity securities (1) | 111,632,091 | - |
| **Total financial expenses** | **111,681,093** | **56,984** |

(1) See Note 3.2

## Note 19: Extraordinary income and expenses

| NON-RECURRING INCOME (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Gain from buyback of treasury shares | 387 | 24,731 |
| Miscellaneous non-recurring income | 5,302 | 2,412 |
| **Total non-recurring income** | **5,689** | **27,143** |

| NON-RECURRING EXPENSES (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Penalties, fines, donations | 363 | 1,320 |
| Net book value of the transferred asset items | - | - |
| Loss from treasury share buybacks | 121,935 | 43,134 |
| Exceptional charges on management operation | - | 2,385 |
| Allocation to non-recurring provisions | 439 | - |
| Error correction | 172,582 | - |
| **Total non-recurring expenses** | **295,319** | **46,839** |

The error correction found in non-recurring expenses for €172 thousand corresponds to attorney fees incurred by the Company in respect of services provided in financial year 2018.

## Note 20: Income taxes

As the Company is operating at a loss from a tax perspective, it does not pay income tax.

The amounts recognized in the income statement for income taxes pertain to:

- the 2019 Research Tax Credit (CIR) for €899 thousand.

The amount of tax losses carried forward indefinitely available to the Company amounted to €91,859 thousand as of December 31, 2019.
The tax rate on applicable income for Genkyotex SA is the rate that is currently applicable in France (28%). This rate will gradually decrease to reach 25% by 2022.

## Note 21: Related parties

### 21.1 Executive compensation (excluding granting capital instruments)

The table below shows compensation allocated by the Company to members of the Board of Directors:

| Executive compensation (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Attendance fees | 49,091 | 60,000 |
| **Total** | **49,091** | **60,000** |

No post-employment benefits were granted to members of the Board of Directors.
All compensation was paid during the financial years presented except for attendance fees awarded for the financial year ended December 31, 2019.

## 22.1 Retirement benefits

Calculation method

The purpose of actuarial valuation is to produce a discounted estimate of the value of Genkyotex SA's commitments for retirement benefits provided for in the collective agreements.

These obligations related to legal or agreement-related retirement payments have been valued on the closing dates for the three financial years presented. These payments are not recognized as provisions in the Company's financial statements but constitute an off-balance sheet commitment.

This amount is determined at different closing dates based on an actuarial valuation that uses the projected unit credit method, taking into account staff turnover and mortality probability.

Actuarial assumptions

The main actuarial assumptions used to measure retirement packages are as follows:

| ACTUARIAL ASSUMPTIONS | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Age at retirement | Voluntary retirement age between 65 and 67 | |
| Collective bargaining agreements | Pharmaceutical industry | |
| Discount rate<br>(IBOXX Corporates AA) | 0.77% | 1.57% |
| Mortality table | INSEE 2018 | INSEE 2017 |
| Salary revaluation rate | 2.00% | 2.00% |
| Turnover rate | High | High |
| Social security expense ratio<br>Managers<br>Non-managers | 47%<br>47% | 44%*<br>46% |

**excluding managers eligible for withholding tax*

Calculated commitments

Calculated commitments for retirement payments are broken down as follows:

| RETIREMENT BENEFITS (Amounts in euros) | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Amount of commitments | 12,714 | 4,571 |

### 22.2 Commercial leases

The Company signed a lease agreement for its premises dedicated to clinical development in Saint-Julien-en-Genevois, France, as part of its business. These premises are located at: 218 Avenue Marie Curie – Forum 2 Archamps Technopole, 74166 Saint-Julien-en-Genevois, France.

Expenses and commitments

| Location | Real estate leases | Effective lease start date | Lease expiration date | Lease expenses exc. charges at 12/31/2019 | No more than 1 year | 1 to 5 years | More than 5 years |
|---|---|---|---|---|---|---|---|
| Saint Julien en Genevois | Batiment Saint-Julien-en-Genevois | 01.08.2011 | 01.08.2020 | 29 802 | 17 385 | - | - |

### 22.3 Licensing agreement with the Institut Pasteur

Genkyotex SA signed a license agreement with the Institut Pasteur that takes effect on January 1, 2018 and replaces the first agreement signed on February 22, 2006.
The new agreement provides for:

- royalties on net proceeds by the Company, categorized by human use and by veterinary use (lack of revenue generated by the Company under the agreement);

- a share in the cost of maintaining the patents;
  The Institut Pasteur is responsible for obtaining the issuance and assuring the continuing validity of patents. However, the Company will reimburse the Institut Pasteur for all of the direct external expenses incurred by the Institut Pasteur to maintain and extend the patents;

- a royalty in the case of sublicensing (to date, the Company has not signed this type of agreement).

### 22.4 Research contract with Baker Heart and Diabetes Institute

On June 28, 2017, the company announced that world-class diabetes experts, Professor Mark Cooper, Head of the Department of Diabetes at Monash University, and Professor Jonathan Shaw, Deputy Director of Clinical and Population Health at the Baker Heart and Diabetes Institute in Melbourne, Australia, will direct a Phase 2 clinical trial to assess the efficacy and safety of the Company's flagship product candidate, GKT831, in patients with type 1 diabetes and kidney disease (diabetic nephropathy).

This investigator-initiated study will be conducted at the Baker Institute and in several clinical centers across Australia. It will be funded by the Juvenile Diabetes Research Foundation of Australia (JDRF Australia), a beneficiary of the Australian Research Council fund dedicated to the Special Research Initiative for Type 1 Juvenile Diabetes, with financial support from the Baker Institute. As part of this study, Genkyotex will provide the GKT831 compound compliant with good manufacturing practices (GMP).

At December 31, 2019, the Company recorded €141 thousand in accrued income under this agreement versus €44 thousand at December 31, 2018.

## Note 23: Workforce

The Company's average workforce over the past two financial years is as follows:

| AVERAGE WORKFORCE | Financial year 2019 | Financial year 2018 |
|---|---|---|
| Managers | 4.2 | 3.4 |
| Administrative staff | 0.0 | 0.0 |
| **Total average workforce** | **4.2** | **3.4** |

The workforce included four employees as of December 31, 2019.

## Note 24: Table of subsidiaries and equity investments

| TABLE OF SUBSIDIARIES AND EQUITY INVESTMENTS (Amounts in €) | Capital | Reserves and retained earnings before allocation of income | Share of capital held | Carrying value of securities held | | Loans to shareholders | Profit or loss for the last year ended | Dividends | Revenue |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Gross | Net | | | | |
| GENKYOTEX SUISSE SA | 4 848 105 | (10 616 537) | 100% | 120 000 000 | 8 367 909 | - | (5 129 629) | - | 279 899 |

## Note 25: Statutory Auditors' fees

| STATUTORY AUDITORS' FEES | Financial year 2019 (12 months) | | Financial year 2018 (12 months) | |
|---|---|---|---|---|
| (Amounts exc. VAT in € thousand) | KPMG | SYGNATURES | GRANT THORNTON | SYGNATURES |
| For auditing the financial statements | 60 | 60 | 63 | 59 |
| Services unrelated to the auditing of accounts (1) | - | - | 6 | 6 |
| **Subtotal** | **60** | **60** | **69** | **65** |
| Other services | | | | |
| - Tax | - | - | - | - |
| - Other | - | - | - | - |
| **Subtotal** | **-** | **-** | **-** | **-** |
| **Total fees** | **60** | **60** | **69** | **65** |

*(1) In 2018, services other than certifying the financial statements, covering services required by laws and regulations (reports related to the General Shareholders' Meeting) as well as services provided upon Genkyotex's request (review of the 2017 Registration Document).*

### Note 26: Post-balance sheet events

January 2020:

- On January 14 and 15, 2020, Yorkville converted the remaining 80 2019 OCAs outstanding at December 31, 2020. See Note 9.2. Following these conversions, 417,816 new shares were issued. As of the reporting date the Company no longer has a bond.

February 2020:

- In February 2020, the company finalized a capital increase with shareholders' pre-emptive rights maintained in the amount of €4.9 million.

### Note 27: Financial risk management and assessment

Genkyotex SA may find itself exposed to various types of financial risk: market risk, credit risk and liquidity risk. When necessary, Genkyotex SA implements simple measures proportional to its size to minimize the potential adverse effects of those risks on its financial performance.

It is Genkyotex SA's policy not to use financial instruments for speculative purposes.

**Interest rate risk**

Genkyotex SA is not significantly exposed to interest rate risk, to the extent that:

- its cash and cash equivalents and financial assets include term deposits,
- no variable rate debt has been obtained.

**Credit risk**

Credit risk is associated with deposits with banks and financial institutions. For its cash investments, Genkyotex SA uses top-tier financial institutions and therefore does not carry significant credit risk on its cash.

**Foreign exchange risk**

The main risks related to the impact of foreign exchange rates are considered immaterial, except for the SIIL contract where some milestone revenue and royalties are denominated in US dollars.

The Company, at its present stage of development, does not use hedging instruments to protect its activity from exchange rate fluctuations. However, the Company cannot rule out the possibility that a major increase in its activity will increase its exposure to exchange rate risk. In such a case, the Company would consider adopting an appropriate policy to hedge such risks.

**Equity risk**

The Company does not hold equity investments or marketable securities on a regulated market.

**Liquidity risk**

As of the reporting date, the Board of Directors considers that the Company will be able to meet its financing needs for anticipated operations until February 2021. Refer to Note 2.1.

KPMG Audit
51 rue de Saint-Cyr
CS 60409
69338 Lyon Cedex 9
France

sygnatures
8, chemin de la Terrasse
BP 45122 Toulouse Cedex 5

*This is a translation into English of the statutory auditors' report on the financial statements of the Company issued in French and it is provided solely for the convenience of English speaking users.*
*This statutory auditors' report includes information required by European regulation and French law, such as information about the appointment of the statutory auditors or verification of the management report and other documents provided to shareholders.*
*This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.*

## Genkyotex S.A.

Registered office: 218, avenue Marie Curie - Forum 2 Archamps Technopole 74166 Saint-Julien-en-Genevois
Share capital: €.11.548.562

## Statutory auditors' report on the financial statements

For the year ended 31 December 2019

Dear Shareholders

### Opinion

In compliance with the engagement entrusted to us by your annual general meeting, we have audited the accompanying financial statements of Genkyotex S.A. for the year ended 31 December 2019. These financial statements were approved by the Board of Directors on 24 February 2020 based on the information available at that date and in the evolving context of the health crisis linked to the Covid-19.

In our opinion, the financial statements give a true and fair view of the assets and liabilities and of the financial position of the Company as at 31 December 2019 and of the results of its operations for the year then ended in accordance with French accounting principles.

The audit opinion expressed above is consistent with our report to the Audit Committee.

### Basis for Opinion

#### *Audit Framework*

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the *Statutory Auditors' Responsibilities for the Audit of the Financial Statements* section of our report.

***Independence***

We conducted our audit engagement in compliance with independence rules applicable to us, for the period from 01 January 2019 to the date of our report and specifically we did not provide any prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No 537/2014 or in the French Code of ethics (code de déontologie) for statutory auditors.

**Justification of Assessments - Key Audit Matters**

In accordance with the requirements of Articles L.823-9 and R.823-7 of the French Commercial Code (code de commerce) relating to the justification of our assessments, we inform you of the key audit matters relating to risks of material misstatement that, in our professional judgment, were of most significance in our audit of the financial statements of the current period, as well as how we addressed those risks.

These matters were addressed in the context of our audit of the financial statements as a whole, approved in the context described above, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the financial statements.

| **Impairment test of investment in Genkyotex Suisse S.A.** | |
|---|---|
| **Key Audit Matter** | **Our response** |
| As at December 31, 2019, the net carrying value of equity investment in Genkyotex Suisse is € 8.4 M and represents 70% of total assets. The depreciation of the year amounts to € 111.6 M and represents 69% of the operating expenses.<br><br>As indicated in paragraph 2.4 « Financial Assets » in Note 2 « Accounting principles, rules and methods » of the notes to the annual financial statements, the value in use of Genkyotex Suisse S.A. is assessed considering the Risk-adjusted Net Present Value (rNPV) valuation method (the historical valuation method used for the business combination of Genticel S.A. and Genkyotex Suisse) and Genkyotex S.A. market capitalization.<br><br>We identified the valuation of investment in Genkyotex Suisse S.A. as a key audit matter given the materiality of the amount with regard to the total assets and due to the sensitivity of the potential impairment to the selected valuation model. | Our procedures mainly focused on:<br><br>- Assessing, with the support of our financial valuation experts, the relevance of the valuation model that prevailed at December 31, 2019 to estimate the impairment with regards to the Group's developments during the year and after the balance sheet date<br><br>- Reperforming the calculation made by the Company<br><br>- Assessing the appropriateness of the information given in Notes 2.4 and 3.2 to the financial statements. |

| Assessment of management evaluation of the going concern | |
|---|---|
| **Key Audit Matter** | **Our response** |
| As indicated in Note 2.1 to the financial statements, Genkyotex S.A. Board of Directors evaluated that the Company will have sufficient financial resources to operate until February 2021.<br><br>At the date the financial statements were approved, the Board of Directors assessed the going concern principle applied in preparing the financial statements based on the following:<br><br>• the €2.417k outstanding cash and cash equivalents at December 31, 2019;<br><br>• the expected collection of the 2019 research tax credit for €899k ;<br><br>• the operational cash outflows forecasted for 2020 and beginning of 2021 ;<br><br>• the conversion in January 2020 of the remaining convertible bonds which were outstanding for €800k at December 31, 2019;<br><br>• the €4.9m share capital increase which was successfully completed in February 2020.<br><br>We identified the assessment of the Company's ability to continue as a going concern as key audit matter because it is dependent upon management assumptions and judgments and because of the inherent risk involved in forecasting future cash flows. | We assessed management evaluation of the Company's ability to continue as a going concern for the 12 months from the financial statements reporting date.<br><br>Specifically we :<br><br>• understood the process used by management to prepare the cash forecast and estimate future expenses,<br><br>• assessed the key assumptions used by management in the cash forecast with regards to our experience with the Company and management's plans<br><br>• evaluated the impact of the conversion of the remaining outstanding convertible bonds and of the share capital increase which occurred after the reporting date on the cash forecast<br><br>• inquired of management whether they were aware of any other events after the reporting date which could question the Company's ability to continue as a going concern.<br><br>We also assessed whether the going concern disclosure in the footnotes to the financial statements was appropriate. |

**Specific Verifications**

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by laws and regulations.

***Information given in the management report and in the other documents with respect to the financial position and the financial statements provided to the Shareholders***

We have no matters to report as to the fair presentation and the consistency with the financial statements of the information given in the management report of the Board of Directors approved on 24 February 2020 and in the other documents with respect to the financial position and the financial statements provided to the Shareholders. With regards to the events that occurred and information that became known after the date the financial statements were approved by the Board of Directors relating to the impact of the crisis linked to Covid-19, management informed us that such events and information will be communicated to annual general meeting called to approve the financial statements.

We attest the fair presentation and the consistency with the financial statements of the information relating to payment deadlines mentioned in Article D.441-4 of the French Commercial Code (*Code de commerce*).

***Information relating to corporate governance***

We attest that the Board of Directors' report on corporate governance sets out the information required by Articles L.225-37-3 and L.225-37-4 of the French Commercial Code.

Concerning the information given in accordance with the requirements of Article L.225-37-3 of the French Commercial Code (code de commerce) relating to remunerations and benefits received by the directors and any other commitments made in their favour, we have verified its consistency with the financial statements, or with the underlying information used to prepare these financial statements and, where applicable, with the information obtained by your company from controlling and controlled companies. Based on these procedures, we attest the accuracy and fair presentation of this information.

***Other information***

In accordance with French law, we have verified that the required information concerning the purchase of investments and controlling interests and the identity of the shareholders and holders of the voting rights has been properly disclosed in the management report.

**Report on Other Legal and Regulatory Requirements**

***Appointment of the Statutory Auditors***

We were appointed as statutory auditors of Genkyotex S.A. by the annual general meeting held on 20 December 2013 for Sygnatures and on 13 June 2019 for KPMG S.A.

As at 31 December 2019, Sygnatures was in the 6th year of total uninterrupted engagement and KPMG S.A in the first year, which are the 6th year and first year since securities of the Company were admitted to trading on a regulated market, respectively.

**Responsibilities of Management and Those Charged with Governance for the Financial Statements**

Management is responsible for the preparation and fair presentation of the financial statements in accordance with French accounting principles and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless it is expected to liquidate the Company or to cease operations.

The Audit Committee is responsible for monitoring the financial reporting process and the effectiveness of internal control and risks management systems and where applicable, its internal audit, regarding the accounting and financial reporting procedures.

The financial statements were approved by the Board of Directors.

**Statutory Auditors'Responsibilities for the Audit of the Financial Statements**

*Objectives and audit approach*

Our role is to issue a report on the financial statements. Our objective is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As specified in Article L.823-10-1 of the French Commercial Code (code de commerce), our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.

- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the financial statements.

- Assesses the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report.

However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.

- Evaluates the overall presentation of the financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

*Report to the Audit Committee*

We submit a report to the Audit Committe which includes in particular a description of the scope of the audit and the audit program implemented, as well as the results of our audit. We also report, if any, significant deficiencies in internal control regarding the accounting and financial reporting procedures that we have identified.

Our report to the Audit Committee includes the risks of material misstatement that, in our professional judgment, were of most significance in the audit of the financial statements of the current period and which are therefore the key audit matters that we are required to describe in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) N° 537/2014, confirming our independence within the meaning of the rules applicable in France such as they are set in particular by Articles L.822-10 to L.822-14 of the French Commercial Code (code de commerce) and in the French Code of Ethics *(code de déontologie)* for statutory auditors. Where appropriate, we discuss with the Audit Committee the risks that may reasonably be thought to bear on our independence, and the related safeguards.

Lyon, on the 23 April 2020

Toulouse , on the 23 April 2020

The statutory auditors

French original signed by

Stéphane Devin

*Partner*

Laure Mulin

*Partner*

## 18.2. INTERIM AND OTHER FINANCIAL INFORMATION

Not applicable.

## 18.3. AUDITING OF HISTORICAL ANNUAL FINANCIAL INFORMATION

See sections 18.1.1.2 to 18.1.1.4 of the Universal Registration Document.

## 18.4. PRO FORMA FINANCIAL INFORMATION

Not applicable.

## 18.5. DIVIDEND POLICY

### 18.5.1. Dividends and reserves distributed by the Company over the last three financial years

None.

### 18.5.2. Distribution policy

In view of the Company's stage of development, no dividend distribution policy has been initiated for the short term.

## 18.6. LEGAL AND ARBITRATION PROCEEDINGS

As of the date of the Universal Registration Document, there exist no governmental, legal or arbitrage proceedings of which the Company is aware that are pending or threaten the Company which are likely to have or have had a significant impact on the financial position or profitability of the Company and/or the Group during the past 12 months.

## 18.7. SIGNIFICANT CHANGE IN THE ISSUER'S FINANCIAL POSITION

To the Company's knowledge, there has been no significant change in the Company's financial position or business situation since December 31, 2019.

## 18.8. OTHER INFORMATION FROM THE MANAGEMENT REPORT

### 18.8.1. Table of results for the last five financial years

| | 12/31/2015 | 12/31/2016 | 12/31/2017 | 12/31/2018 | 12/31/2019 |
|---|---|---|---|---|---|
| **SHARE CAPITAL AT THE END OF THE YEAR** | | | | | |
| Share capital | 1,554,108.60 | 1,557,005.50 | 7,785,000.60 | 7,934,762.10 | 8,683,449 |
| Number of existing ordinary shares | 15,541,086 | 15,570,055 | 77,850.006 | 79,347,621 | 8,683,449 |
| **OPERATIONS AND RESULTS** | | | | | |
| Revenue excluding tax | 89,371 | 222,300 | 4,765.239 | 6,456,433 | 3,442.916 |
| Profit/(loss) before tax, employee shareholding and depreciation, amortization and provisions | (13,547,452) | (9,226,346) | (4,024,704) | (878,584) | (113,564,524) |
| Income tax | (3,036,255) | (2,959,255) | (38,134) | (892,892) | (898,683) |
| Employee profit-sharing for the year | - | - | - | - | - |
| Profit/(loss) after tax, employee shareholding and depreciation, amortization and provisions | (10,567,153) | (7,059,720) | (3,292,523) | 5,036 | (123,904,104) |
| Distributed profit | - | - | - | - | - |
| **EARNINGS PER SHARE** | | | | | |
| Profit/(loss) after tax, employee shareholding, but before depreciation, amortization and provisions | (0.87) | (0.40) | (0.05) | (0.00) | (13.08) |
| Profit/(loss) after tax, employee shareholding and depreciation, amortization and provisions | (0.68) | (0.45) | (0.04) | (0.00) | (14.27) |
| Dividend per share | - | - | - | - | |
| **EMPLOYEES** | | | | | |
| Employee workforce as of December 31 | 34 | 7 | 3 | 4 | 4 |
| Amount of payroll at year end | 2,380,102 | 3,141,584 | 1,406,680 | 286,398 | 299,343 |
| Amount paid in employee benefits for the year | 1,000,641 | 1,392,953 | 314,909 | 104,045 | 156,729 |

### 18.8.2. Adjusted allocation of income for the financial year ended December 31, 2018 and proposed allocation of income for the financial year ended December 31, 2019

The profit of €5,035.82 for the financial year ended December 31, 2018 has been allocated to retained earnings except for the assignment of 5% of this profit, i.e., €251.79, to the legal reserve. Accordingly, a proposal has been made to allocate the sum of €251.79 from the "retained earnings" account to the "legal reserve."

After this adjustment, the "legal reserve" account amounts to €5,702.79 and the credit balance of the "retained earnings" account amounts to €4,784.03.

After deducting all expenses, taxes and depreciation, the Company's earnings, calculated in accordance with French accounting standards (see Section 18.1.8 of the Universal Registration Document) show a loss of €123,904,103.67 that we propose to allocate as follows:

- €(4,784.03) transferred to the "retained earnings" account;
- €(50,370,682.86) transferred to the "issuance premiums" account;
- €(73,528,637.09) transferred to the "contribution premium" account;

After these transfers, the credit balance of the "issuance Premiums" account is €819,927.98, and the "contribution premium" and "retained earnings" accounts have a zero balance.

### 18.8.3. Non-tax-deductible expenses

In accordance with Article 223 quater of the French General Tax Code, there were no sumptuary expenses or non-deductible expenses referred to in Article 39-4 of this Code in the financial statements for the year ended December 31, 2019.

### 18.8.4. Information on payment terms for suppliers and customers

In accordance with the provisions of Articles L. 441-6-1 and D. 441-4 of the French Commercial Code, we would like to inform you of information relating to supplier and customer payment terms mentioned in Article D. 441-4 of the French Commercial Code, and, in particular, invoices received and issued that have not been paid as of the year end which are overdue (table shown in paragraph I of Article D. 441-4 of the French Commercial Code):

**As of December 31, 2019**

| Amounts in € thousands | Article D. 441-I paragraph 1: Overdue invoices **received** but not paid as of year-end | | | | | | Article D. 441-I paragraph 2: Overdue invoices **issued** but not paid as of year end | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 days (for informational purposes only) | 1 to 30 days | 31 to 60 days | 61 to 90 days | 91+ days | Total (1+ days) | 0 days (for informational purposes only) | 1 to 30 days | 31 to 60 days | 61 to 90 days | 91+ days | Total (1+ days) |
| **(A)** Late payment installments | | | | | | | | | | | | |
| Number of invoices concerned | 17 | 1 | | | 7 | 8 | - | | | | | - |
| Total amount of invoices concerned, including tax | 366 | 1 | - | - | 225 | 227 | - | - | - | - | - | - |
| Percentage of the total amount of purchases for the year excluding tax | 8% | 0% | 0% | 0% | 5% | 5% | | | | | | |
| Percentage of revenue for the year including tax | | | | | | | 0% | 0% | 0% | 0% | 0% | 0% |
| **(B)** Invoices excluded from (A) relating to unrecognized or disputed payables and receivables | | | | | | | | | | | | |
| Number of invoices excluded | | | | | | | 1 | - | - | - | 5 | 5 |
| Total amount of invoices excluded, excluding tax | | | | | | | 863 | - | - | - | 8,851 | 8,851 |
| **(C)** Reference payment terms used (contractual or legal payment deadlines - Article L. 441-6 or Article L. 443-1 of the French Commercial Code) | | | | | | | | | | | | |
| Payment terms used to calculate payment delays | - Legal deadlines: Article L. 441-6 of the French Commercial Code | | | | | | - Legal deadlines: Article L. 441-6 of the French Commercial Code | | | | | |

**As of December 31, 2018**

| Amounts in € thousands | Article D. 441-I paragraph 1: Overdue invoices **received** but not paid as of year-end | | | | | | Article D. 441-I paragraph 2: Overdue invoices **issued** but not paid as of year end | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 days (for informational purposes only) | 1 to 30 days | 31 to 60 days | 61 to 90 days | 91+ days | Total (1+ days) | 0 days (for informational purposes only) | 1 to 30 days | 31 to 60 days | 61 to 90 days | 91+ days | Total (1+ days) |
| **(A)** Late payment installments | | | | | | | | | | | | |
| Number of invoices concerned | 43 | | | | | 7 | - | | | | | 6 |
| Total amount of invoices concerned, including tax | 593 | 57 | - | - | 4 | 61 | - | 397 | - | - | 2952 | 2,046 |
| Percentage of the total amount of purchases for the year excluding tax | 8% | 1% | 0% | 0% | 0% | 1% | | | | | | |
| Percentage of revenue for the year including tax | | | | | | | 0% | 6% | 0% | 0% | 46% | 52% |
| **(B)** Invoices excluded from (A) relating to unrecognized or disputed payables and receivables | | | | | | | | | | | | |
| Number of invoices excluded | - | - | - | - | - | - | - | - | - | - | - | - |
| Total amount of invoices excluded, excluding tax | - | - | - | - | - | - | - | - | - | - | - | - |
| **(C)** Reference payment terms used (contractual or legal payment deadlines - Article L. 441-6 or Article L. 443-1 of the French Commercial Code) | | | | | | | | | | | | |
| Payment terms used to calculate payment delays | - Legal deadlines: Article L. 441-6 of the French Commercial Code | | | | | | - Legal deadlines: Article L. 441-6 of the French Commercial Code | | | | | |

# SECTION 19. ADDITIONAL INFORMATION

## 19.1. GENERAL INFORMATION CONCERNING SHARE CAPITAL

### 19.1.1. Amount of share capital

As of the date of the Universal Registration Document, the Company's share capital was €11,548,562 divided into 11,548,562 ordinary shares with a par value of €1 each, fully paid-up and of a single class and reflecting the reverse stock split decided by the Company's Extraordinary General Shareholders' Meeting of January 24, 2019, which took effect on March 29, 2019.

### 19.1.2. Securities not representing equity

None.

### 19.1.3. Acquisition by the Company of its own shares

The Combined General Shareholders' Meeting of June 13, 2019 authorized the Board of Directors, with the power to further delegate under the conditions provided by law, to implement, for a period of eighteen (18) months from the date of the meeting, a share buyback plan in accordance with (i) Articles L. 225-209 of the French Commercial Code, (ii) European Regulation No. 596/2014 of April 16, 2014 on market abuse and its delegated regulations and (iii) Title IV of Book II of the General Regulations of the French Financial Markets Authority (*Autorité des Marchés Financiers*) and the market practices approved thereby.

The main terms of this authorization are as follows:
Maximum number of shares that can be redeemed: 10% of the share capital as of the date that the shares are redeemed. When the shares are redeemed to stimulate trading and liquidity, the number of shares used for the calculation of this 10% limit corresponds to the number of shares purchased, less the number of shares resold over the term of this authorization.

Objectives of the share buyback plan:

- Ensure the liquidity of Company shares through a liquidity contract to be signed with an investment services provider, in accordance with an ethics charter recognized by the French Financial Markets Authority (AMF) or any other market practice accepted by the AMF;
- Permit the Company to honor its obligations under stock option plans, free share allocation plans, employee savings plans or other allocations of shares to the employees and executives of the Company or companies related to it;
- Permit it to deliver shares upon the exercise of rights attached to securities giving access to its capital;
- Purchase shares to be held for future use as exchange or payment in a potential external growth transaction; or
- Cancel all or part of the repurchased shares by way of a capital reduction.

Maximum purchase price: €15 per share, excluding fees and charges.

The number of shares purchased by the Company for future use as payment or exchange in a merger, demerger or contribution may not exceed 5% of the total number of shares.

The maximum amount of funds that can be earmarked for share buyback: €10 million.

During financial year 2019, the Company traded in its own shares as part of the liquidity contract signed for a period of one year with an independent financial services provider.

As of December 31, 2019, the Company held 7,789 treasury shares, accounting for approximately 0.09% of the share capital, purchased for a total cost price of €15,687.

Disposals of treasury shares under the liquidity contract generated a net capital loss of €121,935 in financial year 2019.

The following table summarizes the position:

| ITEMS | 12/31/2019 |
|---|---|
| Initial payment on 4/22/2014 | €200,000 |
| Net loss from sales in financial year 2019 | -€121,935 |
| Securities account (line 277100 “treasury shares”)<br>number of treasury shares<br>cost price of treasury shares<br>closing price of treasury shares | <br>7,789 shares<br>€15,687<br>€2.18 |
| Cash account (line 276100 “Other capitalized receivables”) | €14,389 |
| Unrealized capital gain 12/31/2019 | €1,293 |

### 19.1.4. Securities convertible, exchangeable, or with warrants attached

As of the date of this Universal Registration Document, marketable securities giving access to the Company's share capital and currently valid confer the right to subscribe to 346,712 new shares: 97,280 shares upon exercise of BSAs, 249,432 shares upon exercise of stock options (i.e., a total of 3.00% of the existing capital as of the date of this Universal Registration Document).

### 19.1.4.1. Share subscription warrants (BSAs)

| | BSA Jul-2008 | BSA April-2009 | BSA Feb-2010 | BSA Dec-2010 | BSA Dec-2013 | BSA Sept-2014 | BSA Yorkville |
|---|---|---|---|---|---|---|---|
| ***Date of General Shareholders' Meeting*** | 07/31/08 | 10/24/08 | 02/22/10 | 10/26/09 | 04/22/13 | 03/07/14 | 06/13/18 |
| ***Date of Board decision as from March 1, 2017*** | - | 04/09/09 | - | 12/17/10 | 12/20/13 | 09/12/14 | 06/13/18 |
| *Number of BSAs authorized* | 666,670 | 30,800 | 10,900 | 152,500 | 598,154 | 2,245,000 | 666,312 |
| *Number of BSAs issued* | 666,670 | 30,800 | 2,700 | 152,500 | 116,000 | 35,000 | 666,312 |
| *Maximum number of shares available for subscription* | 133,334 | 3,080* | 270* | 15,295* | 11,631* | 3,509* | 66,845* |
| *Of which available for subscription by members of the Board of Directors* | 133,334 | - | - | - | - | 35,000 | - |
| *Members of the Board of Directors concerned:* | | | | | | | |
| Andera Partners (formerly EdRIP) | 133,334 | - | - | | - | | - |
| Mary Tanner | - | - | - | | - | 35,000 | - |
| *Number of non-corporate-member beneficiaries as of the date of the Universal Registration Document* | 0 | 1 | 1 | 1 | 3 | 0 | 0 |
| *BSA exercise start date* | 07/31/08 | 10/24/09 | 02/22/10 | 12/17/10 | 12/19/14 | 09/11/15 | 08/20/18 |
| *BSA expiration date* | 07/31/18 | 10/23/19 | 02/22/20 | 12/17/20 | 12/23/20 | 09/12/24 | 08/20/23 |
| *BSA issue price* | N/A | €0.00 | €0.00 | €0.00 | €0.20 | €0.58 | N/A |
| *BSA exercise price* | €3 | €30* | €30* | €29.91* | €39.89* | €57.74* | €18.70* |
| *Exercise terms and conditions* | (1) | (1) | (1) | (2) | (2) | (2) | (3) |
| *Number of shares subscribed as of the date of the Universal Registration Document* | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *Total number of BSAs expired or canceled as of the date of the Universal Registration Document* | 666,670 | 30,800 | 2,700 | 0 | 0 | 0 | 0 |
| *Unexercised BSAs outstanding as of the date of the Universal Registration Document* | 0 | 0 | 0 | 152,500 | 116,000 | 35,000 | 666,312 |
| *Total number of shares available for subscription as of the date of the Universal Registration Document* | 0 | 0 | 0 | 15,295* | 11,631* | 3,509* | 66,845* |
| *Total number of shares resulting from the exercise of BSA warrants, taken into account for the purposes of the table in Section 16.1 of the Universal Registration Document (i.e., 97,280)* | 0 | 0 | 0 | 15,295* | 11,631* | 3,509* | 66,845* |

The BSAs listed in the above table are transferable in accordance with the issuance terms and conditions of each BSA (certain ones subject to conditions). Each holder of a BSA should refer to the issuance terms and conditions of their BSAs to become acquainted with the conditions of transfer.

* After the March 29, 2019 effective date of the 1-for-10 reverse stock split of the Company's shares and the exchange ratio adjustment following the February 6, 2020 capital increase with shareholders' pre-emptive rights maintained.

(1) These BSAs had expired as of the date of the Universal Registration Document.

(2) These BSAs were all exercisable as of the date of the Universal Registration Document.

(3) These BSAs may be exercised during a five-year period starting from their issue.

### 19.1.4.2. Stock options

| | Stock options Jan-2018 | Stock options Sept-2018 | Stock options Mar-2019 |
|---|---|---|---|
| **Date of General Shareholders' Meeting** | June 15, 2017 | June 15, 2017 | June 15, 2017 |
| **Date of Board of Directors' Meeting** | January 9, 2018 | September 26, 2018 (3) | March 21, 2019 |
| Total number of stock options granted | 1,159,934 | 20,000 | 1,336,380 |
| Maximum number of shares available for subscription if exercised | 116,306* | 2,006* | 134,076* |
| *of which available for subscription by corporate officers* | *585,369** | *0* | *609,229** |
| *Corporate officer concerned: Ilias (Elias) Papatheodorou (4)* | *585,369** | *0* | *609,229* |
| Stock options exercise start date | 01/08/19 | 09/26/19 | 03/21/20 |
| Stock options expiration date | 01/08/28 | 09/26/28 | 03/21/29 |
| Subscription price of one share | €16.65* | €14.85* | €9.07* |
| Exercise terms and conditions | (1) | (1) (2) | (1) (2) |
| Number of shares subscribed as of the date of the Universal Registration Document | 0 | 0 | 0 |
| Total number of stock options exercised, canceled or expired | 29,781 | 0 | 0 |
| Unexercised stock options outstanding as of the date of the Universal Registration Document | 1,130,153 | 20,000 | 1,336,380 |
| Total number of shares available for subscription as of the date of the Universal Registration Document | 29,076* | 501* | 33,519* |
| *Total number of shares resulting from the exercise of stock options, taken into account for the purposes of the table in Section 16.1 of the Universal Registration Document (i.e., 249,432)* | 113,350* | 2,006* | 134,076* |

* After the March 29, 2019 effective date of the 1-for-10 reverse stock split of the Company's shares and the exchange ratioadjustment following the February 6, 2020 capital increase with shareholders' pre-emptive rights maintained.

(1) These stock options are non-transferable. One-quarter of the stock options may be exercised at the end of each year following their respective grant date, provided that the holder is still in office on the anniversary date in question.

(2) They are not exercisable as of the date of the Universal Registration Document.

(3) The Board of Directors has subdelegated the allocation of stock options completed on October 11, 2018 to the Chief Executive Officer.

(4) Elias Papatheodorou also holds 148,689 Company shares.

### 19.1.4.3. Bonds convertible into shares (OCAs)

In accordance with the provisions of Article L. 225-138 of the French Commercial Code and of Resolution 16 of the Company's General Shareholders' Meeting of June 13, 2019, using the powers granted to him by the Board meeting of August 5, 2019, the Chief Executive Officer of the Company decided to issue 160 convertible bonds on August 19, 2019 for a total nominal amount of €1.6 million, to the benefit of YA II PN, Ltd, a fund managed by the management company, by offsetting this against the debt corresponding to the Investor's prior sale to the Company of 160 2018 OCAs, issued on August 20, 2018, for €1.6 million.

*Main features of the convertible bonds*

The nominal unit value of the OCAs is equal to ten thousand euro (€10,000). Each OCA will be issued at a subscription price per OCA equal to 100% of its nominal unit value, a total nominal amount of one million six hundred thousand euro (€1,600,000).

The OCAs (i) are freely assignable or transferable by the Investor to any of its affiliates and (ii) may not be transferred to any other third party without the prior written consent of the Company.

The OCAs will not be listed or admitted to trading on the regulated markets of Euronext Paris or Euronext Brussels or on any other financial market.

Each OCA expires twelve (12) months from its issue (the "Maturity date"). In the event that an OCA is not converted before the Maturity date, the Company is obliged to repay the outstanding amount in cash.

The OCAs do not bear any interest. However, in the event of the occurrence of a Default (2), each OCA outstanding will bear interest at the rate of 15% per year from the date of the Default and up to (i) the date on which the Default is resolved, or (ii) the date on which the OCA has been fully converted and/or repaid, if the Default has not yet been resolved.

The number of new shares issued by the Company for the benefit of each OCA holder when converting one or more OCAs corresponds to the amount of the conversion divided by the applicable Conversion Price. The "Conversion Price" is equal to 92% of the weighted average share price quoted on Euronext (as reported by Bloomberg) (the "Average Prices") on the five (5) consecutive stock exchange sessions up to the trading session immediately before the conversion date.

*New shares resulting from the conversion of the OCAs*

New shares issued against the conversion of the OCAs will carry dividend rights. They will have the same rights as those attached to the Company's existing ordinary shares and will be admitted to the regulated markets of Euronext Paris and Euronext Brussels on the same market listing.

*Yorkville's commitments*

From the date of completion and until the full conversion and/or redemption of the OCAs outstanding, the Investor agrees and undertakes the following:
• not to transfer any shares making up the Company's capital for a period of thirty (30) days from the Closing Date;
• not to request a seat on the Board of Directors;
• not to hold at any time a number of shares greater than 4.99% of the number of Company shares outstanding. Note that only shares already issued are included in the calculation of this ratio, as the potential shares resulting from the conversion of outstanding OCAs held by the Investor or the exercise of BSAs issued by the Company on August 20, 2018 and held by the Investor are not taken into account.

### 19.1.5. Authorized capital

The issuance resolutions in effect as of the date of this Universal Registration Document are summarized below:

| Type of delegation | Period of validity/Expiration date | Maximum amount of bond issues | Issuance cap for shares and/or marketable securities giving access to capital | Price calculation method | Amount used in 2019 | Amount available as of the date of the URD |
|---|---|---|---|---|---|---|
| Authorization to the Board of Directors to reduce share capital by canceling shares as part of the authorization to buy back its own shares **(Resolution 12 of the AGM of June 13, 2019)** | 18 months<br>December 13, 2020 | | Cancellation subject to a maximum limit of 10% of share capital in any 24 month period | | | |
| Delegation of authority to the Board of Directors to increase capital by issuing ordinary shares and/or any transferable equity instruments giving access to other equity instruments or giving entitlement to debt securities, and/or to securities giving access to future equity instruments, with shareholders' pre-emptive rights maintained **(Resolution 13 of the AGM of June 13, 2019)** | 26 months<br>August 13, 2021 | €90,000,000 | € 4,000,000 (1) | | None | €696,921 |
| Delegation of authority to the Board of Directors to increase capital immediately or in the future by issuing ordinary shares or any transferable equity instruments giving access to other equity instruments or giving entitlement to debt securities, with shareholders' pre-emptive rights waived and offer to the public<br>**(Resolution 14 of the AGM of June 13, 2019)** | 26 months<br>August 13, 2021 | €90,000,000 | €4,000,000 (1) | See (2) | None | €696,921 |
| Delegation of authority to the Board of Directors to increase capital by issuing ordinary shares and/or any transferable equity instruments giving access to other equity instruments or giving entitlement to debt securities, and/or securities giving access to future equity instruments, with shareholders' pre-emptive rights waived, to be issued as part of an offer to qualified investors or a restricted circle of investors as defined in paragraph II of Article L.411-2 of the French Monetary and Financial Code<br>**(Resolution 15 of the AGM of June 13, 2019)** | 26 months<br>August 13, 2021 | €35,000,000 | € 1,600,000 (1) subject to a limit of 20% of the share capital per 12-month period | See (3) | None | €696,921 |
| Delegation of authority to the Board of Directors to increase capital by issuing ordinary shares and/or any transferable equity instruments giving access to other equity instruments or giving entitlement to debt securities, and/or securities giving access to future equity instruments, with shareholders' pre-emptive rights waived, for the benefit of categories of persons who meet specific criteria **(Resolution 16 of the AGM of June 13, 2019)** | 18 months<br>December 13, 2020 | €90,000,000 | € 4,000,000 (1) | See (4) | €855,782 | €696,921 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Authorization to the Board of Directors, when issuing shares or any securities with shareholders' pre-emptive rights waived, to set the issue price subject to an annual limit of 10% of the share capital and in accordance with the conditions set by the general shareholders' meeting **(Resolution 17 of the AGM of June 13, 2019)** | 26 months<br>August 13, 2021 | - | Subject to a limit of 10% of share capital | See (5) | None | 100% of the cap |
| Delegation of authority to the Board of Directors to increase, in the event of a capital increase, the number of securities to be issued with shareholders' pre-emptive rights waived or maintained **(Resolution 18 of the AGM of June 13, 2019)** | 26 months<br>August 13, 2021 | - | Subject to a limit of 15% of the initial issue (1) (6) | Same price as the initial issue | None | €696,921 |
| Delegation of authority to the Board of Directors to issue ordinary shares or any securities giving access to Company capital, in the event of a tender offer that includes an exchange component initiated by the Company **(Resolution 19 of the AGM of June 13, 2019)** | 26 months<br>August 13, 2021 | €90,000,000 | € 4,000,000 (1) | | None | €696,921 |
| Delegation of authority to the Board of Directors to issue ordinary shares of the Company or securities giving access in any way immediately or in the future to ordinary shares of the Company, subject to a limit of 10% of existing share capital, to pay for in-kind contributions of equity instruments or securities giving access to the capital of third-party entities outside a public exchange offer **(Resolution 20 of the AGM of June 13, 2019)** | 26 months<br>August 13, 2021 | €90,000,000 | Subject to a limit of 10% of existing share capital as of the date of the transaction in question (1) | | None | €696,921 |
| Delegation of authority to the Board of Directors to increase capital by incorporating premiums, reserves, profits or other means **(Resolution 22 of the AGM of June 13, 2019)** | 26 months<br>August 13, 2021 | - | €500,.000 | | None | 100% of the cap |
| Authorization to the Board of Directors to grant options to subscribe or buy ordinary shares in the Company **(Resolution 23 of the AGM of June 13, 2019)** | 38 months<br>August 13, 2022 | - | 198,368 shares (7) | See (8) | None | 100% of the cap |
| Authorization to the Board of Directors to allocate existing or future bonus shares **(Resolution 24 of the AGM of June 13, 2019)** | 38 months<br>August 13, 2022 | - | 450,000 shares, subject to a limit of 10% of share capital (7) | | None | 100% of the cap |
| Delegation of authority to the Board of Directors to issue and allocate share subscription warrants to the benefit of (i) members and observers on the Company's Board of Directors in office on the allocation date who are not employees or executives of the Company or of any of its subsidiaries or (ii) persons related by a service or consulting contract to the Company or any of its subsidiaries or (iii) members of any existing or future committee of the Board of Directors who are not employees or executives of the Company or of any of its subsidiaries<br>**(Resolution 25 of the AGM of June 13, 2019)** | 18 months<br>December 13, 2020 | - | 450,000 BSAs (7) | See (9) | None | 100% of the cap |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Overall cap on the amount of issues pursuant to Resolutions 13, 14, 15, 16, 18, 19 and 20 **(Resolution 21 of the AGM of June 13, 2019)** | - | €90,000,000 | €4,000,000 | See (10) | €855.782 | €696,921 |
| Overall cap on the amount of issues pursuant to Resolutions 23, 24 and 25 **(Resolution 26 of the AGM of June 13, 2019)** | - | | 450,000 shares | | - | - |

(1) These amounts are not cumulative. The maximum cumulative cap authorized by the General Shareholders' Meeting as the par value of capital increases, is set at €4.000.000.

(2) The issue price of shares and securities, which may be issued under this delegation, will be set by the Board of Directors, in accordance with the provisions of Article L. 225-136-1° of the French Commercial Code and will therefore be at least equal to the weighted average listed share price of the last three trading days immediately preceding the date on which the issue price is set, minus any maximum legally authorized discount (currently 5%) and adjusted for any difference in entitlement dates, it being understood that (i) in the event of the issue of securities giving access to capital, the issue price of shares that may result from the exercise, conversion or exchange of such securities may, where appropriate, be set, at the discretion of the Board of Directors, by reference to a calculation formula defined by the Board, which will apply after said securities have been issued (for example, during their exercise, conversion or exchange), in which case the above maximum discount may be assessed, if the Board of Directors deems it appropriate, as of the date of application of said formula (not as of the date the issue price is set), and that (ii) the issue price of securities giving access to the capital issued under this resolution will be the sum immediately taken by the Company, plus any sum it may take subsequently during the exercise, conversion or exchange of said securities, thus, for each share issued as a consequence of the exercise, conversion or exchange of said securities, at least equal to the issue price defined above.

(3) The issue price of shares will be set by the Board of Directors, in accordance with the provisions of Article L. 225-136-1° of the French Commercial Code and will therefore be at least equal to the weighted average listed share price of the last three trading days immediately preceding the date on which the issue price is set, minus any legally authorized discount (currently 5%) and adjusted for any difference in entitlement dates, it being understood that (i) in the event of the issue of securities giving access to capital, the issue price of shares that may result from the exercise, conversion or exchange of such securities may, where appropriate, be set, at the discretion of the Board of Directors, by reference to a calculation formula defined by the Board, which will apply after said securities have been issued (for example, during their exercise, conversion or exchange), in which case the above maximum discount may be assessed, if the Board of Directors deems it appropriate, as of the date of application of said formula (not as of the date the issue price is set), and that (ii) the issue price of securities giving access to the capital issued under this resolution will be the sum immediately taken by the Company, plus any sum it may take subsequently during the exercise, conversion or exchange of said securities, thus, for each share issued as a consequence of the exercise, conversion or exchange of said securities, at least equal to the issue price defined above.

(4) The issue price of shares issued under this delegation will be set by the Board of Directors and will be at least equal to the volume-weighted average listed share price of the selected share over a period of between three and thirty consecutive trading days from among the thirty trading days immediately preceding the date on which the issue price is set, adjusted for any difference in entitlement dates and potentially reduced by a maximum 20% discount.

(5) Subject to a limit of 10% of existing Company capital (existing on the transaction date) in any consecutive 12-month period, to override the price-setting conditions specified in the aforementioned resolutions and set the issue price for ordinary shares and/or other securities giving immediate or future access to issued capital, as follows:

- The issue price of an ordinary share will be at least equal to the weighted average share price during the three trading days immediately preceding the date the price is set, potentially discounted by up to 15%, it being understood that in no case can it be lower than the par value of a Company share as the date that the shares in question are issued.
- The issue price of securities giving access to capital will be the sum immediately taken by the Company, plus any sum it may take subsequently, thus, for each share issued as a consequence of the issuance of these securities, at least equal to the issue price defined in the paragraph above.

(6) 15% or any other percentage that may be set by applicable regulations.

(7) These amounts are not cumulative. The cumulative cap authorized by the General Shareholders' Meeting as the maximum number of securities giving access to capital is set at 450,000 shares.

(8) The per-share purchase price or subscription price will be set by the Board of Directors on the day that the option is granted within the limits provided by law and this resolution and cannot be less than the average listed share price over the twenty trading days immediately preceding the date of the Board's decision to grant the options, rounded to the next higher eurocent, not including purchase options, at the average purchase price for Company treasury shares, rounded to the next higher eurocent.

(9) The issue price of a BSA will be set by the Board of Directors on the issue date of said BSA based on the features of the latter and will be at least equal to 5% of the volume-weighted average price of the last five (5) days of trading on the regulated Euronext Paris market prior to the allocation date of said BSA by the Board of Directors,

(10) The maximum purchase price per share (excluding fees and commissions) is €15, with an overall cap of €10 million, it being understood that this purchase price will be adjusted as necessary to take into account capital transactions (particularly in the case of incorporation of reserves, free share awards, stock split or reverse stock split).

### 19.1.6. Disclosures regarding the capital of any Group company that is subject to an option or to a conditional or unconditional agreement providing an option on that capital

To the Company's knowledge, there is no option or any conditional or unconditional agreement providing for the introduction of such an option on the capital of the Company or Group companies.

### 19.1.7. Change in share capital

The Company was registered in the Trade and Companies Register on October 15, 2001, with initial share capital of €48,500.

The share capital was subsequently increased several times through the issue of a total of 62,279,951 new shares to arrive at €7,785,000.60 on February 28, 2017.

On March 29, 2019, the 1-for-10 reverse stock split, decided by the Company's Extraordinary General Shareholders' Meeting held on January 24, 2019, became effective. Since that date, the nominal value of the share has been one (1) euro.

The following table summarizes changes in equity capital since the Company's initial public offering.

| Date of transaction | Type of transaction | Number of shares issued or canceled | Nominal amount (€) | Issue premium or contribution premium (€) | Total par value of share capital (€) | Total number of shares outstanding | Par value (€) |
|---|---|---|---|---|---|---|---|
| 04/03/2014 | Capital increase through offer to the public | 4,367,088 | 436,708.80 | 34,063,286.40 | 1,510,830.30 | 15,108,303 | 0.10 |
| 05/02/2014 | Capital increase (exercise of overallotment option) | 21,604 | 2,160.40 | 168,511.20 | 1,512,990.70 | 15,129,907 | 0.10 |
| 06/02/2014 | Conversion of convertible bonds | 155,164 | 15,516.40 | 1,210,279.20 | 1,528,507.10 | 15,285,071 | 0.10 |
| 09/30/2014 | Conversion of convertible bonds | 155,164 | 15,516.40 | 1,210,279.20 | 1,544,023.50 | 15,440,235 | 0.10 |
| 2015 | Capital increase (ordinary shares) by exercise of BSPCEs | 100,851 | 10,085.10 | 308,007.00 | 1,554,108.60 | 15,541,086 | 0.10 |
| 2016 | Capital increase (ordinary shares) by exercise of BSPCEs | 28,969 | 2,896.90 | 87,399.10 | 1,557,005.50 | 15,570,055 | 0.10 |
| 02/28/2017 | Capital increase | 62,279,951 | 6,227,995.10 | 113,771,486.59 | 7,785,000.60 | 77,850,006 | 0.10 |
| August to December 2018 | Conversion of convertible bonds (2018 contract) | 1,497,615 | 149,761.50 | 1,565,238.50 | 7,934,762.10 | 79,347,621 | 0.10 |

| Date of transaction | Type of transaction | Number of shares issued or canceled | Nominal amount (€) | Issue premium or contribution premium (€) | Total par value of share capital (€) | Total number of shares outstanding | Par value (€) |
|---|---|---|---|---|---|---|---|
| 03/29/2019 | Reverse stock split (1-for-10) | 7,934,762 | - | 0.10 | 7,934,762 | 7,934,762 | 1.00 |
| 2019 | Conversion of convertible bonds (2018 contract) | 310,721 | 310,721 | | 8,245,483 | 8,245,483 | 1.00 |
| 2019-2020 | Conversion of convertible bonds (2019 contract) | 855,782 | 855,782 | | 9,101,265 | 9,101,265 | 1.00 |
| 2020 | Capital increase | 2,447,297 | 2,447,297 | 2,496,242.94 | 11,548,562 | 11,548,562 | 1.00 |

### 19.1.8. Share price trend

The Company's securities were admitted to trading on the regulated Euronext Paris and Euronext Brussels markets on April 9, 2014.

In financial year 2019, the stock market price reached its highest level on January 8, 2019, at €12.78, and its lowest level on October 21, 2019, at €1.91. As of December 31, 2019, the closing price was €2.18.

In the first months of financial year 2020, the share price went up from €2.19 on January 2, 2020 to €2.30 on April 29, 2020, thereby placing the Company's market capitalization at approximately €26.6 million.

## 19.2. ARTICLES OF INCORPORATION AND BYLAWS

### 19.2.1. Company Purposes (Article 3 of the bylaws)

The Company has the following purpose, in France and abroad:

- Research, study, development, production, manufacturing and distribution of medicines and drug and health products in the field of human and animal health using any means and in particular by setting up new French or foreign companies through acquisition, contribution, merger, alliance, demerger, loans, guarantees, endorsements, advances, commissions or otherwise. And in general, any operation, business or financial, commercial, industrial or real estate enterprise of any kind, in particular those directly or indirectly connected with the above-mentioned purpose or any other similar or related purpose that may facilitate, encourage or develop its industry, commerce and services.

### 19.2.2. Statutory or other provisions relating to the members of executive and management bodies

Membership

The Company is administered by a Board of Directors composed of natural persons or legal entities, whose number is set by the Ordinary General Shareholders' Meeting within legal limits.

A legal entity must, if appointed, designate a natural person as a permanent representative to the Board of Directors. The permanent representative's term of office is the same as that of the legal entity that he or she represents. Should a legal entity revoke its permanent representative's right to represent it, it must provide a replacement as promptly as possible. The same applies in the event of the death or resignation of a permanent representative.

The term of office for directors is three (3) years. A director's term of office ends after the Ordinary General Shareholders' Meeting called to approve the financial statements for the past financial year and held in the year during which that director's term of office expires.

Directors are always eligible for re-election; they may be removed at any time by action taken at a General Shareholders' Meeting.

If one or more seats on the Board are vacated by the death or resignation of a director, the Board can, between two General Shareholders' Meetings, make a provisional appointment.

The provisional appointments made by the Board of Directors must be submitted for ratification at the very next Ordinary General Shareholders' Meeting.

Should the appointment not be ratified, the previous deliberations and actions taken by the Board will continue with no less force or validity.

When the number of directors becomes less than the legal minimum, the remaining directors must immediately convene an Ordinary General Shareholders' Meeting with a view to increasing the Board membership.

An employee of the Company can be appointed to the Board as a director. His or her employment contract must, however, correspond to effective employment. In such a case, he or she does not lose the benefit of his or her employment contract.

The number of directors bound to the Company by an employment contract must not exceed one third of the directors in office.

The number of directors over 70 years of age must not exceed one third of the directors in office. If this limit is exceeded during a term of office, the oldest director is automatically deemed to have resigned at the close of the next General Shareholders' Meeting.

Chairmanship

The Board of Directors chooses a Chairman from among its own members, who must be a natural person. The Board sets his or her term of office, which cannot exceed his or her term as Director, and it can revoke his or her functions at any time. The Board sets his or her compensation.

The Chairman of the Board of Directors organizes and directs the work of the Board, and reports on this work to the General Shareholders' Meeting. The Chairman oversees the proper functioning of the Company's bodies and ensures, in particular, that directors are capable of fulfilling their duties.

The Chairman of the Board may not be more than 75 years old. If the Chairman reaches this age limit during his or her term as Chairman, he or she is deemed to have resigned from office. His or her term of office continues until the next Board of Directors meeting, in the course of which his or her successor will be appointed. Subject to this provision, the Chairman of the Board is always eligible for reappointment.

Board of Directors practices

The Board of Directors meets as often as required in the interests of the Company.

The directors are convened to Board meetings by the Chairman. They can be convened by any means, in writing or orally. The Chief Executive Officer may also ask the Chairman to convene a Board meeting to consider a specific agenda. Directors representing a third of the Board members can also validly convene a Board meeting. In such a case, they must set and provide the agenda.

For Board deliberations to be valid, at least half of the Board members must be present.

Board decisions are taken by majority vote; in the case of a tie, the Chairman does not cast the deciding vote.

The internal rules and procedures adopted by the Board of Directors provides that, for quorum and majority purposes, members may be deemed present at a meeting if they attend by videoconference or telephone conference in accordance with applicable regulations. This provision is not applicable for the adoption of decisions relating to Articles L. 232-1 and L. 233-16 of the French Commercial Code.

Powers of the Board of Directors

The Board of Directors determines the strategies for the Company's business and ensures their implementation. Subject to the powers expressly given to the Shareholders' Meetings and within the limits of the corporate purpose, it addresses all questions related to the Company's proper functioning and governs, by its decisions, the affairs that concern it.

In its relations with third parties, the Company is committed by the actions of the Board of Directors even if they are inconsistent with the corporate purpose, unless the Company can prove that the third party knew that the act was beyond the scope of said purpose or the third party could not be unaware of it given the circumstances, since simply publishing the bylaws does not constitute sufficient proof.

Observers

An Ordinary General Shareholders' Meeting may appoint observers. The Board of Directors may also appoint one observer directly, subject to ratification by the next General Shareholders' Meeting.

Observers are appointed for a term of three (3) years expiring at the end of the Ordinary General Shareholders' Meeting called to approve the financial statements for the past financial year.

The college of observers studies the questions that the Board of Directors or its Chairman submit to it for review and opinion. Observers attend Board meetings and take part in the deliberations with a consultative voice only, and their absence does not affect the validity of deliberations.

They are convened to Board of Directors meetings on the same terms as the Board members.

The Board of Directors may remunerate observers by allocating them a portion of the compensation for activity assigned by the General Shareholders' Meeting to members of the Board of Directors.

Executive management

The Company's general management function is the responsibility of either the Chairman of the Board of Directors or another natural person appointed by the Board of Directors and holding the title of Chief Executive Officer (CEO).

The Chief Executive Officer is vested with the most extensive powers to act on behalf of the Company in any circumstance. He or she exercises these powers within the limit of the corporate purpose and subject to the powers that the law expressly grants to the General Shareholders' Meeting and to the Board of Directors.

He or she represents the Company in its relations with third parties. The Company is even bound by acts of the Chief Executive Officer that are not within the scope of the corporate purpose, unless the Company can prove that the third party knew that the act was beyond the scope of said purpose or the third party could not be unaware of it given the circumstances, since simply publishing the bylaws does not constitute sufficient proof.

The Chief Executive Officer may not be more than 65 years old.

If the Chief Executive Officer is a director, his or her term of office as CEO must not exceed that of his or her directorship.

The Board of Directors can revoke his or her appointment as CEO at any time. If the revocation is decided for no fair reason, it may give rise to a claim for damages, unless the Chief Executive Officer takes on the role of Chairman of the Board of Directors.

At the proposal of the Chief Executive Officer, the Board of Directors may appoint one or more natural persons as Deputy Chief Executive Officer, with the responsibility of assisting the Chief Executive Officer.

With the consent of the Chief Executive Officer, the Board of Directors determines the scope and extent of the powers granted to Deputy Chief Executive Officers. The Board sets their compensation. If a Deputy Chief Executive Officer is a director, his or her term of office in that function must not exceed that of his or her directorship.

With respect to third parties, Deputy Chief Executive Officers have the same powers as the Chief Executive Officer; in particular, they have the authority to participate in legal proceedings.

There can be no more than five Deputy Chief Executive Officers.

The position of Deputy Chief Executive Officer can be revoked at any time by the Board of Directors on the recommendation of the CEO. If the revocation is decided for no fair reason, it may give rise to a claim for damages.

A Deputy Chief Executive Officer may not be more than 65 years old. When a Deputy CEO reaches this age limit, he or she is deemed to have resigned his or her office. His or her term of office continues until the next Board of Directors meeting, during which his or her successor may be appointed.

### 19.2.3. Rights, privileges and restrictions attached to shares in the Company

Form of securities

Shares may be registered or bearer shares, at the choice of the shareholder. They cannot be in the form of bearer shares until they are fully paid up.

The shares and all other securities issued by the Company are registered in an individual account, subject to the terms and conditions provided for by the applicable legal and regulatory provisions.

Voting right

The voting right attached to shares is proportional to the share of capital that they represent, and each share gives the right to at least one vote, subject to applicable legal and regulatory provisions.

The bylaws expressly prohibit any mechanism that grants full double voting rights to shares held in registered form for at least two years in the name of the same shareholder (General Shareholders' Meeting of June 11, 2015).

Right to dividends and profits

Each share confers a right to the Company's profits and assets and to the surplus from liquidation in proportion to the fraction of the number and par value of existing shares that it represents.

Pre-emptive right

Company shares benefit from a pre-emptive right to capital increase under the terms and conditions specified in the French Commercial Code.

Limitation on voting rights

No provision of the bylaws restricts the right to vote attached to shares.

Identifiable bearer securities

The Company may also, under the statutory and regulatory conditions in force, demand at any time, on a paid basis, from any authorized body, the name, or if a legal entity, the corporate name, nationality and address of holders of securities conferring immediate or future voting rights at its own shareholders' meeting, as well as the number of securities held by each of them and any restrictions that may apply to those securities.

### 19.2.4. Procedure for modifying shareholders' rights

Shareholders' rights as explained in the Company's bylaws can be modified only by an Extraordinary General Shareholders' Meeting.

### 19.2.5. General Shareholders' Meetings

Due to the COVID-19 pandemic, the Board of Directors decided to hold the June 10, 2020 General Meeting in camera, without the physical presence of shareholders, and under the conditions described in the “General Shareholders' Meeting” section of the Company's website.

The notice of meeting including the draft agenda and draft resolutions, as well as the methods for participating in the General Shareholders' Meeting, will be published in the Mandatory Legal Notice Bulletin (*Bulletin des annonces légales obligatoire*s—BALO) within the prescribed period and will be available on the Company's website.

However, given the current uncertainty and acceleration of the COVID-19 pandemic worldwide, the date and procedures for holding the General Shareholders' Meeting of June 10, 2020 could change depending on health and/or legal requirements. Shareholders are therefore invited to consult regularly the section dedicated to the General Shareholders' Meeting on the Company's website.

General Shareholders' Meetings are convened and deliberate under the conditions laid down in applicable laws and regulations. When the Company wishes to call a meeting by electronic means rather than by post, it must first obtain the consent of the shareholders involved and their email addresses.

The meetings are held at the registered office or at any other place specified in the notice of meeting.

The right to participate in General Shareholders' Meetings is governed by applicable laws and regulations and is, in particular, conditional on the registration of shares in the name of the shareholder or of the authorized intermediary registered on the shareholder's behalf, by 12:00 a.m. (midnight) Paris time of the second business day before the meeting, either in the registered share accounts kept by the Company or in the bearer share accounts kept by the authorized intermediary.

Shareholders, if not personally attending the meeting, can choose any of the following three methods to participate:

- Assign a proxy in accordance with applicable laws and regulations,
- Vote by correspondence, or
- Send a form of proxy to the Company without indicating a delegate,

in accordance with applicable laws and regulations.

The Board of Directors may organize, in accordance with applicable laws and regulations, the participation and voting of shareholders at meetings via videoconferencing or other telecommunications methods that allow shareholders to be identified. If the Board of Directors decides to exercise this option for a particular meeting, it must state this decision in the notice of meeting. Shareholders participating in meetings by videoconference or by any other telecommunication method indicated above that the Board of Directors may choose are deemed to be present for the purposes of calculating quorum and majority.

General Shareholders' Meetings are chaired by the Chairman of the Board of Directors, failing which, the meeting itself can elect a chairman for its meeting.

The roles of scrutineers are performed by the two willing shareholders present at the start of the meeting who represent the greatest number of votes. The meeting officers appoint a secretary, who may be chosen from outside the shareholders.

An attendance sheet is maintained under the conditions provided by law.

An Ordinary General Shareholders' Meeting on first convocation may validly deliberate only if the shareholders present or represented possess at least one fifth of the shares with voting rights. An Ordinary General

Shareholders' Meeting on second convocation may validly deliberate regardless of the number of shareholders present or represented.

Resolutions of Ordinary General Shareholders' Meetings are passed by a majority of the shareholders present or represented.

An Extraordinary General Shareholders' Meeting on first convocation may only validly deliberate if the shareholders present or represented possess at least one quarter of the shares with voting rights. An Extraordinary General Shareholders' Meeting on second convocation may validly deliberate only if the shareholders present or represented possess at least one fifth of the shares with voting rights.

Resolutions of Extraordinary General Shareholders' Meetings are passed by a two-thirds majority of the shareholders present or represented.

Copies or excerpts of the minutes of the meeting are validly certified by the Chairman of the Board of Directors, by a director performing the functions of a Chief Executive Officer, or by the Secretary of the Meeting.

Ordinary and Extraordinary General Shareholders' Meetings exercise their respective powers under the conditions provided by law.

#### 19.2.6. Provisions to delay, defer or prevent a change of control

The bylaws do not contain any provisions to delay, defer or prevent a change of control of the Company.

#### 19.2.7. Breach of statutory thresholds

None.

#### 19.2.8. Special stipulations governing changes to capital

There are no special stipulations in the Company's bylaws governing changes to its capital that would be more stringent than provided by law.

# SECTION 20. MATERIAL AGREEMENTS

The main terms of material agreements are summarized below:

## 20.1. LICENSE AGREEMENT CONCLUDED ON FEBRUARY 2, 2015 WITH THE PHARMACEUTICAL COMPANY SERUM OF INDIA LTD. (SIIL)

On February 2, 2015, the Company signed a license agreement with the pharmaceutical company Serum Institute of India Ltd. (SIIL) for its Vaxiclase technology as part of the development by SIIL of acellular and multivalent vaccines containing antigens for whooping cough.

The license granted by the Company to SIIL permits the introduction of the Vaxiclase technology platform in certain multivalent vaccines that protect against (among others) the bacterium Bordetella pertussis, the agent responsible for whooping cough. The license covers all countries of the world, with the exception of major pharmaceutical markets, including the United States, Canada, New Zealand, Australia, Japan, Israel, Turkey and the enlarged Europe.

In return for access to and use of the Vaxiclase platform in the authorized indication, the Company could receive up to €150 million in initial payments and development and sales milestone payments based on criteria defined in the terms and conditions of the agreement, as well as royalties as a percentage of net sales.

In addition, additional options allow the extension of the partnership to markets not yet included in the agreement.

The agreement was signed for a period expiring on the date on which SIIL no longer owes royalties to the Company under the agreement or, if later, on the date on which all the obligations of all parties specified in the agreement have been met or expired.

The parties may, however, terminate the license agreement early in the following cases:

- At the request of either party, in the event the other party has materially breached or defaulted in the performance of any of its material obligations, not remedied within 90 days.
- By SIIL, at any time from February 2, 2016 and without reason, subject to 90 days written notice.
- At the request of either party, if the other party is the subject of collective insolvency proceedings or finds itself insolvent.

## 20.2. SERVICE AGREEMENTS WITH SYNGENE

On May 2, 2017, Genkyotex signed a framework service agreement with Syngene International Limited, a CRO (contract research organization, specialized in the manufacture and characterization of pharmaceutical substances and medical drugs), to provide the necessary products for the preclinical studies and Phase 1 clinical trials with GKT771 in patients. This agreement was signed for an initial term of three years, automatically renewable for an additional year.

## 20.3. SERVICE AGREEMENT WITH CMED

On January 12, 2017, Genkyotex Group signed a framework service agreement with Cmed, a CRO (contract research organization, specialized in clinical trial services), to conduct the Phase 2 clinical trial in PBC. This agreement was signed for an initial term of five years, automatically renewable for an additional year. The study will be conducted in more than 60 centers.

## 20.4. RESEARCH CONTRACT WITH THE BAKER HEART AND DIABETES INSTITUTE

On June 28, 2017, the Company announced that the world-class diabetes experts, Professor Mark Cooper, Head of the Department of Diabetes at Monash University, and Professor Jonathan Shaw, Deputy Director of Clinical and Population Health at the Baker Heart and Diabetes Institute in Melbourne, Australia, will direct a Phase 2 clinical trial to assess the efficacy and safety of the Company's flagship product candidate, GKT831, in patients with type 1 diabetes and kidney disease (diabetic nephropathy).

This investigator-initiated study will be conducted at the Baker Institute and in several clinical centers across Australia. It will be funded by the Juvenile Diabetes Research Foundation of Australia (JDRF Australia), a beneficiary of the Australian Research Council fund dedicated to the Special Research Initiative for Type 1 Juvenile Diabetes, with financial support from the Baker Institute. As part of this study, Genkyotex will provide the GKT831 compound compliant with good manufacturing practices (GMP).

With the exception of the contracts described below, the Genkyotex Group has only entered into contracts relating to the normal course of business.

## SECTION 21. DOCUMENTS AVAILABLE

During the period of validity of this Universal Registration Document, the following documents can be found on the Company's website (www.genkyotex.com):

- The 2017 Registration Document (https://www.genkyotex.com/en/investors/regulated-information/financial-information/2018),
- The 2018 Registration Document (https://www.genkyotex.com/en/investors/regulated-information/financial-information/2019), and
- Where necessary, all reports, letters and other documents, assessments and statements prepared by an expert at the request of the Company, part of which is included in this Universal Registration Document.

This Universal Registration Document can also be found on the AMF website (www.amf-france.org).

The bylaws, minutes of General Shareholders' Meetings and other Company documents, as well as historical information and all assessments and reports issued by an expert at the Company's request, which are required to be available to the shareholders in accordance with applicable laws, can be consulted free of charge at the Company's registered office.

# GLOSSARY

| Abbreviation / Term | Definition |
|---|---|
| **MA** | Marketing Authorization |
| **CHMP** | Committee for Medicinal Products for Human Use, which is a committee of the European Medicines Agency (EMA) |
| **CRO** | Contract research organization, a company specializing in the organization and conduct of clinical trials |
| **DKD** | Diabetic kidney disease |
| **HPV** | Human papillomavirus |
| **IPF** | Idiopathic pulmonary fibrosis |
| **KOL** | Key opinion leaders |
| **NASH** | Nonalcoholic steatohepatitis |
| **NOX** | NADPH oxidase enzymes |
| **PBC** | Primary biliary cholangitis |
| **PSC** | Primary sclerosing cholangitis |
| **Clinical Phases** | Phase I: Study of the behavior of a molecule tested in an organism, on the basis of time (the pharmacokinetics of absorption and elimination) and analysis of safety and tolerance in humans. This phase is conducted on a small number of healthy volunteers.<br><br>Phase II: Assessment of the safety and efficacy of the molecule and determination of the therapeutic dose of the molecule<br><br>Phase III: Comparison of the efficacy of a new drug to the benchmark treatment. This phase involves a large number of patients. Patients are selected in accordance with precise criteria designed to determine the |

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| | efficacy and benefits of the drug being tested as a new standard treatment for the disease concerned. |
| **Preclinical phases** ..... | Laboratory tests to evaluate the principal effects of a molecule and its toxicity |
| **SIIPL** ..... | Serum Institute of India Private Ltd. |

## APPENDIX: TABLE OF CONCORDANCE

The table of concordance below shows the headings in the Company's 2018 Registration Document (in accordance with the headings in Annexes 1 and 2 to Delegated Regulation (EU) No. 2019/980 of March 14, 2019) that have been updated in this Universal Registration Document.

| Annex 1 to Delegated Regulation (EU) No. 2019/980 | | 2018 Registration Document | Universal Registration Document |
|---|---|---|---|
| 1. | Persons responsible, third party information, experts' reports and competent authority approval | 1. | Section 1 |
| 1.1 | Name and function of person responsible | 1.1 | 1.1 |
| 1.2 | Declaration by those responsible for the document | 1.2. | 1.2. |
| 1.3 | Statements by experts and declarations of any interest | 23. | - |
| 1.4 | Third party information | 23. | - |
| 1.5 | Declaration by the competent authority relating to the approval of this document | - | AMF insert Flyleaf |
| 2. | Statutory auditors | 2. | Section 2 |
| 2.1 | Principal statutory auditors | 2.1 | Section 2.1 |
| 2.2 | Alternate statutory auditors | 2.2 | Section 2.2 |
| 3. | Risk factors | Replaced by Section 3 of the URD | Section 3 |
| 4. | Information about the issuer | 5. | Section 4 |
| 4.1 | Legal and commercial name of the company | 5.1.1 | Section 4 |
| 4.2 | Place of registration, registration number and LEI of the company | 5.1.2 | 4.2 |
| 4.3 | Date of incorporation and length of life of the issuer | 5.1.3 | 4.3 |
| 4.4 | Registered office, legal form, governing law and website | 5.1.4 | 4.4 |

| Annex 1 to Delegated Regulation (EU) No. 2019/980 | | 2018 Registration Document | Universal Registration Document |
|---|---|---|---|
| 5. | BUSINESS OVERVIEW | 6. | Section 5 |
| 5.1 | Principal activities | 6. | Section 5 |
| 5.2 | Principal markets | 6. | Section 5 |
| 5.3 | Important events | 6. | Section 5 |
| 5.4 | Strategy and objectives | 6.1.2 | 5.1.2 |
| 5.5 | The issuer's dependence on patents, licenses, contracts and manufacturing processes | 11. | 3.4 |
| 5.6 | The issuer's competitive position | 6. | Section 5 |
| 5.7 | Investments | 5.2 | Section 5 |
| 5.7.1 | Material investments | 5.2.1 | Section 5 |
| 5.7.2 | Material investments for which firm commitments have been made | 5.2.3 | - |
| 5.7.3 | Investments in undertakings in which the issuer holds an interest | N/A | N/A |
| 5.7.4 | Environmental issues that may affect the issuer's utilization of its tangible fixed assets | - | - |
| 6. | Organizational structure | 7. | Section 6 |
| 6.1 | Brief description of the group | 7.2 | Section 6 |
| 6.2 | List of significant subsidiaries | 7. | Section 6 |
| 7. | OPERATING AND FINANCIAL REVIEW | 9. | Section 7 |
| 7.1 | Financial condition | 9.1. | Section 7 |
| 7.1.1 | Development of the issuer's results | 9.1. | Section 7 |
| 7.1.2 | The issuer's likely future development and its activities in the field of R&D | 6. | Section 7 |
| 7.2 | Operating results | 9.2.1 | Section 7 |

| Annex 1 to Delegated Regulation (EU) No. 2019/980 | | 2018 Registration Document | Universal Registration Document |
|---|---|---|---|
| 8. | Capital resources | 10. | Section 8.1 |
| 8.1 | Information about the issuer's capital resources | 10.1. | Section 8.1.1 |
| 8.2 | The issuer's cash flows | 10.2 | Section 8.2 |
| 8.3 | Borrowing requirements and funding structure of the issuer | 10.3 | Section 8.1.2 to 8.1.4 |
| 8.4 | Restrictions on the use of the issuer's capital resources | 10.4 | Section 8.4 |
| 8.5 | Sources of funds for anticipated cash flows | 10.5 | Section 8.5 |
| 9. | Regulatory environment | - | Section 9 |
| 10. | Trend information | 12. | Section 10 |
| 11. | Profit forecasts or estimates | - | Section 11 |
| 12. | Administrative, management and supervisory bodies and senior management | 14 | Section 12 |
| 12.1 | Composition of the administrative, management and supervisory bodies and senior management | 14.1.1 | Section 12 |
| 12.2 | Conflicts of interest in the company's administrative, management and supervisory bodies and senior management | 14.2 | Section 12 |
| 13. | COMPENSATION AND BENEFITS | 15. | Section 13 |
| 13.1 | Compensation, benefits in kind, options and free shares granted to corporate officers | 15.1.1 | Section 13 |
| 13.2 | Total amounts set aside to provide pension, retirement or similar benefits | 15.2 | Section 13 |
| 14. | Board practices | 16. | Section 14 |
| 14.1 | Date of expiration of terms of office | 16.1.1 | Section 14 |

| Annex 1 to Delegated Regulation (EU) No. 2019/980 | | 2018 Registration Document | Universal Registration Document |
|---|---|---|---|
| 14.2 | Service contract between the company's administrative, management or supervisory bodies | 16.2 | Section 14 |
| 14.3 | Committees, Scientific Advisory Board and observers | 16.3 | Section 14 |
| 14.4 | Statement regarding corporate governance | 16.4 | Section 14 |
| 14.5 | Impact of future changes in board composition | - | N/A |
| 15. | Employees | 17. | Section 15 |
| 15.1 | Number of employees | 17.1 | Section 15 |
| 15.2 | Shareholdings and stock options | 17.2 | Sections 15, 19.1.4.1 and 19.1.4.2 |
| 15.3 | Arrangements for employee shareholding in the capital | 17.3 | Section 15 |
| 16. | Major shareholders | - | Section 16 |
| 16.1 | Shareholders with an interest exceeding 5% in the share capital or voting rights | - | Section 16.1.1 |
| 16.2 | Existence of different voting rights | - | Section 16.1.1 |
| 16.3 | Control of the company by major shareholders | 18.4 | - |
| 16.4 | Agreements that may trigger a change of control | 18.5 | - |
| 17. | Related-party transactions | 19. | Section 17 |
| 18. | Financial information concerning the company's assets and liabilities, financial position and profits and losses | 20. | Section 18 |
| 18.1 | Historical financial information | 20.1 | Section 18 |
| 18.1.1 | Consolidated financial statements as of December 31, 2018 and Statutory Auditors' Report | 20.1 | Section 18 |

| Annex 1 to Delegated Regulation (EU) No. 2019/980 | | 2018 Registration Document | Universal Registration Document |
|---|---|---|---|
| 18.1.2 | Change of accounting reference date | N/A | N/A |
| 18.1.3 | Accounting standards | 20.1 | Section 18 |
| 18.1.4 | Change of accounting framework | - | Section 18 |
| 18.1.6 | Consolidated financial statements | 20.1 | Section 18 |
| 18.1.7 | Date of the latest financial information | 20.5 | Section 18 |
| 18.2 | Interim and other financial information | 20.6 | Section 18 |
| 18.3 | Auditing of historical annual financial information | 20.4 | Section 18 |
| 18.4 | Pro forma financial information | 20.2 | Section 18 |
| 18.5 | Dividend policy | 20.7 | - |
| 18.6 | Legal and arbitration proceedings | 20.8 | Section 18 |
| 18.7 | Significant change in the issuer's financial position | 20.9 | Section 18 |
| 19. | Additional information | 21. | Section 19 |
| 19.1 | General information concerning share capital | 21.1 | Section 19 |
| 19.2 | Articles of Incorporation and bylaws | 21.2 | Section 19 |
| 20. | Material agreements | 22. | Section 20 |
| 21. | Documents available | 24. | Section 21 |

| | Annex 2 to Delegated Regulation (EU) No. 2019/980 | 2018 Registration Document | Universal Registration Document | |
|---|---|---|---|---|
| 1.2 | Declaration by the competent authority | | Cover page | AMF insert |

The table of concordance below may be used to identify the following items in this Universal Registration Document:

- The information contained in the annual financial report (Article L. 451-1-2 of the French Monetary and Financial Code and Article 222-3 of the AMF General Regulations);

- The information contained in the annual management report of the Company and the Group, together with the Corporate Governance report (Article L. 225-100-1 of the French Commercial Code).

| **Annual Financial Report** | | **Universal Registration Document** |
|---|---|---|
| 1 | Declaration of the person responsible for the annual financial report | § 1.2 |
| 2 | Management Report | See index below |
| 3 | Statement relating to statutory auditors' fees | § 2.3 |
| 4 | Consolidated Financial Statements prepared in accordance with IFRS | § 18.1.1.1. |
| 5 | French GAAP Parent Company Financial Statements | §18.1.8 |
| 6 | Report of the Statutory Auditors on the IFRS Consolidated Financial Statements | §18.1.1.2. |
| 7 | Report of the Statutory Auditors on the French GAAP Parent Company Financial Statements | § 18.1.9 |

| **Annual Management Report** | | **Universal Registration Document** |
|---|---|---|
| 1 | Situation and activity of the Group during the past financial year | § 5, § 7 and § 18 |
| 2 | Review of the financial statements and results | § 7 and § 18 |
| 3 | Progress made and difficulties encountered | § 5, 7 and 8 |
| 4 | Main risks and uncertainties<br>Use of financial instruments by the Company | § 3 |
| 5 | Group research and development activities | § 5.1 |
| 6 | Activities of subsidiaries and controlled companies | § 5 and 7.2.2 |
| 7 | Foreseeable developments in the Group's situation and future outlook | § 10 |
| 8 | Significant events since the financial year end | § 18.1 and § 18.8 |
| 9 | Main characteristics of internal control and risk management procedures relating to the preparation and processing of accounting and financial information (Article L. 225-100-1 5°) | § 14.5 |
| 10 | Proposed appropriation of profit or loss | § 18.8.2 |

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| 11 | Non-tax-deductible expenses | § 18.8.3 |
| 12 | Dividends distributed over the last three financial years | § 18.5.1 |
| 13 | Information on payment terms for suppliers and customers | § 18.9.4 |
| 14 | Employee share ownership at year end | § 15.3 |
| 15 | Summary of transactions by executives and the persons mentioned in Article L. 621-18-2 of the French Monetary and Financial Code involving Company securities in the financial year ended | § 13.4 |
| 16 | Acquisition of significant shareholdings in companies domiciled in France, or acquisition of control of such companies; disposal of such shareholdings | § 6.2 |
| 17 | Information relating to the distribution of share capital and treasury shares – Share repurchase plan | § 16.1, 16.2 and 19.1.3 |
| 18 | Changes in the composition of share capital during the financial year | § 19.1.7 |
| 19 | Share trend | § 19.1.8 |
| 20 | Information relating to the allocation of options for the subscription or purchase of shares and bonus shares | § 19 |
| 21 | Table of results for the last five financial years | § 18.8.1 |
| 22 | Corporate Governance Report | See table below |
| 24 | Corporate Social Responsibility Report | N/A |
| 25 | Independent third party body report on CSR reporting | N/A |

| **Corporate Governance Report** | | **Universal Registration Document** |
|---|---|---|
| 1 | List of all directorships and positions held in any company by each corporate officer during the financial year | § 12.1.2 |
| 2 | Agreements between a corporate officer or shareholder controlling at least 10% of the voting rights of a company, and another company controlled by the first company as defined under Article L. 233-3 of the French Commercial Code. | N/A |
| 3 | Summary table of financial delegations in force and their use during the financial year | § 19.1.5 |
| 4 | Choice of one of the two methods of exercising general management in accordance with Article L. 225-51-1 of the French Commercial Code | § 14.1 |
| 5 | Composition of the Board of Directors and conditions for preparing and organizing its work | § 12.1.1, 14.3 and 19.2.2 |

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| 6 | Description of the diversity policy applied to members of the Board of Directors | § 14.3 |
| 7 | Any limitations placed on the powers of the Chief Executive Officer by the Board of Directors | § 14.1 |
| 8 | Reference to a corporate governance code | § 14.4 |
| 9 | Specific instructions for the participation of shareholders in the General Shareholders' Meeting or the provisions of the bylaws which provide for such arrangements | § 19.2.5 |
| 10 | Procedure established by the Board of Directors to assess regularly whether agreements relating to current operations and concluded under normal conditions fulfill these conditions | § 17.4 |
| 11 | Ownership structure of the company | § 16.1 |
| 12 | Restrictions in bylaws on the exercise of voting rights and transfer of shares, or clauses of agreements brought to the Company's attention pursuant to Article L. 233-11 of the French Commercial Code | N/A |
| 13 | Direct or indirect holdings in the Company's share capital of which it is aware pursuant to Articles L. 233-7 and L. 233-12 of the French Commercial Code | § 16.1 |
| 14 | List and description of holders of any securities with special control rights | N/A |
| 15 | Control mechanisms stipulated in a possible employee shareholding system, when control rights are not exercised by the shareholders | N/A |
| 16 | Agreements between shareholders of which the Company is aware and which may result in restrictions on the transfer of shares and the exercise of voting rights | N/A |
| 17 | Rules applicable to the appointment and replacement of members of the Board of Directors and to amendments to the bylaws | § 19.2.2 and § 19.2.4 |
| 18 | Powers of the Board of Directors, in particular with regard to the issue or redemption of shares | § 19.1.5 |
| 19 | Agreements entered into by the Company amended or terminated in the event of a change of control of the Company, unless such disclosure would seriously harm its interests | N/A |
| 20 | Agreements providing for severance payments for directors or employees in the event of resignation or dismissal without just cause or termination of employment resulting from a takeover bid or exchange offer | N/A |
| 21 | Restrictions imposed by the Board of Directors with respect to share subscription or purchase options awarded to corporate officers | § 14.4 |

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| **Compensation Policy** | | |
| For all corporate officers: | | |
| 22 | How the Company's compensation policy is in line with corporate interest and contributes to the Company's business strategy and sustainability | § 13.1.2.1 |
| 23 | Decision-making process followed to determine the Company's compensation policy, its implementation and revision, and how the terms and conditions of compensation and employment of the Company's employees are taken into account | § 13.1.2 and § 13.1.2.1 |
| 24 | Assessment methods to be applied to corporate officers to determine to what extent the performance criteria for variable and share-based compensation have been met | |
| 25 | Description and explanation of any substantial changes if the compensation policy is amended, and how the most recent votes of shareholders on this policy are taken into account and any opinions expressed at the last Shareholders' Meeting | N/A |
| 26 | Criteria for the distribution of the annual fixed amount allocated by the Shareholders' Meeting to directors | § 13.1.1 – Table 3 and § 13.1.2.1 |
| 27 | Terms of application of the provisions of the compensation policy to newly appointed corporate officers and to those whose term of office has been renewed | § 13.1.2.1 |
| 28 | Where the Board of Directors provides for waivers from the application of the compensation policy, procedural conditions under which such waivers may be applied | N/A |
| For each corporate officer: | | |
| Ex ante | | |
| 29 | Fixed, variable and exceptional components that comprise total compensation and benefits of any kind that may be granted to a corporate officer due to the office held, as well as their respective size | § 13.1.1 and § 13.1.2.1 |
| 30 | Where the Company awards share-based compensation, vesting periods, share lockup periods applicable after vesting and how share-based compensation contributes to the objectives of the compensation policy | § 19.1.4 |
| 31 | Possible deferral periods and, where appropriate, the company may request the return of variable compensation | N/A |
| 32 | Where the Company assigns variable compensation components, criteria used for their award, and an indication of how these criteria contribute to the objectives of the compensation policy | N/A |
| 33 | Term(s) and, if applicable, any employment or service agreements with the Company, notice periods and conditions for revocation or termination of the terms and conditions applicable to them | § 12.1, 1 and 14.2 |

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| 34 | A description of the commitments made by the company or any controlled company or which controls it corresponding to components of compensation, allowances or benefits due to or after the termination or change of duties, or conditional rights granted under defined benefit pension obligations | N/A |
| 35 | When the company assigns conditional obligations and rights, conditional criteria for their allocation and how these criteria contribute to the objectives of the compensation policy. | N/A |
| Ex post | | |
| 36 | Total compensation and benefits of any kind | § 13.1.2.2 |
| 37 | Relative proportion of fixed and variable compensation | N/A |
| 38 | Use of the option to request the return of variable compensation | N/A |
| 39 | Commitments entered into by the Company corresponding to elements of compensation, allowances or benefits due or likely to be due as a result of the assumption, termination or change in their duties or subsequent to the exercise thereof (including retirement obligations and other annuity benefits) | N/A |
| 40 | Compensation paid or awarded by a company included in the consolidation scope within the meaning of Article L. 233-16 | § 13.1.2.2; § 13.1.1 – Table 11 |
| 41 | Equity ratios referred to in Article L 225-37-3 of the French Commercial Code | § 13.1.2.3 |
| 42 | Annual changes in the Company's compensation, performance, average compensation for non-executive employees, and equity ratios over the last five years | § 13.1.2.3 |
| 43 | Explanation of how total compensation meets the compensation policy adopted (including contribution to long-term performance and how performance criteria are applied) | § 13.1.2.2 |
| 44 | How the vote of the last Ordinary Shareholders' Meeting provided for in Article L. 225-100 was taken into account | N/A |
| 45 | Any deviations from the procedure for implementing the compensation policy and any possible waiver applied | N/A |
| 46 | Suspension of the compensation of directors in respect of their activity in the event of non-compliance with the diversity rules among directors | N/A |