



A Swiss joint stock company (*société anonyme*) with share capital of 1,488,046.65 Swiss francs  
Registered and principal office: 3 chemin du Pré-Fleuri – 1228 Plan-les-Ouates – Geneva – Switzerland  
CHE-112.754.833 *Registre du commerce* (commercial register) of Geneva

## 2023

# UNIVERSAL REGISTRATION DOCUMENT

## including the Annual Financial Report



This Universal Registration Document was filed on April 30, 2024 with the Autorité des marchés financiers (“AMF”) as competent authority under Regulation (EU) 2017/1129, without prior approval in accordance with Article 9 of the said Regulation.

This Universal Registration Document may be used for the purpose of an offer to the public of securities or the admission of securities to trading on a regulated market if it is supplemented by a securities note and, if applicable, by a summary and any amendments made to the Universal Registration Document. These documents are being together approved by the AMF in accordance with Regulation (EU) 2017/1129.

Copies of this Universal Registration Document are available at no cost at the headquarters of GeNeuro SA (3 chemin du Pré-Fleuri - 1228 Plan-les-Ouates / Geneva – Switzerland), as well as electronically on the GeNeuro website ([www.geneuro.com](http://www.geneuro.com)) or on the AMF website ([www.amf-france.org](http://www.amf-france.org)).

## **GENERAL OBSERVATIONS**

Unless otherwise indicated, in this universal registration document (the “**Universal Registration Document**”) the terms “**Company**” or “**GeNeuro**” mean GeNeuro SA and the term “**Group**” means the Company and its subsidiaries GeNeuro Innovation SAS (“**GeNeuro Innovation**”), in France.

This Universal Registration Document was prepared pursuant to Annex 1 and Annex 2 of the delegated regulation (EU) 2019/980 of the Commission of 14 March 2019 which complements Regulation (EU) 2017/2019 of the European Parliament and Council and, pursuant to article 19 of the Regulation (EU) 2017/1129, incorporates by reference (i) the Company’s consolidated financial statements for the year ended December 31, 2022, prepared in accordance with IFRS, and the auditors’ report related thereto presented in section 18.3 of the Universal Registration Document filed with the AMF on 28 April 2023 and (ii) the Company’s consolidated financial statements for the year ended December 31, 2021, prepared in accordance with IFRS, and the auditors’ report related thereto presented in section 18.3 of the Universal Registration Document filed with the AMF on 27 April 2022.

This Universal Registration Document contains statements about the Group’s objectives. These statements are sometimes identified by the use of the future tense, the conditional tense, and expressions with forward-looking character, such as “think,” “has as an objective,” “expects,” “intends,” “should,” “with the ambition of,” “consider,” “believe,” “wish,” “could,” etc. This information is based on data, assumptions, and estimates considered reasonable by the Company. They may change or be changed because of uncertainties related to any business as well as to the economic, financial, competitive and regulatory environment.

Furthermore, the achievement of the Group’s objectives assumes the success of its strategy, which is set forth in Section 5.1.2 of the Universal Registration Document. The Company can make no commitment or give any assurance that the objectives set forth in this Universal Registration Document will be achieved.

Investors are urged to give consideration to the risk factors set forth in Chapter 3 “Risk Factors” of this Universal Registration Document before making their investment decision. The occurrence of such risks could have a negative effect on the Group’s business, financial condition, results of operations, or prospects. Furthermore, other risks, not presently identified or not considered material by the Company, could have the same negative effect, and investors could lose all or part of their investment.

This Universal Registration Document also contains information about the markets in which the Group competes, some of which information was obtained from sources external to the Company. Unless otherwise indicated, the information relating to the markets in which the Group competes or its competitive position contained in this Universal Registration Document comes from the Company’s internal estimates. These internal estimates are based on reports of analysts, specialized studies, industry publications, any and all information published by market survey companies, and public and governmental sources, as well as internal knowledge of the market by the Company. Even though such information is considered reliable, it has not been independently verified by the Company. Furthermore, in light of the very rapid changes occurring in France, in the world, and in the industry in which the Group competes, it is possible that such information may prove erroneous or not be up to date. The Group’s business, accordingly, could evolve in a different way from the one described in this Universal Registration Document. The Company has not committed or agreed to publish any update of the information contained herein, except in connection with any legal or regulatory obligation that may apply to it.

A glossary that contains definitions of certain technical terms used in this Universal Registration Document, as well as an index of abbreviations used, are set forth in Appendix of this Universal Registration Document.

A reconciliation table with the Annual Financial Report is located at the end of this Universal Registration Document.

This Universal Registration Document has been prepared on the basis of the Company’s annual consolidated financial statements for the financial years ending December 31, 2022 and 2023.

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## **CHAPTER 1.** **PERSONS RESPONSIBLE FOR THIS UNIVERSAL REGISTRATION DOCUMENT**

### **1.1 Person Responsible For The Universal Registration Document**

Mr. Jesús Martin-Garcia, Chairman of the Board of Directors and Chief Executive Officer of GeNeuro.

### **1.2 Certificate Of The Person Responsible For The Universal Registration Document**

I certify that, to my knowledge, the information contained in this Universal Registration Document is in accordance with the facts and contains no omission likely to affect its import.

I certify that, to my knowledge, the financial statements of GeNeuro have been prepared in accordance with applicable accounting standards and give a fair view of the assets, liabilities, financial position and results of the Company and all the subsidiaries included in the scope of consolidation, and that the management report of the board of directors, as referenced in the cross reference list included on page 241 gives a true and fair view of the business trends, results and financial position of the Company and its subsidiaries included in the scope of consolidation and describes the main risks and uncertainties with which they have to contend.

Mr. Jesús Martin-Garcia, Chairman of the Board of Directors and Chief Executive Officer of GeNeuro.

### **1.3 Information From Third Parties, Experts' Statements or Reports**

Certain market information set forth in CHAPTER 5, "Description of the Group's Business" of this Universal Registration Document, come from third-party sources. The Company certifies that such information has been faithfully reproduced and that, to the Company's knowledge, on the basis of data published or provided by such sources, no fact has been omitted that would make the information reproduced inaccurate or misleading.

### **1.4 Declaration relating to the registration document**

Not applicable.

### **1.5 Person Responsible For The Financial Information**

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Group Chief Financial Officer  
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### **1.6 Indicative Timetable for Financial Communication**

April 30, 2024	2023 annual results
April 30, 2024	Q1 2024 cash position
June 12, 2024	Annual general meeting of shareholders
July 23, 2024	Q2 2024 cash position
September 30, 2024	1H 2024 results
October 25, 2024	Q3 2024 cash position

\* This timetable is indicative and the Company reserves the right to amend the above-mentioned dates should it deem it necessary to do so.

## **CHAPTER 2.**

### **STATUTORY AUDITORS OF THE FINANCIAL STATEMENTS**

#### **2.1 Principal Statutory Auditor**

The Company's statutory auditor is:

PricewaterhouseCoopers SA  
Avenue Giuseppe-Motta 50  
CH-1202 Geneva

The auditor in charge is Mr. Luc Schulthess.

PricewaterhouseCoopers SA, Geneva branch, is registered at the *Registre du commerce et des sociétés* (Registry of Commerce and Companies) of Geneva under number CHE-390.062.005.

PricewaterhouseCoopers SA is a member of EXPERTsuisse – Swiss Expert Association for Audit, Tax and Fiduciary.

The auditors were re-appointed at the General Shareholders' Meeting held on June 14, 2023, for a term of one (1) financial year; their engagement is to end at the close of the General Shareholders' Meeting to be held to approve the financial statements for the financial year ended December 31, 2023.

#### **2.2 Subsidiary Statutory Auditor**

None. GeNeuro is a Swiss company, and the concept of a subsidiary statutory auditor does not exist in Switzerland.

### CHAPTER 3. RISK FACTORS

The Company operates in a changing environment that involves risks, some of which are out of its control. Investors are advised to take into consideration all the information contained in this Universal Registration Document, including the risk factors set forth in this chapter. Pursuant to Article 16 of Regulation (EU) 2017/1129 and of Delegated Regulation (EU) 2019/980, this chapter only presents the risks that the Company believes, as of the date of filing of this Universal Registration Document, in the event they should occur, might have a material adverse effect on the Group's business and operations, its results of operations, its financial position, earnings, prospects or ability to hit its targets.

In order to identify and assess such risks, the Company has mapped the risks associated to its activity and has grouped them into five categories below, it being stipulated that within each category and sub-category, risk factors are presented by order of decreasing importance with an evaluation of their probability (high, medium, low), negative impact (high, medium, low), and the net level of criticality, estimated by combining for each risk its probability of occurrence and its negative impact, as assessed by the Company as at the date on which the Registration Document was filed, together with taking into account the potential actions and preventive measures undertaken by the Company at that date. The occurrence of new events, both internal and external to the Company, may however alter this order of importance in the future.

Section	Risks Factors	Probability	Negative impact	Net level of criticality
<b>3.1</b>	<b>Risks Related To The Development and Potential Future Commercialization of the Group's Product Candidates</b>			
3.1.1	GeNeuro has developed a new approach, the therapeutic benefit of which has not yet been demonstrated, that is not based on confirmed pathways such as the immunomodulation and immunosuppression approaches used by existing therapies for the treatment of autoimmune diseases.	High	High	High
3.1.2	The Company's products, including its most advanced product candidate, temelimab, may never be approved for marketing due to regulatory reasons	High	High	High
3.1.3	The Company's product candidates may never be approved for marketing due to operational reasons.	High	High	High
3.1.4	The Company may not be competitive in its market.	High	High	High
3.1.5	The Company has limited visibility on its future prospects and financial results.	Medium	High	High
3.1.6	The uncertainty about reimbursement rates and measures to reform healthcare systems could delay or compromise acceptance of products by the market.	Medium	High	Medium
3.1.7	Other clinical applications of temelimab for conditions such as Post-COVID are based solely on pre-clinical work, and the Company may never succeed in developing and marketing effective treatments based on such technology.	High	High	High
<b>3.2</b>	<b>Risks Related To The Company's Financial Situation and Capital Needs</b>			
3.2.1	The Company does not have sufficient funds needed to continue its clinical development for the next twelve months..	High	High	High
3.2.2	The Company should continue to sustain operating losses in relation to its research and development activities.	High	High	High
3.2.3	The Group benefits from Research Tax Credits from the French government which regime may be challenged or modified in the future.	Medium	Medium	Medium
3.2.4	The Company could be unable to carry tax losses forward.	Medium	Low	Low
3.2.5	Full exercise of all securities carrying the right to acquire shares granted and outstanding would result in a dilution of existing shareholders.	Medium	Low	Low
3.2.6	Exchange Rate Risk.	Medium	Low	Low
<b>3.3</b>	<b>Risks Related To The Company, Its Operations and Organization</b>			
3.3.1	The Company is dependent on its key employees and, as such, could fail to continue attracting and retaining its key employees and scientific advisors.	Medium	High	Medium
3.3.2	The Company faces the risk of liability linked to its products or operations and it may not be able to obtain adequate insurance coverage at an acceptable cost.	Medium	High	Medium
3.3.3	Shareholders might be unable to achieve a control premium in the event of a change of control of the Company based on the fact that French and	Low	Low	Low

<b>Section</b>	<b>Risks Factors</b>	<b>Probability</b>	<b>Negative impact</b>	<b>Net level of criticality</b>
	Swiss regulations concerning mandatory public takeover offers are not applicable.			
<b>3.4</b>	<b>Risks Related To The Company's Dependency on Third Parties</b>			
<b>3.4.1</b>	The Company does not have manufacturing capabilities and is exposed to the risks associated with relying on third party raw material providers and manufacturers for its most advanced product candidate temelimab and its other products.	<i>Medium</i>	<i>High</i>	<i>Medium</i>
<b>3.4.2</b>	The Company does not have experience in the areas of sales, marketing and distribution and may be required to rely on third parties and/or mobilize new internal resources for this purpose.	<i>High</i>	<i>Medium</i>	<i>Medium</i>
<b>3.4.3</b>	The Company relies on external scientific collaborators.	<i>Medium</i>	<i>Medium</i>	<i>Medium</i>
<b>3.5</b>	<b>Risks Relating To The Company's Intellectual Property Rights</b>			
<b>3.5.1</b>	If the Company is unable to maintain or protect its intellectual property rights, it could lose its competitive advantage and be unable to operate profitably.	<i>Medium</i>	<i>High</i>	<i>Medium</i>
<b>3.5.2</b>	The Company's products and technologies could infringe or be claimed to infringe patents and patent applications held or controlled by third parties.	<i>Medium</i>	<i>High</i>	<i>Medium</i>
<b>3.5.3</b>	If the Company does not comply with its obligations under the license agreement with bioMérieux, it could lose rights that are very important for its business.	<i>Medium</i>	<i>High</i>	<i>Medium</i>
<b>3.5.4</b>	The Company's business could be affected if it is unable to protect the confidentiality of its information and know-how.	<i>Medium</i>	<i>High</i>	<i>Medium</i>

### **3.1 Risks Related To The Development and Potential Future Commercialization of The Group's Product Candidates**

#### **3.1.1 GeNeuro has developed a new approach, the therapeutic benefit of which has not yet been demonstrated, that is not based on confirmed pathways such as the immunomodulation and immunosuppression approaches used by existing therapies for the treatment of autoimmune diseases.**

The Company is presently pursuing the development of its lead drug candidate, temelimab, in two indications: Multiple sclerosis (“**MS**”) and neuropsychiatric syndromes affecting Post-COVID patients (“**Long-COVID**”, “**Post-COVID**” or **PASC** - Post Acute Sequelae of COVID-19). In MS, the Company has developed a new treatment approach that differentiates itself from therapies being sold on the date hereof. The same treatment approach is being tested in Post-COVID, which is a new indication for which there is at present no approved therapy.

The Company is exploring a new medical path that involves Human Endogenous Retrovirus (“**HERV**”) genes that constitute approximately 8% of the human genome. The capacity for the abnormal expression of various elements of a HERV of the W family (“**HERV-W**”) has been detected in chronic diseases like MS as well as in acute COVID-19 and Post-COVID. The Company seeks to develop, on the basis of this finding, a treatment designed to block the deleterious properties of a protein, **W-ENV**, which is encoded by genes of the HERV-W family. Recent publications have demonstrated that W-ENV may directly inhibit remyelination and that axonal injury in MS can be significantly driven by W-ENV through activation of microglia and that this contributes to neurodegeneration, particularly in progressive forms of MS. The primary analysis of ProTECT-MS, the Company's Phase 2 clinical trial in MS conducted at the Karolinska Institutet in Stockholm, Sweden, that was completed in Q1 2022, have showed that the primary endpoint of the study was met, with results confirming the excellent safety profile and tolerability of higher doses of temelimab administered concomitantly with a high-efficacy anti-inflammatory drug; in addition, efficacy data, obtained in this patient group already effectively treated against inflammation, showed that temelimab, an antibody that neutralizes W-ENV, has a favorable impact on key MRI measures of neurodegeneration; the observed effect sizes in this new patient population were consistent with the ones shown in the previous CHANGE-MS and ANGEL-MS studies.

The Company's Phase IIb clinical trials in the MS indication have shown that temelimab has only modest effects on neuroinflammation in the “active inflammatory patients” population as a monotherapy, but also that temelimab has positive impacts on key MRI measures and soluble biomarkers associated with disability progression; as a result, GeNeuro is now focusing on neurodegeneration and disability progression, most likely with temelimab as a combination therapy together with marketed immunomodulatory drugs addressing neuroinflammation, rather than as a monotherapy for “non-active” progressive patients. Whilst the Company's ProTECT-MS clinical trial enrolled “non-active” progressive patients, it is important to note that neurodegeneration, and disability progression as a biological feature, are present from the onset of disease, i.e. before patients are categorized as being in progressive MS. This means that the indication of temelimab is not restricted to the latter stage of disease, but may include all forms of MS.



In Post-COVID, publications show that SARS-CoV-2 infection triggers the expression of W-ENV, and that W-ENV is found in hospitalized patients and associated with disease severity. In the aftermath of COVID-19, the analysis of preliminary data from patients with Post-COVID depressive and/or cognitive disorders has also shown the persistence of W-ENV in the blood in significant numbers of patients, suggesting that the neuropsychiatric symptomatology seen in “Post-COVID” patients may be due to activation of W-ENV expression by SARS-CoV-2 in these individuals, and to its persistence long after the acute COVID phase. GeNeuro initiated in the fall of 2020 prospective collections of samples with Academic Institutes testing patients who suffered from neurological and psychiatric syndromes post COVID, leading to a recent publication made available on MedRxiv that has shown that W-ENV was observed in more than 25% of patients with persistent syndromes after having had COVID.

At the end of 2022, GeNeuro launched a precision medicine, biomarker-based, Phase 2 trial, called GNC-501, that is evaluating the clinical efficacy of a six-month treatment with temelimab, the anti-W-ENV antibody developed by GeNeuro, on the improvement of fatigue, cognitive impairment and self-reported neuropsychiatric symptoms, covering cognition, fatigue, anxiety, depression, and Quality Of Life in Post-COVID patients who are positive for the presence of W-ENV protein in their blood. This study is now fully recruited, with 203 randomized patients; in the course of this trial, 1’092 patients severely affected by neuropsychiatric symptoms (severe fatigue, cognition problems) signed an informed consent and were tested for W-ENV in their blood, with 36% of them testing positive for W-ENV. This opens the door to a personalized medicine approach that could, if the current clinical trial is successful, offer a therapeutic solution to a well identified subset of the millions of patients affected by Post-COVID. The results for this trial are expected in June 2024.

As of the filing date of this Universal Registration Document, there is no treatment that targets endogenous retroviral genes approved for sale by the competent authorities, and such a treatment intended to block a protein expressed by a HERV is, therefore, unproven.

Accordingly, the prospects for the development and profitability of the Company’s most advanced product candidate, temelimab, for Post-COVID or MS, or other indications, its safety, its effectiveness, and its acceptance by patients, prescribers, and paying agencies, are uncertain. The positive results observed for temelimab for MS in connection with Phase I, on the one hand, and successive Phases II, on the other hand, and more generally, those relating to existing or future products in the Company’s portfolio or based on its technology at the time of the research or preclinical phase, may not be confirmed by future trial phases. Such a situation could have a very material adverse impact on the Company’s business, results, financial situation, and prospects.

**3.1.2 The Company’s products, including its most advanced product candidate, temelimab, may never be approved for marketing due to regulatory reasons.**

The Company is subject to regulations that are numerous and evolving and it may not be able to obtain the necessary approvals to market and sell its products, including its product candidate at the most advanced stage of development, temelimab. To obtain a product license for its candidate products, the Company must show, through long, numerous and very expensive clinical trials with uncertain outcomes, that the use of the candidate products is without danger and is effective in humans. Clinical trials are subject to supervision by regulatory authorities as well as by ethics committees, in order to protect the persons participating in the medical research. If the Company does not meet its development calendar (please see Section 5 of this Universal Registration Document), or if it is unable to conduct the expected clinical trials successfully within applicable time limits, its business and operations could be materially and adversely affected.

The Company’s ability to obtain product licenses for its products will depend on several factors, including, but not limited to:

- the possibility of pursuing the development of those of its products presently in early clinical trials, or presently in pre-clinical development to a clinical stage;
- its ability, or that of its partners, to conduct clinical trials successfully and within relevant time periods without having to devote significantly greater resources than initially expected;
- its clinical trials showing the efficacy and safety of its products;
- its products 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 biotechnology and pharmaceutical industries, it often happens that favorable results of pre-clinical studies and Phase I/II clinical trials are not confirmed in later stages of clinical development. Regulatory authorities in various countries in which the Company intends to market its products could 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, the preclinical safety, and post-treatment follow-up), or impose additional or unexpected requirements at the time of such trials. Furthermore, the Company might decide, or might be required by regulatory agencies, to suspend or terminate clinical trials, if new evidence suggests that patients are exposed to unexpected risks. Deaths or other adverse events could occur during a clinical trial, because of medical problems both linked and not linked to the treatments administered, forcing the Company to delay or interrupt the trial. Also, on the basis 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 then be withdrawn from the market, or they could produce different effects from those initially expected, which could, in turn, limit or prevent them having any commercial use. The occurrence of all or some of these events could have material adverse effects on the Company's business, results, and prospects.

As of the date hereof, none of the Company's products, including its most advanced product candidate, temelimab, has received a marketing authorization from any regulatory authority. The Company cannot be sure that it will receive the necessary approvals to market and sell any of its products. The products may be subject to very stringent laws, and regulatory requirements that are uncertain and subject to change and Universal Registration Document (for a summary presentation of such laws and regulations in the United States and Europe, please see Chapter 9 "Regulatory Environment") of this Universal Registration Document). The U.S. Food and Drug Administration ("FDA") and the European Medicines Agency (the "EMA") as well as their counterparts in other countries regulate, among other things, research and development, pre-clinical tests, clinical trials, manufacturing, safety, efficacy, records retention, labeling, and the marketing, sale, and distribution of therapeutic products. In particular, without the FDA's approval, it would be impossible for the Company to access the U.S. market, which is the largest pharmaceutical market in the world, particularly for the therapeutic areas targeted by the Company (MS, Post-COVID, Amyotrophic Lateral Sclerosis ("ALS"), etc.).

These regulatory steps are costly; they may take several years; and their outcomes are unpredictable. The data from pre-clinical and clinical developments may give rise to different interpretations, which could delay obtaining or restrict the scope of regulatory approval. 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 approval on a timely basis in each relevant country. Since the Company's products are based on new, constantly changing technologies and have not been tested on an in-depth basis in humans, the applicable regulatory requirements remain uncertain and could be subject to significant differences of interpretation and changes. Changes in laws and regulations during the development of a product and its regulatory review could cause delays in or the denial of approval.

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 products;
- limit the indications for which it might be authorized to market and sell its products;
- impose new, stricter requirements, suspend approval of the Company's products, or require the Company to stop the clinical trials it is conducting or stop the marketing and sales of the products (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.

The Company has already completed for temelimab, its product candidate at the most advanced stage of development, three clinical Phase I trials<sup>1</sup> to define the pharmacological, immunogenic, and safe use on healthy volunteers. The results of these trials have been published in scientific journals (Hartung et al.; MSJ2021) and are considered positive regarding temelimab's safety, tolerability and efficacy.

The Company has also completed four Phase II trials on a patient population having MS and one Phase II trial on a patient population having Type 1 Diabetes ("T1D"):

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<sup>1</sup> "Preclinical" and "clinical" phases are defined in the Appendix.

- a Phase IIa clinical trial for MS<sup>2</sup>, intended principally to show temelimab's tolerance over a period of one year by the injection of potentially therapeutic doses and, secondarily, to take initial measurements on the clinical evolution of treated patients; and
- a 1-year Phase IIb clinical trial (CHANGE-MS<sup>3</sup>) for MS in patients with the relapsing remitting form of MS (RRMS), with a primary endpoint evaluating the efficacy of repeated doses of temelimab versus placebo in patients based on the cumulative number of Gadolinium-enhancing ("Gd+") T1 lesions on brain MRIs and with secondary endpoints to evaluate measures of MRI markers associated with neuroprotection, notably brain atrophy, hypointense T1 lesions ("black holes") and magnetization transfer ratio ("MTR"), considered to be an indirect measure of the integrity of myelin; and
- a 1-year Phase II extension study of CHANGE-MS (ANGEL-MS<sup>4</sup>) of the above Phase IIb clinical trial, which allowed patients who took part in the Phase IIb study to benefit from two additional years of treatment; following the decision from the Company's former development partner, in September 2018, not to exercise its option for a license on temelimab, this extension study underwent an early termination and topline results were presented on March 12, 2019; and
- a Phase IIa clinical trial (ProTECT-MS) for MS in patients treated with rituximab and in whom disability was worsening in the absence of relapses. This 1-year clinical trial enrolled patients with confirmed disability progression without relapses, following previous treatment with the anti-CD20 drug rituximab, a highly potent and efficacious drug against acute disease activity (relapses and brain lesion formation). All patients in the trial received rituximab in the eight weeks preceding their enrollment in ProTECT-MS. The primary endpoint for the study was safety of temelimab in combination with rituximab, and secondary and exploratory endpoints were designed to assess efficacy measures based on the latest imaging and biofluid markers associated with disease progression. The primary analysis of ProTECT-MS was presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2022) Congress in Amsterdam, Netherlands and showed that the primary endpoint of the ProTECT-MS study was met, with results confirming the excellent safety profile and tolerability of higher doses of temelimab administered concomitantly with a high-efficacy anti-inflammatory drug; in addition, efficacy data, obtained in this patient group already effectively treated against inflammation, showed that temelimab has a favorable impact on key MRI measures of neurodegeneration; the observed effect sizes in this new patient population were consistent with the ones shown in the previous CHANGE-MS and ANGEL-MS studies; New exploratory data on soluble biomarkers also showed favorable impact on measures of neurodegeneration at one year: the study showed a reduction of GFAP biomarkers in cerebrospinal fluid (CSF). GFAP is a biomarker for astrocytic activation associated with diffuse neuroaxonal damage leading to MS disease progression. The results on these CSF biomarkers confirm the synergistic potential to treat neurodegeneration with temelimab in addition to a high-efficacy anti-inflammatory therapy in MS. The analysis of the data now also allows GeNeuro to determine the optimal dose for future temelimab trials in MS, in conjunction with potential partners.
- In addition, the Company has completed a Phase IIa clinical trial for T1D in adult patients, which has met its primary endpoint of safety at six months, and whose full 12-month results were announced in May 2019.

At the end of 2022, GeNeuro launched a Phase 2 trial, called GNC-501, that is evaluating the clinical efficacy of a six-month treatment with temelimab on the improvement of cognitive impairment and/or fatigue in 203 Post-COVID patients who are positive for the presence of W-ENV protein in their blood. Results are expected in June 2024.

The use of temelimab for MS or Post-COVID requires additional clinical development to be completed, including Phase III clinical trials (in Post-COVID, even in the case where an emergency marketing authorization were granted). Accordingly, if the Company does not receive approval of temelimab for the treatment of MS or Post-COVID, its financial condition, results of operations, and prospects will be significantly and adversely affected.

### **3.1.3** The Company's product candidates may never be approved for marketing due to operational reasons.

The Company's clinical trials, especially for its leading product candidate, temelimab, could be delayed or not occur in a satisfactory manner.

The Company's ability to conduct clinical trials successfully depends on many factors, especially on the pace of patient recruitment, the size of the eligible patient population, the type of clinical protocol, the proximity of patients to clinical sites, eligibility criteria, possible secondary 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.

In general, the Company could encounter difficulties in recruiting and retaining patients to participate in future clinical trials of its products, in particular for temelimab, its most advanced product candidate for MS and Post-COVID. The

<sup>2</sup> Source: Derfuss T et al Mult Scler. 2015 Jun;21(7):885-93.

<sup>3</sup> Source: Hartung et al., Efficacy and safety of temelimab in multiple sclerosis: Results of a randomized phase 2b and extension study, Multiple Sclerosis Journal, July 2021

<sup>4</sup> Source: Hartung et al. ibid

strict criteria for inclusion in the trials could also make recruitment of patients difficult, notably for Post-COVID where patients must test positive for the presence of W-ENV protein in their blood. Once recruited, the patients participating in such trials could suspend or terminate their participation at any time without cause, or might be unable to continue participating in a trial if medical, or other, emergencies lead governments to impose quarantines or enforced isolation or require existing medical human resources or medical amenities to be solely dedicated to the treatment of such emergencies. Delays in patient recruitment could also increase the costs, delay, or even cause the cancellation of clinical trials (including in relation to the potential need to adjust existing protocols and have such adjustments be agreed by the regulators). 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.

Furthermore, large-scale clinical trials could lead to complexity in the management and supply of inventories of the product candidate temelimab. Logistical difficulties and errors in storing and shipping products, and/or poor management of inventories and their supply could cause delays in the completion of the trials.

Likewise, clinical trials designed and coordinated by the Company are conducted by medical and hospital centers and companies that specialize in the organization of trials (a contract research organization or “CRO”) and the quality of their work (the selection of populations, base-line measurements, compliance with protocols, doses, the number of administrations, intermediate delays and the collection of data) is determinant in the analysis and precision of results. In addition, because Phase II and Phase III clinical trials are typically conducted in numerous centers located in multiple countries, the Company cannot rule out heterogeneity and errors in the performance of such centers, which could impact the precision of the results.

Furthermore, the Company has limited experience in conducting clinical trials at multiple centers and has turned or will turn, now and in the future, to third parties to assist it in supervising and monitoring its trials. A breach or failure by one of such third parties or CROs in performing their task or their failure to comply with applicable regulatory standards could cause delays or even the premature termination of the trials.

#### **3.1.4** The Company may not be competitive in its market

The market for MS treatments for which temelimab is intended, as well as the markets for which its other products are intended, are characterized by rapid technological change, the predominance of protected products, and intense competition. Many organizations, including pharmaceutical and biotechnology companies, academic institutions, and other research entities, are actively engaged in the discovery, research, development, and marketing and sale of products intended to treat MS. If the Company were to obtain a marketing license for temelimab, it might compete with other presently prescribed therapies and/or those under development. Whilst there are today in MS no approved drugs that address disease progression (as opposed to reducing the number of inflammatory relapses, which is the area for which the existing immunotherapies such as immunomodulators and immunosuppressors drugs have been approved), it is possible that new drugs under development could prove effective against neurodegeneration and disease progression and thus be direct and strong competitors to temelimab.

A great number of companies developing immunomodulators or immuno-suppressors for MS, when compared with GeNeuro, have much greater resources and experience in management, manufacturing, marketing and sales, and research. In particular, major pharmaceutical companies like Bayer, Biogen, Bristol-Myers Squibb, Johnson & Johnson, Merck KGaA, Novartis, Roche, Sanofi and Teva, which market and sell medications for MS, have much greater experience than GeNeuro in conducting clinical trials and obtaining regulatory approvals. All such companies could also compete with the Company to acquire rights to promising antibodies as well as other complementary technologies.

The Company can give no assurance that its products:

- will be granted regulatory approval, protected by patents, or marketed sooner than those of its competitors;
- will remain competitive against other products developed by its competitors that are safer, more effective, or less costly;
- will be competitive against products of companies that might be more efficient in their production, marketing and sales;
- will be a commercial success; or
- will not be made obsolete or unprofitable by technological progress or other therapies developed by its competitors.

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

- the safety and efficacy of its therapeutic products, as demonstrated during clinical trials;
- the existence of undesirable side effects;

- ease of administration;
- the success of its marketing, sales, and public relations strategy;
- the availability of alternative treatments;
- pricing;
- the reimbursement policies of governments and other third parties;
- the effective adoption and implementation of a publication strategy; and
- obtaining the support of recognized external opinion leaders.

Even if temelimab for MS or Post-COVID is approved for marketing, the market targeted by the Company could turn out to be less significant than previously thought. The revenues that the Company may receive in connection with the marketing and sale of temelimab may be limited by the number of patients with MS or Post-COVID, by the categories of patients who respond well to treatment, by the perception of health providers as to the therapeutic benefit, by its ability to achieve appropriate pricing and reimbursement levels, and by the impact of competition.

If the Company does not market and sell temelimab successfully, its revenues could not materialize and / or decrease as a result, and it could find itself unable to finance the development and marketing of other products for other indications.

### **3.1.5 The Company has limited visibility on its future prospects and financial results.**

GeNeuro has a limited operating history, which does not allow it to estimate its prospects and future revenues. The Company's operations have been so far limited to developing a humanized monoclonal antibody technology aimed at a pathogenic protein expressed by a HERV and, on the basis of such technology, to conduct, with the assistance of CROs, pre-clinical and clinical trials for the purpose of developing, marketing and selling therapeutic solutions.

Notwithstanding the experience and abilities of its management and scientific team, the Company has not yet shown an ability to overcome the high number of risks and uncertainties that are frequently encountered by biopharmaceutical companies in a rapidly evolving, highly uncertain and speculative industry. The Company's ability to evaluate its future results or commercial prospects with precision, similarly, is more limited than if it had a long operating history or products that had already received marketing approval.

As a result, the likelihood of the Company's success must be evaluated in light of the numerous potential challenges and contingencies that are faced, at an early stage, by a company operating in the business of developing medications, most of which are beyond its control. Considering its development schedule and, assuming the receipt of relevant regulatory authorizations and the commercialization and marketing of its product candidate, GeNeuro estimates as of the date of this Universal Registration Document that the potential sale of its most advanced product candidate, temelimab, could commence between 2025 and 2027 for MS and/or Post-COVID. This timing is however dependent on the success of the Phase III trial, or possibly of a Phase II trial that could be registration enabling subject to its results, the absence of any event or setback delaying the proper conduct of the trials, and the absence of other events which the Company is currently unable to identify or anticipate.

### **3.1.6 The uncertainty about reimbursement rates and measures to reform healthcare systems could delay or compromise acceptance of products by the market.**

The uncertainty about reimbursement rates and measures to reform healthcare systems could delay or compromise acceptance of products by the market.

If the Company succeeds in marketing and selling the products developed in collaboration with partners, or by itself, their acceptance in the market will depend, in part, on the rate at which government health funds and private insurers reimburse them. Primary insurance health funds and other third-party payors often attempt to limit the cost of care by restricting or refusing to cover costly products and therapies. At present there are several immunomodulating products for the treatment of MS, but none specifically targets a causal factor or the progression of the illness, so that there is little or no experience relating to potential payments for such a treatment by insurance providers. As for Post-COVID, due to the recent occurrence of this disease and the absence of approved disease-modifying therapies, there is no experience with reimbursement rates and measures.

In some foreign markets, the price of prescription pharmaceuticals is subject to control by the government. The Company's ability to market and sell its products successfully will depend, in part, on the establishment by governmental authorities, private insurers, and other agencies in the United States and Europe of a sufficient reimbursement rate for its products and related treatments. In addition, the determination of the price and the reimbursement rate for the Company's products could be influenced by an announcement by competitors of more promising clinical results than those of the Company's products. Such a situation could have an adverse effect on

the conditions for setting the price and the reimbursement rate of products that could lose their competitive advantage over other competing products. Third-party payors are questioning the price of therapeutic products and medical services more and more frequently. Cost control measures that healthcare service providers and reimbursement agencies adopt and healthcare system reforms could adversely affect the Company's operating results. Also, as a result of the COVID-19 Pandemic, it may be expected that healthcare will be an important public policy subject of focus and that associated increase of healthcare spending will be more carefully monitored. The Company could thus fail to obtain satisfactory reimbursement for its products, which could impede their acceptance by the market, in which case the Company would be unable to earn a sufficient return on its research and development investments.

The Company's relations with clients and third-party payors are subject to U.S. anti-corruption (anti-kickback), anti-fraud, and anti-abuse laws or other laws and regulations relating to healthcare which could expose it to civil penalties and sanctions, damages, and interest, injury to its reputation, and diminution of its profits and future income. Healthcare professionals, doctors, and third-party payors play a key part in the recommendation and prescription of any product for which the Company may obtain a product license. Its future agreements with third-party payors and customers could expose it more broadly to U.S. anti-fraud and anti-abuse laws and regulations, or other laws and regulations relating to healthcare that may restrict business or financial agreements as well as relationships on the basis of which the Company markets, sells, and distributes any product for which it may hold a product license. Restrictions in accordance with U.S. federal anti-kickback, anti-fraud, and anti-abuse or other laws relating to healthcare are as follows:

- the U.S. federal anti-kickback statute prohibits people from, among other things, deliberately and knowingly soliciting, offering, receiving, or supplying compensation, directly or indirectly, in cash or in kind, to induce or compensate a business connection, or from purchasing, ordering, or recommending any product or service payment which could be made in connection with a healthcare program in the United States, such as Medicare and Medicaid;
- U.S. federal law intended to prevent fraud by companies that are parties to public contracts (the "**U.S. False Claims Act**") provides, among other things, for civil and criminal sanctions against individuals or companies that knowingly present false or fraudulent requests for payment to the U.S. federal government, or make false statements to avoid, reduce, or hide an obligation to pay money to the U.S. government. Such specific actions are open to whistleblowers or any other entity (qui tam actions);
- under the U.S. Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") a perpetrator of actions intended to defraud any program for providing healthcare services or who makes false statements relating to healthcare problems may be held civilly or criminally liable;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and regulations thereunder, also imposes obligations, including mandatory contractual language, to protect the confidentiality, security, and transmission of personally identifiable health information;
- U.S. federal law requires that manufacturers of medications report payments and other transfers of value to doctors and university hospitals; and
- analogous laws and regulations of U.S. or foreign states, such as anti-kickback laws, and those prohibiting false claims, could apply to sales or commercial agreements as well as to claims about health products or services reimbursed by non-governmental third-party payors, including private insurers.

If the Company's operations are deemed to be contrary to applicable U.S. law and regulations, the Company could be liable for significant sanctions and penalties, including fines, damages, imprisonment, civil and criminal prosecution, or exclusion of its products from governmental healthcare programs, such as Medicare or Medicaid, or even the restructuring of its business. Any doctor, healthcare professional, or company involved in commercial activities found to violate applicable laws and regulations could be exposed to civil or criminal actions or administrative sanctions, including exclusion from government healthcare programs.

**3.1.7 Other clinical applications of temelimab for conditions such as Post-COVID are based solely on pre-clinical work, and the Company may never succeed in developing and marketing effective treatments based on such technology.**

Temelimab has been tested pre-clinically for its effect on chronic inflammatory demyelinating polyradiculoneuropathy (**CIDP**), for which temelimab has received Orphan Drug Designation from the U.S. Food and Drug Administration (the "FDA") in February 2018. Temelimab has also been tested in a Phase IIa trial for T1D in adult patients, which has met its primary endpoint of safety at six months, and whose full 12-month results were announced in May 2019<sup>5</sup>. Published research data has also opened the potential of temelimab as a therapeutic candidate in Post-COVID (or PASC, Post Acute Sequelae of SARS-CoV-2 infection) patients, *i.e.*, COVID-19 patients who develop long-term neurological and psychiatric Post-COVID ("neuropsychiatric") symptoms.

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<sup>5</sup> Source: Curtin et al Diabetes Obesity and Metabolism, submitted 2019

On December 13, 2021, the Company announced it had been selected as one of the four projects retained by the Swiss Federal Office of Public Health ("FOPH") within the framework of the CHF 50 million "Federal Funding Programme for COVID-19 Medicines" incentive, and that it would receive a grant of 6.7 million Swiss francs (€6.4 million) to co-fund (up to 50%) a Phase II clinical trial to treat patients with long-standing COVID who exhibit neurological and psychiatric ("neuropsychiatric") symptoms. In March 2023, GeNeuro announced it had entered into a EUR 25 million credit line with the European Investment Bank ("EIB"), backed by InvestEU, to support clinical developments against Post-COVID. These two funding programs have helped finance the Company's GNC-501 study in Post-COVID.

The Company is also using the technology it has developed in the area of endogenous retroviruses to develop new approaches through pre-clinical programs that target, for example, ALS. In 2017, the Company entered into a research agreement with the U.S. National Institutes of Health ("NIH") for developing new approaches against pathogenic HERV-K Env protein as a target in the treatment of ALS, following which the Company has signed in October 2018 an exclusive worldwide license with the National Institute of Neurological Disorders and Stroke ("NINDS"), part of the NIH. The agreement covers the development of an antibody program to block the activity of HERV-K ENV (pathogenic envelope protein of the HERV-K family of Human Endogenous Retroviruses), a potential key factor in the development of ALS. In August 2022, GeNeuro and NINDS announced the publications in the leading scientific journal "Annals of Neurology" of the results of their collaboration on two publications describing the novel pathogenic mechanism of HERV-K in sporadic ALS and confirming the rationale for the therapeutic relevance of GeNeuro's antibody to neutralize this neurotoxic protein.

If the Company wishes to complete the development of its products and sell them for such indications, it will have to devote significant research effort and undertake numerous tests and clinical trials, obtain regulatory approvals, and make significant financial investments. In developing and marketing products based on its technology, the Company is confronted with a high degree of risk and uncertainty that could slow or even suspend its efforts to develop its products and have a material adverse effect on its business and operations. Even if the Company were in a position to obtain and maintain regulatory approvals for marketing its products, it is possible that:

- it may not obtain the regulatory approvals required for it to conduct clinical trials for such indications;
- it may neither develop nor obtain a marketing approval for its products quickly enough to ensure a competitive position in the target markets;
- it may not be in a position to manufacture and market its future products successfully at a price, reimbursement rate, or scale that allow them to be profitable;
- its future products may not be accepted by medical centers, hospitals, practitioners, and patients, nor be preferred to existing treatments at the time they are introduced, nor, more generally, meet with the expected commercial success;
- its future products may lose their competitive advantage and may become obsolete by the development of new competing products; or
- its future products may not be marketable because of third-party property rights.

If the Company is not successful in developing and marketing other products resulting from its technologies, its revenues will continue to be limited, and its operating results could be significantly affected.

## **3.2 Risks Related To The Company's Financial Situation and Capital Needs**

### **3.2.1 The Company does not have sufficient funds needed to continue its clinical development for the next twelve month periods.**

All of the Company's products are currently in the pre-clinical or clinical trial phase. The Company is currently running a pivotal Phase 2 clinical trial in Post-COVID, called GNC-501, which is now fully recruited and for which top-line results are planned for June 2024. Taking into account the net proceeds from the €5 million capital increase completed in February 2024, the Company has enough financial resources to allow it to complete the GNC-501 clinical trial but its net working capital is insufficient to meet its obligations, including funding its operations, for a period of twelve months from the date of this Universal Registration Document, as its financial runway will only extend to the next five months from the date of this Universal Registration Document.

Attention is drawn to the fact that the Company is over-indebted as such term is defined under Article 725b of the Swiss Code of Obligations (CO), as of December 31st, 2023. In order to meet its obligations for a period of twelve months from the date of this Universal Registration Document, the Company estimates that its additional net working capital requirement amounts to €3.5 million, excluding any costs in connection with the preparation of a Phase 3 study or marketing authorization in Post-COVID but taking into account the last payment of €1.4 million expected from the Swiss Federal Office of Public Health (FOPH), which is conditional upon submitting to Swissmedic a marketing authorization application and submitting to the FOPH the preliminary final material & financial report. Without the FOPH payment, the additional net working capital requirement amounts to €5 million.

Failure to raise additional financing to remedy such insufficient net working capital would force the Company to declare itself insolvent and to request a debt-restructuring moratorium, which could lead the Company to initiate bankruptcy proceedings in case the moratorium does not allow to find additional financing. The Company continues to be engaged in discussions with investors, suppliers and lenders, including ongoing negotiations with the EIB, with the objective to secure further additional financing to provide sufficient financial runway until Q1 2025.

Assuming positive results from the GNC-501 clinical trial, the Company will need to finance manufacturing of additional batches of temelimab to allow further clinical studies, including a Phase III trial including in the United States, as well as prepare large scale manufacturing to allow distribution of temelimab following the securing of marketing approvals, as well as work with Bio-Techne, the supplier of the digital automated Western-Blot capillary detection system used for the detection of W-ENV in patients' serum, in order to industrialize the test through the development of kits that could be used by specialized decentralized labs for phase III. In addition, further clinical studies will be necessary for the development of temelimab for MS or other indications until the Company may eventually apply for and receive a marketing authorization. The amount of €3.5 million of additional net working capital requirement mentioned above does not take into account any of these costs.

Since its incorporation, the Company has mainly financed its growth by capital increases, including notably the capital increase completed at the time of its initial public offering and listing on the regulated market of Euronext Paris and four subsequent capital increases, the latest being in February 2024, as well as the FOPH subsidy and EIB financing for its Post-COVID program, which expose it to liquidity risk resulting from indebtedness. The Company will be required to seek additional funding to continue its development in MS, Post-COVID or ALS, which may include, without limitation, revenues from new partnership agreements, funds from capital increases or other funding, such as subsidies, grants, or other forms of financing.

As of December 31, 2023, cash and cash equivalents of the Company amounted to €1.8 million; in addition, the Company received in January 2024 €1 million from a non-recourse bank pre-financing of its €1.3 million French Research Tax Credit for 2022, and completed a €5 million capital increase in February 2024.

The Company has performed a specific review of its liquidity risk as of the filing date of this Universal Registration Document. Taking into account the net proceeds of the capital increase completed on February 7, 2024, the Company considers that, on the filing date of this Universal Registration Document, its financial resources are sufficient to complete the GNC-501 pivotal clinical trial, with results expected in June 2024, and to extend its financial visibility until the end of the third quarter of 2024 taking into account the last payment of €1.4 million expected from the FOPH, which is conditional upon submitting to Swissmedic a marketing authorization application and submitting to the FOPH the preliminary final material & financial report. Without the FOPH payment, the net working capital is sufficient until mid-August 2024. The Company continues to be engaged in discussions with investors, suppliers and lenders, including ongoing negotiations with the EIB, with the objective to secure further additional financing required to extend its financial visibility until the second quarter of 2025.

In March 2023, the Company entered into a €25 million credit line with the EIB, backed by InvestEU, to support its clinical developments against Post-COVID. This €25 million credit line comprised a first tranche of €7 million, which was drawn down in March 2023, and two additional tranches of €10 million and €8 million being intended for the preparation and launch of Phase 3 respectively, subject to certain conditions, including the need to raise, for each additional tranche, €30 million in cash, in the form of equity, license revenues or customer advances. The Company is renegotiating the terms of the credit line with the EIB, with the objective of securing an early draw-down of part of the second tranche but cannot presume the outcome of such negotiations.

The Company's cash burn was €10.1 million during 2023, compared to €13.1 million during 2022. The lower cash burn in 2023 is due to the favorable change in working capital of €3.9 million, compared to a negative amount of €1.9 million in 2022, which offset the increase of €2.9 million in cash outflow from activities resulting from the higher R&D expenses in 2023 for the completion of patient recruitment and conduct of the Post-COVID program. Not taking into account the possible strategic and operational implications of the GNC-501 clinical trial results, the Company expects that its cash burn for 2024 will be significantly lower than in 2023 due to the completion of the GNC-501 trial in June 2024 and its limited current research and development programs. For 2024, the Company's actual cash burn will depend largely upon its ability and decision to launch further Phase III trials in Post-COVID and to launch additional manufacturing batches of temelimab and prepare technology transfers to large-scale antibody manufacturers to allow eventual commercialization of temelimab in the Post-COVID indication should a marketing, or temporary use, authorization be granted to the Company. However, neither the 2024 cash burn nor the 2025 cash burn are necessarily indicative of future cash burn that will largely depend on future R&D and, possibly, commercialization programs actually undertaken.

Although management continues to pursue its plans to finance the development of its products, there is no assurance that the Company will be successful in obtaining sufficient funding in the future, when needed or at all, on terms acceptable to the Company to fund its continuing operations.

The Company will have to bear, if it obtains approval from a country's authorities to test its product candidate in humans in that territory, the significant cost of development of temelimab. Assuming positive results from the GNC-



501 clinical trial in Post-COVID, the Company considers that it will need to launch a Phase III clinical trial including the United States and other countries to allow broad market access to temelimab in this indication; based on the costs of the GNC-501 clinical trial and assuming a Phase III study would be several times larger than the Phase II GNC-501, such costs would exceed €50 million, whereas such costs would likely exceed €100 million for a Phase III study in MS.

In order to finance the continued clinical development of temelimab in MS, where the Company considers that the most likely development pathway is a combination therapy approach with efficacious anti-inflammatory compounds targeting inflammatory relapses, the Company is seeking to enter into licensing and distribution, or other agreements with pharmaceutical companies which will be expected to have sufficient capability for conducting the Phase III trials, manufacturing on an industrial scale, and distributing, marketing and selling the product. GeNeuro is engaged in these partnering discussions but there is no certainty that these discussions may result in a new partnership.

The Company also believes that the negative cash flow from its operations may increase significantly during future years because of the need for conducting additional clinical trials, manufacturing its products, and extending its research and development programs. It will need considerable funding to pursue its research and development programs, conduct other pre-clinical and clinical trials of its products, and extend its manufacturing, quality control capabilities, and regulatory and administrative capabilities.

The Company's future capital needs will depend on many factors, such as, among others:

- the progress of its research and development programs;
- the scale of such programs;
- the extent of the costs and results of pre-clinical and clinical trials;
- the time and costs necessary for obtaining regulatory approvals, including the time to prepare the application files for regulatory bodies;
- the marketing and sale of product, especially temelimab for MS or for Post-COVID;
- the Company's ability to establish and maintain collaboration agreements with new partners;
- the cost of improving its manufacturing and marketing capabilities; and/or
- its need to acquire additional technologies or products, as the case may be.

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

- costs associated with possible requests or requirements (for example if trials are interrupted by emergencies such as the COVID-19 epidemic) to change studies, or to include a greater number of patients;
- costs of preparing, filing, defending, and maintaining its patents and other intellectual property rights;
- competing technological developments; and/or
- higher costs and longer lead times than those anticipated to obtain regulatory approvals for the marketing of its products and access to reimbursement.

Finally, if the necessary funds should not be available or not available on a timely basis, the Company may be forced to:

- delay, reduce, or eliminate the number and scope of its pre-clinical and clinical trials;
- grant licenses to technologies to partners or third parties;
- 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;
- obtain funds through alliance, collaboration or partnering agreements that could force the Company to give up rights to certain of its technologies or its products, rights which it would not have given up in different circumstances; and/or
- delay, reduce, or even cancel research and development programs, and reduce the number of its employees;

The occurrence of one or more of the risks mentioned above could have a material adverse effect on the Group's business, financial condition, results, development, and prospects.

### **3.2.2 The Company should continue to sustain operating losses in relation to its research and development activities.**

The Company has sustained operating losses since its formation, except for the 2014 financial year. Such losses, which amounted to €14.8 million for the 2023 financial year and €12.2 million for the 2022 financial year reflect both the significance of the expenses incurred in research and development and the absence of revenues. The Company foresees that such losses will continue over the next few years, at least until the potential marketing and sale of its products, because of the significant investments required for research, development, manufacture, quality control, and distribution of its products, pre-clinical and clinical trials, administrative activities, and activities linked to the development of intellectual property, as well as license agreements for new products and for the acquisition of new technologies that may become necessary, as the case may be.

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

- some of its products move beyond the stage of pre-clinical development to clinical development;
- it is confronted with increased regulatory requirements for manufacturing, and trials for its product candidates (including temelimab for MS or Post-COVID, which is its only product in an advanced stage of development);
- it begins to pay fees in connection with applications for product licenses from regulatory bodies;
- it increases its portfolio of products by adding new products for future development;
- it makes milestone payments to third parties (such as bioMérieux) which have already licensed their technologies to it;
- it develops its research and development activities and buys new technologies, products or licenses, as the case may be;
- it develops its business worldwide; 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 pre-clinical developments and clinical trials;
- the calendar 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; and
- other factors, a great number of which are beyond the Company's control.

Given the development stage of its most advanced product, the Company has not yet received any revenue from product sales and the Company's operating revenue and operating profit (or loss) have fluctuated in the past and could continue to do so in the future. Accordingly, its revenues for a given period are not a reliable indicator of its future performance and the Company may never market or sell any products and, as a result, may never become profitable. The Company expects that its main sources of revenue and funds until the potential marketing and sale of its first product candidate, temelimab for MS or post-COVID, will be:

- payments that may be made by future partners of the Company, if the Company enters into one or more agreements with future partners relating to the development and/or marketing and sale of temelimab for MS or post-COVID or other revenue of the Company;
- public and private subsidies, including the remaining CHF 1.3 million balance from the Swiss FOPH subsidy and other public funding it is continuing to seek;
- debt financing, such as the €25 million credit facility recently established with the EIB, from which the Company has already drawn a first tranche of €7 million in March 2023, and is currently negotiating to draw down an additional amount through an early availability of part of the second tranche;
- potential net proceeds of funds raised by the Company through capital markets transactions.

Any interruption of such financing sources could have a material impact on the operating revenue and operating profit (loss) of the Company.

### **3.2.3 The Group benefits from Research Tax Credits from the French government which regime may be challenged or modified in the future.**

The Company's subsidiary GeNeuro Innovation, a French company, benefits from the French Research Tax Credit (Crédit Impôt Recherche, "CIR") that provides a tax incentive to support the scientific and technical research efforts of French companies. The research expenses that are eligible for the CIR include, under certain conditions, the salaries and compensation of researchers and research technicians, the amortization of fixed assets dedicated to research, services subcontracted to approved research entities (public or private), and expenses for maintaining patents.

The amounts received by GeNeuro Innovation in respect of the CIR are as follows:

- payment of the CIR for financial years 2011 to 2020 of €6,719 K, all of which was received;
- payment of the CIR for financial year 2021 of €1,007 K, received in September 2022.

Companies must provide evidence to the French tax authorities, upon request, of the outstanding amount of the CIR and the eligibility of the operations taken into account to benefit from this aid.

For the financial year 2022, the Company has accrued a CIR amount of €1,316 K. Whereas until 2022 GeNeuro Innovation benefited from the early payment of the CIR (i.e., immediately, rather than three years following application), this is no longer applicable as of 2023 onwards, which means that the Company must either wait the statutory three-year period before being reimbursed, or must seek prefinancing alternatives, with the attending financial cost. The Company has put in place a bank pre-financing from which it has received €990 K, net of up-fronted interest charges, during January 2024; an amount of €132 K remains collectible in 2026 subject to the full payment by the French tax authorities of the amount claimed.

If in the future the Company should no longer receive amounts under the CIR, or its status or calculations should be questioned, this could have a material adverse effect on the Group's business, prospects, ability to achieve its objectives, financial condition, cash position or operating profit (loss).

#### **3.2.4** The Company could be unable to carry tax losses forward.

As of December 31, 2023, the Company had carried-forward tax losses of € 51,607K (CHF 50,394K converted at the 2023 average rate). In Switzerland, tax carryforwards may be used within seven years of incurrence and are as follows:

- € 9,610.2 originated in 2023 and expiring in 2031
- € 9,673.4 originated in 2022 and expiring in 2030
- € 7,783.8 originated in 2021 and expiring in 2029
- € 10,827.7 originated in 2020 and expiring in 2028
- € 4,318.9 originated in 2019 and expiring in 2027
- € 5,478.8 originated in 2018 and expiring in 2026
- € 3,913.8 originated in 2017 and expiring in 2025

At the 2023 annual shareholders' meeting of GeNeuro SA, shareholders approved the resolution to apply EUR 30 million of additional paid-in capital to carried-forward losses, which reduced the amount of carried-forward losses applicable for taxes. If the Company continues to apply additional paid-in capital to reduce its carried-forward losses, it may reduce the amount of carried forward tax losses.

It is possible that future changes to Swiss tax law could alter such provisions by limiting or eliminating the possibilities for attributing the tax loss carryforwards, which could have a material adverse effect on the Group's business, prospects, ability to achieve its objectives, financial condition, cash position, or operating profit (loss).

#### **3.2.5** Dilution Risk

Since its formation, the Company has granted stock options to its management and employees. In March 2024, the Board of Directors awarded a total of 1,885,118 stock options to employees, directors and executive managers of the Company, of which 1,021,000 were in "conversion" of cancelled cash bonuses and 774,118 were in "conversion" of waived cash compensation by directors and the Company's Chief Executive Officer and Chief Financial Officer. Accordingly, as of the filing date of this Universal Registration Document and taking into account the expiration of unexercised stock options, the cancellation of unvested stock options for departing employees and the warrants issued to the EIB in connection with its € 7 million Venture Debt financing of March 2023, full exercise of all securities carrying the right to acquire shares granted and outstanding as of the date hereof would lead to the issuance of 3,380,323 shares, resulting in a potential dilution of 10.2% (such options are described in sections 13.1.3 and 19.1.5 of this Universal Registration Document). The weighted average exercise price of all such securities is €2.56, compared to the market closing price for the Company's shares on Euronext Paris of €1.42 on April 15, 2024.

In connection with its incentive strategy for motivating its executives and employees and to attract additional skills, the Company could 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. Dilution could cause a drop in the price of the Company's shares.

#### **3.2.6** Exchange Rate Risk

The Company is exposed to exchange rate risks relating to changes in the exchange rate between the euro ("EUR") and the Swiss franc ("CHF") because a portion of the Company's operating expenses is incurred in the latter currency.

If the Company succeeds in marketing and selling its products in the United States, it could earn a portion of its revenue in U.S. dollars and, therefore, would be exposed to an exchange rate risk relating to changes in the exchange rate between the U.S. dollar and the euro.

The Company will follow changes in its exposure to exchange rate risks on the basis of changes in its situation. If the Company does not manage to take effective hedging steps in the future, its results of operations could be negatively impacted.

### **3.3 Risks Related To The Company, Its Operations and Organization**

#### **3.3.1 The Company is dependent on its key employees and, as such, could fail to continue attracting and retaining 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, especially its Chairman and Chief Executive Officer (*Président Directeur Général*), Mr. Jesús Martin-Garcia; its Chief Scientific Officer, Dr. Hervé Perron; its Chief Financial Officer, Mr. Miguel Payró; and its Chief Development Officer, Dr. Alois B Lang. The Company's previous Chief Medical Officer, Dr. David Leppert, has retired effective December 31, 2023 and will remain a consultant to the Company; he has been replaced effective January 1, 2024 by Dr. Anke Post, MD, PhD, who has in-depth academic and medical knowledge and training in the field of neurosciences, psychiatry and neurology as well as broad pharmaceutical industry experience after holding positions as senior physician and leader with more than 25 years of academic and Pharmaceutical R&D activity in three major multinational pharmaceutical organizations as well as in biotech and medical device companies. The loss of their expertise could alter 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 such competition is very intense, the Company could 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 personnel could prevent it from reaching its overall objectives.

#### **3.3.2 The Company faces the risk of liability linked to its products or operations and it may not be able to obtain adequate insurance coverage at an acceptable cost.**

The Company is exposed to the risk of liability, particularly product liability, arising in connection with the manufacture and sale of therapeutic products for use in humans. Liability against the Company may also result from clinical trials in connection with the testing of therapeutic products or unexpected adverse side effects resulting from the administration of such products. Complaints or legal proceedings could be filed or brought against the Company by patients, regulatory authorities, biotechnology and biopharmaceutical companies, and other third parties using or selling its products. Such actions could include complaints resulting from actions by its partners, licensees, and subcontractors over which it has little or no control. The Company can give no assurance that its present insurance coverage will suffice to respond to liability actions that could be brought against it. If its partners, licensees, and subcontractors or the Company itself are not in a position to obtain and maintain appropriate insurance coverage at an acceptable cost or protect themselves in some way against product liability actions, they could be held significantly liable, which could have the consequence of seriously affecting marketing and sale of the Company's products and, more generally, harm its business.

The Company is also subject to environmental protection and health and safety laws and regulations that could expose it to liability and restrict its operations. In its research and development programs and pre-clinical tests, the Company uses hazardous substances and biological materials such as human cell lines. Accordingly, in countries in which the Company operates, it is subject to environmental protection and safety laws and regulations governing the use, storage, manipulation, production, and disposal of hazardous substances, including chemical and biological products. The Company is also subject to laws and regulations relating to the use and manipulation of genetically modified organisms under French, European, and U.S. laws and regulations.

In the event of a failure to comply with applicable laws and regulations, the Company could be subject to fines and might have to suspend part or all of its operations. To comply with environmental, and health and safety laws and regulations, the Company would incur additional costs and it could, in the future, incur significant expenses in doing so in the relevant jurisdictions in which it operates. In complying with environmental, health and safety laws and regulations, the Company may have to acquire equipment, modify facilities, and more generally, incur other material expenses. In the event of accidental contamination, injuries, or any kind of damage, the Company could be held liable for damages, which might not be paid by or covered under its insurance policies and which could harm the Company's business.

**3.3.3 Shareholders might be unable to achieve a control premium in the event of a change of control of the Company based on the fact that French and Swiss regulations concerning mandatory public takeover offers are not applicable.**

In so far as the Company's registered office is in Switzerland whilst its shares are listed only on Euronext Paris's regulated market, neither French regulations on mandatory public tender offers and buyouts, nor Swiss regulations on public takeover offers (purchase or exchange offer) are applicable to public tender offers concerning the Company's shares.

Under these conditions, a person might acquire shares in the Company to an extent representing a controlling stake as defined under Swiss or French law without a legally enforceable obligation to file a public tender offer to all the shareholders.

Similarly, because of the unenforceability of French and Swiss law on compulsory public tender offers, a person could issue a public tender offer to some, but not all, shareholders.

**3.4 Risks Related To The Company's Dependency on Third Parties**

**3.4.1 The Company does not have manufacturing capabilities and is exposed to the risks associated with relying on third party raw materials providers and manufacturers for its most advanced product candidate temelimab and its other products.**

The Company has chosen to outsource the manufacturing of its products. Its dependence on third parties to manufacture and assemble certain of its products and its lack of experience in manufacturing other products on an industrial scale could affect its ability to develop and sell its products within a reasonable timeframe and on a competitive basis. In particular, the Company depends on third parties to produce its most advanced product candidate, temelimab for MS. In this respect, it has entered into an agreement with the contract manufacturing organization ("CMO") Polymun Scientific GmbH ("Polymun"), to manufacture its antibody on the basis of good manufacturing practices ("GMP"), for determined quantities of product at a pre-determined cost, without future royalties. The Company will also depend on subcontracting agreements for the fill and finish of its products, both for future clinical trials and for subsequent stages of sales and marketing.

The Company could also be unable to enter into subcontracting agreements for the future commercial supply of temelimab, or to do so on acceptable terms and conditions. If it is unable to enter into acceptable subcontracting agreements, the Company may be unable to market and sell temelimab successfully.

In the current post-COVID-19 pandemic and geopolitical situation, supply of culture media for antibody manufacturing and other products continues to face considerable strain and competition for deliveries, which may lead to delays in the manufacturing of future batches of temelimab.

Furthermore, dependency on third-party manufacturers involves additional risks to which the Company might not be exposed if it manufactured temelimab itself, such as:

- non-compliance of such third parties with regulatory and quality control standards;
- the violation of such agreements by such third parties;
- the termination or non-renewal of such agreements for reasons beyond its control; and
- the insolvency of such third parties.

If the products manufactured by such third-party suppliers do not comply with regulatory standards, sanctions and penalties could be imposed. Such sanctions could include fines; court orders; civil penalties; refusal of regulatory authorities to grant product licenses; delays, suspension or withdrawal of approvals; revocation of product licenses; product recalls or seizures; operating restrictions and criminal prosecutions, all of which are measures that could have a material adverse effect on the Company's business, operations, its financial position and its financial results.

If the Company is unable to maintain its collaboration agreements with its existing partners, including the CMO Polymun, or enter into new agreements on acceptable terms and conditions, it will have to develop and sell its products at its own expense, or it will have to turn to other partners. This could increase its capital needs and limit its growth and marketing and sales efforts to other areas. In addition, even if the Company, in connection with its agreements, has included provisions designed to impose strict compliance by its partners with their commitments, it cannot control either the extent or the timing of the resources that its existing and future partners will devote to the development or sale of the Company's products. Such partners might also not meet their obligations as set out in the contracts that the Company has, or may have, with them or under the terms it is expecting. In such cases, the Company could be confronted with significant delays and not achieve success in obtaining the support of third

parties for the Company's new technology based on the neutralization of W-ENV, or support for the introduction of the Company's products in various markets.

Even though the Company tries to include non-competition clauses in its collaboration agreements, no assurance can be given that such restrictions will ensure sufficient protection to the Company. The Company's partners could develop technologies alone or together with others, including its competitors.

#### Impact of the Russian-Ukrainian and Israeli-Palestinian conflicts

Current wars in Ukraine and the Middle East could further aggravate the global economic situation, which continues to be impacted by the various crises and geopolitical tensions. Although the Company is not directly impacted by these conflicts, as it has no commercial, development or clinical activities planned or underway in Russia, Ukraine, Israel, the Palestinian territories or in the Middle East, it is possible that the stalemate, intensification or globalization of these conflicts may lead to disruptions that could have a significant unfavorable effect on its business and clinical trials, notably:

- Delays in the production and receipt by clinical sites of supplies and equipment required for the Company's clinical trials;
- Delays in obtaining the authorizations required to launch potential future clinical trials by the Company from the relevant administrative authorities;
- Changes in local regulations due to conflict-related measures, which could force the Company to modify the terms of its clinical trials, thereby incurring unforeseen costs or even interrupting them;
- Disruption of global air and sea trade, which could affect the transportation of raw materials required for the production of clinical trial materials;
- Slow-down or Interruption of key clinical trial activities, such as clinical trial site monitoring, due to travel restrictions imposed or recommended by federal or state authorities, employers or others;
- Potential Increase in the costs associated with the clinical trials entrusted to CROs as a result of the conflicts (although, as of the date of this Registration Document, the Company has not however observed an increase in costs due to this conflict). and
- Delays or delays induced by increased cybersecurity risks leading the Company to curtail its activity in order to preserve the integrity of its data.

#### **3.4.2 The Company relies on external scientific collaborators.**

The Company relies on external scientific collaborators, including researchers attached to CROs or universities, to successfully conduct relevant research activities, including in connection with development programs for products, such as the conduct of clinical trials. The competition to maintain such networks is intense, and it may not be possible to maintain them on acceptable conditions. In general, such external collaborators may terminate their commitments at any time. Accordingly, the Company can control their activities only within certain limits and cannot prevent them from devoting a portion of their time to research on and development of other products. Furthermore, such scientific collaborators may be subject to intellectual property rights agreements, or other rights in relation to the results of tests or research and development conducted jointly. Furthermore, they may not wish to grant a license to such intellectual property rights on acceptable terms.

#### **3.4.3 The Company does not have experience in the areas of sales, marketing and distribution and may be required to rely on third parties and/or mobilize new internal resources for this purpose.**

The Company also lacks experience in the areas of sales, marketing and distribution. If it secures a marketing authorization for its products, it will therefore have to develop its own marketing and sales capabilities either alone, or with strategic partners. In connection with its strategy, it could, therefore, be led to search for partners for the sale, marketing, and distribution of some of its products. In the event of the direct marketing and sale of temelimab by the Company, it will have to develop its own sales and marketing infrastructure, which would involve incurring additional expenses, mobilizing management resources, organizing new skills and taking the time needed to create the appropriate organization and structure to support the product in accordance with applicable law and, more generally, optimizing its marketing and sales efforts. The Company is evaluating the strategic and financial advantages of an alliance with one or several partners for the marketing and sale of temelimab for MS in worldwide markets, if the opportunity should arise. It is possible that the Company may not succeed in entering into an alliance for the marketing and sale of temelimab or any of its products on economically reasonable terms and conditions or maintaining such alliances or marketing and selling its products itself.

The Company expects growth in all areas of its business while it develops and, subject to obtaining required regulatory approvals, markets and sells its products, directly or through potential partners. It will therefore need to recruit staff and expand its capabilities, which could significantly increase its managerial, operating, financing, and other resources. To remain competitive and control its growth, the Company would have to:

- train, motivate, and retain a growing number of employees;

- forecast with precision the demand for its products and the revenue that they may be capable of generating; and
- increase the size of its existing operating, computer, and financial and management systems.

The inability to manage its growth effectively could harm the Company's business and prospects.

### **3.5 Risks Relating To The Company's Intellectual Property Rights**

#### **3.5.1 If the Company is unable to maintain or protect its intellectual property rights, it could lose its competitive advantage and be unable to operate profitably.**

The Company's rights under existing agreements, some of which give it access to future products and proprietary processes belonging to third parties (such as its rights to various patents targeting the W-ENV envelope protein under its agreement with bioMérieux-INSERM) or jointly owned with third parties (such as its rights to the HERV-K patent targeting the -K Env envelope protein under its agreement with the NINDS/NIH) could expire or be terminated. In addition, it might not be able to obtain licenses to other rights which it might need. If it is unable to secure such rights or licenses, or to preserve them, it will have to search for other alternatives or develop the necessary products itself so as to avoid infringing patents or technology rights belonging to third parties. It is possible that such alternatives would not exist or that this could cause a significant increase in costs as well as development time for its products.

It is important to the success of its business that the Company, as well as the licensor and any future licensees, be able to obtain, maintain, and enforce its patent and other intellectual property rights in Europe, the United States, and other countries. It cannot be ruled out that:

- the Company may fail to develop new inventions that are patentable;
- patent applications that are being reviewed, including certain important patents in several jurisdictions, are not granted;
- the patents granted or licenses 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 is not sufficient to protect the Company from competition; or
- 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.

The grant of a patent does not guarantee its validity or scope, and third parties may challenge both aspects. The validity and scope of a patent in the area of biotechnology are highly uncertain and raise complex legal and scientific questions. Until now, no uniform policy has emerged at a worldwide level in terms of the content of patents granted in the area of biotechnology and the scope of individual claims. Legal action may be necessary to enforce the Company's intellectual property rights, protect its trade secrets, or determine the validity and scope of its intellectual property rights. Any dispute could entail considerable expense, reduce profits, and not provide the protection sought. The Company's competitors could successfully challenge in court or through other proceedings the patents the Company has been granted or has had licensed to it, which could have the consequence of reducing the scope of its patents. In addition, such patents could be infringed or successfully avoided as a result of innovations.

#### **3.5.2 The Company's products and technologies could infringe or be claimed to infringe patents and patent applications held or controlled by third parties.**

The Company's products and technologies could infringe or be claimed to infringe patents and patent applications held or controlled by third parties. The Company's success depends on its ability to avoid the infringement or misuse of patents or other intellectual property rights of third parties. The growth of biotechnology and the increase in the number of patents granted in the field increase the risk that third parties will take the position that the Company's products and technologies, including its processes, infringe their patents. In general, a patent application is not published until 18 months after the priority date of the application. In the United States, some patent applications are not published prior to issuance of the patent itself and may be granted on the basis of the date of invention, which does not always result in the issuance of a patent to the party that was the first to file the application. Discoveries or patent applications are made sometimes only months or often even years after the discovery. For this reason, the Company cannot be certain that third parties have not been the first to invent products or file patent applications for inventions covered by its own patent applications or those of its partners. In such cases, the Company could need to obtain licenses to such third-party patents (licenses which it might not be able to obtain on reasonable terms and conditions, if at all), terminate the production and sale of certain product lines, or develop alternative technologies.

In addition, the Company uses antibodies and cells that are available on the market to manufacture certain products, and the use of such antibodies and cells could infringe third-party rights, in which case the Company could be obligated to acquire a license to such rights (a license that it may not be able to obtain on reasonable terms and conditions, if at all), become involved in costly litigation, or stop using such antibodies or cells.

Any litigation or claim brought against the Company, regardless of the outcome, could involve substantial costs and compromise its reputation. Some of the Company's competitors have greater resources than the Company and could be in a better position to bear the cost of complex proceedings. Any dispute of this type could seriously affect the Company's ability to continue in business. More specifically, intellectual property disputes could force the Company to:

- stop selling or using one or more of its products that depend on the challenged intellectual property rights, which could reduce revenue;
- obtain a license from the holder of intellectual property rights deemed infringed, a license that it may not be able to obtain on reasonable terms and conditions, if at all; and
- redesign or, in the event of claims relating to trademarks, rename its products to avoid violating intellectual property rights of third parties. This may not prove to be possible or, in any event, given the time and financial resources that would have to be dedicated to doing so, it may prove to be too costly and, as a result, it could disrupt the Company's sales and marketing efforts.

**3.5.3** If the Company does not comply with its obligations under the license agreements with bioMérieux or the NINDS/NIH, it could lose rights that are very important for its business.

If the Company does not comply with its obligations under the license agreement with bioMérieux or under the license agreement with the NINDS/NIH, it could lose rights that are very important for its business. The Company's business depends on a license agreement to use various significant patents relating to temelimab that was granted to the Company by bioMérieux and INSERM, and on a license agreement to use the first HERV-K patent that was granted to the Company by the NINDS/NIH. The patent licenses granted to the Company may be revoked if the Company does not comply with various terms and conditions set forth therein (in particular, milestone and other payments). To comply with such conditions, the Company could be required to increase the resources dedicated to development projects contemplated by such licenses. Such license agreements also include provisions with which the licensor must comply. Among other things, the Company is counting on its licensor to prosecute any infringement of the licensed patents by third parties. The Company can, however, give no assurance that its licensor is or will be willing to undertake such proceedings.

**3.5.4** The Company's business could be affected if it is unable to protect the confidentiality of its information and know-how.

The Company's business could also be affected if it is unable to protect the confidentiality of its information and know-how. The Company provides information and materials from time to time to researchers at academic institutions as well as other public or private entities (including CMO manufacturers) with which it seeks to have various tests or clinical trials conducted.

In both cases, the Company relies on the execution of confidentiality agreements. Its business also depends on non-patented proprietary technology, processes, know-how, and data that it treats as trade secrets and that it protects, in part, through confidentiality agreements with its employees, consultants, and various subcontractors. These agreements and other means of protecting trade secrets may not provide the protection sought or may be violated, the Company may not have effective recourse against such violations, or its trade secrets may be disclosed to its competitors or developed independently by them.



## **CHAPTER 4.** **INFORMATION ABOUT THE COMPANY AND THE GROUP**

### **4.1 History And Development Of The Company And The Group**

#### **4.1.1 Legal and commercial name of the Company**

Company legal name: GeNeuro SA  
Company commercial name: GeNeuro

#### **4.1.2 Place and number of registration and legal identity identifier (LEI)**

The Company is registered at the *Registre du commerce* (commercial register) of Geneva, Switzerland, under number CHE-112.754,833. The legal entity identifier (LEI) of GeNeuro is 213800FUJCKXO9LK3444.

#### **4.1.3 Date of incorporation and length of life**

The Company was incorporated on February 6, 2006 for an indefinite term.

#### **4.1.4 Registered/principal office, legal form and applicable law**

Registered/principal office: 3 chemin du Pré-Fleuri, CH-1228 Plan-les-Ouates, Switzerland  
Telephone: +41 22 552 4800  
Electronic address: [contact@geneuro.com](mailto:contact@geneuro.com)  
Web page: [www.geneuro.com](http://www.geneuro.com)

The Company is a *société anonyme* (company limited by shares) organized under Swiss law and governed by its Articles of Association and, in particular, Title XXVI of the Swiss Code of Obligations.

#### **4.1.5 Major events in the development of the Company's and the Group's business**

**2024** On March 18, 2024, GeNeuro held an extraordinary shareholders' meeting at which two new directors were elected and at which the capital band and conditional capital were increased to give the Company additional funding flexibility following the February 2024 capital increase.

On February 2, 2024, GeNeuro announced the successful completion of a €5 million capital increase with cancellation of the preferential subscription rights through an international private placement reserved for specialized or strategic investors of (the "Private Placement") 4,666,901 new ordinary bearer shares of GeNeuro and through a public offering for retail investors in France via the PrimaryBid platform (the "PrimaryBid Offer", and together with the Private Placement, the "Offering") of 95,004 new ordinary bearer shares of GeNeuro. All new ordinary shares have a par value of CHF 0.05 each (the "New Shares").

The New Shares have been offered at a price of €1.05 each, including nominal value and issue premium (the "Subscription Price"). In connection with the Private Placement, GNEH SAS ("GNEH"), a subsidiary of Institut Mérieux and Servier ("Servier"), which are existing shareholders of GeNeuro, have subscribed to 2,087,451 and 1,135,070 New Shares, respectively, in cash. In accordance with applicable Swiss laws and regulations, the GNEH representative on the Board of directors of the Company did not vote on board of directors' decisions relating to the Offering. As a result, following the Offering, GNEH owns 40.2% of the share capital and 40.5% of the voting rights of the Company on a non-diluted basis and Servier owns 8.4% of the share capital and 8.5% of the voting rights of the Company on a non-diluted basis.

The proceeds of the Offering, combined with the Company's existing cash, are intended primarily to complete the financing for the ongoing Phase 2 trial in Post-COVID, with results expected in June 2024, and extend the company's runway into mid third quarter 2024. The funds would also be used to finance the Company's general corporate needs. In parallel to the post-COVID program, GeNeuro continues its discussions in the multiple sclerosis area with potential partners to define the best development path for combining an effective anti-inflammatory treatment, to treat relapses, with temelimab, to address neurodegeneration and disability progression.

The New Shares issued represent 19% of the Company's share capital prior to the Offering on a non-diluted basis and 16% of the Company's share capital after the Offering.

The Subscription Price of €1.05 per New Share represented a discount of 16.7% on the closing market price of the Company's shares on Euronext Paris on the last trading day preceding the closing date of the Offering, i.e. €1.26 on January 31, 2024.

Based on the information available to the Company, the breakdown of the Company's share capital and voting rights before and after the Offering is as follows:

	Ownership and voting rights before the Offering		Ownership and voting rights after the Offering	
	Number of shares and voting rights	% of the share capital and voting rights	Number of shares and voting rights	% of share capital and voting rights
GNEH SAS <sup>(1)</sup>	9,886,195	39.55%	11,973,646	40.23%
Eclosion2 & Cie SCPC	6,228,041	24.91%	6,228,041	20.93%
Citigroup Global Markets Limited	2,139,917	8.56%	2,139,917	7.19%
Servier International BV	1,365,659	5.46%	2,500,729	8.40%
<b>Total institutional investors</b>	<b>19,619,812</b>	<b>78.48%</b>	<b>22,842,333</b>	<b>76.75%</b>
<b>Total employees and directors</b>	<b>149,000</b>	<b>0.60%</b>	<b>149,000</b>	<b>0.50%</b>
Treasury shares <sup>(2)</sup>	164,739	0.66%	164,739	0.55%
Free Float	5,065,477	20.26%	6,604,861	22.19%
<b>TOTAL</b>	<b>24,999,028</b>	<b>100.00%</b>	<b>29,760,933</b>	<b>100%</b>

(1) A subsidiary of Institut Mérieux

(2) Shares held in treasury have their voting rights suspended in accordance with Swiss law

On January 5, 2024, the Company announced the appointment of Anke Post, MD, PhD as Chief Medical Officer, effective immediately, as David Leppert, MD, took retirement.

**2023** On December 11, 2023, the Company announced that, based on the planned interim analysis of efficacy and safety data, which included an analysis for futility, the Independent Data Monitoring Committee Board IDMC recommended to "continue the trial without any modifications. The IDMC was established to perform independent, periodic assessments of safety data generated during the conduct of the GNC-501 Trial.

On November 28, 2023, the Company announced that it had completed the recruitment of the GNC-501 Trial, with a total of 203 patients being randomized, and confirmed the timeline for topline results for the end of June 2024.

On October 19, 2023, the Company announced a collaboration with Verily, an Alphabet precision health technology company, to investigate biomarkers related to activation of the proinflammatory HERV-W envelope protein (W-ENV) in SARS-CoV-2 infection.

On September 29, 2023, the Company reported its half-year financial results for the period ended June 30, 2023 and provided a corporate update.

On September 27, 2023, the Company announced the publication in the journal "Proceedings of the National Academy of Sciences of the United States of America" (PNAS) of a study resulting from a collaboration between the Heinrich-Heine University in Düsseldorf, research teams from the Universities of Zürich and Bern with GeNeuro, which confirms that the expression of the HERV-W Env protein (W-Env) causes a neurodegenerative environment, through the fostering of demyelination and the reduction of remyelination, which may explain the long-term neurodegeneration suffered by MS patients.

On June 15, 2023, the Company announced that its shareholders have approved all resolutions proposed at its Annual General Meeting (AGM) of June 14, 2023.

On May 3, 2023, the Company announced the publication in the leading open science journal iScience from "Cell Press" of the new results from the collaboration between GeNeuro and the CIRI, Centre

International de Recherche en Infectiologie, in Lyon, France, on the link between SARS-CoV-2 and the pathogenic HERV-W proinflammatory envelope protein (W-ENV).

On April 15, 2023, the Company reported its full-year results for the year ended December 31, 2022, and provided a corporate update in which it updated the expected timeline for the first results from the Post-COVID study to be available between 1Q and 2Q 2024.

On March 7, 2023, GeNeuro announced the signature of a credit agreement for a total amount of up to €25 million with the European Investment Bank ("EIB"), supported by the InvestEU programme, from which a first Tranche A of €7 million was drawn immediately.

**2022** On November 16, 2022, GeNeuro announced the recruitment of first patients in its Phase 2 trial evaluating temelimab against Post-COVID at the Geneva University Hospitals post-COVID clinic (lead centre), as well as in all the other Swiss clinical centres participating to the study, i.e., Inselspital in Bern, REHAB Basel, Kantonsspital Graubünden in Chur and the Centre Hospitalier du Valais Romand in Sion.

On October 28, 2022, the primary analysis of the Phase 2 ProTEct-MS study was presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2022) Congress in Amsterdam, Netherlands, by Dr. Fredrik Piehl, Professor of Neurology at the Department of Clinical Neurosciences of the Karolinska Institutet, head of research at the MS clinic of the Academic Specialist Center (ASC), and Principal Investigator of the study.

On October 11-14, 2022, GeNeuro unveiled new data further documenting the presence of W-ENV in cohorts of post-COVID patients at the 18th Symposium of the International Society of Neuro Virology (ISNV).

On August 30, 2022, GeNeuro announced the joint publications in the leading scientific journal "Annals of Neurology" of the results of the collaboration between GeNeuro and the National Institute of Neurological Disorders and Stroke (NINDS). NINDS is part of the National Institutes of Health (NIH) of the United States. The two publications describe the novel pathogenic mechanism of HERV-K in sporadic ALS and confirm the rationale for the therapeutic relevance of GeNeuro's antibody to neutralize this neurotoxic protein.

On May 2022, GeNeuro announced the successful completion of a €7.7 million capital increase with cancellation of the preferential subscription rights through an international private placement only to certain qualified and institutional investors of 2,678,251 new ordinary bearer shares of GeNeuro with a par value of CHF 0.05 each.

On May 11, 2022, GeNeuro announced it had received the authorization by the Swiss Health Authority (Swissmedic) to initiate a Phase II study evaluating temelimab in patients with severe neuropsychiatric post-COVID syndromes.

On April 13, 2022, GeNeuro announced the first results of its collaboration with FondaMental Foundation for the development of diagnostic and therapeutic options for patients with Post-COVID neuropsychiatric syndromes. The study showed a strong correlation between SARS-CoV-2 infection, W-ENV protein and markers of innate immunity, in patients with psychiatric disorders, confirming the interest of treating Post-COVID neuropsychiatric syndromes by neutralizing the W-ENV protein with the temelimab antibody. GeNeuro is preparing to launch a phase 2 clinical trial in 200 patients with Post-COVID syndromes and positive for W-ENV.

On March 21, 2022, GeNeuro presented the top-line results from its ProTEct-MS clinical trial, which showed that the primary endpoint of the study was met, with results confirming the excellent safety profile and tolerability of higher doses of temelimab administered concomitantly with a high-efficacy anti-inflammatory drug. In addition, efficacy data, obtained in patients already effectively treated against inflammation, showed that temelimab had a favorable impact on key MRI parameters measuring neurodegeneration.

On January 27, 2022, GeNeuro announced that it had completed its ProTEct-MS clinical trial and confirmed that results from this study would be available by the end of March 2022. The Company also reported its cash position as of December 31, 2021, and provided a business update.

**2021** On December 13, 2021, GeNeuro announced that it was one of the four projects selected by the Swiss Federal Office of Public Health (FOPH) FOPH to benefit from the "Federal Funding Programme for COVID-19 Medicines" and that it would receive for a grant of 6.7 million Swiss francs (€6.4 million) to co-fund a Phase II2 clinical trial to treat patients with long-standing COVID who exhibit neurological and psychiatric ("neuropsychiatric") symptoms.

On September 24, 2021, GeNeuro announced it had entered into a research collaboration with Northwestern University, Chicago, Illinois, USA, to confirm evidence of the expression of human endogenous retrovirus W envelope protein (W-ENV or W-ENV) in long-haul COVID patients, and identify affected patients who may benefit from a treatment with GeNeuro's temelimab.

On July 13, 2021, GeNeuro announced a successful €6.0 million capital increase through an international private placement only to certain qualified and institutional investors (the "2021 Offering").

On July 5, 2021, GeNeuro presented data supporting the pathogenic role of the endogenous retroviral protein W-ENV in Post-COVID neuropsychiatric syndromes, and announced collaborations with the FondaMental Foundation to accelerate the development of diagnostic and therapeutic options for Post-COVID patients.

On June 24, 2021, GeNeuro announced it had renewed its collaboration agreement with the CIRI with an expanded focus to Post-COVID syndromes.

On April 15, 2021, the Company announced recent research data on the detection of W-ENV in COVID-19 patients and linking its expression to disease severity. A publication in the Lancet's EBioMedicine by researchers from the "Tor Vergata" University of Rome, Italy, has shown that the pathogenic envelope protein of the human endogenous retrovirus W (W-ENV) is found on lymphocytes of hospitalized patients with COVID-19, and that its level of expression is associated with disease severity. W-ENV's pro-inflammatory properties are thought to act as an "accelerant" of the activation of the innate immune system, fueling the severity of COVID-19 evolution and impacting long term recovery. In addition, through the parallel effort supported by the ANR, preliminary data generated by GeNeuro and the CIRI in Lyon (International Center for Research in Infectious Diseases), made available on Research Square, also shows W-ENV expression in lymphocytes following in vitro exposure to SARS-CoV-2 in about 20% of healthy blood donors, suggesting individual susceptibility. With W-ENV as a possible aggravating agent of COVID-19, GeNeuro's temelimab, an anti-W-ENV monoclonal antibody already in a Phase II clinical trials with an excellent tolerability and safety, could, without any prejudice to its existing programs, start tests against COVID-19 as early as this summer.

On February 18, 2021, the Company announced the completed patient recruitment in its Phase 2 ProTECT-MS trial of temelimab in MS patients, conducted at the Karolinska Institutet's Academic Specialist Center (ASC), in Stockholm (Sweden).

On January 26, 2021, GeNeuro announced it had received an award from the French national research agency, ANR (Agence Nationale de Recherche), for its COVERI project focused on understanding the role of human endogenous retrovirus (HERV) proteins in the abnormal immune-inflammation or the neurological damages suffered by important subsets of COVID-19 patients.

**2020** On September 14, 2020, GeNeuro presented the rationale and outline of its Phase 2 ProTECT-MS clinical study of temelimab at MSVirtual2020 (8th Joint ACTRIMS-ECTRIMS Meeting).

On July 20, 2020, GeNeuro announced the publication in Science Advances of data establishing a clear link between human endogenous retroviral proteins and psychotic disorders.

On June 25, 2020, the Company announced the recruitment of the first patient in its Phase 2 trial of temelimab in MS at the Karolinska Institutet's Academic Specialist Center (ASC), in Stockholm, Sweden.

On April 21, 2020, the Company announced the nomination, effective May 1, 2020, of its new Chief Medical Officer, Dr. David Leppert, who is a highly experienced medical and industry professional.

On March 19, 2020, the Company announced that it was postponing the launch of its Karolinska Trial to prioritize healthcare resources behind the fight of COVID-19 and to reduce the risk for MS patients.

On January 31, 2020, the Company announced that it had completed a €17.5 million capital increase through a share offering to certain qualified and institutional investors. Its shareholder GNEH SAS participated for €7.5 million in this offering and paid for its new shares by way of set-off with the €7.5 million loan it had granted to the Company in 2019.

**2019** On November 25, 2019, GeNeuro announced an agreement with the Karolinska Institutet / Academic Specialist Center (ASC) of Stockholm to launch a new single center, Phase II clinical study of temelimab in multiple sclerosis. The trial, to be conducted at the Center for Neurology of ASC (which, with approximately 2,400 patients, is the largest MS center in Sweden), will be a one-year study that will enroll, initially, 40 patients whose disability progresses without relapses, and will document the safety and tolerability of temelimab following higher doses, as well as measures of efficacy based on the latest biomarkers associated with disease progression. The study aimed to start enrolling patients in Q1 2020

with last patient out and top line results expected in H2 2021; however, due to the COVID-19 crisis, the Company announced on March 19, 2020, that it was temporarily postponing this trial to prioritize healthcare resources behind the fight of COVID-19 and to reduce the risk for MS patients. Assuming recruitment can be completed by the end of 2020, the Company expects that results would still be communicated in H2 2021.

On September 16, 2019, GeNeuro presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2019) Congress in Stockholm, Sweden the full results of the Phase II CHANGE-MS trial and ANGEL-MS extension trial in relapsing-remitting MS (RRMS), which confirmed that the neuroprotective effects of temelimab in MS patients extend to 96 weeks and that temelimab is safe to use and well tolerated for a prolonged period.

In June 2019, GeNeuro announced that data supporting the mode of action of its lead product (temelimab) in treating MS was published in the Proceedings of the National Academy of Sciences (PNAS). Temelimab is a monoclonal antibody designed to neutralize a pathogenic, viral envelope protein, W-ENV, which plays a causal role in the development of MS. The PNAS paper, entitled “W-ENVELOPE protein fuels microglial cell-dependent damage of myelinated axons in multiple sclerosis”, demonstrates that axonal injury in MS can be significantly driven by W-ENV through activation of microglia and this contributes to neurodegeneration, particularly in progressive forms of MS. In addition to the already published data demonstrating that W-ENV may directly inhibit remyelination, these data provide additional neurobiological rationale for the results from recently completed CHANGE-MS and ANGEL-MS Phase IIb trials. In these studies, performed in patients with relapsing remitting MS, temelimab showed consistent neuroprotective effects on MRI measures known to be associated with disability progression in MS, through neutralization of W-ENV.

On May 7, 2019, the Company announced that a six-month extension of its Phase IIa study of temelimab (GNbAC1) in T1D confirmed all previously-observed positive observations in the trial, meeting its primary objective. GeNeuro believes these data open the door to further development in early-onset T1D pediatric patient population.

On March 12, 2019, the Company announced positive results from the ANGEL-MS study of its lead product, temelimab (GNbAC1), in MS. The ANGEL-MS data confirmed that treatment with temelimab for 2 years (96 weeks) had a continued, positive impact on key MRI measures of disease progression in multiple sclerosis patients, confirming and extending the data reported at Week 48 in the CHANGE-MS Phase IIb study. This includes reductions in brain atrophy, particularly in the cortex and thalamus, and maintenance in myelin integrity, as measured by magnetization transfer ratio (MTR) imaging. Importantly, for the first time, encouraging dose-dependent effects were seen on clinical measures of disease progression. This has been evidenced by a lower proportion of patients with 12-week confirmed EDSS progression, or with 20% worsening in 25-foot timed walk.

In January 2019, GeNeuro announced positive safety and tolerability results from a Phase 1 study assessing the administration of high doses of temelimab (GNbAC1) to treat MS and other auto-immune diseases. These results suggest that higher dose regimens or a front-loading could be evaluated in a future next clinical study of temelimab in MS and other potential therapeutic indications.

**2018** In December 2018, the Company signed a financing agreement with GNEH SAS, a subsidiary of Institut Mérieux, to establish a €7.5 million credit line, allowing it to extend the Company’s runway with all ongoing programs until Q3 2020.

On October 17, the Company announced that following a successful collaboration in preclinical amyotrophic lateral sclerosis (ALS) models, GeNeuro has signed an exclusive worldwide license with the National Institute of Neurological Disorders and Stroke (NINDS), part of the U.S. National Institutes of Health (NIH). The agreement covers the development of an antibody program to block the activity of pHERV-K Env (pathogenic envelope protein of the HERV-K family of Human Endogenous Retroviruses), a potential key factor in the development of ALS.

On October 11, the Company presented at ECTRIMS 2018 in Berlin the results from its 48-week CHANGE-MS Phase IIb clinical trial in the MS indication, confirming a robust and coherent impact on the key MRI markers associated with disease progression. Moreover, the benefits have also been observed in patients with lower inflammatory burden, which are not served by existing anti-inflammatory treatments.

On September 26, the Company released the six-month results from the RAINBOW-T1D Phase IIa clinical trial of temelimab in the T1D indication. The data showed that the study met the primary endpoint, with temelimab showing an excellent safety and tolerability profile in T1D patients; some encouraging signals were observed, such as a 32% reduction in the total number of hypoglycemic episodes in the treated group versus placebo ( $p < 0.0001$ ), and a 21% decrease of anti-insulin antibodies in the treatment group, versus an increase of 23% in the placebo group ( $p < 0.01$ ). But given the low occurrence of events in this well-controlled population and the small size of the Phase IIa cohort, these signals require confirmation at Week 48, as well as through investigation in larger populations with a more recent onset.

On September 17, Servier, based on R&D strategic reasons and its international development priorities, decided to decline the option to license temelimab in MS and to return worldwide rights ex US and Japan for temelimab in MS. Should Servier have had exercised its option, it would have had to finance the global development of temelimab, including in the USA and Japan. As a result, GeNeuro engaged in new partnership discussions for its lead MS program. Following this notification by Servier, the ANGEL-MS two-year extension study, undertaken at Servier's request and with Servier's funding, was terminated one year before its expected end, with Servier bearing the study's closure costs. This early termination allowed to generate 48-week results for ANGEL-MS, which were presented on March 12, 2019.

In March, the Company released the full results from its 48-week CHANGE-MS Phase IIb clinical trial in the MS indication. The 12-month data of this 270-patient study, conducted in 12 European countries, confirmed that there was a modest effect on most MRI measures of neuroinflammation, with no significant separation between treatment groups. Full study results however showed robust and coherent impact at the highest dose of 18 mg/kg on the key MRI markers associated with disease progression. Moreover, the benefits are also observed in patients with lower inflammatory burden, which are not served by present anti-inflammatory treatments. Safety of temelimab is confirmed.

In February, the Company's temelimab drug received the Orphan Drug Designation from the US FDA for the chronic inflammatory demyelinating polyradiculoneuropathy ("CIDP") indication.

- 2017** Publication of the six-month results from the 48-week CHANGE-MS Phase IIb clinical trial on temelimab. The data showed that temelimab is well tolerated and that there is no statistical difference at 6 months between temelimab and placebo in the study's primary endpoint of reducing the number of cerebral Gad-enhancing lesions as measured by MRI, nor on the other MRI measures of neuroinflammation. Post hoc analyses of 6-month data however showed an anti-inflammatory effect in active patients at the highest (18 mg/kg) of the three doses tested at Week 24. In addition, at the same dose, a promising effect on remyelination was observed at 24 weeks.  
Launch of a Phase IIa clinical trial with temelimab in the Type 1 diabetes indication, with 60 recently diagnosed adult patients, in over 10 centers in Australia. The primary endpoint will be the safety of temelimab in this new patient population.  
The Company entered into a research agreement with the US NIH for developing new approaches against pHERV-K (K-ENV) protein as a target in the treatment of Amyotrophic Lateral Sclerosis (ALS).
- 2016** At the end of December 2016, completion of the recruitment of the 260 patients of the CHANGE-MS Phase IIb clinical trial on temelimab, 4 months ahead of planning. A Data Safety Monitoring Board reviewed the 3-month data for the first 30 patients and confirmed the very good tolerance profile of temelimab. Servier decides to finance a new ANGEL study which will allow patients having taken part in the Phase IIb study to benefit from two additional years of treatment.  
In April 2016, Initial Public Offering on Euronext's regulated market in Paris, coupled with a capital increase, allowing the Company to raise gross proceeds of €33 million.  
Launch of the CHANGE-MS Phase IIb clinical trial on temelimab, contemplating the recruitment of 260 patients initially through 69 clinical centers in 13 European countries. The trial's main endpoint is the cumulative number of brain lesions evidenced by MRI at 6 months, then 12 months together with patients' clinical evaluation.
- 2015** Servier International B.V. (owned 100% by Servier) acquires 8.6% of GeNeuro's outstanding shares through a sale by Eclosion<sup>2</sup> for €15 million on December 11, 2015. Servier exercises its first option under the Collaboration Agreement to finance the Phase IIb trial of temelimab and makes a milestone payment of €17.5 million to GeNeuro.  
GeNeuro conducts a pharmacological study controlled against placebo to confirm the safety and penetration in the central nervous system of high doses of the immunoglobulin temelimab on healthy volunteers in preparation for launching a Phase IIb study.
- 2014** A Collaboration Agreement is signed by GeNeuro, Servier and Institut de recherches internationales Servier for the development of a drug targeting a suspected causal factor of multiple sclerosis.  
Completion of the one-year Phase IIa trial on 10 patients with good results in safety as well as pharmacodynamic effects and the first signs of therapeutic responses in patients.
- 2011** GeNeuro announces the completion of the Phase I clinical trial of temelimab, showing that the product is well tolerated.
- 2010** GeNeuro obtains a favorable opinion from the German committee for scientific regulation, the Paul Ehrlich Institute, on the pre-clinical file for the temelimab monoclonal antibody to treat MS.
- 2009** GeNeuro Innovation, the subsidiary of the Company, is organized in Lyon, France.
- 2008** A capital increase of CHF 12 million is underwritten by Eclosion and Institut Mérieux to broaden GeNeuro's operations and develop its medicines portfolio through clinical trials.



**2006** GeNeuro, a spin-off of French diagnostics company bioMérieux, is founded in Switzerland by Dr. Hervé Perron, Dr. Christophe Mérieux, and Jesús Martin-Garcia, with Ecllosion, a Swiss start-up incubator and long-term investor in biotechnology, and bioMérieux as principal shareholders.

## CHAPTER 5. DESCRIPTION OF THE GROUP'S BUSINESS

### 5.1 General Presentation

GeNeuro is a clinical-stage biopharmaceutical company focused on understanding and stopping causal factors driving the progression of neurodegenerative and autoimmune diseases. GeNeuro's most advanced therapeutic candidate, temelimab, is a humanized monoclonal antibody that neutralizes a pathogenic protein of the HERV-W family ("W-ENV") that has been identified as a potential causal factor in MS and has already completed Phase II clinical trials in this indication with an excellent tolerability and safety profile; in addition, efficacy data, obtained both in naïve patients and in patients already effectively treated against inflammation, showed that temelimab has a favorable impact on key MRI parameters measuring neurodegeneration, indicating a positive effect of temelimab in preserving neocortical anatomy and myelin integrity. The effect sizes in patients treated with highly effective anti-inflammatory treatments were of comparable magnitude to those previously observed in the CHANGE-MS and ANGEL-MS trials in patients without treatment. Furthermore, new exploratory data on soluble biomarkers also showed favorable impact on measures of neurodegeneration, as the study showed a reduction of GFAP biomarkers in cerebrospinal fluid (CSF) at one year. GFAP is a biomarker for astrocytic activation associated with diffuse neuroaxonal damage leading to MS disease progression. The results on CSF biomarkers confirm the synergistic potential to treat neurodegeneration with temelimab in addition to a high-efficacy anti-inflammatory therapy in MS.

GeNeuro has also initiated a program with temelimab in Post-COVID for patients with persistent neuropsychiatric syndromes and launched at the end of 2022 a Phase 2 trial, called GNC-501, that is evaluating the clinical efficacy of a six-month treatment with temelimab on the improvement of cognitive impairment and/or fatigue in Post-COVID patients who are positive for the presence of W-ENV protein in their blood. In observational cohorts, the W-ENV protein was observed in more than 25% of patients with persistent syndromes after having had COVID, as evidenced in a recent publication made available on MedRxiv<sup>6</sup>, whereas real world experience from the GNC-501 trial shows that 36% of all patients who were screened in the study were positive for the presence of W-ENV. This personalized medicine approach could, if the current clinical trial is successful, offer a therapeutic solution to a large and well identified subset of the millions of patients affected by Post-COVID.

GeNeuro's program against Post-COVID is based on the initial discovery by academic collaborators that W-ENV was found on lymphocytes of hospitalized patients with COVID-19, with a level of expression correlated with disease severity. W-ENV's pro-inflammatory properties are thought to act as an "accelerant" of the activation of the innate immune system, fueling the severity of COVID-19 evolution and impacting long term recovery. Published data also shows the expression of W-ENV in lymphocytes following in vitro exposure to SARS-CoV-2 in about 20% of healthy blood donors, suggesting individual susceptibility<sup>7</sup>. Furthermore, data presented in July 2021<sup>8</sup> showed that the neuropsychiatric symptomatology seen in Post-COVID patients may be due to the continued presence of W-ENV expression in these individuals, which may extend long after the acute COVID phase. These data provide a biologic rationale explaining why so many COVID-19 patients develop long-term neurological and psychiatric symptoms long after the initial infection, and open the door for a therapeutic intervention with temelimab targeting W-ENV.

According to recent large-scale studies, more than 10% of people infected by SARS-CoV-2 fail to fully recover and/or develop new symptoms, with a high proportion of neurological and/or psychiatric affections. A recent study published in Nature Reviews Microbiology states that at least 65 million individuals worldwide are estimated to have long COVID, with cases increasing daily<sup>9</sup>. Of note, in more than 90% of the cases the original COVID-19 symptoms were not severe enough to warrant hospitalization. With close to 500 million confirmed COVID-19 cases worldwide, of which more than 225 million in the USA, Canada and Western Europe, Post-COVID is recognized as a major public health emergency affecting millions of persons.

More broadly, GeNeuro is leveraging the potential of HERVs through research and academic partnerships to develop new treatments for poorly understood autoimmune and neurodegenerative diseases, such as the Cooperative Research and Development Agreement ("CRADA") signed in 2017 with the NINDS, part of the NIH, to develop novel therapeutic antibodies for the treatment of ALS. In addition, W-ENV has been identified as a potential causal factor in Type 1 Diabetes, CIDP, a rare autoimmune disorder of the peripheral nervous system and Inflammatory Psychosis, although none of these indications is being pursued presently.

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<sup>6</sup> Source: Charvet et al., April 2023, MedRxiv - <https://doi.org/10.1101/2023.03.31.23288003>

<sup>7</sup> Source: Charvet et al., April 2023, Cell Press - SARS-CoV-2 awakens ancient retroviral genes and the expression of proinflammatory HERV-W envelope protein in COVID-19 patients.

<sup>8</sup> Source: Neuro Sciences Psychiatry and Neurology Days held in Paris, France, on July 1-2, 2021

<sup>9</sup> Source: Davis et al., Nature Reviews Microbiology, January 2023.



### GeNeuro’s novel approach against HERVs

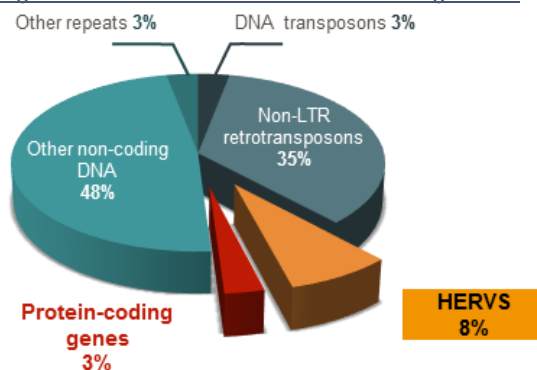
The immune system is a complex set of defense mechanisms that seek to protect the body by identifying and destroying potential threats, including infectious agents. Autoimmune diseases are defined as conditions where the immune system of the patient is activated without known cause, and attacks and damages its own tissues. There are many autoimmune diseases, affecting many organ classes, such as rheumatoid arthritis, juvenile (type 1) diabetes, psoriasis, and multiple sclerosis. Since there is no known cause for autoimmune diseases, treatments in these indications target the immune system of the patient to reduce the damage caused by the immune attack and/or provide relief for the damage inflicted to an organ.

GeNeuro is developing a novel approach against autoimmune and neurodegenerative diseases by trying to block potential causal factors of these disorders. This novel approach is the result of more than 25 years of research on human endogenous retroviruses (“HERV”), 15 of which at Institut Mérieux and INSERM before the creation of GeNeuro in 2006.

HERV DNA, which represents up to 8% of the human genome (see [Figure 1](#) below), has originated from infections by viruses whose DNA was integrated into the human germline during evolution. Since HERV DNA is normally silent, HERVs are generally not expressed. In certain disease settings, however, such as MS, HERV genes can be reactivated, which leads to significant levels of some HERV proteins in affected tissues.<sup>10</sup> In Post-COVID, the International Center for Infectiology Research in Lyon, France (CIRI) has shown that when human peripheral blood mononuclear cells from healthy donors were cultured and exposed to SARS-CoV-2, about 20% of donors responded by expressing W-ENV in lymphocytes, cells in which the virus did not replicate. This expression was triggered specifically by the spike protein of SARS-CoV-2, independently from cytokine release.

These proteins, considered as “self” by the body as encoded by its own cells, may retain some of their original viral properties, which could explain in some disease settings the triggering of the immune system and local toxicity.

*Figure 1 : DNA breakdown of the human genome*



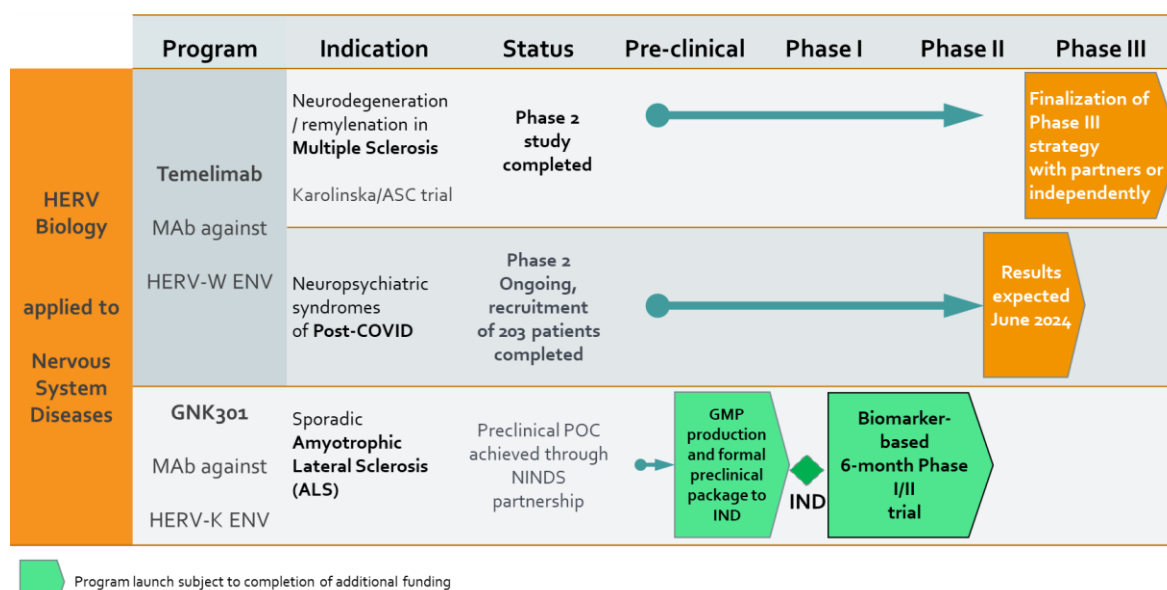
As detailed below, GeNeuro and some leading academic centers have developed and published strong evidence suggesting that the envelope (ENV) protein of the HERV-W family could play a causal role in MS and Post-COVID, as well as in other indications such as Inflammatory Psychosis or T1D. The NINDS, part of the NIH, has also published the potential causal role of the ENV protein of the HERV-K family in ALS, and has confirmed in publications made in *Annals of Neurology*<sup>11</sup> in pre-clinical models of ALS the neurotoxic properties of HERV-K ENV and the therapeutic potential of GeNeuro’s antibody developed to neutralize HERV-K ENV.

And the amount of evidence for the involvement of HERV proteins in poorly understood diseases keeps building up. If these proteins do indeed play a causal role in these pathologies, neutralizing them through therapeutic molecules could, for the first time, allow medicine to have a direct impact on the onset and progression of these diseases. GeNeuro leads the effort of leveraging these promising discoveries into novel and effective treatments for patients, with its research and clinical work currently focused on a number of key indications shown below.

<sup>10</sup> Source: Engel & Hiebert, *Nature Med.* 2010, May; 16(5): 517-8.

<sup>11</sup> Source: Steiner et al, *Annals of Neurology* July 2022; Garcia-Montojo et al., *Annals of Neurology* – July 2022

Figure 2 : GeNeuro development pipeline



NINDS: National Institute of Neurological Disorders and Stroke, part of the United States National Institutes of Health  
 IND : Investigational New Drug      HERV : Human endogenous retroviruses

### Multiple Sclerosis

MS is a long-term, degenerative disease that affects the central nervous system (consisting of the brain and spinal cord) in which the immune system attacks the myelin sheath that protects nerve fibers and is characterized by neuroinflammation and neurodegeneration. Without the protection of myelin, nerves lose functionality, become damaged and are ultimately destroyed, which leads to the formation of scar tissue (sclerosis). In 85% of the cases at the original diagnosis, MS presents itself in a form called relapsing-remitting MS (RRMS), which will usually degenerate over time into a more aggressive form of the disease: the secondary progressive form (SPMS) during which the loss of neuronal function increases. Approximately 15%<sup>12</sup> of patients present from the outset with a progressive form of the disease called primary progressive MS (PPMS). There is currently no cure for MS, and no treatment presently available has shown a determining impact on the progression of long-term disability resulting from the disease. Present treatments work by reducing the number of relapses, speeding recovery from attacks, and managing the symptoms of the disease, and are approved for the relapsing-remitting forms of MS (which include the “active secondary progressive” form, which the FDA<sup>13</sup> has defined as one of the relapsing forms of MS). In fact, based on the recent definition by the FDA<sup>14</sup>, it is even possible to split MS patients in two broad categories: patients with inflammatory relapses (or “active inflammatory” patients), and patients with progression of their disability without inflammatory relapses (“non-active progressive” patients).

Sales of medications for the treatment of MS in 2022 have been estimated at USD 20.5 billion<sup>15</sup>. All presently approved medications target the adaptive immune system of the patient by altering or suppressing the functions of the patient’s adaptive immune system in order to reduce the number of relapses. The reduction in the number of relapses in the RRMS form, however, has shown to have little or no long-term impact on the progression of disability<sup>16</sup>. Treating all forms of MS with safe and effective medications able to stop the chronic neurodegeneration leading to the build-up of disability remains a huge unmet medical need in MS.

In MS, W-ENV has been identified as a potential key factor fueling the inflammatory and neurodegenerative components of the disease in all its forms, most recently in a publication in the Proceedings of the National Academy of Science<sup>17</sup>. The Company believes that temelimab is the first treatment against a suspected causal factor of neurodegeneration in MS, and, as such, temelimab has the potential to offer a safe and effective treatment which could slow or even stop disability progression in all major forms of MS.

GeNeuro initiated in early 2016 a 48-week, multicentric Phase IIb double-blind placebo-controlled study called “CHANGE-MS” to test its temelimab drug candidate in 270 patients in 50 clinical centers and 12 countries in Europe.

<sup>12</sup> Source: United States National MS society  
<sup>13</sup> FDA Press release on Siponimod approval, March 26, 2019  
<sup>14</sup> ibid  
<sup>15</sup> Source: 2022 annual reports of companies active in this field  
<sup>16</sup> Source: Ebers et al.: study of 730 patents over a period of 28 years  
<sup>17</sup> Source: Kremer, Gruchot et al., PNAS, May 2019

Three doses were tested: 6 mg/kg, 12 mg/kg and 18 mg/kg, via intravenous injections every 4 weeks. The Company presented 24-week results (including the study's primary endpoint) in August and October 2017, as well as full 48-week results in March 2018.

Whilst the CHANGE-MS study confirmed the safety profile of temelimab, the primary outcome at 24 weeks, which measured inflammation through the reduction of the cumulative number of Gd+ lesions<sup>18</sup>, did not reach statistical significance. This could be due to the mode of action of the drug, which neutralizes a pathogenic factor but does not have an immediate impact on active adaptive immunity cells. However, at CHANGE-MS completion at 48 weeks, data showed that temelimab administration had a significant, consistent positive impact on key neuroprotection markers known to be linked to disability progression, such as reduction of brain atrophy, reduction of the number of chronic black holes (permanent tissue damage) and stabilization of MTR values (a measure of myelin integrity). At the ECTRIMS congress in Berlin in October 2018, the Company presented further analysis of the CHANGE-MS 48-week results that showed that the neuroprotective effects of temelimab were comparable in the active and inactive subpopulations, i.e., with or without new inflammatory lesions, suggesting a mode of action specific to neurodegeneration.

The patients who had completed CHANGE-MS were offered to continue treatment with temelimab in an extension study called ANGEL-MS. 95% of these patients chose to continue treatment, or a total of 219 patients. At the time the study was interrupted, when Servier stepped out of its former partnership with GeNeuro, 154 patients had already completed 96 weeks of treatment (including the 48 weeks of CHANGE-MS), and over 90% had over 86 weeks of treatment, providing a solid basis for evaluating the effect of longer treatment with temelimab.

The topline results of ANGEL-MS after a total of 96-weeks<sup>19</sup> of treatment were presented on March 12, 2019. These results showed a continued, positive impact on key MRI measures of neurodegeneration in multiple sclerosis patients, confirming and extending the data reported at Week 48 in the CHANGE-MS Phase IIb study. This includes reductions in brain atrophy, particularly in the cortex and thalamus, and maintenance of myelin integrity, as measured by magnetization transfer ratio ("MTR") imaging, a surrogate measure of remyelination. Importantly, for the first time, encouraging dose-dependent effects were seen on clinical measures of disease progression. This has been evidenced by a lower proportion of patients with 12-week confirmed EDSS progression, or with 20% worsening in 25-foot timed walk. At the same time, ANGEL-MS confirmed that temelimab had only a modest effect on neuroinflammation, as evidenced by a non-significant reduction in the number of T2 lesions. As a result, the positive results observed suggest that the effect of temelimab is not mediated by inflammation but rather by a specific effect reducing neurodegeneration, which is highly encouraging as temelimab which is the clear unmet need in MS. The CHANGE-MS and ANGEL-MS results also provide the first evidence of the effect from neutralizing a pathogenic HERV protein in an autoimmune disease, opening the way to multiple applications in other autoimmune and neurodegenerative diseases. For a more detailed review of the results, please refer to sections 5.2.1.2 and 5.2.2.1 of the Universal Registration Document.

In 2020, GeNeuro launched a new single center Phase II clinical study of temelimab in multiple sclerosis at the Karolinska Institutet / Academic Specialist Center (ASC) of Stockholm, which, with approximately 2,400 patients, is the largest MS center in Sweden. The one-year trial enrolled 41 patients whose disability progressed without relapses as they were previously treated with an anti-CD20 antibody, a high efficacy anti-inflammatory drug. On October 27, 2022, GeNeuro presented the primary analysis of the Phase 2 ProTECT-MS study at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2022) Congress in Amsterdam, Netherlands:

- The primary endpoint of the ProTECT-MS study was met, with results confirming the excellent safety profile and tolerability of higher doses of temelimab administered concomitantly with an anti-CD20 treatment. The drug was well tolerated with no treatment related discontinuations, no serious or severe treatment emergent adverse events, and no differences in overall clinical or laboratory safety findings, which meets the primary endpoint of the study.
- Efficacy data, obtained in this patient group already effectively treated against inflammation, showed that temelimab has a favorable impact on key MRI parameters measuring neurodegeneration, as temelimab showed a positive effect in preserving neocortical anatomy and myelin integrity. The effect sizes were of comparable magnitude to those previously observed in the prior CHANGE-MS and ANGEL-MS trials in patients without an anti-inflammatory treatment.
- New exploratory data on soluble biomarkers also showed favorable impact on measures of neurodegeneration at one year: the study showed a reduction of GFAP biomarkers in cerebrospinal fluid (CSF). GFAP is a biomarker for astrocytic activation associated with diffuse neuroaxonal damage leading to MS disease progression. The results on these CSF biomarkers confirm the synergistic potential to treat neurodegeneration with temelimab in addition to a high-efficacy anti-inflammatory therapy in MS.
- The analysis of the data also allows GeNeuro to determine the optimal dose for future temelimab trials in MS, in conjunction with potential partners.

<sup>18</sup> Gd+: gadolinium-enhancing lesions, as measured by MRI

<sup>19</sup> 48 weeks of CHANGE-MS + 48 weeks of ANGEL-MS

Based on the results of CHANGE-MS, ANGEL-MS and ProTEct-MS showing the impact of temelimab on MRI measures and soluble biomarkers associated with disease progression, the Company has defined its development path forward for temelimab in MS as targeting the key unmet medical need in MS: curbing the progression of disability.

GeNeuro is therefore focusing on neurodegeneration and disease progression, which could be as a monotherapy for “non-active”<sup>20</sup> progressive patients, or, more likely, as an adjunctive therapy for remitting patients in combination with existing immunomodulatory drugs addressing neuroinflammation, such paths being non-exclusive.

Following the announcement of the Karolinska Trial’s results, GeNeuro has resumed discussions with potential partners to define the best development path combining temelimab and anti-inflammatory treatments to treat relapses and disability progression, the key unmet medical need in MS. Given the high costs of the international clinical trials necessary to confirm efficacy and register a product in MS with both the FDA and the EMA, which the Company estimates would exceed €100 million, continued development in MS requires a partnership.

### **Post-COVID**

COVID-19 was the most severe global pandemic since the influenza pandemic of 1918. As of April 19, 2023, according to the World Health Organization (WHO) there have been more than 750 million confirmed cases and almost 7 million global deaths from COVID-19. Three years after the onset of this pandemic, although the majority of patients infected with SARS-CoV-2 recover within a few weeks, “Post-COVID” is estimated to occur in 10–20% of cases and affects people of all ages, including children, with most cases occurring in patients with mild acute illness<sup>21</sup>. The consequence is widespread global harm to people’s health, wellbeing, and livelihoods—an estimated one in ten people who develop long COVID stop working, resulting in an extensive social and economic burden.

Current knowledge about this condition, known as post-COVID-19, PASC (Post Acute Sequelae of COVID-19), or “Post-COVID”, as well as about COVID-19 itself, is as recent as these conditions and continues to evolve daily.

Post-COVID collectively refers to the constellation of perduring symptoms that some patients experience after contracting COVID-19. To estimate the prevalence and burden of this syndrome, Santé publique France conducted an initial study on a large sample of the general adult population, the results of which showed that 30% of people who had been infected with SARS-CoV-2 subsequently presented the criteria for “long COVID”. On the scale of the French population, the “post-COVID-19 condition” would thus concern 2 million people over the age of 18. In parallel, large-scale academic studies indicate that up to 10% of people infected with SARS-CoV-2 do not fully recover and/or develop new symptoms, with a high proportion of neurological and/or psychiatric disorders. A January 2023 publication in Nature Reviews Microbiology<sup>22</sup> thus estimates that at least 65 million people worldwide now suffer from Post-COVID.

In 2021, results published in the Lancet journal EBioMedicine<sup>23</sup> showed the presence of the W-ENV protein on lymphocytes of hospitalized patients with COVID-19. These same results indicate a correlation between the level of expression of the protein and the severity of the disease. In addition, recent data showed that SARS-CoV-2 was able to induce in vitro expression of W-ENV in human blood cells from approximately 20% of healthy volunteers<sup>24</sup>. The expression of the pathogenic W-ENV protein triggered by SARS-CoV-2 infection can continue long after the resolution of the acute phase and may play a major role in the persistence of neurological and psychiatric syndromes in many Post-COVID patients.

Studies conducted on cohorts of several hundred European and American Post-COVID patients have detected the presence of the W-ENV protein in over 25% of these patients<sup>25</sup>, whereas in the GNC-501 clinical trial 36% of the patients presenting long-COVID syndromes who were screened were positive to the presence of W-ENV in their blood.

W-ENV is found in specific disease situations, and its presence is always tied to negative disease outcomes for the patient. The pro-inflammatory effects of W-ENV are mediated through the activation of the TLR4 innate immune receptor, a pathway closely associated with some of the key features of COVID-19, such as hyper-activation of innate immunity, endothelial cell activation, vasculitis as well as coagulopathy. W-ENV has mostly been studied in neurodegenerative diseases, with widely observed pathogenic effects on peripheral and central nervous system cells. After the primary SARS-CoV-2 infection is over, if W-ENV has reached a self-fueling expression level, it could

<sup>20</sup> Defined as MS patients experiencing progression of disability independent of the relapse activity

<sup>21</sup> Source: The Lancet, March 2023 - [https://doi.org/10.1016/S0140-6736\(23\)00493-2](https://doi.org/10.1016/S0140-6736(23)00493-2)

<sup>22</sup> Source: Davis et al., Nature Reviews Microbiology, January 2023.

<sup>23</sup> Source: Balestrieri et al., Lancet eBioMedicine, April 2021

<sup>24</sup> Source: Charvet et al., April 2023, Cell Press - SARS-CoV-2 awakens ancient retroviral genes and the expression of proinflammatory HERV-W envelope protein in COVID-19 patients.

<sup>25</sup> Source: Charvet, Koralnik, Perron et al.: Blood biomarkers-defined subgroups show heterogeneity in post-acute COVID-19 syndrome: a rationale for precision medicine - <https://doi.org/10.1101/2023.03.31.23288003>



cause persistent damage to endothelial cells in blood vessels and also to cells from the peripheral and central nervous system, which could explain many of the long-term neurological and psychiatric symptoms experienced by patients long after SARS-CoV-2 infection.

GeNeuro is at the forefront of addressing this issue with the first personalized medicine clinical trial against Post-COVID, evaluating temelimab as a disease-modifying therapy in Post-COVID patients who are positive for the pathogenic protein W-ENV in their blood.

Temelimab has already been approved in Switzerland, Italy, Spain and the United Kingdom to conduct Phase 2 clinical trials to evaluate the efficacy and safety of this treatment in patients with cognitive impairment ("brain fog") and severe fatigue and in whom the presence of W-ENV protein in the blood can be confirmed by a serum test.

The GNC-501 study, entitled "Temelimab as a Disease Modifying Therapy in Patients with Neurological, Neuropsychological, and Psychiatric Symptoms in Post-COVID-19 or Post-Acute Sequelae of COVID-19 (PASC) Syndrome", has now enrolled 203 patients from Italian, Spanish and Swiss clinical centers. The study has enrolled only those patients who also test positive for the pathogenic protein W-ENV, as the basis of a personalized medicine approach. Topline results are planned for June 2024.

## **ALS**

The scientific corpus supporting the involvement of HERVs in poorly understood diseases is growing, and GeNeuro is working with leading research centers in the United States and Europe to apply this technology to the treatment of other human diseases where HERVs could also be playing a key role and which are still incurable, such as amyotrophic lateral sclerosis ("**ALS**"), which is a motor neuron disease. "Sporadic" or non-inherited ALS, accounts for roughly 90% percent of cases, and 10% of cases are due to known genetic mutations<sup>26</sup>. The sporadic form affects approximately 10,000 new patients per year in the US and EU, with a poor prognosis of survival. GeNeuro entered into a Cooperative Research And Development Agreement with the US National Institutes of Health in February 2017 to advance research in the link between HERVs and ALS. This collaboration resulted in joint-intellectual property on a novel antibody able to neutralize the pathogenic effects on the pathogenic envelope protein in of the HERV-K family, which has been shown to be present in the CSF of sporadic ALS patients and cause the death of motor neurons. GeNeuro signed in October 2018 an exclusive worldwide license with the National Institute of Neurological Disorders and Stroke (NINDS), part of the U.S. National Institutes of Health (NIH) on the jointly owned intellectual property. The agreement covers the development of an antibody program to block the activity of the pathogenic envelope protein of the K family of Human Endogenous Retroviruses (HERV-K ENV, simplified as "K-ENV").

In August 2022, GeNeuro and the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH) of the United States, announced the joint publication in the leading scientific journal "Annals of Neurology" of the results of their collaboration. The two publications<sup>27 28</sup> describe the novel pathogenic mechanism of HERV-K in sporadic ALS and confirm the rationale for the therapeutic relevance of GeNeuro's antibody to neutralize this neurotoxic protein.

GeNeuro continues to work with NINDS to define the optimal path for the clinical development of the antibody. GeNeuro has completed the characterization and selection of humanized antibody now identified as GNK301. The first non-GMP batches of the antibody have been produced, and are now used in preclinical studies to ascertain the route of administration for clinical trials., The Company continues to seek partnerships to fund this development.

### **Possible commercialization and marketing timelines**

GeNeuro estimates that the potential sale of its lead product candidate, temelimab for MS or Post-COVID, could, considering its development schedule, the receipt of regulatory authorizations and the commercialization and marketing of its product candidate, commence between 2025 and 2027, subject to the success of one or several Phase III trials, the absence of any event delaying the proper conduct of the trials, and the absence of other events that the Company is currently unable to identify or anticipate.

#### **5.1.1 Competitive Advantages**

GeNeuro's competitive strengths are rooted in its novel approach against autoimmune and neurodegenerative diseases, supported by strong IP and an experienced executive team with a strong track record.

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<sup>26</sup> Source : NIH Amyotrophic Lateral Sclerosis (ALS) Fact Sheet.

<sup>27</sup> Source: Human Endogenous Retrovirus K Envelope in Spinal Fluid of Amyotrophic Lateral Sclerosis Is Toxic, J. Steiner et al., Annals of Neurology, July 2022

<sup>28</sup> Source: Antibody response to HML-2 may be protective in Amyotrophic Lateral Sclerosis, M. Garcia-Montojo et al., Annals of Neurology, July 2022

- **Temelimab has demonstrated its potential to offer a therapeutic option of great value for patients suffering from MS.** No presently available treatment has demonstrated a major impact on the progression of long-term disability for any form of MS. By blocking upstream a potential key factor present in all types of MS that fuels neurodegeneration, temelimab may provide a safe and effective treatment to serve the key unmet medical need of disability progression which is common to all major forms of the disease in combination with available high-efficacy anti-inflammatory drugs. This would best address the need of MS patients, which need treatment against inflammation and against neurodegeneration.
- **Recent findings on the link between W-ENV and Post-COVID open the avenue to a new, large and highly underserved market.** Studies conducted on cohorts of several hundred European and American Post-COVID patients have detected the presence of the W-ENV protein in over 25% of these patients, whilst the GNC-501 clinical trial patient recruitment screening process has shown that the W-ENV protein was detected in over 36% of the screened patients. With the number of affected persons estimated to exceed several millions, GeNeuro has launched the first personalized medicine trial, a pivotal Phase 2 trial in Switzerland, Italy and Spain, to evaluate the efficacy and safety of temelimab in patients with severe fatigue and cognitive impairment ("brain fog") and in whom the presence of W-ENV protein in the blood can be confirmed by a serum test. The GNC-501 study, entitled "Temelimab as a Disease Modifying Therapy in Patients with Neurological, Neuropsychological, and Psychiatric Symptoms in Post-COVID-19 or Post-Acute Sequelae of COVID-19 (PASC) Syndrome", has now completed patient recruitment with the enrollment of 203 patients from European and Swiss clinical centers. The study has only enrolled those patients who also test positive for the pathogenic protein W-ENV, as the basis of a precision medicine approach. Topline results are expected in June 2024.
- **GeNeuro has full worldwide rights to temelimab.** GeNeuro has full worldwide ownership of all rights to temelimab and has all options open for geographic and/or indication-specific partnerships to develop its lead compound worldwide, as a single agent for patients with progressive forms of MS, or in combination with existing therapies for relapsing forms of the disease.
- **GeNeuro has demonstrated the efficacy of the W-ENV detection.** With the GNC-501 trial offering real-world conditions, the diagnostic test developed by GeNeuro with the support of INSERM has demonstrated its ability to detect the presence of W-ENV in the serum of patients (in the case of the GNC-501 trial, 1'092 patients were screened patients, of whom 36% were shown to be positive to W-ENV) thus opening the way to a biomarker-based precision medicine approach to serve severely affected patients in the absence of any disease modifying treatment to date.
- **Broad and strong intellectual property supports GeNeuro's first mover advantage in the HERV space.** GeNeuro's leadership position in the HERV space is supported by its acknowledged expertise in the field and a portfolio of 17 patent families that cover Europe, the United States, and other major markets. These patents (owned or under exclusive license from bioMérieux-Inserm, or with the NIH for HERV-K) cover antibodies targeting W-ENV in the treatment of a wide range of therapeutic indications including MS, Post-COVID or Inflammatory Psychosis and targeting HERV-K ENV in the treatment of ALS. GeNeuro believes that the scope and quality of its patent portfolio give it a strong competitive position in the area of W-ENV and contribute to protecting GeNeuro's first-mover advantage as a leader in HERV-mediated diseases.
- **GeNeuro has an experienced and highly synergistic management team assisted by internationally renowned scientific and medical advisors.** GeNeuro has assembled a talented team of professionals with complementary skills who have demonstrated during the last ten years their ability to move research from the laboratory to the clinic. The Company's management is supported by a team of internationally renowned experts who assist on scientific and strategic matters. As key opinion leaders ("KOLs") in their respective fields, they help to promote temelimab in the scientific, medical, and patient communities.

### 5.1.2 Company Strategy and Objectives

GeNeuro's strategy is to continue the development of temelimab to make it available as soon as possible to patients affected with post-COVID and MS, to complete its GNC-501 clinical trial in post-COVID-19 during the first half of 2024 and, subject to funding, to continue the pre-clinical development of its anti-HERV-K antibody in ALS to reach an IND and then launch a clinical trial in this orphan indication.

Large-scale academic studies indicate that more than 10% of people infected with SARS-CoV-2 do not fully recover and/or develop new symptoms, with a high proportion of neurological and/or psychiatric disorders. This post-COVID problem is now recognized as a major public health emergency, as it is affecting millions of people.

In Post-COVID, GeNeuro has launched a Phase 2 trial, called GNC-501, that is evaluating the clinical efficacy of a six-month treatment with temelimab, the anti-W-ENV antibody developed by GeNeuro, on the improvement of fatigue and/or cognitive impairment in Post-COVID patients who are positive for the presence of W-ENV protein in their blood. This trial is running in 14 sites in Switzerland, Spain and Italy, and is now fully recruited, with the W-ENV protein having been detected in more than 36% of screened patients suffering from persistent syndromes after having had COVID which confirms the potential to identify and treat a well-defined sub-population within the huge numbers of patients affected by Post-COVID.

Given the six-month treatment duration, topline results are expected by the end of June 2024. This personalized medicine approach could, if the current clinical trial is successful, offer a therapeutic solution to a well identified subset of the millions of patients affected by Post-COVID. Subject to positive results, the Company intends to file for an emergency marketing authorization or temporary use authorization.

GeNeuro's Post-COVID program is supported both by the Swiss Federal Office of Public Health (FOPH), which selected GeNeuro to receive a grant of 6.7 million Swiss francs (€6.7 million), and by the European Investment Bank (EIB), with which GeNeuro entered into a credit agreement for a total amount of up to €25 million, supported by the InvestEU program, of which a first tranche of €7 million was immediately available and was drawn down in March 2023; the Company is currently negotiating with the EIB for an early draw-down of part of the second tranche of €10 million.

In MS, GeNeuro's assessment of its Phase 2 MS trials, in discussions with potential partners and key medical opinion leaders, made clear that the impact of temelimab on MRI markers and soluble biomarkers associated with disease progression indicates a very high potential against the key unmet medical need in MS: curbing the progression of disability. GeNeuro has therefore decided to focus on neurodegeneration and disease progression, which could be either as a monotherapy for "non-active" progressive patients, or, more likely, as an adjunctive therapy for remitting patients in combination with existing immunomodulatory drugs addressing neuroinflammation, such paths being non-exclusive. The results of the Karolinska Trial, presented atECTRIMS 2022 in Amsterdam, the Netherlands, in October 2022, have confirmed the safety of higher doses of temelimab and its synergistic potential to address neurodegeneration on top of anti-inflammatory treatment in multiple sclerosis, with efficacy data, obtained in patients already effectively treated against inflammation, showing that temelimab has a favorable impact on key MRI parameters measuring neurodegeneration. Given the high costs of the international clinical trials necessary to confirm efficacy and register a product in MS with both the FDA and the EMA, which the Company estimates to exceed €100 million, continued development in MS requires a partnership and, following the results from the ProTECT-MS trial, the Company has reactivated partnership discussions for the MS indication.

## 5.2 Temelimab: Clinical Development as of the Date Hereof

To date, ten clinical studies of temelimab have been or are being conducted on humans, which are summarized in Table 1:

*Table 1: Summary of clinical studies<sup>29</sup>*

Clinical Study N°	Design	Subjects	Temelimab dose, regimen, route of administration	Formulation	Placebo or comparator	Key results
<b>GNC-001</b>  Clinicaltrials.gov identifier: NCT01699555	Randomized placebo-controlled first-in-human study with temelimab	33 healthy male subjects (cohorts 0.15 to 6.00 mg/kg were analyzed for PK)	Single doses, 0.0025 mg/kg 0.025 mg/kg 0.15 mg/kg 0.60 mg/kg 2.00 mg/kg 6.00 mg/kg intravenous	Liquid	Placebo	Well tolerated with all adverse events mild or moderate
<b>GNC-002</b>  Clinicaltrials.gov identifier: NCT01639300	Randomized placebo-controlled first-in-human study with temelimab  Repeated dose phase Open label	10 MS patients (cohorts 2 and 6 mg/kg)	Single doses, 2 mg/kg 6 mg/kg Intravenous Open label: repeated doses 2 mg/kg, 6 mg/kg intravenous	Liquid	Placebo  No Placebo in open label phase	Single dose phase: well tolerated, linear PK and $t_{1/2}$ : 17 – 49 days  Repeated dose phase: well tolerated, AR: ~3.0, overall stability of MRI
<b>GNC-001B</b>  Clinicaltrials.gov identifier: NCT02452996	Randomized placebo-controlled pharmacology study with temelimab	21 healthy male subjects	Single doses, 6 mg/kg 18 mg/kg 36 mg/kg Intravenous	Liquid	Placebo	Well tolerated with all adverse events mild or moderate
<b>GNC-003 CHANGE-MS</b>	Phase IIb, randomized, placebo-controlled, parallel-group,	270 RRMS patients	Period 1: 4 cohorts in, receiving either placebo or	Liquid	Placebo	Well tolerated with all adverse events mild or moderate.

<sup>29</sup> Source: GeNeuro.

Clinical Study N°	Design	Subjects	Temelimab dose, regimen, route of administration	Formulation	Placebo or comparator	Key results
24-week and 48 week completed NCT02782858	multicenter study with two treatment periods in RRMS patients: Period 1 (Day 1 to Day 169) and Period 2 (Day 169 to Day 337). Period 2 is dose-blind with all placebo patients re-randomized to 1 of the temelimab dose cohorts		temelimab i.v every 4 weeks for 24 weeks with 69 subjects in the placebo group and 67 subjects in each of the following temelimab groups: 6 mg/kg, 12 mg/kg, and 18 mg/kg  Period 2: 3 cohorts receiving temelimab (same doses as in Period 1) i.v. every 4 weeks for 24 weeks			Significant and consistent positive impact on key neuroprotection markers known to be linked to disease progression.
<b>GNC-004 ANGEL -MS</b> extension study 48 weeks completed NCT03239860	Two-year open-label extension study to GNC-003 in RRMS patients; early termination in October 2018.	219 RRMS patients	3 cohorts receiving temelimab at 6 mg/kg, 12 mg/kg and 18 mg/kg i.v. over 2 hours every 4 weeks until optimal dose is decided based on GNC-003 results; then all patients to be shifted to this dose	Liquid	none	Well tolerated with all adverse events mild or moderate. Continued positive impact on key MRI measures of disease progression in MS patients, with encouraging dose-dependent effects on clinical measures of disease progression.
<b>GNC-301 RAINBOW</b> 24-week, extended to 48-week, completed NCT03179423	Randomized placebo-controlled first-in-human multicenter study with temelimab in T1D.  The first part of the trial is double-blind and the second part is open-label with all participants receiving the active treatment.	60 T1D adult patients	Period 1: 2 cohorts, receiving either placebo or temelimab i.v every 4 weeks for 24 weeks with 20 subjects in the placebo group and 40 subjects temelimab 6 mg/kg group.  Period 2: open-label with all participants receiving the active treatment	Liquid	Placebo	Safety demonstrated in T1D patients, positive pharmacodynamic signs with decrease in hypoglycaemia frequencies and in anti-insulin antibody levels in patients treated with temelimab
<b>GNC-006</b> completed	Randomized placebo-controlled high-dose pharmacology study	24 healthy male subjects	Single doses, 36 mg/kg, 60 mg/kg, 85 mg/kg, 110 mg/kg intravenous	Liquid	Placebo	Well tolerated with all adverse events mild or moderate
<b>GNC-401 ProTECT-MS</b> 48-week, completed NCT04480307	Phase IIa, randomized, double-blind, placebo-controlled, parallel-group, single center study in RRMS patients following treatment with rituximab	41 MS patients	4 cohorts, receiving either placebo or temelimab i.v every 4 weeks for 48 weeks with 10 subjects in the placebo group and 10 subjects in each of the following	Liquid	Placebo	Primary endpoint was met: results confirm the excellent safety profile and tolerability of higher doses of temelimab administered



Clinical Study N°	Design	Subjects	Temelimab dose, regimen, route of administration	Formulation	Placebo or comparator	Key results
			temelimab groups: 18 mg/kg, 36 mg/kg, and 54 mg/kg			concomitantly with rituximab. Efficacy data showed that temelimab has a favorable impact on key MRI parameters measuring neurodegeneration.
<b>GNC-402</b> extension study of GNC-401, closed	Phase IIa, randomized, double-blind, active treatment, parallel-group, single center study in RRMS patients following treatment with rituximab	33 MS patients	Temelimab 18, 36 and 54 mg/kg groups. Patients from the placebo arm of the GNC-401 study were re-randomised in a 1:1:1 ratio to the temelimab 18, 36 and 54 mg/kg groups.	Liquid	None	None. The GNC-402 study was terminated early because the IMP (temelimab) was not available for clinical supply, following the worldwide shortage of culture media and supplies due to the COVID-19 pandemic
<b>GNC-501</b> 24-week, on-going NCT05497089	Phase 2, randomized, placebo-controlled, double-blind, multicenter study in patients experiencing neuropsychiatric symptoms and functional impairment in the course of PASC – Post-COVID	203 MS patients	2 cohorts, receiving either placebo or 54 mg/kg temelimab i.v every 4 weeks for 24 weeks	Liquid	Placebo	Pending

A full description of the trials, excluding GNC-501, is available in the 2021 Universal Registration Document.

## **5.2.1** CHANGE-MS

### 5.2.1.1 Study design and objectives

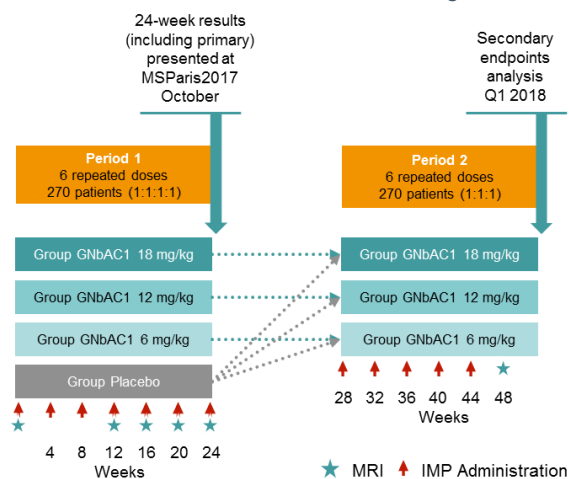
GeNeuro conducted a double-blind placebo-controlled study, called CHANGE-MS, in patients with RRMS. The study based the efficacy evaluation of the drug on MRI brain imaging. The primary objective was to assess the efficacy of repeated doses of temelimab versus placebo in patients based on the cumulative number of Gadolinium-enhanced T1 lesions on brain MRIs — a study end-point recommended by regulatory authorities for this development phase of MS.<sup>30</sup> The study also assessed pre-determined secondary objectives, among which: (i) efficacy on other brain MRI end points; (ii) effect on the relapse rate; (iii) safety and tolerability of repeated doses of temelimab; (iv) pharmacokinetics of repeated doses of temelimab in a subgroup of patients; (v) identify an optimal dose for Phase III studies based on efficacy and safety findings; (vi) study the pharmacodynamic response on biomarkers, including W-ENV markers; (vii) assess the immunogenicity of temelimab; and (viii) assess the health-related quality of life.

The study enrolled a total of 270 patients (*please see the illustration below*). Patients inclusion criteria were: (i) RRMS according to the 2010 revised McDonald criteria; (ii) age between 18 and 55 years; (iii) present disease activity characterized by at least one documented relapse within one year or one Gd-enhancing T1 lesion at screening or evidenced within the last three months; and (iv) EDSS score less than 6.0. No other MS treatments were provided during the study other than corticosteroids and symptomatic treatments such as fampridin.

The study was performed over two periods:

<sup>30</sup> Source: EMA 2015.

Figure 3: Design of CHANGE-MS Study<sup>31</sup>



- Period 1 (weeks 1–24): a double-blind randomized, placebo-controlled study with the following groups: temelimab 6 mg/kg, 12 mg/kg or 18 mg/kg; or placebo with a randomization ratio (1:1:1:1).
- Period 2 (weeks 25–48): extension where all patients receive only active treatment. In Period 2, patients from the placebo group were re-randomized to temelimab 6 mg/kg, 12 mg/kg or 18 mg/kg (randomization 1:1:1).

Temelimab was administered intravenously over a 2-hour infusion in a glucose 5% solution bag at ~2 mL/min.

Centers located in the following countries participate in the study: Bulgaria, Croatia, the Czech Republic, Estonia, Germany, Hungary, Italy, Poland, Russia, Serbia, Spain, and Ukraine. Fifty centers, mainly university hospital centers, participated in the study. The final 48-week results were announced in March 2018.

### 5.2.1.2 CHANGE-MS results

On August 28, 2017, GeNeuro announced the first results of CHANGE-MS as they became available. The first output was the excellent safety profile of temelimab as can be seen in [Table 2](#) below.

Table 2: CHANGE-MS safety results at 24 weeks

	GNbAC1 6 mg/kg N=67	GNbAC1 12mg/kg N=66	GNbAC1 18 mg/kg N=67	Placebo N=68
24-week completers	60 (90%)	59 (90%)	64 (95%)	66 (97%)
SAE	1	1	0	2
Serious-related AE*	0	1	0	0
AE leading to early termination	2	1	1	0
AE leading to death	0	0	0	0

\* Macroscopic hematuria: resolved

There was a very good balance in terms of frequencies of serious adverse events or events leading to discontinuation among the different treatment groups and there was no evidence of more frequent or more severe adverse events with higher doses of temelimab, comforting favorable safety results observed so far in the development of temelimab.

#### **Primary endpoint at 24 weeks: results on inflammatory end-points**

The primary endpoint was not met and is presented in table below. Although the total number of lesions was reduced by approximately 50% in the 18 mg/kg treatment group compared to placebo, after accounting for Baseline imbalances, there were no statistically significant differences in the number of gadolinium enhancing T1 lesions compared to placebo at 24 weeks for any active dose group.

<sup>31</sup> Source: GeNeuro.

Table 3: main CHANGE-MS endpoints at 24 weeks

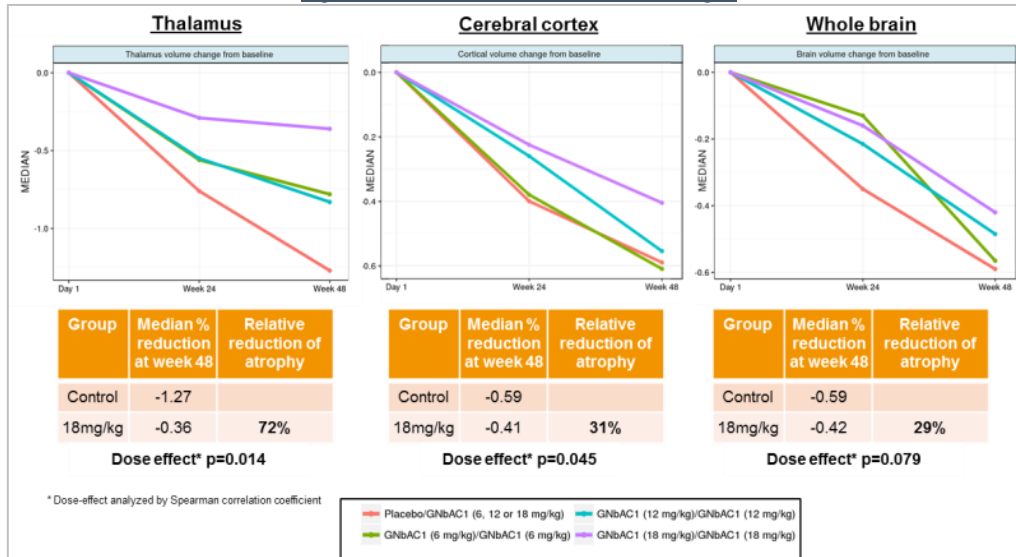
			GNbAC1 6 mg/kg	GNbAC1 12mg/kg	GNbAC1 18 mg/kg	Placebo
<b>Primary Endpoint</b>						
Total Gd+ lesions	Week 12-24	# of lesions	510	407	339	666
		Mean (Med)	8.4 (2.0)	6.9 (2.0)	5.3 (1.0)	10.1 (1.5)
		P value	p = 0.539	p = 0.704	p = 0.481	
Secondary endpoints include: total # new/enlarging T2 / CUAL / T1 BH; T2 / T1 BH volume, ARR, EDSS, MSFC, MSQOL-54						
% change in whole brain volume	Baseline – week 24	Mean (Med)	-0.32 (-0.13)	-0.35 (-0.22)	-0.24 (-0.16)	-0.34 (-0.35)
# of relapses	Baseline – week 24		18 p = 0.492	21 p = 0.217	21 p = 0.291	15
Total Gd+ lesions	Week 24	Mean (Med)	2.7 (1.0)	2.3 (0)	2.0 (0)	4.1 (0)
		P value	p = 0.103	p = 0.907	p = 0.083	

**CHANGE-MS neuroprotection and remyelination endpoints at 48 weeks.**

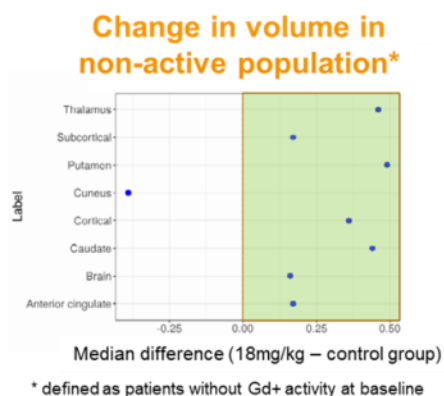
At 48 weeks, pre-specified, key secondary endpoints were assessed. For the second 24-week period, the group of patients originally randomized to placebo and then (at week 24) re-randomized into the three active treatment arms was used as the Control Group in the 48-week analyses.

**Brain volume changes** were analyzed for the whole brain and several cerebral structures. Benefits of temelimab were seen, with less atrophy in the cerebral cortex and thalamus, with relative reductions of 31% and 72% respectively between the 18 mg/kg (the highest dose studied) and Control Group, with a statistically significant dose-relationship across treatment groups assessed by the Spearman correlation coefficient (p=0.045 for cortex atrophy and p=0.014 for thalamic atrophy). For whole brain atrophy, there was a 29% relative reduction in brain volume loss over 12 months for the 18 mg/kg group versus the Control Group. The Spearman correlation analysis showed a trend for a dose-relationship (p=0.079).

Figure 4: CHANGE-MS brain volume changes

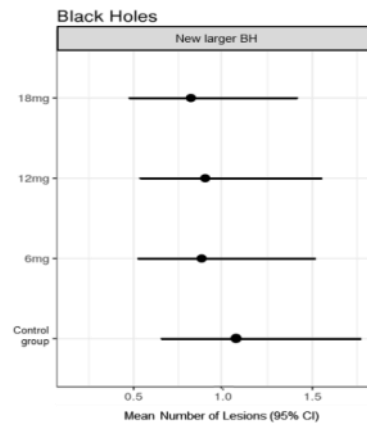


Importantly, the benefits observed were not dependent on reducing inflammatory activity. As illustrated in the figure below, the reductions in atrophy were at least as robust in “non-active” patients (patients with no inflammatory activity at baseline). This is evidence that the effect of temelimab is mediated through its target cells (OPC and microglia) and not through the modulation or suppression of adaptive immunity. This is particularly important as the critical unmet medical need in MS is to treat non-active progressive patients, either because they progress while taking existing, highly effective immunomodulatory DMTs, or because they have reached the stage where adaptive

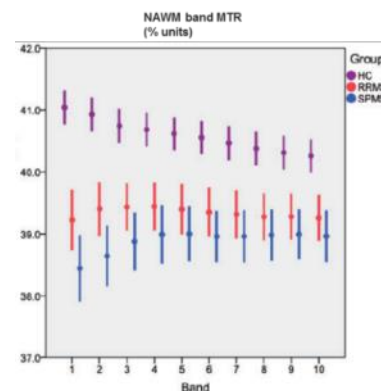


inflammation has a much lower influence on the course of the disease (i.e. “non-active progressive MS”).

The number of **T1 hypointense lesions**, or black holes, was a key secondary measure of the study. The number of new T1 black holes of at least 14mm<sup>3</sup> volume (3mm in diameter) was reduced by 63% at 48 weeks in the 18mg/kg versus the Control Group (pairwise comparison p= 0.014). Reductions compared to the Control Group were also observed at lower temelimab doses. The figure below shows the average number of black holes by treatment group at 48 weeks. These data were supported by analyses of changes in T1 black hole volume, which were smaller in the groups having received temelimab throughout the 48 weeks of CHANGE-MS compared to the Control Group with a statistically significant dose-response effect (Spearman correlation coefficient p = 0.030).



Magnetization transfer imaging involves the measurement of the transfer of magnetization between the free and bound proton pools in tissue. Images during two sequences are subtracted leading to a magnetization transfer ratio (MTR) image, which is proposed as a measure of myelin. Remyelination following treatment with temelimab was measured by MRI with magnetization transfer ratio (MTR) analyses performed in the normal appearing white matter (NAWM) and cerebral cortex of patients.



Recent studies have observed that there is a reduction in MTR signal in NAWM and cerebral cortex in patients with MS versus controls, with a pathological gradient of MTR signal loss, as illustrated in the figure above. A decrease of the MTR signal in the NAWM is associated with clinical disability<sup>32</sup>. Despite the variability inherent in a 50-center MTR study, the Baseline data reproduced the pathological gradients observed in prior studies.

A benefit in **Magnetization Transfer Ratio (MTR)** signal for 18mg/kg dose group was observed in comparison with the Control Group at 48 weeks, in both normal appearing white matter and cerebral cortex, consistent with a potential benefit on myelin integrity. The table below presents the distributions and medians for MTR signal values by treatment group at 24 and 48 weeks for normal appearing white matter (periventricular bands 1 to 3), showing positive median changes in the 18 mg group (meaning that ≥ 50% of patients had an absolute increase in MTR signal), while all other groups had a decrease in MTR signal, as would be expected in an MS patient population. The results were consistent across all six normal appearing white matter and cerebral cortical bands.

Table 4: CHANGE-MS MTR results

Change in MTR signal (% units)		WEEK 24*		WEEK 48	
		Mean	Median	Mean	Median
PV Band 1	18mg/kg	0.68	0.28	0.128	-0.265
	Placebo/ 6-12-18mg	-0.35	-0.58	-0.855	-1.01
	<b>18mg vs. Placebo / 6-12-18mg</b>	<b>Gain vs. placebo</b>	<b>P value</b>	<b>Gain vs. placebo / 6-12-18mg</b>	<b>P value</b>
		1.03	0.188	0.98	0.271
PV Band 2	18mg/kg	0.64	0.30	0.179	-0.155
	Placebo/ 6-12-18 mg	-0.32	-0.64	-0.763	-0.94
	<b>18mg vs. Placebo / 6-12-18 mg</b>	<b>Gain vs. placebo</b>	<b>P value</b>	<b>Gain vs. placebo / 6-12-18mg</b>	<b>P value</b>
		0.96	0.188	0.94	0.277
PV Band 3	18mg/kg	0.66	0.34	0.223	-0.145
	Placebo/ 6-12-18 mg	-0.28	-0.61	-0.712	-0.91
	<b>18mg vs. Placebo / 6-12-18 mg</b>	<b>Gain vs. placebo</b>	<b>P value</b>	<b>Gain vs. placebo / 6-12-18mg</b>	<b>P value</b>
		0.94	0.194	0.94	0.269

MTR: Magnetization Transfer Ratio  
\* Recalculated with the same number of qualifying MTR scans at 48 weeks

<sup>32</sup> Source: Traboulsee A, Dehmeshki J, Peters Kr et al. Disability in multiple sclerosis is related to normal appearing brain tissue MTR histogram abnormalities Mult Scler 2003;9:566-73

For secondary endpoints related to **MRI measures of neuroinflammation**, patients in all treatment groups improved from Week 24 to Week 48, however there was no significant separation between treatment groups. The effect of temelimab on adaptive immune-mediated inflammation is not clinically relevant, and any reduction in inflammatory activity does not appear to be responsible for the effects seen on neurodegenerative endpoints.

In terms of **safety** at 48 weeks, there were no organ-class specific toxicities and no dose dependent adverse events were observed. As shown in Table 5 below, serious adverse events in general and those potentially related to the treatment were infrequent and well balanced across treatment groups.

*Table 5: CHANGE-MS safety results*

	GNbAC1 6 mg/kg N=88	GNbAC1 12mg/kg N=90	GNbAC1 18 mg/kg N=89	Overall N=267
SAE	3	4	1	8
Serious-related AE*	0	1	0	-
AE leading to early termination	2	2	2	6
AE leading to death	0	0	0	0

Temelimab continued to show an excellent tolerability profile throughout the second part of the CHANGE-MS study.

## **5.2.2** ANGEL-MS Extension

ANGEL-MS (Assessing the W-ENV ANtagonist temelimab for Evaluation in an open label Long-term Safety Study in Patients with MS) is an international long-term extension study of the Phase IIb Study GNC-003 (CHANGE-MS) in patients with Relapsing Remitting Multiple Sclerosis (RRMS) with the primary objective of demonstrating the long-term safety of monthly repeated doses of temelimab. The study was planned to last 96 weeks and patients continued their temelimab treatment dose from GNC-003 (i.e. 6 mg/kg, 12 mg/kg or 18 mg/kg, administered intravenously, with 4-week administration intervals). The primary endpoint is the long-term safety of temelimab, based notably on adverse events (AEs) and clinical safety laboratory. The secondary objective is long-term efficacy based on brain MRI markers, annualized relapse rate, disability, disease activity, EDSS and MSFC Scores.

### **5.2.2.1** ANGEL-MS Results

The study started on June 6th, 2017 and 219 patients in total enrolled, representing 94% of all patients who completed the CHANGE-MS study. ANGEL-MS was fully funded by Servier and had an early termination due to Servier's decision to end its partnership with GeNeuro, with all patients being offered end-of-study visits. Across the two studies (CHANGE-MS and ANGEL-MS), a total of 154 patients received temelimab treatment for 96 weeks or more. For patients not having completed 96 weeks, the end-of-study visit results were used in the analysis (last observation carried forward). As there was no longer an administration of placebo during ANGEL-MS, to ensure consistency, analyses of efficacy endpoints in ANGEL-MS were based on comparing the original groups in the CHANGE-MS study: temelimab (18mg/kg, 12mg/kg, 6mg/kg) and Control Group (i.e. patients originally randomized to placebo for 6 months in CHANGE-MS and re-randomized into the three active treatment arms for the last 6 months of CHANGE-MS).

Brain volume changes were analyzed on the whole brain and different anatomical locations, atrophy of the brain and more specifically of certain of its parts such as the thalamus being often considered as a predictor of the progression of disability. Benefits of temelimab were seen in a lower cortical and thalamic atrophy rate, with relative volume loss reductions of 42% and 43% respectively between the highest dose of 18 mg/kg and the Control group, with a dose-effect across treatment groups assessed by linear regression showing a trend value of  $p=0.058$  for cortical atrophy and a statistically significant value of  $p=0.038$  for thalamic atrophy). Table 6 below presents the evolution of median thalamic atrophy by time and by treatment groups since the original baseline of CHANGE-MS.

In terms of **safety** at 96 weeks (CHANGE-MS + ANGEL-MS), there were no organ-class specific toxicities and no dose dependent adverse events observed. As shown in Table 6 below, serious adverse events in general and those potentially related to the treatment were infrequent and well balanced across treatment groups. Temelimab continued to show an excellent tolerability profile throughout the second part of the study.

*Table 6: ANGEL-MS safety results*

Number of patients (%)	18 mg/kg (N=77)	12 mg/kg (N=68)	6 mg/kg (N=74)
Adverse Events (AEs)	34 (44.2%)	32 (47.1%)	33 (44.6%)
Serious adverse events (SAEs)	5 (6.5%)	1 (1.5%)	6 (8.1%)
Serious related AEs	3 (3.9%)	0	0
AEs leading to study discontinuation	2 (2.6%)	1 (1.5%)	1 (1.4%)
Fatality*	1 (1.3%)	0	0

\* Patient had previously voluntarily exited the study; the Investigator considered the event as unrelated.

In order to ensure consistency, analyses of efficacy endpoints in ANGEL-MS were based on comparing the original randomized groups from the CHANGE-MS study: temelimab (18mg/kg, 12mg/kg, 6mg/kg) and Control Group (i.e. patients originally randomized to placebo for 6 months in CHANGE-MS and re-randomized into the three active treatment arms for the last 6 months of CHANGE-MS).

Further, in order to examine the robustness of the efficacy analyses, several sensitivity analyses were performed. First by dose groups, i.e. by the randomized dose received in ANGEL-MS, irrespective of time treated. Then by absolute dose received, separating the total dose of temelimab into quartiles, irrespective of body weight or randomized dose group. And finally separating the patients having received 18mg/kg during 96 weeks against all other treatments. No corrections were performed for multiple testing.

Overall, the ANGEL-MS data confirmed that treatment with temelimab for 2 years had a continued, positive impact on key MRI-based paraclinical measures, associated with disease progression in multiple sclerosis, extending the data reported at Week 48 in the CHANGE-MS study. These include reductions in brain atrophy (notably in the cerebral cortex and thalamus) and maintenance of myelin integrity, as measured by magnetization transfer ratio (MTR) imaging. Importantly, for the first time, encouraging dose-dependent effects were seen on clinical measures of disease progression.

In terms of **MRI measures of neuroinflammation**, all groups improved with treatment, however no significant separation between treatment groups was observable. The effects of temelimab are unlikely to be driven by an anti-inflammatory effect.

Number of T2 lesions	18 mg/kg	12 mg/kg	6 mg/kg	Control Group	P-value
Median number of new or newly enlarged T2 lesions from ANGEL-MS Baseline	5.0	5.0	6.0	6.0	0.31*
Volume of T2 lesions	18 mg/kg	12 mg/kg	6 mg/kg	Control Group	P-value
Median % increase of T2 lesion volume from ANGEL-MS Baseline	8.1%	8.7%	13.7%	11.8%	0.28* *

\*Non parametric analysis SAS Proc NPAR1WAY, excluding Control group from analysis  
\*\*Regression analysis SAS Proc GLM, excluding Control group from analysis

Effects of temelimab on **brain atrophy measures** observed in CHANGE-MS were confirmed in ANGEL-MS after 96 weeks of total treatment. As illustrated in Figure 5 and Figure 6 below, this was notable in the cerebral cortex and thalamus, with relative reductions in volume loss of 42% and 43%, respectively, between the 18 mg/kg (highest dose studied) and Control Group, with a trend for a dose-response across treatment groups for cortical atrophy (p=0.058) and a statistically significant dose-response for thalamic atrophy (p=0.038).

Figure 5: ANGEL-MS cortical atrophy results

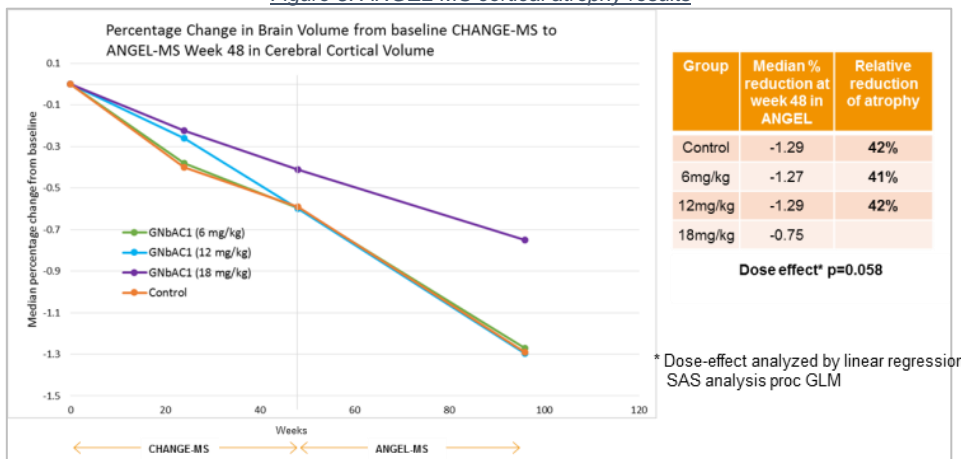
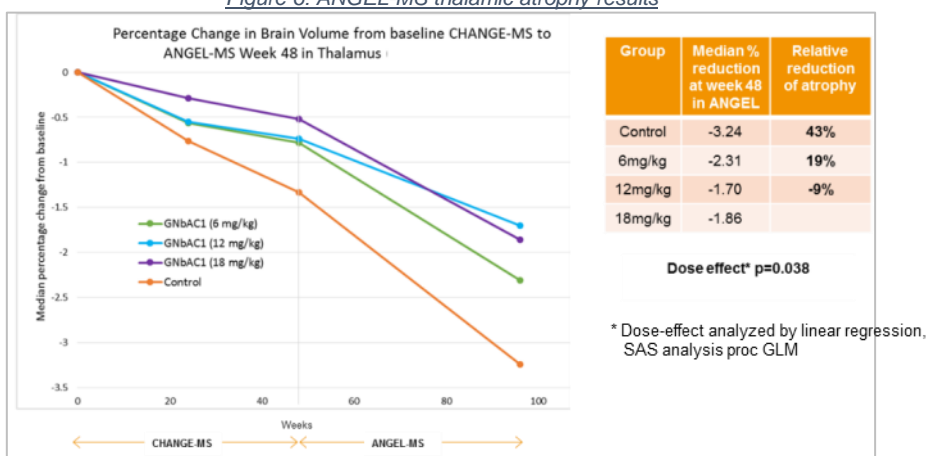
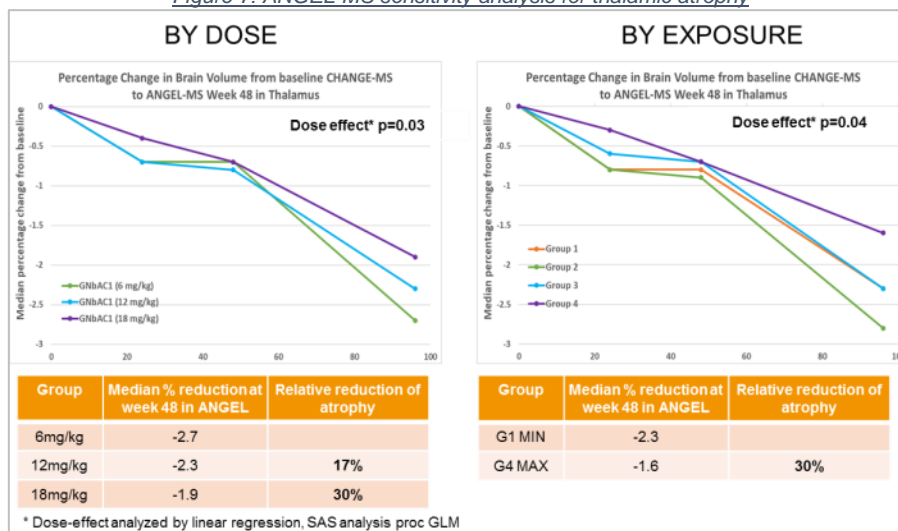


Figure 6: ANGEL-MS thalamic atrophy results



As illustrated in Figure 7, for thalamic atrophy, all sensitivity analyses were consistent on the effect of the 18mg/kg dose versus any other treatment arm.

Figure 7: ANGEL-MS sensitivity analysis for thalamic atrophy



The number of **T1 hypointense lesions** was not analyzed at the end of ANGEL-MS. This was because, in order to protect patients from unnecessary exposure to gadolinium, no gadolinium contrast was given in the ANGEL-MS study. As a result, it was technically not possible to differentiate between acute T1 Black Holes (due to edema associated with acute, inflammatory lesions) and chronic T1 Black Holes (due to permanent tissue destruction).

Nonetheless, the effect of temelimab on lesion evolution into permanent tissue destruction was shown, with less increase in mean T1 Black Hole lesion volume in the 18 mg/kg group versus the Control Group.

	18 mg/kg	12 mg/kg	6mg/kg	Control
Median percent increase in T1 hypointense lesion volume	8.7	9.2	14.5	21.3
Pairwise comparisons vs Control, p-values*	0.12	0.80	0.41	

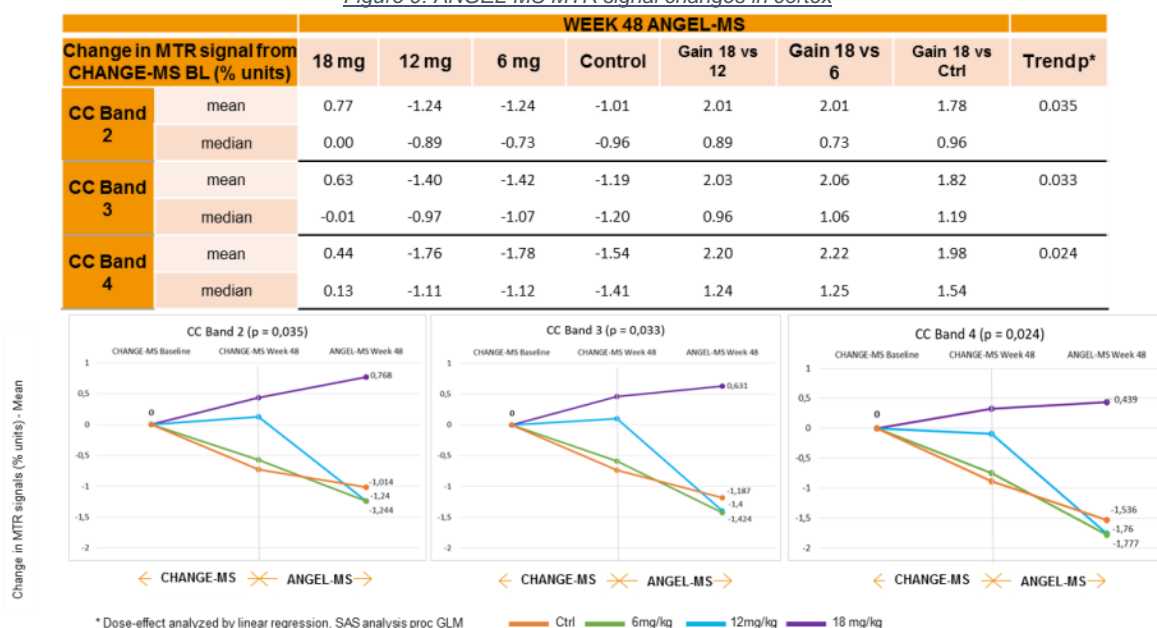
\*Analysis of covariance on rank transformed data

The effect on **Magnetization Transfer Ratio (MTR)** signal of 18mg/kg dose group relative to the Control Group, observed at 24 and 48 weeks of CHANGE-MS, was confirmed in comparison with the Control Group at 96 weeks, in both normal appearing white matter and cerebral cortex, consistent with a potential benefit on remyelination. Figure 8 and Figure 9 below present the distributions and medians of MTR signals by treatment group at 48 weeks of ANGEL-MS for periventricular bands and for cortical bands.

Figure 8: ANGEL-MS MTR signal changes in Normal Appearing White Matter



Figure 9: ANGEL-MS MTR signal changes in cortex

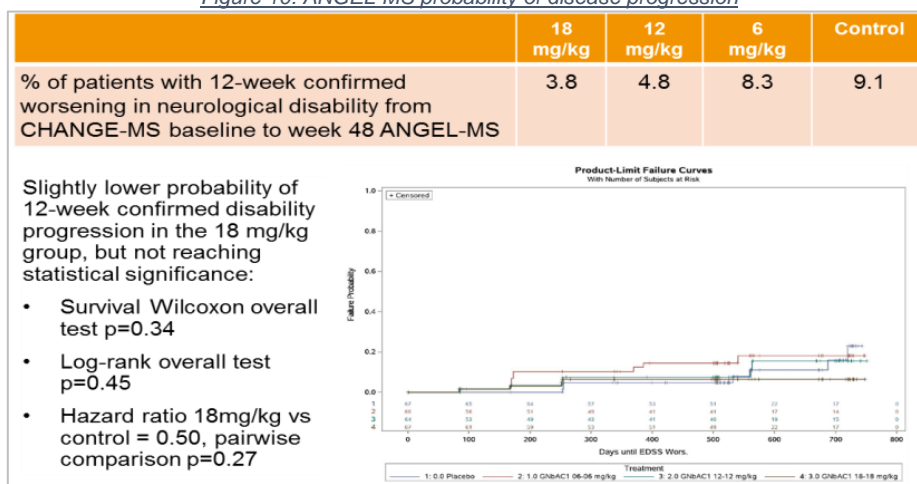




Importantly, and for the first time, encouraging, dose-dependent effects were seen on **clinical measures of disease progression**. This was as measured by a lower proportion of patients with 12-week confirmed EDSS progression, or with 20% worsening in Timed 25-Foot Walk from Baseline of CHANGE-MS to week 96 (or end-of-study) in ANGEL-MS.

A lower probability of 12-week **confirmed disability progression** in the 18 mg/kg group versus all other groups is illustrated in Figure 10 below.

Figure 10: ANGEL-MS probability of disease progression



When pooling all groups against the 18mg/kg group, the result nearly reaches statistical significance. However, the cohort of patients is small, as the study was not designed to examine disability progression, and the number of events recorded is also very low. Therefore, although encouraging, these results are not conclusive.

Also encouraging, and consistent with the EDSS data, is the proportion of patients with a worsening of > 20% or more in the **Timed 25-Foot Walk Test** when comparing CHANGE-MS Baseline to the end of ANGEL-MS, as may be seen in Table 7 below.

Table 7: ANGEL-MS proportion of patients with worsening >20% of Timed 25-foot walk

Timed 25-foot walk – Original CHANGE-MS Groups	18 mg/kg	12 mg/kg	6 mg/kg	Control	P-value**
Percentage of patients with worsening $\geq$ 20% in the Timed 25-Foot Walk Test compared to CHANGE-MS Baseline*	2.4	23.1	13.3	10.2	0.03

\* Fifteen patients with extreme walking disability removed from analysis –for whom the test was almost impossible to perform – excluded patients distributed equally across treatment groups  
 \*\* Fisher exact test

At 96 weeks of treatment, a lower proportion of patients in the 18mg/kg group experienced a clinically relevant worsening, than in any other group, with statistical significance of p=0.03. All of the sensitivity analyses performed confirmed the results, as illustrated in Table 8 below.

Table 8: ANGEL-MS – sensitivity analysis of proportion of patients with worsening >20% of Timed 25-foot walk

Timed 25-foot walk – By Dose Groups	18 mg/kg	12 mg/kg	6 mg/kg	P-Value**
Percentage of patients with worsening $\geq$ 20% in the Timed 25-Foot Walk Test compared to CHANGE-MS Baseline*	3.6	16.9	15.0	0.04
Timed 25-foot walk – By 18 vs Others	18 mg/kg	Others	P-value**	
Percentage of patients with worsening $\geq$ 20% in the Timed 25-Foot Walk Test compared to CHANGE-MS Baseline*	2.4	15.0	0.03	

\* Fifteen patients with extreme walking disability removed from analysis –for whom the test was almost impossible to perform – excluded patients distributed equally across treatment groups  
 \*\* Fisher exact test

The same caution as above holds true, but these results at 96 weeks appear to indicate that the positive effect observed in MRI measures may translate into a clinical benefit.

Overall at 96 weeks of temelimab treatment, there was a consistent and sustained benefit with temelimab at the dose of 18mg/kg on key independent markers of neurodegeneration, such as thalamic, cortex and whole brain volumes, as well as MTR in cortical and normal appearing white matter. These markers are linked to long term disease progression and worsening of disability in MS. Importantly, for the first time, encouraging dose-dependent effects were seen on clinical measures of disease progression. This has been evidenced by a lower proportion of patients with 12-week confirmed EDSS progression, or with 20% worsening in 25-foot timed walk. Moreover, temelimab appeared safe during the whole duration of the trial.

These results are coherent with the pre-clinical knowledge to date on the mechanisms of action of W-ENV and of temelimab.

### 5.2.3 GNC-401 (ProTECT-MS) Study: confirmation of safety of higher doses of temelimab and synergistic potential to address neurodegeneration on top of anti-inflammatory treatment

Temelimab was used as a monotherapy in the one-year CHANGE-MS trial and its one-year ANGEL-MS extension. The primary endpoint of CHANGE-MS at 6 months was not met (reduction of cumulative number of gadolinium (Gd)-enhancing T1 lesions from week 12-24 in temelimab groups (6, 12, and 18mg/kg) compared with placebo). However, at one year already, patients originally randomized to temelimab 18mg/kg in CHANGE-MS showed evidence for relative improvements in MRI-measured neurodegenerative outcomes such as brain volumes, MTR and blackholes during CHANGE-MS, compared to all other groups. The ANGEL-MS one-year extension confirmed and enlarged the observed relative improvements in MRI-measured neurodegenerative outcomes. It also demonstrated that temelimab is safe to use and well tolerated for a prolonged period. These data suggested a possible neuroprotective effect of temelimab and supported further clinical development towards a treatment for progression of MS-disability.

The key questions left open by the CHANGE-MS and ANGEL-MS trials were related to the MS population treated and to the dose used:

- In the earlier trials, temelimab was used as a monotherapy in an active RRMS population. However, today the majority of patients in developed countries receive an effective therapy against inflammation and, while approved anti-inflammatory therapies only have a modest impact on long-term disability progression, a treatment against neurodegeneration could only be administered on top of existing therapies, in order to tackle both inflammation and neurodegeneration.

**The question was therefore whether temelimab's effect would still be visible and coherent with previous results in combination with a potent anti-inflammatory drug and in a population whose disability progresses.**

- In the earlier trials, 18mg/kg was the dose providing robust results, while the lower doses had little or no impact on the above-described measures. As temelimab is well tolerated and could be used at higher doses, there was uncertainty whether GeNeuro had found the "maximally effective minimal dose", which is a key requirement before launching a Phase III.

**The question was therefore whether a higher dose of temelimab would be confirmed as safe in a treated population and provide additional efficacy signals.**

The ProTECT-MS study was designed to answer these two questions. As described by Prof. Fredrik Piehl, Professor of neurology, Karolinska Institutet in Stockholm, Sweden, and Principal Investigator of the study, at MS Virtual 2020, "Because temelimab has no significant anti-inflammatory effect, combination with a highly effective DMT, such as an anti-CD20-antibody, to protect against new focal neuroradiological disease activity is likely needed to properly explore temelimab's tissue protective, anti-neurodegenerative effect: This represents the rationale for the ProTECT-MS study."

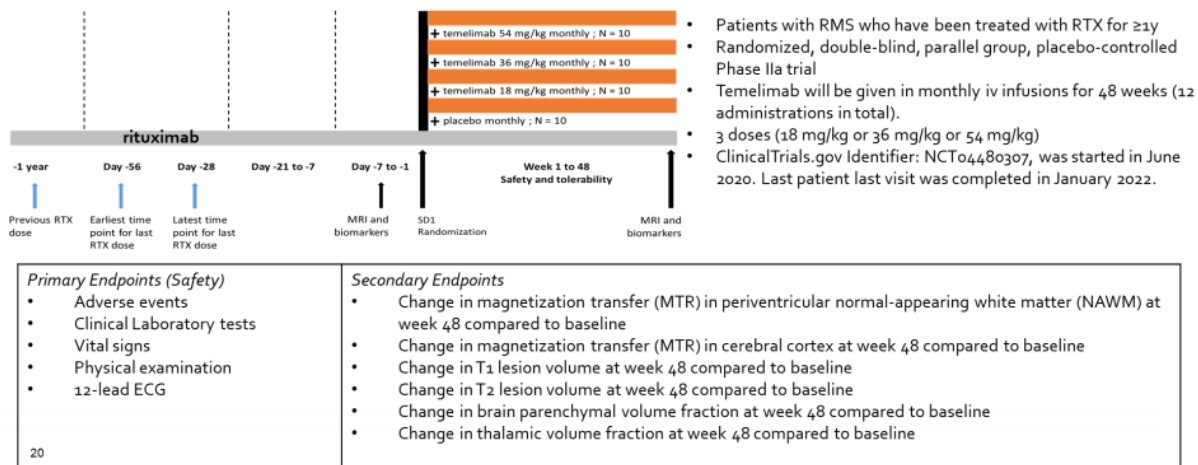
This study was a Phase IIa, single-center, randomized, double-blind, placebo-controlled, parallel-group, study in 41 RRMS patients following treatment with rituximab.

Four cohorts of patients received (following treatment with rituximab) either placebo or temelimab i.v every 4 weeks for 48 weeks with 10 subjects in the placebo group and 10 subjects in each of the following temelimab groups: 18 mg/kg, 36 mg/kg, and 54 mg/kg.

*Figure 11: ProTECT-MS design*

**Primary objective:** to assess safety and tolerability of iv temelimab in patients with RMS treated with RTX

**Secondary objective:** to determine the pharmacodynamic effects of temelimab on neuroprotection and remyelination based on innovative neuroimaging techniques<sup>5</sup>, as well as biomarkers studies (exploratory objectives)



1. Ouellette et al, Ann Neurol 2020

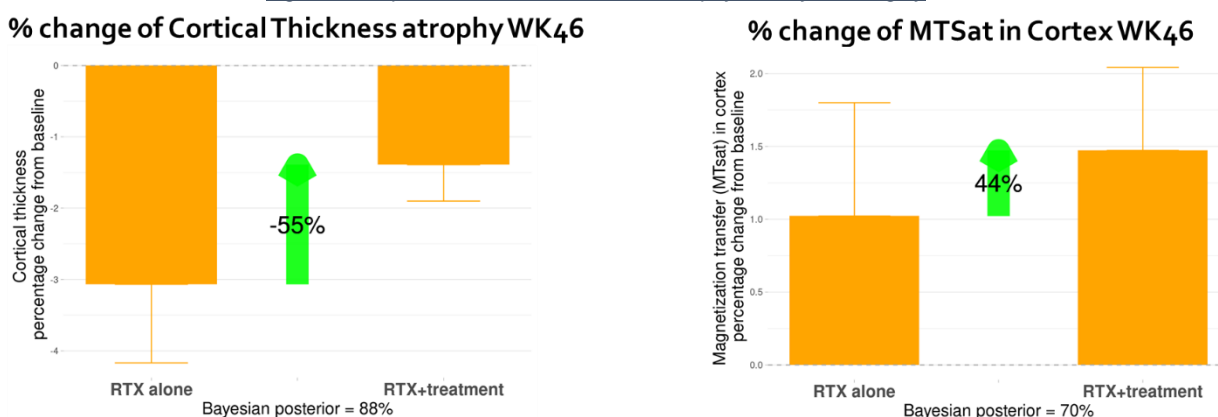
### 5.2.3.1 ProTECT-MS Results

On October 27, 2022, GeNeuro presented the primary analysis of the Phase 2 ProTECT-MS study at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2022) Congress in Amsterdam, Netherlands. This study was performed in Stockholm, Sweden, at the Karolinska Institutet’s Academic Specialist Center in Stockholm under the leadership of Prof. Fredrik Piehl:

- The primary endpoint of the ProTECT-MS study was met, with results confirming the excellent safety profile and tolerability of higher doses of temelimab administered concomitantly with an anti-CD20 treatment, a high-efficacy anti-inflammatory drug. The drug was well tolerated with no treatment related discontinuations, no serious or severe treatment emergent adverse events, and no differences in overall clinical or laboratory safety findings, which meets the primary endpoint of the study.
- Efficacy data, obtained in this patient group already effectively treated against inflammation, showed that temelimab has a favorable impact on key MRI parameters measuring neurodegeneration, which showed a positive impact of temelimab in preserving neocortical anatomy and myelin integrity. The effect sizes were of comparable magnitude to those previously observed in the prior CHANGE-MS and ANGEL-MS trials in patients without an anti-inflammatory treatment.
- New exploratory data on soluble biomarkers also showed favorable impact on measures of neurodegeneration at one year: the study showed a reduction of GFAP biomarkers in cerebrospinal fluid (CSF). GFAP is a biomarker for astrocytic activation associated with diffuse neuroaxonal damage leading to MS disease progression. The results on these CSF biomarkers confirm the synergistic potential to treat neurodegeneration with temelimab in addition to a high-efficacy anti-inflammatory therapy in MS.
- The analysis of the data now also allows GeNeuro to determine the optimal dose for future temelimab trials in MS, in conjunction with potential partners.

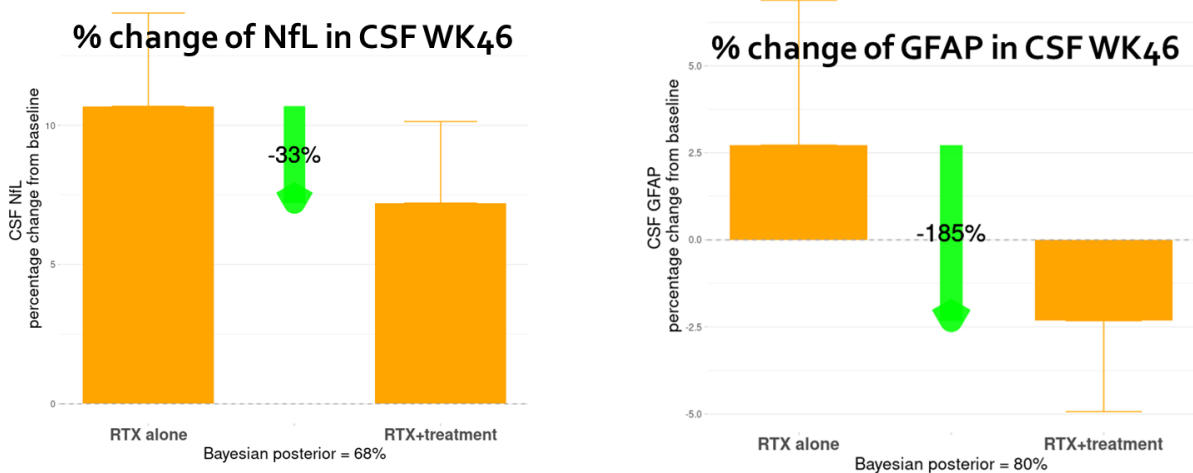
The analyses of efficacy endpoints showed a favorable impact of temelimab in preserving neocortical anatomy and myelin integrity. The effect sizes were of comparable magnitude to those previously observed in the CHANGE-MS and ANGEL-MS trials. The combined treatment of temelimab and rituximab protected against loss of cortical thickness by more than 50% relative to rituximab alone. Furthermore, cortical tissue integrity, as measured by magnetization transfer saturation, was improved with temelimab, potentially reflecting remyelination.

Figure 12: Impact on measures of cortical atrophy and myelin integrity



Benefits were also seen in soluble biomarkers of damage to nervous system cells

Figure 13: Biomarkers of damage to nervous system cells



The observed trends on MRI measures of neurodegeneration were consistent with CHANGE-MS and ANGEL-MS results, but this time in a population of patients already treated with a highly effective anti-inflammatory drug. There were favorable treatment effects on top of rituximab in all volume measures. The results in MTSat were also favorable in Cortex, but not in NAWM. As expected, there were no relevant clinical signal given the size of the patient cohorts and the one-year treatment duration.

The observed effect sizes are relevant (20-50%) in arms treated with temelimab versus rituximab alone, which provides the expectation of yielding a clinical benefit in larger and longer trials. PK analysis and other are still pending to define optimal fixed dose for future temelimab trials in MS. Since there was no clear advantage of higher doses than 18mg/kg, and all doses were very well tolerated, the analysis of the data now also allows GeNeuro to determine the optimal dose for future temelimab trials in MS, in conjunction with potential partners.

The ProTECT-MS trial provides an important step forward for temelimab in its path to treat MS patients in whom disability progresses despite effective control of inflammation and relapses. Despite progresses made, the need to address neurodegeneration and its associated disease progression remains a huge opportunity in MS.

ProTECT-MS has shown that temelimab could bring additional benefits on key markers of neurodegeneration in a population of MS patients already treated with a highly effective anti-inflammatory drug. The data show the synergistic potential of targeting neurodegeneration with temelimab on top of inflammation, by seeking to boost myelin repair mechanisms and to block damaging mechanisms. This opens the path for future combination treatments addressing both relapses and disability progression, a novelty in MS.

During ProTECT-MS, GeNeuro had initiated an extension study aimed at providing treatment to patients having completed their treatment duration, until the results of the trial were available. The study was closed at the end of April 2022.

### **5.3 Continued Clinical Development in MS**

The 48-week results of the CHANGE-MS study and the 96-week results of the ANGEL-MS extension trial (resulting from the addition of the 48-week CHANGE-MS study and the 48-week of the ANGEL-MS study) both showed that the 18 mg/kg dose induced a positive response for neuroprotection markers such as brain volumes, black holes and MTR, and showed encouraging dose-dependent effects on clinical measures of disease progression. In addition, the safety profile over 96 weeks of temelimab at all tested doses appeared very favorable. The positive results of the ProTECT-MS trial show that temelimab's pathway is synergistic with anti-inflammatory treatments and opens the way towards combination treatments for MS patients in whom disability progresses despite effective control of inflammation and relapses. Based on these results, temelimab may provide a safe treatment option enhancing neuroprotection in all forms of the disease, that could result in the reduction of the disability progression, which is the key unmet medical need in MS. Accordingly, GeNeuro has resumed discussions with potential partners to define the best development path combining temelimab and anti-neuroinflammatory treatments to bring the synergistic benefits of temelimab to patients.

Regulatory authorities, such as the FDA, and the MS community have clearly identified “progression without relapses” as the urgent medical need in MS. GeNeuro's temelimab results indicate a true potential in this area where there is no medication available, and thus has a wide number of options on how to continue development in MS. Yet developing a drug against progressive forms of MS is a complex endeavor, as patients' condition evolves slowly over time, and clinical trials require large cohorts treated for long periods of time. Inclusion criteria for such trials aiming at having homogenous patient populations are a key success factor.

Given the high costs of the international clinical trials necessary to confirm efficacy and register a product in MS with both the FDA and the EMA, which the Company estimates to exceed €100 million, continued development in MS requires a partnership and, following the results from the ProTECT-MS trial, the Company has reactivated partnership discussions for the MS indications.

### **5.4 Post-COVID**

**GeNeuro is not pursuing development in acute COVID-19, where a broad range of vaccines, anti-viral drugs and other treatments are not available to prevent and treat patients, but is focusing its efforts on Post-COVID, also called Long-COVID or PASC (Post Acute Sequelae of COVID-19).**

#### ***i) Origin and prevalence***

COVID-19 was the most severe global pandemic since the influenza pandemic of 1918. As of January 2024, according to the World Health Organization (WHO) there have been more than 770 million confirmed cases and almost 7 million global deaths from COVID-19. Almost four years after the onset of this pandemic, although the majority of patients infected with SARS-CoV-2 recover within a few weeks, post-COVID is estimated to occur in as many as 10% of COVID-19 cases and affects people of all ages, including children, with most cases occurring in patients with mild acute illness. The consequence is widespread global harm to people's health, wellbeing, and livelihoods—an estimated one in ten people who develop long COVID stop working, resulting in extensive economic losses.

Current knowledge about post-COVID-19, PASC (Post Acute Sequelae of COVID-19), or “Post-COVID”, as well as about COVID-19 itself, is as recent as these conditions and continues to evolve almost on a daily basis.

Post-COVID collectively refers to the constellation of long-term symptoms that some people experience after contracting COVID-19. A January 2023 publication in Nature Reviews Microbiology estimated that at least 65 million people worldwide now suffer from post-COVID. According to WHO Europe (the European Regional Office of the World Health Organization), 36 million patients in the European Union (8% of the total EU population and 13% of the confirmed COVID-19 cases in the EU) are affected by Post-COVID/PASC. In France alone, according to a December 2023 report from the National Academy of Medicine, around 2 million people are thought to be affected by post-COVID in France, out of a total number of SARS-Cov-2 infections in excess of 40 million.

#### ***ii) Major findings***

The onset and time course of symptoms differ across individuals and by symptom type. Neurological symptoms often have a delayed onset of weeks to months: among participants with cognitive symptoms, 43% reported a delayed onset of cognitive symptoms at least 1 month after COVID-19, with the delay associated with younger age. Several neurocognitive symptoms worsen over time and tend to persist longer, whereas gastrointestinal and respiratory symptoms are more likely to resolve.

Few people with long COVID demonstrate full recovery, with one study finding that 85% of patients who had symptoms 2 months after the initial infection reported symptoms 1 year after symptom onset. Future prognosis is uncertain, although diagnoses of ME/CFS and dysautonomia are generally lifelong.

The scientific community has emitted several hypothesized mechanisms for Post-COVID pathogenesis, including:

- immune dysregulation,
- microbiota disruption,
- autoimmunity,
- clotting and endothelial abnormality,
- and dysfunctional neurological signaling.

GeNeuro's approach is based on the hypothesis of immune dysregulation: in 2021, results published in the Lancet journal EBioMedicine showed the presence of the W-ENV protein on lymphocytes of hospitalized patients with COVID-19. These same results indicate a correlation between the level of expression of the protein and the severity of the disease. In addition, recent data showed that SARS-CoV-2 was able to induce in vitro expression of W-ENV in human blood cells from approximately 20% of healthy volunteers .

The expression of the pathogenic W-ENV protein triggered by SARS-CoV-2 infection can continue long after the resolution of the acute phase and may play a major role in the persistence of neurological and psychiatric syndromes in many post-COVID patients.

Studies conducted on cohorts of several hundred European and American post-COVID patients have detected the presence of the W-ENV protein in over 25% of these patients .

W-ENV is found in specific disease situations, and its presence is always tied to negative disease outcomes for the patient. The pro-inflammatory effects of W-ENV are mediated through the activation of the TLR4 innate immune receptor, a pathway closely associated with some of the key features of COVID-19, such as hyper-activation of immune functions, endothelial cell activation, vasculitis as well as coagulopathy. W-ENV has mostly been studied in neurodegenerative diseases, with widely observed pathogenic effects on peripheral and central nervous system cells. After the primary SARS-CoV-2 infection is over, if W-ENV has reached a self-fueling expression level, it could cause persistent damage to endothelial cells in blood vessels and also to cells from the peripheral and central nervous system, which could explain many of the long-term neurological symptoms experienced by patients long after SARS-CoV-2 infection.

### ***iii) Current treatments***

There are currently no specifically approved or broadly effective treatments for post-COVID, but treatments for certain components have shown some efficacy for subsets of populations.

GeNeuro is at the forefront of addressing this issue with the first personalized medicine clinical trial against post-COVID, evaluating temelimab as a disease-modifying therapy in post-COVID patients presenting severe neuropsychiatric symptoms hampering their pursuit of daily living and professional activities and who are positive for the pathogenic protein W-ENV in their blood.

Temelimab has already been approved in Spain, Italy and Switzerland to conduct Phase 2 clinical trials to evaluate the efficacy and safety of this treatment in patients with cognitive impairment ("brain fog") and severe fatigue and in whom the presence of W-ENV protein in the blood can be confirmed by a serum test.

The GNC-501 study, entitled "Temelimab as a Disease Modifying Therapy in Patients with Neurological, Neuropsychological, and Psychiatric Symptoms in Post-COVID-19 or Post-Acute Sequelae of COVID-19 (PASC) Syndrome", has enrolled 203 patients from European and Swiss clinical centers. The ongoing study has enrolled only those patients who also test positive for the pathogenic protein W-ENV, to have a personalized medicine approach. From the 1'092 patients who were screened to participate in the study, 36% were positive to W-ENV. Participants will receive intravenous (IV) temelimab at a dose of 54 mg/kg every 4 weeks for 6 months, or placebo, both in addition to standard-of-care treatment. The study's primary endpoint is the occurrence of an improvement in fatigue, measured by a decrease of  $\geq 3$  points in the Patient-Reported Outcomes Measurement Information System Fatigue Short Form 7a (PROMIS Fatigue SF 7a) score, at Week 24 as compared to baseline endpoint. Secondary endpoints aim to evaluate the efficacy of treatment with temelimab plus local Standard of Care (SoC) treatment versus local SoC alone over 6 months on measures of cognition, fatigue, anxiety, depression, functional impairment/disability, and quality of life in PASC patients, and other safety and W-ENV biomarkers. The study incorporates a built-in interim analysis for safety, futility, or overwhelming efficacy; in December 2023, the Independent Data Monitoring Committee (IDMC) met to review the unblinded safety and efficacy data of the first 90 patients after three months of treatment and, based on the planned interim analysis of efficacy and safety data, which included an analysis for futility, the IDMC recommended to "continue the trial without any modifications.

Recruitment started at the end of 2022 and was completed at the end of November 2023, and results are now expected by the end of June 2024.

## 5.5 The HERV Platform in other indications

Recent biomedical research is showing that most chronic conditions affecting human beings are the consequence of a combination of factors that include genetic, hormonal, and environmental triggers. HERVs belong to this modern view of disease, acting through the combination of genetic predisposition and external factors to become reactivated and acting directly as causal agents for disease.

Over 26 families of HERVs have been identified and GeNeuro believes that they represent factors for chronic, multifactorial diseases with an autoimmune component. Developing the knowledge of the role played by HERV proteins in such diseases makes it possible to envision the development of therapies for many diseases for which there are currently no satisfactory treatments.

GeNeuro has focused its research on the HERV proteins W-ENV and HERV-K ENV and has established relationships with third-party research groups studying this protein and other HERV proteins in different diseases.

### 5.5.1 Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis (“ALS”) is a devastating motor neuron disease that occurs most often as a sporadic disease with no known cause or inheritance pattern. It was first described by the French neurologist Jean-Martin Charcot. The name ALS reflects both the degeneration of corticospinal motor neurons, the descending axons of which show altered structure in the lateral spinal cord (lateral sclerosis) and the demise of spinal motor neurons, with secondary denervation associated with muscle wasting (amyotrophy). ALS is a rapidly progressive and ultimately fatal neurodegenerative disease resulting from motor neurons degeneration in the cerebral motor cortex, the brainstem and spinal. ALS can affect people of any age, but usually starts around the age of 60 and in inherited cases around the age of 50. The average survival from onset to death is three to five years. According to research by the ALS Association, a little over 5,000 people in the U.S. are diagnosed with ALS each year, as many as 20,000 Americans have the disease at any given time and as many as 150’000 worldwide<sup>33</sup>. About 10% of ALS cases appear to be genetically transmitted in families (hereditary ALS) in association with specific genomic mutations whereas 90% are sporadic<sup>34</sup>. ALS is also considered a multisystem neurodegenerative disorder that can include cognitive and behavioral changes in addition to muscle weakness.

Today, there is no cure for ALS. There are three current approved medications that may extend life by a few months but do not stop the process of motor neuron death and do little to treat the underlying cause of ALS. Costs associated with ALS are greater than that of other neurological diseases, indicating a continued need for medical advances and financial support for patients and families. Most patients with ALS condition die from respiratory failure.

Increased reverse transcriptase (RT) activity was found in the serum of ALS patients, which led to the speculation that RT activity may derive from inherited active human endogenous retroviruses (HERVs). HERVs represent 8% of the human genome and the HERV-K family comprises recently integrated copies in the human genome. Sequencing studies revealed that HERV-K sequences are more frequently expressed in patients with ALS compared to controls<sup>35</sup>. HERV-K gag- pol and env RNA have significantly elevated expression in brains from ALS patients compared to controls.

Dr. Nath, Clinical Director of the National Institute of Neurological Disorders and Stroke (“NINDS”), part of the U.S. National Institutes of Health (“NIH”), and his research group have discovered the expression and the pathogenic effects of the envelope protein from HERV-K in ALS<sup>36</sup>. Their research has evidenced that:

- pathogenic HERV-K ENV proteins are expressed in the brains of ALS patients, and observed in the anterior horn of the spinal cord, the site of lower motor neurons that degenerate in ALS<sup>37</sup>.
- HERV-K RT expression correlates with TDP-43 (TAR - transactivation responsive- DNA binding protein 43) deposits which are thought to be critical in motor neuron degeneration and are considered the final hallmark of ALS<sup>38</sup>
- HERV-K ENV induces toxicity in human motor neurons *in vitro*. Transgenic mice expressing the HERV-K ENV gene developed an ALS-like motor neuron dysfunction and develop profound weakness of the limbs and spinal muscles, including those for respiration, resulting in 50% mortality by 10 months. These signs of motor dysfunction observed in transgenic mice expressing HERV-K ENV support the pathophysiological role of HERV-K ENV in this disorder<sup>39</sup>

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33 Sources: [alsa.org](http://alsa.org), [arsla.org](http://arsla.org)

34 Source : NIH Amyotrophic Lateral Sclerosis (ALS) Fact Sheet.

35 Source: Douville, Liu et al. 2011, Douville and Nath 2014

36 Source: Li W, Lee MH, Henderson L, et al. Human endogenous retrovirus-K contributes to motor neuron disease. *Sci Transl Med.* 2015 Sep

37 Source: Douville R et al. *Ann Neurol.* 2011; Alfahad et al. *Antiviral Res.* 2013; Li et al. *ibid*; Dolei A et al. *Int J Mol Sci.* 2019

38 Source: Manghera M et al. *Neurobiol Dis.* 2016; Li et al. *ibid*; Krug et al. *PLoS Genet.* 2017; Chang et al. *Curr Biol.* 2019

39 Source : Li et al, *ibid*

- HERV-K ENV expression appears to be specific to ALS, since it could not be found in patients with MS, Parkinson's or Alzheimer's disease<sup>40</sup>.

The possibility that HERV-K plays a crucial role in the pathophysiology of ALS could explain why several researchers have detected RT in ALS brain and blood samples, but have not been able to demonstrate human-to-animal or human-to-human transmission of the disease, because HERVs arise from the genome and not from the environment. Further, it may also explain the anatomical spread of the illness through paracrine activation of permissive autologous cells, which generally starts in one region of the body and then spreads along an anatomical pathway<sup>41</sup>.

Taken together, these findings suggest that endogenous retroviral elements and HERV-K in particular are involved in the pathophysiology of ALS and could be the missing link between TDP43 and ALS<sup>42</sup>. Thus, HERV-K ENV protein expression within neurons of patients with ALS may contribute to neurodegeneration and disease pathogenesis.

In February 2017, GeNeuro signed a Cooperative Research and Development Agreement (“**CRADA**”) with the NINDS to develop novel therapeutic antibodies for the treatment of amyotrophic lateral sclerosis. The research has evaluated the ability of these antibodies to neutralize a potential causal factor of ALS, the envelope protein of HERV-K (a family of Human Endogenous Retroviruses, HERVs). Under the terms of the agreement, GeNeuro provided antibodies designed to block the activity of HERV-K Envelope protein. These candidate antibodies were tested in cellular and animal models of HERV-K associated ALS by the NINDS, and have achieved preclinical proof-of-concept of this novel therapeutic avenue addressing ALS pathogenesis.

Following the positive results of this pre-clinical work, GeNeuro has in October 2018 entered into an agreement with the NIH granting GeNeuro an exclusive license on the jointly owned HERV-K patent. Based on this, the Company has now launched a preclinical development program for its GNK301 HERV-K ENV antibody, a high quality preclinical humanized mAb that is now ready for GMP production. In October and December 2021, the NINDS and GeNeuro presented novel pre-clinical results of their joint ALS preclinical research program. These results:

- confirm that HERV-K ENV is present in the cerebro-spinal fluid of sporadic ALS patients;
- elucidate the pathogenic effect of HERV-K ENV on motor neurons; and
- show in preclinical models the therapeutic potential of GeNeuro's specific anti-HERV-K ENV antibody.

This joint NINDS/GeNeuro study has unveiled and characterized new pathogenic mechanism and has shown the specific and efficient inhibition of HERV-K ENV neurotoxic effects from the extracellular medium in vitro and in vivo, using GeNeuro's anti HERV-K K01 monoclonal antibody. This novel preclinical data holds promises that neutralizing HERV-K ENV with GeNeuro's antibody could become a treatment option for patients with sporadic ALS and GeNeuro's preclinical development program has enabled its anti-HERV-K ENV antibody to now be humanized and ready to enter GMP manufacturing. Subject to funding, the program could start clinical trials as early as 2023. Based on its current resources, the Company has decided to open active partnership discussions for this program.

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40 Source: Li et al, *ibid.*; Arru et al. *Eur J Neurol.* 2018; Douville et al. *ibid*

41 Source: Kury, Nath, et al. 2018

42 Source: Alfahad et al, *ibid*



## **Bibliography**

### **Main Publications**

Antony JM, van Marle G, Opii W, Butterfield DA, Mallet F, Yong VW, Wallace JL, Deacon RM, Warren K, Power C (2004), "Human endogenous retrovirus glycoprotein-mediated induction of redox reactants causes oligodendrocyte death and demyelination". *Nat Neuroscience* 7:1088-95.

Balestrieri E, Matteucci C et al, "Evidence of the pathogenic W-Envelope expression in T lymphocytes in association with the respiratory outcome of COVID-19 patients", *Lancet EBioMedicine*, 2021 April: DOI:<https://doi.org/10.1016/j.ebiom.2021.103341>

Blond, J.L., et al., "Molecular characterization and placental expression of HERV-W, a new human endogenous retrovirus family". *J Virol*, 1999. 73(2):1175-85

Brudek, T., et al., "Simultaneous presence of endogenous retrovirus and herpes virus antigens has profound effect on cell-mediated immune responses: implications for multiple sclerosis." *AIDS Res Hum Retroviruses*, 2004. 20(4): 415-23.

Brudek, T., et al., "Activation of endogenous retrovirus reverse transcriptase in multiple sclerosis patient lymphocytes by inactivated HSV-1, HHV-6 and VZV" *J Neuroimmunol*, 2007. 187(1-2): 147-55.

Charvet B, Perron H et al, "SARS-CoV-2 induces transcription of human endogenous retrovirus RNA followed by type W envelope protein expression in human lymphoid cells", *MedRxiv* January 2022, doi: <https://doi.org/10.1101/2022.01.18.21266111>

Charvet et al., "SARS-CoV-2 awakens ancient retroviral genes and the expression of proinflammatory HERV-W envelope protein in COVID-19 patients", *iScience Cell Press*, April 2023

Charvet et al., "Blood biomarkers-defined subgroups show heterogeneity in post-acute COVID-19 syndrome: a rationale for precision medicine" – *MedRxiv*, April 2023

Christensen, T. et al. "Association of human endogenous retroviruses with multiple sclerosis and possible interactions with herpes viruses." *Rev Med Virol*, 2005. 15(3):179-211.

Christensen, T., et al., "Gene-environment interactions in multiple sclerosis: innate and adaptive immune responses to human endogenous retrovirus and herpesvirus antigens and the lectin complement activation pathway". *J Neuroimmunol*, 2007. 183(1-2): p. 175-88.

Curtin F, Lang AB, Perron H, Laumonier M, Vidal V, Porchet HC, Hartung HP (2012), "temelimab, a Humanized Monoclonal Antibody Against the Envelope Protein of Multiple Sclerosis-Associated Endogenous Retrovirus: A First-in-Humans Randomized Clinical Study". *Clin Ther* 34:2268-78.

Derfuss T, Curtin F, Guebelin C, Bridel C, Rasenack M, Matthey A, Du Pasquier R, Schlupe M, Desmeules J, Lang AB, Perron H, Faucard R, Porchet H, Hartung HP, Kappos L, Lalive PH. "A phase IIa randomized clinical study testing temelimab, a humanized monoclonal antibody against the envelope protein of multiple sclerosis associated endogenous retrovirus in multiple sclerosis patients — a twelve month follow-up". *J Neuroimmunol*. 2015 Aug. 15; 285:68-70.

Derfuss T, Curtin F, Guebelin C, Bridel C, Rasenack M, Matthey A, Du Pasquier R, Schlupe M, Desmeules J, Lang AB, Perron H, Faucard R, Porchet H, Hartung HP, Kappos L, Lalive PH. "A phase IIa randomised clinical study of temelimab, a humanised monoclonal antibody against the envelope protein of multiple sclerosis-associated endogenous retrovirus in multiple sclerosis patients". *Mult Scler*. 2015 Jun; 21(7):885-93.

Duperray A, Barbe D, Raguenez G, Weksler BB, Romero IA, Couraud PO, Perron H, Marche PN. Inflammatory response of endothelial cells to a human endogenous retrovirus associated with multiple sclerosis is mediated by TLR4. *Int Immunol*. 2015 Nov;27(11):545-53.

Faucard R, Madeira A, Gehin N, Authier FJ, Panaite PA, Lesage C, Burgelin I, Bertel M, Bernard C, Curtin F, Lang AB, Steck AJ, Perron H, Kuntzer T, Créange A. Human Endogenous Retrovirus and Neuroinflammation in Chronic Inflammatory Demyelinating Polyradiculoneuropathy. *EBioMedicine*. 2016 Apr;6:190-8.

Garcia-Montojo M, Dominguez-Mozo M, Arias-Leal A, Garcia-Martinez Á, De las Heras V, Casanova I, Faucard R, Gehin N, Madeira A, Arroyo R, Curtin F, Alvarez-Lafuente R, Perron H. The DNA copy number of human endogenous retrovirus-W (MSRV-type) is increased in multiple sclerosis patients and is influenced by gender and disease severity. *PLoS One*. 2013;8(1):e53623. doi:10.1371/journal.pone.0053623.

Garson JA, Tuke PW, Giraud P, Paranhos-Baccala G, Perron H (1998), "Detection of virion-associated MSRV-RNA in serum of patients with multiple sclerosis". *Lancet* 351:33.

Gruchot J, Küry P et al, "Transgenic expression of the HERV-W envelope protein leads to polarized glial cell populations and a neurodegenerative environment", *PNAS* September 2023

Johanson EM, Groc L et al, "Human endogenous retroviral protein triggers deficit in glutamate synapse maturation and behaviors associated with psychosis", *Science Advances* 2020 July

Kornmann G, Curtin F, "Temelimab, an IgG4 Anti-Human Endogenous Retrovirus Monoclonal Antibody: An Early Development Safety Review", *Drug Safety* 2020 Dec;43(12):1287-1296. doi: 10.1007/s40264-020-00988-3

- Kremer D, Schichel T, Förster M, Tzekova N, Bernard C, van der Valk P, van Horssen J, Hartung HP, Perron H, Küry P. "Human endogenous retrovirus type W envelope protein inhibits oligodendroglial precursor cell differentiation". *Ann Neurol*. 2013 Nov; 74(5):721-32.
- Kremer D, Förster M, Schichel T, Göttle P, Hartung HP, Perron H, Küry P. "The neutralizing antibody temelimab abrogates W-ENVELOPE protein-mediated oligodendroglial maturation blockade". *Mult Scler*. 2015 Aug; 21(9):1200-03.
- Kremer D, Gruchot J, Weyers V, Oldemeier L, Göttle P, Hartung H-P, Küry P. "W-ENVELOPE protein fuels microglial cell dependent damage of myelinated axons in multiple sclerosis", *Proc Natl Acad Sci U S A*. 2019 May
- Küry P, Nath A, Créange A, Dolei A, Marche P, Gold J, Giovannoni G, Hartung HP, Perron H. Human Endogenous Retroviruses in neurological diseases. *Trends In Molecular Medicine* 2018: DOI information: 10.1016/j.molmed.2018.02.007
- Levet S, Medina J, Joanou J, Demolder A, Queruel N, Réant K, Normand M, Seffals M, Dimier J, Germi R, Piofczyk T, Portoukalian J, Touraine JL, Perron H. "An ancestral retroviral protein identified as a therapeutic target in type-1 diabetes." *JCI Insight*. 2017 Sep 7;2(17). pii: 94387.
- Madeira A, Burgelin I, Perron H, Curtin F, Lang AB, Faucard R. MSR/V envelope protein is a potent, endogenous and pathogenic agonist of human toll-like receptor 4: Relevance of temelimab in multiple sclerosis treatment. *J Neuroimmunol*. 2016 Feb. 15;291:29-38.
- Mameli, G., et al., "Brains and peripheral blood mononuclear cells of multiple sclerosis (MS) patients hyperexpress MS-associated retrovirus/HERV-W endogenous retrovirus, but not Human herpesvirus 6." *J Gen Virol*, 2007. 88(Pt 1): 264-74.
- Medina J, Perron H. DNA sequences from mobile genetic elements, a hidden half of the human genome. *Med Sci (Paris)*. 2017 Feb;33(2):151-158.
- Medina, J., et al., Endogenous retroviral sequences in the human genome can play a physiological or pathological role. *Med Sci (Paris)*, 2017. 33(4): p. 397-403.
- Morandi, E., et al., The association between human endogenous retroviruses and multiple sclerosis: A systematic review and meta-analysis. *PLoS One*, 2017. 12(2): p. e0172415.
- Perron H, Lalande B, Gratacap B, Laurent A, Genoulat O, Geny C, Mallaret M, Schuller E, Stoebner P, Seigneurin JM. Isolation of retrovirus from patients with multiple sclerosis. *Lancet*. 1991 Apr 6;337(8745):862-3.
- Perron H, Garson JA, Bedin F, Beseme F, Paranhos-Baccala G, Komurian-Pradel F, Mallet F, Tuke PW, Voisset C, Blond JL, Lalande B, Seigneurin JM, Mandrand B. Molecular identification of a novel retrovirus repeatedly isolated from patients with multiple sclerosis. The Collaborative Research Group on Multiple Sclerosis. *Proc Natl Acad Sci U S A*. 1997 Jul 8;94(14):7583-8.
- Perron H, Germi R, Bernard C, Garcia-Montojo M, Deluen C, Farinelli L, Faucard R, Veas F, Stefas I, Fabriek BO, Van-Horssen J, Van-der-Valk P, Gerdil C, Mancuso R, Saresella M, Clerici M, Marcel S, Creange A, Cavaretta R, Caputo D, Arru G, Morand P, Lang AB, Sotgiu S, Ruprecht K, Rieckmann P, Villoslada P, Chofflon M, Boucraut J, Pelletier J, Hartung HP (2012). "Human endogenous retrovirus type W envelope expression in blood and brain cells provides new insights into multiple sclerosis disease". *Mult Scler*. 2012 Dec;18(12):1721-36.
- Perron H, Jouvin-Marche E, Michel M, Ounanian-Paraz A, Camelo S, Dumon A, Jolivet-Reynaud C, Marcel F, Souillet Y, Borel E, Gebuhrer L, Santoro L, Marcel S, Seigneurin JM, Marche PN, Lafon M. Multiple sclerosis retrovirus particles and recombinant envelope trigger an abnormal immune response in vitro, by inducing polyclonal Vbeta16 T-lymphocyte activation. *Virology*. 2001 Sep 1;287(2):321-32
- Perron, H., et al., "Endogenous retrovirus type W GAG and envelope protein antigenemia in serum of schizophrenic patients." *Biol Psychiatry*, 2008. 64(12): 1019-23.
- Perron, H., et al., "Molecular characteristics of Human Endogenous Retrovirus type-W in schizophrenia and bipolar disorder". *Transl Psychiatry*, 2012. 2: p. e201.
- Rolland A, Jouvin-Marche E, Viret C, Faure M, Perron H, Marche PN (2006), "The envelope protein of a human endogenous retrovirus-W family activates innate immunity through CD14/TLR4 and promotes Th1-like responses". *J Immunol* 176:7636-44.
- Ruprecht, K., et al., "Lack of immune responses against multiple sclerosis-associated retrovirus/human endogenous retrovirus W in patients with multiple sclerosis." *J Neurovirol*, 2008. 14(2):143-51.
- Saresella, M., et al., "Multiple sclerosis-associated retroviral agent (MSRV)-stimulated cytokine production in patients with relapsing-remitting multiple sclerosis". *Mult Scler*, 2009. 15(4): p. 443-7.
- van Horssen J, van der Pol S, Nijland P, Amor S, Perron H. Human endogenous retrovirus W in brain lesions: Rationale for targeted therapy in multiple sclerosis. *Mult Scler Relat Disord*. 2016 Jul;8:11-8.
- Zimmermann M, Sanderson NS, Rasenack M, Lalive PH, Lang AB, Curtin F, Lindberg RL, Kappos L, Derfuss T. Immunologic monitoring during a Phase IIa trial of the temelimab antibody in patients with MS. *Neurol Neuroimmunol Neuroinflamm*. 2015 Aug20;2(5):e144.

### **Other Publications**

- Alvarez-Lafuente, R., et al., Herpesviruses and human endogenous retroviral sequences in the cerebrospinal fluid of multiple sclerosis patients. *Mult Scler*, 2008. 14(5): p. 595-601.
- Brutting, C., et al., Cooccurrences of Putative Endogenous Retrovirus-Associated Diseases. *Biomed Res Int*, 2017. 2017: p. 7973165.
- Curtin F, Perron H, Faucard R, Porchet H, Lang AB. "Treatment Against Human Endogenous Retrovirus: A Possible Personalized Medicine Approach for Multiple Sclerosis". *Mol Diagn Ther*. 2015 Oct; 19(5):255-65.
- Curtin F, Perron H, Kromminga A, Porchet H, Lang AB. "Preclinical and early clinical development of temelimab, a humanized IgG4 monoclonal antibody targeting endogenous retroviral MSR-V-Env protein". *MABS*. 2015; 7(1):265-75.
- Curtin F, Vidal V, Bernard C, Kromminga A, Lang AB, Porchet H. „Serum pharmacokinetics and cerebrospinal fluid concentration analysis of the new IgG4 monoclonal antibody temelimab to treat multiple sclerosis: A Phase 1 study." *MABs*. 2016 Jul;8(5):854-60
- Curtin, F., et al., A placebo randomized controlled study to test the efficacy and safety of temelimab, a monoclonal antibody for the treatment of multiple sclerosis - Rationale and design. *Mult Scler Relat Disord*, 2016. 9: p. 95-100.
- Dalakas MC (2011). "Advances in the diagnosis, pathogenesis and treatment of CIDP". *Nat Rev Neurol* 7:507-17.
- De Sousa EA, Brannagan TH, 3rd (2006). "Diagnosis and treatment of chronic inflammatory demyelinating polyneuropathy". *Curr Treat Options Neurol* 8:91-103.
- do Olival, G.S., et al., Genomic analysis of ERVWE2 locus in patients with multiple sclerosis: absence of genetic association but potential role of human endogenous retrovirus type W elements in molecular mimicry with myelin antigen. *Front Microbiol*, 2013. 4: p. 172.
- Dolei (2006). "Endogenous retroviruses and human disease". *Expert Rev Clin Immunol* 2:149-67.
- Dolei A, Serra C, Mameli G, Pugliatti M, Sechi G, Cirotto MC, Rosati G, Sotgiu S (2002). "Multiple sclerosis-associated retrovirus (MSRV) in Sardinian MS patients". *Neurology* 58:471-73.
- Dolei, A., et al., "Multiple sclerosis-associated retrovirus and related human endogenous retrovirus-W in patients with multiple sclerosis". *J Neuroimmunol*, 2014. 266(1-2): 87-8.
- Dolei, A., "The aliens inside us: HERV-W endogenous retroviruses and multiple sclerosis". *Mult Scler*, 2018. 24(1): 42-47.
- Duperray, A., et al., "Inflammatory response of endothelial cells to a human endogenous retrovirus associated with multiple sclerosis is mediated by TLR4" *Int Immunol*, 2015. 27(11): 545-53.
- Firouzi R, Rolland A, Michel M, Jouvin-Marche E, Hauw JJ, Malcus-Vocanson C, Lazarini F, Gebuhrer L, Seigneurin JM, Touraine JL, Sanhadji K, Marche PN, Perron H. "Multiple sclerosis-associated retrovirus particles cause T lymphocyte-dependent death with brain hemorrhage in humanized SCID mice model". *J Neurovirol*. 2003 Feb; 9(1):79-93.
- Garcia-Montojo et al., "Antibody response to HML-2 may be protective in Amyotrophic Lateral Sclerosis"- *Annals of Neurology*, July 2022
- Garson J, Créange A, Dolei A, Ferrante P, Jouvin-Marche E, Marche PN, Rieger F, Ruprecht K, Saresella M, Sotgiu S, Tedder R, Perron H. "MSRV, Syncytin and the role of endogenous retroviral proteins in demyelination". *Mult Scler*. 2005 Apr; 11(2):249-50.
- Gröger V Cynis H "Human Endogenous Retroviruses and their putative role in the development of autoimmune disorders such as Multiple Sclerosis" *Frontiers in Microbiology* |2018;9:1-8
- Gruchot J, Kremer D, Küry P "Neural Cell Responses Upon Exposure to Human Endogenous Retroviruses", *Frontiers in Genetics* July 2019
- Kremer, D., et al., Prehistoric enemies within: The contribution of human endogenous retroviruses to neurological diseases. Meeting report: "Second International Workshop on Human Endogenous Retroviruses and Disease", Washington DC, March 13th and 14th 2017. *Multiple Sclerosis and Related Disorders*, 2017. 15:18–23.
- Kremer, D., Küry, P., Hartung, H.P. "ECTRIMS/ACTRIMS 2017: Closing in on neurorepair in progressive Multiple Sclerosis" *Multiple Sclerosis Journal* In Press
- Küry P, Nath A, Créange A, Dolei A, Marche PN, Gold J, Giovannoni G, Hartung HP, Perron H. "Human Endogenous Retroviruses in Neurological Diseases". *Trends in Molecular Medicine* In Press
- Leboyer, M., et al., Human endogenous retrovirus type W (HERV-W) in schizophrenia: a new avenue of research at the gene-environment interface. *World J Biol Psychiatry*, 2013. 14(2): p. 80-90.
- Mameli G, Poddighe L, Astone V, Delogu G, Arru G, Sotgiu S, Serra C, Dolei A (2009). "Novel reliable real-time PCR for differential detection of MSR-Env and syncytin-1 in RNA and DNA from patients with multiple sclerosis". *J Virol Methods* 161:98-106.

- Mameli, G., et al., Expression and activation by Epstein Barr virus of human endogenous retroviruses-W in blood cells and astrocytes: inference for multiple sclerosis. *PLoS One*, 2012. 7(9): p. e44991.
- Mameli, G., et al., Activation of MSRv-type endogenous retroviruses during infectious mononucleosis and Epstein-Barr virus latency: the missing link with multiple sclerosis? *PLoS One*, 2013. 8(11): p. e78474.
- Morandi, E., et al., "The association between human endogenous retroviruses and multiple sclerosis: A systematic review and meta-analysis." *PLoS One*, 2017. 12(2): p. e0172415.
- Nath, A., et al., *First international workshop on human endogenous retroviruses and diseases, HERVs & disease 2015*. Mobile DNA, 2015. 6(20): p. 1-9
- Nath, A., et al., "First international workshop on human endogenous retroviruses and diseases, HERVs & disease 2015." *Mobile DNA*, 2015. 6(20): 1-9.
- Nellaker C, Yao Y, Jones-Brando L, Mallet F, Yolken RH, Karlsson H (2006). "Transactivation of elements in the human endogenous retrovirus W family by viral infection". *Retrovirology* 3:44.
- Nociti V, Frisullo G, Marti A, Luigetti M, Iorio R, Patanella AK, Bianco A, Tonali PA, Grillo RL, Sabatelli M, Batocchi AP (2010). "Epstein-Barr virus antibodies in serum and cerebrospinal fluid from multiple sclerosis, chronic inflammatory demyelinating polyradiculoneuropathy and amyotrophic lateral sclerosis". *J Neuroimmunol* 225:149-52.
- Noorali S, Rotar IC, Lewis C, Pestaner JP, Pace DG, Sison A, Bagasra O (2009). "Role of HERV-W Syncytin-1 in Placentation and Maintenance of Human Pregnancy". *Appl Immunohistochem Mol Morphol*.
- Perron H, Dougier-Reyraud HL, Lomparski C, Popa I, Firouzi R, Bertrand JB, Marusic S, Portoukalian J, Jouvin-Marche E, Villiers CL, Touraine JL, Marche PN. "Human endogenous retrovirus protein activates innate immunity and promotes experimental allergic encephalomyelitis in mice". *PLoS One*. 2013 Dec. 6; 8(12):e80128.
- Perron H, Lang A (2009). "The human endogenous retrovirus link between genes and environment in multiple sclerosis and in multifactorial diseases associating neuroinflammation". *Clin Rev Allergy Immunol* 39:51-61.
- Rotondi M, Chiovato L (2011). "The chemokine system as a therapeutic target in autoimmune thyroid diseases: a focus on the interferon-gamma inducible chemokines and their receptor". *Curr Pharm Des* 17:3202-16.
- Ruprecht K, Obojes K, Wengel V, Gronen F, Kim KS, Perron H, Schneider-Schaulies J, Rieckmann P (2006). "Regulation of human endogenous retrovirus W protein expression by herpes simplex virus type 1: implications for multiple sclerosis". *J Neurovirol* 12:65-71.
- Sotgiu S, Arru G, Mameli G, Serra C, Pugliatti M, Rosati G, Dolei A (2006a). "Multiple sclerosis-associated retrovirus in early multiple sclerosis: a six-year follow-up of a Sardinian cohort". *Mult Scler* 12:698-703.
- Sotgiu S, Mameli G, Serra C, Zarbo IR, Arru G, Dolei A (2010). "Multiple sclerosis-associated retrovirus and progressive disability of multiple sclerosis". *Mult Scler* 16:1248-51.
- Steiner et al., "HERV-K envelope in spinal fluid of Amyotrophic Lateral Sclerosis is toxic" *Annals of Neurology* July 2022.
- Tran JQ, Rana J, Barkhof F, Melamed I, Gevorkyan H, Wattjes MP, de Jong R, Brosfsky K, Ray S, Xu L, Zhao J, Parr E, Cadavid D. "Randomized phase I trials of the safety/tolerability of anti-LINGO-1 monoclonal antibody BIIB033". *Neurol Neuroimmunol Neuroinflamm*. 2014 Aug. 21; 1(2):e18.
- Van Horsen J, Lee P, van der Pol S, Nijland P, Amor S, Nath A, Perron H. "Expression of Human Endogenous Retrovirus-W and in demyelinated brain lesions support the rationale for a novel targeted therapy in Multiple Sclerosis". *Brain* 2015 (submitted).
- Voisset C, Blancher A, Perron H, Mandrand B, Mallet F, Paranhos-Baccala G (1999). "Phylogeny of a novel family of human endogenous retrovirus sequences, HERV-W, in humans and other primates". *AIDS Res Hum Retroviruses* 15:1529-33.

## 5.6 Research And Development and Intellectual Property

The Company engages in research and development activities to develop:

- new therapeutic products, especially monoclonal antibodies, for the treatment of diseases associated with the expression of HERVs;
- diagnostic products to act as companions for the therapeutic products; and
- novel solutions for the study and treatment of HERV diseases.

GeNeuro files patent applications to protect its product candidates, technical processes and the processes used to prepare its product candidates, the compounds or molecules contained in these product candidates and medical treatment methods. GeNeuro also licenses rights to patents owned by third parties or jointly owned with third parties.

By 2006, the Mérieux group and INSERM had accumulated 15 years of work on HERVs, which led to a broad intellectual property portfolio. GeNeuro has taken exclusive licenses to and/or holds 17 patent families offering strong coverage of the W-ENV field, ranging from DNA sequences to products and their therapeutic applications, plus one patent in the HERV-K field. GeNeuro's portfolio of patents is divided into four broad categories:

- the "SEP 16" patent family covers W-ENV sequences necessary for the preparation of an antibody, particularly an antibody targeting the identified sequences. Patents in this category have been granted in all major markets and are owned by bioMérieux and INSERM. GeNeuro holds an exclusive license to such intellectual property for therapeutic uses. These patents include HERV-W fusion, SEP 6, SEP 12, SEP 13, SEP 15, SEP 16, SEP 18, SEP 19, SEP 20, SEP 21, and the INTERECO families described below;
- the "TLR4" patent family broadly covers the use of any antibody targeting W-ENV in MS and other neurological indications. This patent, described below, was granted in all principal markets and is owned by bioMérieux and INSERM. GeNeuro has an exclusive license to such intellectual property for therapeutic uses;
- the "MSRV ligand" patent family covers specific epitopes and antibodies against such epitopes (including GeNeuro's first product candidate) and their use in a broad spectrum of therapeutic indications, including MS, CIDP, and T1D. The basic patent, dating from 2009, was granted in the United States and is still pending in Europe. GeNeuro has filed several patents thereafter on its products, the most recent dating from 2014. GeNeuro owns these patents. These patents cover the MSRV ligand, and the endogenous antiviral, remyelination, and the anti-TM family of antibodies described below;
- the "antipsychotic treatment" patent covers an anti-HERV-W envelope protein antibody for use in the treatment of psychotic diseases, and
- the "HERV-K" patent, which covers the anti-HERV-K Envelope antibody and uses thereof.

Based on more than 25 years of work in the field and a systematic effort to optimize and develop intellectual property, GeNeuro believes that its portfolio of intellectual property and its constant efforts to protect new discoveries put the Company in a strong competitive position.

The term of individual patents depends upon the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application or its foreign equivalent in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. In the United States, a patent may also be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (see Section 9.1.9 of this Universal Registration Document).

For information on the accounting for costs related to research and development activities, please refer to section 7.2.1.2 "Operating Expenses by Function", as well as to notes 2, 10, 12 and 14 of the consolidated financial statements for the year ended December 31, 2023 in Chapter 18 of this Universal Registration Document.

### 5.6.1 Intellectual Property

The table below summarizes the patent families to which the Company has obtained or has rights.

*Table 9: Patent families*

Patent Family	Name	Owners/Holder(s)
Family 1	MSRV Ligand	GeNeuro
Family 2	Endogenous antiretroviral	GeNeuro
Family 3	Remyelination	GeNeuro
Family 4	SEP 16	bioMérieux
Family 5	TLR4	bioMérieux & INSERM
Family 6	SEP 12	bioMérieux
Family 7	SEP 15	bioMérieux
Family 8	SEP 18	INSERM
Family 9	INTERECO	bioMérieux
Family 10	AntiTM antibody	GeNeuro
Family 11	HERV-W fusion	bioMérieux & INSERM
Family 12	SEP 6	bioMérieux
Family 13	SEP 13	bioMérieux
Family 14	SEP 19	bioMérieux
Family 15	SEP 20	bioMérieux
Family 16	SEP 21	bioMérieux
Family 17	Antipsychotic Treatment	GeNeuro
Family 18	HERV-K antibody in ALS	GeNeuro and the NIH, with exclusive license to GeNeuro on jointly owned IP

#### 5.6.1.1 Summary of Patent Families by Products

##### **Antibodies directed against SU region of the ENV envelope protein of MSRV**

The Company holds intellectual property rights to the monoclonal antibody being developed at the clinical stage:

- the use of an anti-ENV-SU antibody capable of binding specifically to the soluble fraction of the Env protein of MSRV (Family 5);
- ligands, more specifically an antibody, including sequences corresponding to specific CDRs of the Env envelope protein for MSRV (Family 1);
- the use of such ligands in the treatment of MS, schizophrenia, CIDP, epilepsy, psoriasis, cancer, inflammatory pancreatitis and, diabetes, in particular T1D (Family 1);
- the use of an antibody against the envelope protein of HERV-W/MSRV, its fragment, and its derivatives as a global antiretroviral agent (Family 2); and
- the use of an antibody directed against HERV-W/W-ENV for its use in the prevention of a blockage of the capacity for repairing myelin (Family 3), particularly in pathologies such as RRMS, chronic progressive MS, CIDP, and schizophrenia or bipolar disorders.

##### **MSRV Genetic Sequences**

The Company is licensed under several patent families that cover genetic sequences of MSRV, including:

- the Env gene sequence of MSRV (Family 4), as well as the Env gene sequence of the endogenous retrovirus HERV-7q. (Family 8); and
- the gag and pol gene sequences of MSRV (Family 6).

##### **Therapeutic product**

The Company holds a license to a patent family that covers a compound that consists of a therapeutic agent capable of inhibiting superantigenic activity and the use of such compound for prophylaxis and/or treatment of a disease, particularly an autoimmune disease such as MS (Family 16).

##### **Diagnostic method**

The Company holds a license to two patent families that cover methods for detecting the expression of an envelope protein of an endogenous retrovirus (Family 11) and to detecting the MSRV-1 retrovirus (Family 15).

The Company also holds a license to a patent family that covers a composition of two pathogenic agents and/or infectants associated with MS and which are useful in diagnostic or treatment methods, particularly for MS (Family 12).

The Company holds a license to a patent family that covers nucleic material capable of being used in a diagnostic method, a prophylaxis method, or a method for treating MS or rheumatoid polyarthritis (Family 13).

The Company also holds a license to a patent family that covers an endogenous nucleic fragment that includes at least a part of the gag gene of an endogenous retrovirus and which is useful for detecting autoimmune diseases, particularly MS, or monitoring a pregnancy (Family 14).

The Company holds a license that covers an anti-HERV-W envelope protein antibody for use in the treatment of psychotic diseases.

The Company also holds a license that covers an antibody directed against the HERV-K Envelope protein, and uses thereof.

### 5.6.1.2 Patents and Patent Applications

Below is a description of the patents which GeNeuro holds or for which GeNeuro holds a license from a third party or for which an application has been made, with a special reference to the PCT, European, and United States and PCT patents, to which should be added the patents obtained or applied for in certain other countries which are not included below.

#### **Family 1: MSRV Ligand**

Family 1 involves ligands including sequences corresponding to specific CDRs of the envelope protein EnSv of MSRV.

In particular, it covers humanized antibodies directed against the envelope protein Env of MSRV.

This family covers, in a particular way, humanized antibodies directed against the epitope of the SU region of the envelope protein Env of MSRV necessary for the activation of TLR4.

It thus covers the antibody presently being tested in MS. It also covers the use of such a humanized antibody in the treatment of MS, schizophrenia, CIDP, epilepsy, psoriasis, cancer, inflammatory pancreatitis and diabetes, particularly T1D.

Family 1 is wholly owned by the Company.

FAMILY 1: MSRV LIGAND									
Owner	GeNeuro								
Title	Therapeutic use of particular ligands in diseases associated with the MSRV retrovirus								
PCT Extension & Engagements in National and/or Regional Phases									
Theoretical Expiration Date <sup>43</sup> : July 8, 2029									
<b>Claims subject matters</b>					<b>Combinations of claims</b>				
A: GNBAC1 (Temelimab) Antibody					1 = A + B + C				
B: Pharmaceutical composition comprising the GNBAC1 (Temelimab) antibody					2 = A + H				
C: Method of treatment of a MSRV-associated disease using the GNBAC1 (Temelimab) antibody, in particular treatment of multiple sclerosis, progressive multiple sclerosis, relapsing remitting multiple sclerosis					3 = A + B + C + D + E				
D: Method of treating multiple sclerosis using the GNBAC1 (Temelimab) antibody					4 = A + B + C + G + H				
E: Method of treating MSRV-associated diabetes using the GNBAC1 (Temelimab) antibody					5 = A + B + G + H				
F: Method of binding an MSRV-ENV protein using the murine parental version of GNBAC1 (Temelimab) antibody					6 = A + B + H				
G: Method of detection of the anti-ligand of the GNBAC1 (Temelimab) antibody in a sample using the murine parental version of GNBAC1					7 = A + C + G + H				
H: Immunoassay kit for the detection of an anti-ligand comprising the murine parental version of GNBAC1 (Temelimab) antibody					8 = A + G + H				
					9 = D + F				
Country	Priority date	Country / N° of priority	Filing Date	N° of Application	Issue date	N° of Patent	Expiry Date	Status	Claims

<sup>43</sup> Subject to the due and punctual payment of applicable maintenance fees. This date does not take into consideration the possibility of obtaining an additional protection certificate.

<b>PCT</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	EP2009/0 58663			08/01/2011	Engaged	
<b>Australia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20092680 25	13.11. 2014	2009268025	08/07/2029	Granted	<b>1</b>
<b>Brazil</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	PI 0915667-4	25.05. 2021	PI0915667-4	08.07.2029	Granted	
<b>Canada</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	2,729,869	13.02. 2018	2,729,869	08/07/2029	Granted	<b>7</b>
<b>China</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20098013 4828.3	31.12. 2014	ZL 200980134828.3	08/07/2029	Granted	<b>6</b>
<b>Hong Kong</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	25/11/2011	11112831. 5	16.10. 2015	1158232	08/07/2029	Granted	<b>6</b>
<b>South Africa</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	2011/0044 6	25.01. 2012	2011/00446	08/07/2029	Granted	<b>7</b>
<b>USA</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	12/997 486	06.05. 2014	8,715,656	09/08/2030	Granted	<b>6</b>
<b>USA (Division)</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	14/221 963	24.01. 2017	9,550,824	25/08/2029	Granted	<b>9</b>
<b>USA Continuation</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	15/367 864	14.11. 2017	9,815,888	08/07/2029	Granted	<b>E</b>
<b>USA Continuation</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	26/10/2017	15/794 541	28.08. 2018	10,059,758	08/07/2029	Granted	<b>A</b>
<b>India</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	336/KOLN P/2011	24.12. 2018	304912	08/07/2029	Granted	<b>2</b>
<b>Israel</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	210204	01.07. 2015	210204	08/07/2029	Granted	<b>4</b>
<b>Japan</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	2011- 517153	16.12. 2016	6058264	08/07/2029	Granted	<b>5</b>
<b>Japan (Division)</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	2015- 048795	17.03. 2017	6109869	08/07/2029	Granted	<b>E</b>
<b>Japan (Division)</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	2017- 043877	15.03. 2019	6495361	08/07/2029	Granted	<b>3</b>
<b>Mexico</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	MX/A/201 0/014319	21.11. 2013	315557	08/07/2029	Granted	<b>4</b>
<b>New-Zealand</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	590515	30.04. 2013	590515	08/07/2029	Granted	<b>4</b>
<b>Republic of Korea</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	10-2011- 7002937	28.11. 2016	10-1682040	08/07/2029	Granted	<b>7</b>
<b>Ukraine</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	a2011014 04	26.05. 2014	105495	08/07/2029	Granted	<b>7</b>
<b>Eurasia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	31.10. 2016	24655	08/07/2029	Granted	<b>7</b>
<b>Armenia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia
<b>Azerbaijan</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia
<b>Belarus</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia
<b>Russia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia
<b>Kazakhstan</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia
<b>Kirghizstan</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia
<b>Moldavia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia



<b>Tajikistan</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia
<b>Turkmenistan</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	20110016 0	01.11. 2016	24655	08/07/2029	Granted	same as Eurasia
<b>Europe</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validated	<b>8</b>
<b>Germany</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Austria</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Belgium</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Bulgaria</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Cyprus</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Croatia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Denmark</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Spain</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Estonia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Finland</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>France</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>United Kingdom</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Greece</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Hungary</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Ireland</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Iceland</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Italy</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Latvia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Lithuania</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Luxembourg</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Macedonia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Malta</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Monaco</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Norway</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Netherlands</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe

<b>Poland</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Portugal</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Czech republic</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Romania</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>San Marino</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Slovakia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Slovenia</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Sweden</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Swiss</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Turkey</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	09780311. 8	26.04. 2017	2315777	08/07/2029	Validation	same as Europe
<b>Europe (Division)</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	08/07/2009	17159699. 2	17.03. 2021	3211005	08/07/2029	Validated	C
<b>Hong Kong</b>	15/05/2009 13/03/2009 08/07/2008	US 61/213 189 US 61/202 581 US 61/129 613	28/02/2018	18102934. 5	03.09. 2021	1243436B	08/07/2029	Granted	C+D

\*: As provided under the "Patent Term Adjustment" mechanism, the U.S. Patent and Trademark Office granted an additional term of protection for this patent of 397 days

\*\* : As provided under the "Patent Term Adjustment" mechanism, the U.S. Patent and Trademark Office granted an additional term of protection for this patent of 48 days

### **Family 2: Endogenous Antiretroviral**

Family 2 involves the use of an antibody directed against the envelope protein HERV-W/MSRV, its fragments, and its derivatives as a global antiretroviral agent.

This family also covers the use of the combination of such an antibody, its fragments, or derivatives, with a classic antiretroviral. The Company has also considered the synergistic effect of such a combination.

Family 2 is wholly owned by GENEURO.

### **Claims subject matters**

A = Composition or combined preparation comprising the antibody GNbAC1 (temelimab) and a retroviral reverse-transcriptase inhibitory drug

B = Combination of the antibody GNbAC1 (temelimab) with a retroviral reverse-transcriptase inhibitory drug for treating multiple sclerosis

FAMILY 2: ENDOGENOUS ANTIRETROVIRAL									
Owner/Holder		GeNeuro							
Title		Antiretroviral drug targeting human endogenous retrovirus							
Country	Priority date	Country / N° of priority	Filing date	N° of Application	Issue date	N° of Patent	Expiration date	Status	Claim
<b>PCT</b>	28/05/2014	EP 14305806.3	27/05/2015	EP2015/061691			28/11/2016	Engaged	
<b>Australia</b>	28/05/2014	EP 14305806.3	27/05/2015	2015265936	12.11.2020	2015265936	27/05/2035	Granted	A B
<b>Brazil</b>	28/05/2014	EP 14305806.3	27/05/2015	11 2016 027671 0			27/05/2035	Pending	
<b>Canada</b>	28/05/2014	EP 14305806.3	27/05/2015	2 949 884			27/05/2035	Pending	

<b>China</b>	28/05/2014	EP 14305806.3	27/05/ 2015	201580027652. 7			27/05/2035	Pending	
<b>Hong-Kong</b>	28/05/2014	EP 14305806.3	27/05/ 2015	17109624.6			27/05/2035	Pending	
<b>Eurasia</b>	28/05/2014	EP 14305806.3	27/05/ 2015	201692471	27.02.2020	0 34612	27/05/2035	Granted	A B
<b>Belarus</b>	28/05/2014	EP 14305806.3	27/05/ 2015	201692471	27.02.2020	0 34612	27/05/2035	Validation	as in Eurasia
<b>Russia</b>	28/05/2014	EP 14305806.3	27/05/ 2015	201692471	27.02.2020	0 34612	27/05/2035	Validation	as in Eurasia
<b>Kazakhstan</b>	28/05/2014	EP 14305806.3	27/05/ 2015	201692471	27.02.2020	0 34612	27/05/2035	Validation	as in Eurasia
<b>Europa</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Granted	A B
<b>Germany</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27/05/2035	Validation	as in Europe
<b>Austria</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27/05/2035	Validation	as in Europe
<b>Belgium</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Denmark</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Spain</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Finland</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>France</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Great Britain</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Greece</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Hungary</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Ireland</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Italia</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Luxembourg</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Norway</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Netherlands</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Poland</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Portugal</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Czech Republic</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Romania</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Sweden</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Switzerland</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Turkey</b>	28/05/2014	EP 14305806.3	27/05/ 2015	15725326.1	31.07.2019	3148582	27.05.2035	Validation	as in Europe
<b>Israel</b>	28/05/2014	EP 14305806.3	27/05/ 2015	249040	31.05.2020	249040	27/05/2035	Granted	A B
<b>India</b>	28/05/2014	EP 14305806.3	27/05/ 2015	201617043958			27/05/2035	Pending	
<b>Mexico</b>	28/05/2014	EP 14305806.3	27/05/ 2015	MX/A/2016/0155 60	11.08.2020	374177	27/05/2035	Granted	A B
<b>Russia</b>	28/05/2014	EP 14305806.3	27/05/ 2015	2016151471	27.05.2019	2,689,326	27/05/2035	Granted	A B

Ukraine	28/05/2014	EP 14305806.3	27/05/ 2015	a201613240	11.11.2019	120274	27/05/2035	Granted	A B
USA (Continuation)	28/05/2014	EP 14305806.3	22.03. 2019	16/362 193	19.01.2021	10,894,820	27.05.2035	Granted	B
South of Africa	28/05/2014	EP 14305806.3	27/05/ 2015	2016/08050	27.05.2020	2016/08050	27/05/2035	Granted	A B

### **Family 3: Remyelination**

This application covers compounds and compositions for the prevention and/or treatment of a mechanism that blocks the endogenous myelin repair capability of the adult nervous system in disorders associated with the expression of the envelope protein W-ENV, particularly its subtype, MSRV.

This family also covers the use of an antibody directed against W-ENV for use in the prevention of the blockage of the endogenous myelin repair capability, particularly in disorders such as RRMS, chronic progressive MS, CIDP, and schizophrenia or bipolar disorders.

Family 3 is wholly owned by GENEURO.

FAMILY 3: REMYELINATION	
Owner/Holder	GeNeuro
Title	Compound for treatment of inhibition of remyelination in diseases and disorders associated with expression of the envelope protein HERV-W
PCT Extension & Engagements in National and/or Regional Phases Theoretical Expiration Date <sup>44</sup> : October 1, 2033	

#### **Claims subject matters**

- A Composition comprising the antibody GNbAC1 (temelimab) and a nitric oxide inhibitory drug or Combined composition (kit) comprising the antibody GNbAC1 (temelimab) and a nitric oxide inhibitory drug
- B Method for preventing or treating diseases associated with W-ENV using the antibody GNbAC1 (temelimab), in particular multiple sclerosis, progressive multiple sclerosis, relapsing remitting multiple sclerosis
- C Method for preventing or treating diseases associated with HERV-W EN using the antibody GNbAC1 (temelimab) and a nitric oxide inhibitory drug or using a composition comprising the antibody GNbAC1 (temelimab) and a nitric oxide inhibitory drug, in particular multiple sclerosis, progressive multiple sclerosis, relapsing remitting multiple sclerosis
- D Method for preventing or treating progressive multiple sclerosis using the antibody GNbAC1(temelimab)

Country	Priority date	Country / N° of priority	Filing date	N° of Application	Issue date	N° of Patent	Expiration date	Status	Claims
PCT	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	EP2013/070452			02/04/2015	Engaged	
Saudi Arabia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	515360207	18.09.2018	6097	01/10/2033	Granted	A
Australia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	2013326552	06.09.2018	2013326552	01/10/2033	Granted	A
Australia (Division)	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	2018217328	02.01.2020	2018217328	01/10/2033	Granted	C
Brazil	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	122020015957-0				Pending	C
Canada	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	2 882 781	15.06.2021	2,882,781	01/10/2033	Granted	C
China	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201380051713.4	19.06.2018	ZL 201380051713.4	01/10/2033	Granted	C
China (Division)	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201610152679.5	05.06.2020	ZL 201610152679.5	01/10/2033	Granted	A B
Hong Kong	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/08/2016	16109172.3	22.01.2021	1221399B	01/10/2033	Granted	A B
Colombia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	15-095895	01.10.2013	33485	01/10/2033	Granted	A
United Arab Emirates	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	P431/15			01/10/2033	Pending	C
USA	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	14/429 199	12.12.2017	9,840,550	01/10/2033	Granted	A

<sup>44</sup> Subject to the due and punctual payment of applicable maintenance fees. This date does not take into consideration the possibility of obtaining an additional protection certificate.

<b>USA (Division)</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	15/812 745	25.08.2020	10,752,675	01/10/2033	Granted	<b>C</b>
<b>Eurasia</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	<b>A B</b>
<b>Armenia</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	as in Eurasia
<b>Azerbaijan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	as in Eurasia
<b>Belarus</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	as in Eurasia
<b>Russia</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	as in Eurasia
<b>Kazakhstan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	as in Eurasia
<b>Kirghizistan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	as in Eurasia
<b>Tadjikistan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	as in Eurasia
<b>Turkmenistan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	31.10.2017	028245	01/10/2033	Granted	as in Eurasia
<b>Eurasia (Division)</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201791525	26.02.2021	37253	01/10/2033	Granted	<b>C</b>
<b>Armenia</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	26.02.2021	028245	01/10/2033	Granted	as in Eurasia
<b>Azerbaijan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	26.02.2021	028245	01/10/2033	Granted	as in Eurasia
<b>Belarus</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	26.02.2021	028245	01.10.2033	Granted	as in Eurasia
<b>Russia</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	26.02.2021	028245	01/10/2033	Granted	as in Eurasia
<b>Kazakhstan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	26.02.2021	028245	01/10/2033	Granted	as in Eurasia
<b>Kirghizstan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	26.02.2021	028245	01/10/2033	Granted	as in Eurasia
<b>Tajikistan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	26.02.2021	028245	01/10/2033	Granted	as in Eurasia
<b>Turkmenistan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	201590678	26.02.2021	028245	01/10/2033	Granted	as in Eurasia
<b>Israël (Division)</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01.10.2013	264382	31.05.2020	264382	01/10/2033	Granted	<b>A B</b>
<b>Israël (Division)</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01.10.2013	274047	01.03.2021	274047	01/10/2033	Granted	<b>C</b>
<b>Japan</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	2015-533633	10.08.2018	6379331	01/10/2033	Granted	<b>C</b>
<b>Japan (Division)</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	2017-214696	14.06.2019	6538138	01/10/2033	Granted	<b>A</b>
<b>Malaisia</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	PI 2015700643	15.11.2019	MY-172209-A	01/10/2033	Granted	<b>A B</b>
<b>Mexico</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	MX/A/2015/003572	26.07.2019	366846	01/10/2033	Granted	<b>A B</b>
<b>Mexico (Division)</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	MX/A/2019/008916	02.08.2021	385,003	01/10/2033	Granted	<b>C</b>
<b>Singapore</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	11201501274V	06.04.2017	11201501274V	01/10/2033	Granted	<b>A B</b>
<b>Thailand</b>	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	1501001128			01/10/2033	Pending	

South of Africa	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	2015/01491	27.01.2016	2015/01491	01/10/2033	Granted	
Europe	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Granted	<b>A B</b>
Albania	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Germany	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Austria	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Belgium	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Bulgaria	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Cyprus	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Croatia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Denmark	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Spain	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Estonia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Finland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
France	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
United Kingdom	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Greece	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Hungary	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Ireland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Iceland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Italia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Latvia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Lithuania	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Luxembourg	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Macedonia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Malta	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Monaco	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Norway	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Netherlands	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe

Poland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Portugal	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Czech Republic	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Romania	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
San Marino	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Serbia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Slovakia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Slovenia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Sweden	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Switzerland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Turkey	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	13770926.7	21.11.2018	2904009	01/10/2033	Validation	as in Europe
Europe (Division)	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Granted	C
Albania	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Germany	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Austria	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Belgium	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Bulgaria	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Cyprus	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Croatia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Denmark	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Spain	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Estonia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Finland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
France	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
United Kingdom	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Greece	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Hungary	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Ireland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe

Iceland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Italia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Latvia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Lithuania	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Luxembourg	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Macedonia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Malta	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Monaco	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Norway	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Netherlands	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Poland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Portugal	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Czech Republic	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Romania	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Serbia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Slovakia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Slovenia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Sweden	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Switzerland	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Turkey	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	18198309.9		3447070	01/10/2033	Validation	as in Europe
Russia	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	2015116149		3447070	01/10/2033	Granted	<b>A</b> <b>B</b>
New Zealand (Division)	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	740726	03.11.2020	740726	01/10/2033	Granted	<b>A</b> <b>B</b>
Republic of Korea	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	10-2015-7011152	01.04.2020	10-2098033	01/10/2033	Granted	<b>C</b>
Ukraine	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	a201504292	25.04.2019	119032	01/10/2033	Granted	<b>A</b>
Ukraine (Division)	28/12/2012 02/10/2012	US 61/746 792 US 61/708 779	01/10/2013	a201809345	02.11.2022	126558	01/10/2033	Granted	<b>C</b>



#### **Family 4: SEP 16**

Patent family 4 covers the sequence of the env gene.

This family covers the sequence necessary for the development of humanized antibodies directed against the epitope of the envelope protein Env of MSRV necessary for the activation of TLR4.

Family 4 is wholly owned by bioMérieux.

FAMILY 4: SEP 16				
Owner/Holder	bioMérieux			
Title	Retroviral nucleic material and nucleotide fragments, in particular associated with multiple sclerosis and/or rheumatoid arthritis, for diagnostic, prophylactic and therapeutic uses			
Extensions				
Theoretical Expiration Date <sup>45</sup> : July 7, 2018				
Country	Filing date and number	Publication date and number	Issue date and number	Status
Canada	CA 2 295 935 July 7, 1998		CA 2 295 935 Sep. 9, 2014	Patent issued
Europe	EP 98936467.4 July 7, 1998	EP 0 996 731 May 3, 2000	EP 0 996 731 Aug. 31, 2005	Patent issued and confirmed in FR, SP, IT, GB, GER, SW
Europe (division)	EP 05017735.1 July 7, 1998	EP 1 612 270 Jan. 4, 2006	EP 1 612 270 Sep. 2, 2009	Patent issued and confirmed in FR, SP, IT, GB, GER, SW
Japan	JP 11-508255 July 7, 1998	JP 2002-509437 March 26, 2002	JP 4 272 264 March 6, 2009	Patent issued
United States	US 09/319 156 July 7, 1998		US 7 771 927 Aug. 10, 2010	Patent issued
United States (division)	US 12/776 893 July 7, 1998		US 8 088 910 Jan. 3, 2012	Patent issued

#### **Family 5: TLR4**

This patent family covers the use of an anti env-SU antibody capable of binding itself to the soluble fraction of the Env protein of MSRV for preparation of a medication intended to treat MS or schizophrenia by inhibiting the pro-inflammatory cascade involving the soluble fraction of Env of MSRV and such receptor.

This patent family, therefore, broadly covers an antibody directed against Env-SU of MSRV for use in the treatment of MS or schizophrenia.

Family 5 is owned by bioMérieux and INSERM.

FAMILY 5: TLR4				
Owner/Holder	bioMérieux and INSERM			
Title	Composition for treating pathology associated with MSRV/HERV-W			
Priority				
Country	Filing date and number	Publication date and number	Issue date and number	Status
France	FR 04 00675 Jan. 23, 2004	FR 2 865 403 June 1, 2005	FR 04 00675 June 12, 2009	Patent issued
PCT Extension & Engagements in National and/or Regional Phases				
Theoretical Expiration Date: <sup>46</sup> January 24, 2025				
PCT	PCT/FR2005/00156 Jan. 24, 2005	WO2005/080437 Sep. 1, 2005		Application engaged
Canada	CA 2 554 263 Jan. 24, 2005		CA 2 554 263 Aug. 5, 2014	Patent issued
China	CN 20058006462.3 Jan. 24, 2005	CN 1926153 A March 7, 2007	ZL200580006462.3 May 4, 2011	Patent issued
Europe	EP 05717480.7 Jan. 24, 2005	EP 1 709 082 Oct. 11, 2006	EP 1 709 082 March 12, 2014	Patent issued and confirmed in SW, GER, SP, FR, GB, IT, AU, BE, BG, CY, DK, EE, FI, GR, HU, IE, IS, LT, LU, MC, NL, PL, PT, CZ, RO, SI, SK, SE, TR
Europe (division)	EP 10183899.3 Jan. 24, 2005	EP 2 365 002 Sep. 14, 2011		Examination pending
India	IN 3065/CHENP/2006 Jan. 24, 2005		IN 241 921 July 30, 2010	Patent issued
Japan	JP 2006-550240 Jan. 24, 2005	JP 2008-505847 Feb. 28, 2008	JP 4 991 314 May 11, 2012	Patent issued
United States	US 10/586 742 Jan. 24, 2005	US-2008-0038279 Feb. 14, 2008	US 7 666 420 Feb. 23, 2010	Patent issued*.

\*: As provided under the "Patent Term Adjustment" mechanism, the U.S. Patent and Trademark Office granted an additional term of protection for this patent of 103 days.

45 Subject to the due and punctual payment of applicable maintenance fees.

46 Subject to the due and punctual payment of applicable maintenance fees.

### Family 6: SEP 12

This patent family covers the gag and pol sequences of MSRV. Family 6 is wholly owned by bioMérieux.

FAMILY 6: SEP 12				
Owner/Holder	bioMérieux			
Title	Viral material and nucleotide fragments associated with multiple sclerosis useful for diagnostic, preventive and therapeutic purposes			
PCT Extensions & Engagements in National and/or Regional Phases				
Theoretical Expiration Date <sup>47</sup> : August 2, 2016				
Country	Filing date and number	Publication date and number	Issue date and number	Status
PCT	PCT/FR1996/01244 Aug. 2, 1996	WO1997/06260 Feb. 20, 1997		Application engaged
Canada	CA 2 201 282 Aug. 2, 1996		CA 2 201 282 01 April 2013	Patent issued
Europe	EP 96420265.9 Aug. 2, 1996	EP 0 789 077 Aug. 13, 1997	EP 0 789 077 Sep. 26, 2007	Patent issued and confirmed in FR, GER, IT, SP, SW, GB
Europe (division)	EP 07018564.0 Aug. 2, 1996	EP 1 916 304 April 30, 2008	EP 1 916 304 Jan. 18, 2012	Patent issued and confirmed in FR, GER, IT, SP, SW, GB
Japan	JP 9-508179 Aug. 2, 1996		JP 4 444 372 Jan. 22, 2010	Patent issued
Japan (division)	JP 2009-265658 Aug. 2, 1996		JP 5 143 814 Nov. 30, 2012	Patent issued
United States	US 08/691 563 Aug. 2, 1996		US 6 001 987 Dec. 14, 1999	Patent issued
United States (division)	US 09/374 766 Aug. 2, 1996		US 6 579 526 June 17, 2003	Patent issued
United States (division)	US 11/463 109 Aug. 2, 1996		US 7 932 350 May 24, 2007	Patent issued.*

\*: As provided under the "Patent Term Adjustment" mechanism, the U.S. Patent and Trademark Office granted an additional term of protection for this patent of 1133 days.

### Family 7: SEP 15

This patent family covers a particular sequence that is expressed in the placenta.

Family 7 is wholly owned by bioMérieux.

FAMILY 7: SEP 15				
Owner/Holder	bioMérieux			
Title	Endogenic retroviral sequences associated with autoimmune diseases or with pregnancy disorders			
PCT Extension & Engagements in National and/or Regional Phases				
Theoretical Expiration Date <sup>48</sup> : July 6, 2018				
Country	Filing date and number	Publication date and number	Issue date and number	Status
PCT	PCT/FR1998/01442 July 6, 1998	WO1999/02696 Jan. 21, 1999		Application engaged
Canada	CA 2 298 834 July 6 1998		CA 2 298 834 March 23, 2015	Patent issued
Europe	EP 98935106.9 July 6, 1998	EP 1 000 158 May 17, 2000	EP 1 000 158 Nov. 22, 2006	Patent issued and confirmed Abandoned in confirmed countries
Japan	JP 11-508244 July 6, 1998	JP 2002-512530 April 23, 2002	JP 4 249 269 Jan. 23, 2009	Patent issued

### Family 8: SEP 18

This patent family covers the env gene of the HERV-7q endogenous retrovirus.

Family 8 is wholly owned by INSERM.

FAMILY 8: SEP 18				
Owner/Holder	INSERM			
Title	Nucleic sequence and deduced protein sequence family with human endogenous retroviral motifs, and their uses			
Priority				
Country	Filing number and date	Publication number and date	Issue number and date	Status
France	FR 98 07920 June 23, 1998	FR 2 780 069 Dec. 24, 1999	FR 98 07920 June 28, 2002	Patent issued
Extensions				
Theoretical Expiration Date <sup>49</sup> : June 23, 2019				
Canada	CA 2 331 923 23 June 23, 1999		CA 2 331 923 Feb. 18, 2014	Patent issued
Europe	EP 99926538.2 June 23, 1999	EP 1 090 122 April 11, 2001	EP 1 090 122 July 16, 2008	Patent issued and confirmed in GER, FR, NL, GB
United States	US 09/719 554 June 23, 1999		US 6 919 438 July 16, 2005	Patent issued
United States (division)	US 11/028 539 June 23, 1999	US 2005-0118573 June 2, 2005	US 7 534 439 May 19, 2009	Patent issued. *

\*: As provided under the "Patent Term Adjustment" mechanism, the U.S. Patent and Trademark Office granted an additional term of protection for this patent of 235 days.

47 Subject to the due and punctual payment of applicable maintenance fees.

48 Subject to the due and punctual payment of applicable maintenance fees.

49 Subject to the due and punctual payment of applicable maintenance fees.

### **Family 9: INTERECO**

This patent family covers the peptide domain required for interaction between the envelope of a virus pertaining to the HERV-W interference group and an hASCT receptor. This area plays a part in the transmission of information and the merger of cells.

Family 9 is wholly owned by bioMérieux.

FAMILY 9: INTERECO				
Owner/Holder	bioMérieux			
Title	Peptide domain required for interaction between the envelope of a virus pertaining to the HERV-W interference group and an hASCT receptor			
Priority				
Country	Filing date and number	Publication date and number	Issue date and number	Status
France	FR 06 50468 Feb. 9, 2006	FR 2 897 062 Aug. 10, 2007	FR 06 50465 Nov. 4, 2011	Patent issued
PCT Extension & Engagements in National and/or Regional Phases				
Theoretical Expiration Date <sup>50</sup> : February 9, 2027				
PCT	PCT/FR2007/000236 Feb. 9, 2007	WO2007/090967 Aug. 16, 2007		Application engaged
Australia	AU 2007213591 Feb. 9, 2007		AU 2007213591 Feb. 19, 2012	Patent issued
Canada	CA 2 640 793 Feb. 9, 2007		CA 2 640 793	Patent issued Awaiting official deed
China	CN 200780004699.7 Feb. 9, 2007	CN 101379079 A March 4, 2009	ZL200780004699.7 Nov. 14, 2012	Patent issued
Europe	EP 07730950.8 Feb. 9, 2007	EP 1 981 904 Oct. 22, 2008		Examination pending
India	4129/CHENP/2008 Feb. 9, 2007			Examination pending
Israel	IL 193 353 Feb. 9, 2007			Examination pending
Japan	JP 2008-553798 Feb. 9, 2007	JP 2009-525741 July 16, 2009		Examination pending
Japan (division)	JP 2015-200607 Feb. 9, 2007			Examination pending
United States	US 14/847 941 Feb. 9, 2007			Examination pending

### **Family 10: Ac AntiTM**

This patent family covers a humanized antibody directed against the W-ENvelope protein, in particular the C-terminal extremity of the SU region of the envelope protein of HERV-W, to the exclusion of any antibody specifically directed against the liaison site of such Env protein and the hASCT1 or hASCT2 receptor. Such antibodies can be advantageous for monitoring pathological pregnancies.

Family 10 is wholly owned by GENEURO.

FAMILY 10: Ac ANTITM				
Owner/Holder	GeNeuro			
Title	Pharmaceutical composition containing antibodies directed against the W-ENvelope			
Priority				
Country	Filing number and date	Publication number and date	Issue number and date	Status
France	FR 07 00952 Feb. 9, 2007	FR 2 912 314 Aug. 15, 2008	FR 07 00952 Aug. 3, 2012	Patent issued – theoretical expiration date <sup>51</sup> : February 9, 2027
PCT Extension & Engagements in National and/or Regional Phases				
PCT	PCT/FR2008/000166 Feb. 11, 2008	WO2008/113916 Sep. 25, 2008		Application engaged
Europe	EP 08761866.6 Feb. 11, 2008	EP 2 117 594 Nov. 18, 2009		Application abandoned
United States of America	US 12/449,327 Feb. 11, 2008	US 2010-0074894 March 25, 2010		Application abandoned

The extensions of the patent filed subsequently were abandoned, because the MSRV ligand patent, providing broader protection, was filed in the meantime; such extensions, therefore, were no longer of interest.

<sup>50</sup> Subject to the due and punctual payment of applicable maintenance fees.

<sup>51</sup> Subject to the due and punctual payment of applicable maintenance fees.

**Family 11: HERV-W fusion**

This patent family covers a process for detecting the expression of the envelope protein of a HERV based on the detection of the fusogenic power of such protein in a cellular tissue or of a cellular culture, by showing the formation of syncytia.

Family 11 is owned by bioMérieux and INSERM.

FAMILY 11: HERV-W FUSION				
Owner/Holder	bioMérieux and INSERM			
Title	Method for detecting the expression of an envelope protein of a human endogenous retrovirus and uses of a gene coding for said protein			
PCT Extension & Engagements in National and/or Regional Phases theoretical expiration date <sup>52</sup> : September 1, 2020				
Country	Filing number and date	Publication number and date	Grant number and date	Status
PCT	PCT/FR00/02429 Sep. 1, 2000	WO01/16171 Sep. 8, 2011		Application engaged
Europe	EP 00960783.9 Sep. 1, 2000	EP 1 212 359 June 12, 2002	EP 1 212 359 Nov. 12, 2011	Patent granted
Europe	EP 10 183 612.0 Sep. 1, 2000	EP 2 385 058 Nov. 9, 2011	EP 2 385 058 Nov. 6, 2013	Patent granted
Japan	JP 2001-519732 Sep. 1, 2000	JP 2003-510032 March 18, 2003	JP 4 283 475 March 27, 2009	Patent granted
Japan	JP 2008-244988 Sep. 1, 2000	JP 2009-72194 April 9, 2009	JP 4 824 731 Sep. 16, 2011	Patent granted
Canada	CA 2 383 877 Sep. 1, 2000		CAK 2 383 877 April 15, 2014	Patent granted
United States of America	US 10/069,883 Feb. 11, 2008	US 2010-0074894 March 25, 2010	7 442 550 Oct. 28, 2008	Patent granted

**Family 12: SEP 6**

This patent family covers a composition that consists of two pathogenic agents and/or infectants associated with MS.

These agents are, respectively:

- a first agent being a human virus possessing reverse transcriptase activity and which is related to a family of endogenous retroviral elements or a variant of such virus, and
- a second agent or variant of such agent.

Both of these pathogenic and/or infectant agents come from the same viral source chosen from the sources called, respectively, POL-2.

This composition may be used in a diagnostic method, a prophylaxis method, or as a treatment method, particularly for MS. Family 12 is wholly owned by bioMérieux.

FAMILY 12: SEP 6				
Owner/Holder	bioMérieux			
Title	MMSRV1 virus linked to multiple sclerosis, its nucleic components and their applications			
PCT Extension & Engagements in National Phase				
Country	Filing number and date	Publication number and date	Grant number and date	Status
PCT	PCT/FR95/00142 Feb. 6, 1995	WO95/21256 Aug. 10, 1995		Application engaged
United States	US 08/384 137 Feb. 6, 1995		US 5 871 996 Feb. 6, 1999	Patent granted
United States	US 08/470 006 Feb. 6, 1995		US 5 962 217 Jan. 5, 1999	Patent granted
United States	US 09/133 411 Feb. 6, 1995		US 6 342 383 Jan. 29, 2002	Patent granted
United States	US 08/471 969 Feb. 6, 1995		US 5 871 745 Feb. 16, 1999	Patent granted
United States	US 09/200 990 Feb. 6, 1995		US 6 184 025 B1 Feb. 6, 2001	Patent granted

<sup>52</sup> Subject to the due and punctual payment of applicable maintenance fees.

### **Family 13: SEP 13**

This patent family relates to nucleic medicine capable of being used in a diagnostic mode, a method for prophylaxis, or as a method for treating MS or rheumatoid polyarthritis.

Family 13 is wholly owned by bioMérieux.

FAMILY 13:SEP 13				
Owner/Holder	bioMérieux			
Title	Viral material and nucleotide fragments associated with multiple sclerosis, for diagnostic, prophylactic and therapeutic purposes			
PCT Extension & Engagements in National and/or Regional Phases theoretical expiration date <sup>53</sup> : November 26, 2017				
Country	Filing number and date	Publication number and date	Grant number and date	Status
PCT	PCT/IB97/01482 Nov. 26, 1997	WO98/23755 June 4, 1998		Application engaged
Europe	EP 97 911 411.3 Nov. 26, 1997	EP 0 942 987 Sep. 22, 1999	EP 0 942 987 Aug. 19, 2009	Patent granted
Canada	CA 2 272 845 Nov. 26, 1997		CA 2 272 845 Jan. 12, 2010	Patent granted
Japan	JP 10-524475 Nov. 26, 1997	JP 2001-505768 May 8, 2001	JP 4 226 657 Dec. 5, 2008	Patent granted
United States	US 08/979 847 Nov. 26, 1997		US 6 582 703 June 24, 2003	Patent granted
United States	US 11/581 030 Nov. 26, 1997	US 2007-0031452 Feb. 8, 2007	US 7 674 888 Nov. 26, 1997	Patent granted

### **Family 14: SEP 19**

This patent family relates to endogenous nucleotide fragments having at least one part of the gag gene of an endogenous retrovirus associated with an autoimmune disorder or a failed pregnancy or pregnancy disorders. This family also covers the use of such a fragment to detect, in a biological sample, susceptibility to an autoimmune disease, especially MS, or for monitoring or following a pregnancy.

Family 14 is wholly owned by bioMérieux.

FAMILY 14: SEP 19				
Owner/Holder	bioMérieux			
Title	Process for the detection of an endogenous nucleic acid fragment associated with an autoimmune disease			
PCT Extension & Engagements in National and/or Regional Phases theoretical expiration date <sup>54</sup> : January 21, 2020				
Country	Filing number and date	Publication number and date	Grant number and date	Status
PCT	PCT/FR00/00144 July 21, 2000	WO00/043521 July 27, 2000		Application engaged
Europe	EP 00 900 645.3 Jan. 21, 2000	EP 1 147 187 Oct. 24, 2001	EP 1 147 187 June 27, 2012	Patent granted
United States	US 10/632 793 Jan. 21, 2000	US 2004-0048298 March 11, 2004	US 7 632 931 Dec. 15, 2009	Patent granted

<sup>53</sup> Subject to the due and punctual payment of applicable maintenance fees.

<sup>54</sup> Subject to the due and punctual payment of applicable maintenance fees.

### **Family 15: SEP 20**

This family relates to a nucleic fragment of the LTR-RU5 region. This patent family also covers probes and methods capable of hybridation with such fragment, the protein it encodes, an antibody directed against such protein, and a protein for detecting the MSRV-1 retrovirus through such probe or the antibodies described in the invention.

Family 15 is wholly owned by bioMérieux.

FAMILY 15: SEP 20				
Owner/Holder	bioMérieux			
Title	The LTR region of MSRV-1 and the proteins it encodes, and probes and methods for detecting the MSRV-1 retrovirus			
PCT Extension & Engagements in Regional Phase theoretical expiration date <sup>55</sup> : February 15, 2020				
Country	Filing number and date	Publication number and date	Grant number and date	Status
PCT	PCT/IB00/00159 Feb. 15, 2000	WO00/47745 Aug. 17, 2000		Application engaged
Europe	EP 00 902 825.9 Feb. 15, 2000	EP 1 151 108 Nov. 7, 2001	EP 1 151 108 Nov. 30, 2005	Patent granted

### **Family 16: SEP 21**

This invention covers, in particular, a method for detecting superantigenic activity in a biological sample, including demonstration of a majority expansion of lymphocytes.

This application also covers a composition consisting of a therapeutic agent capable of inhibiting superantigen activity and the use of such composition for prophylactic steps and/or the treatment of a disease, particularly an autoimmune disease, such as MS.

Family 16 is wholly owned by bioMérieux.

FAMILY 16: SEP 21				
Owner/Holder	bioMérieux			
Title	Method for detecting MSRV-1 induced superantigen activity in a biological sample			
PCT Extension & Engagements in Regional Phase theoretical expiration date <sup>56</sup> : March 20, 2020				
Country	Filing number and date	Publication number and date	Grant number and date	Status
PCT	PCT/FR00/00691 March 20, 2000	WO00/57185 Sep. 28, 2000		Application engaged
Europe	EP 00 912 720.0 March 20, 2000	EP 1 163 522 Sep. 28, 2000	EP 1 163 522 Nov. 22, 2006	Patent granted

### **Family 17: Antipsychotic Treatment**

This invention covers an anti-HERV-W envelope protein antibody for use in the treatment of psychotic diseases.

Family 17 is wholly owned by GeNeuro.

Claims subject matters

A = Antibody GN\_mAb\_Env-K01 defined by CDRs

B = Method of treatment of ALS with antibody GN\_mAb\_Env-K01

Country	Priority date	Country / N° of priority	Filing date	N° of Application	Issue date	N° of Patent	Expiration date	Status	Claims
PCT	28.05.2020	EP20305561.1	28.05.2021	EP2021/064364				Engaged	
Australia	28.05.2020	EP20305561.1	28.05.2021	2021281054				Pending	
Canada	28.05.2020	EP20305561.1	28.05.2021	3,185,024				Pending	
China	28.05.2020	EP20305561.1	28.05.2021					Pending	
Eurasia	28.05.2020	EP20305561.1	28.05.2021	202293499				Pending	
Europe	28.05.2020	EP20305561.1	28.05.2021	21727188.1				Pending	
Israel	28.05.2020	EP20305561.1	28.05.2021	298594				Pending	
Japon	28.05.2020	EP20305561.1	28.05.2021	2022-573646				Pending	
Republic of Korea	28.05.2020	EP20305561.1	28.05.2021	10-2022-7046045				Pending	
South Africa	28.05.2020	EP20305561.1	28.05.2021	2022/13084				Pending	
USA	28.05.2020	EP20305561.1	28.05.2021	17/927 764				Pending	

55 Subject to the due and punctual payment of applicable maintenance fees.

56 Subject to the due and punctual payment of applicable maintenance fees.

### **Family 18: HERV-K''**

This invention covers an antibody directed against the HERV-K Envelope protein, and uses thereof.

Family 18 is jointly owned by GeNeuro and the NIH; the NIH has entered into an exclusive license of its rights to GeNeuro.

FAMILY 17: HERV-K								
Owner/Holder		GeNeuro and the NIH						
Title		Pharmaceutical composition containing antibodies directed against the HERV-K Envelope						
Country	Priority date	Country / N° of priority	Filing date	N° of Application	Issue date	N° of Patent	Expiry date	Status
Europe			20/01/2017	17305062.6			20/01/2037	Pending
Argentina	20/01/2017	EP 17305062.6	19/01/2018	20180100129			19/01/2038	Pending
Taiwan	20/01/2017	EP 17305062.6	22/01/2018	107102219			22/01/2038	Pending
PCT	20/01/2017	EP 17305062.6	19/01/2018	US2018/014489			20/07/2019	Engaged
South Africa	20/01/2017	EP 17305062.6	19/01/2018	2019/04587			19/01/2038	Pending
Australia	20/01/2017	EP 17305062.6	19/01/2018	2018210388			19/01/2038	Pending
Brazil	20/01/2017	EP 17305062.6	19/01/2018	not yet allocated			19/01/2038	Pending
Canada	20/01/2017	EP 17305062.6	19/01/2018	not yet allocated			19/01/2038	Pending
China	20/01/2017	EP 17305062.6	19/01/2018	not yet allocated			19/01/2038	Pending
Eurasia	20/01/2017	EP 17305062.6	19/01/2018	not yet allocated			19/01/2038	Pending
Japan	20/01/2017	EP 17305062.6	19/01/2018	not yet allocated			19/01/2038	Pending
Korea	20/01/2017	EP 17305062.6	19/01/2018	not yet allocated			19/01/2038	Pending
Ukraine	20/01/2017	EP 17305062.6	19/01/2018	not yet allocated			19/01/2038	Pending
US	20/01/2017	EP 17305062.6	19/01/2018	16/478 576			19/01/2038	Pending
Europe	20/01/2017	EP 17305062.6	19/01/2018	18713060.4			19/01/2038	Pending
India	20/01/2017	EP 17305062.6	19/01/2018	201917027958			19/01/2038	Pending
Israel	20/01/2017	EP 17305062.6	19/01/2018	267955			19/01/2038	Pending
Mexico	20/01/2017	EP 17305062.6	19/01/2018	MX/A/2019/00864 8			19/01/2038	Pending
New Zealand	20/01/2017	EP 17305062.6	19/01/2018	755432			19/01/2038	Pending

## **5.7 Organization of the Company**

### **5.7.1 Operating Organization Chart**

GeNeuro is managed by its management under the supervision of its Board of Directors, which is composed of internationally known persons. The Company also has a scientific committee that contributes significant expertise in MS.

Detailed biographies of the members of the Board of Directors and management are set forth in CHAPTER 14, "Corporate Governance, Administration, Management and Supervisory and General Management Bodies" of this Universal Registration Document.

### **Present Organization**

The Company is led by Jesús Martin-Garcia, CEO, to whom report:

- Dr. Anke Post, Chief Medical Officer (since January 1, 2024)
- Dr. Hervé Perron, Chief Scientific Officer;
- Dr. Alois B Lang, Chief Development Officer; and
- Mr. Miguel Payró, Chief Financial Officer, also in charge of human resources.

Mr. Martin-Garcia, Dr. Post, Dr. Lang, Mr. Payró and Dr. Perron are part of GeNeuro's Executive Committee.

### **5.7.2 Product and Manufacturing**

GeNeuro SA has substantial experience in the development of biopharmaceutical products such as therapeutic monoclonal antibodies. This experience includes a broad scientific background, which incorporates the application of analytical and bioanalytical technologies in the quality control of therapeutic antibodies, in the technical assessment of the immunogenicity of such products, and in the humanization of therapeutic monoclonal antibodies and its optimized manufacturability. Experience in the development of antibody-based technologies led to strong interest from third parties.

GeNeuro has a mix of in-house expertise and working with highly qualified CMOs. Dr. Alois B. Lang is a biopharmaceutical product development specialist, with particular expertise in the development of therapeutic monoclonal antibody-based products. He has long-term industrial experience and successfully led the development of several antibody-based products from the pre-clinical phase to the clinical trial phase.

GeNeuro's temelimab is manufactured by Polymun. Polymun developed both cell culture and downstream purification processes suitable for the manufacture of the antibody in accordance with GMP and with clinical-grade quality. The production and purification of temelimab uses established production protocols. The manufacturing process is typical for a monoclonal antibody.

The Company believes that Polymun has sufficient capacity in terms of net fermentation volume as well as matching capacity in downstream processing for the manufacturing of GeNeuro's antibody temelimab up to a Phase III clinical trial or marketing application. Polymun has been successfully audited by the FDA. The process is optimized and well characterized and was successfully presented by GeNeuro to relevant regulatory authorities, such as the Paul Ehrlich Institute and Swissmedic. Polymun is already manufacturing other biopharmaceuticals for Phase III clinical studies or for drugs which are already on the market and thus has the experience and know-how for related procedures such as process validation and documentation for all stages of clinical development and applications for market approval with the relevant authorities.

Since the COVID-19 pandemic, supply of culture media for antibody manufacturing and other products is facing considerable strain and competition for deliveries. While the Company and its suppliers have been able to manage this situation without any disruptions, tense supply conditions may lead to delays in the manufacturing of future batches of temelimab and may have consequences on the timing of clinical trials.

### **5.7.3 Clinical Development Expertise**

The clinical development team includes several experts, including one senior physician and a senior clinical operations director who have long experience in clinical research and development and in obtaining product licenses for medications and biological products. In particular, they have participated directly in the development and/or registration of three products indicated for MS: ocrelizumab (Ocrevus®), siponimod (Mayzent®) and ofatumumab (Kesimpta®).

As for clinical trials, the Company has already completed three Phase I clinical trials, three Phase IIa trials, one Phase IIb trial and a Phase IIb extension trial, all in different countries in Europe and Australia, as described elsewhere in this Universal Registration Document. These trials were the subject of several publications and communications in international congresses and conferences in Europe and the United States as well as several scientific articles<sup>57</sup> published in international medical literature.

The clinical team also receives high-quality expertise on a consultative basis from Dr. Gordon S. Francis, who has more than 30 years' experience in industrial development and who has played an important role in the registration of three of the most important reference treatments for MS: beta interferon (Rebif®); natalizumab (Tysabri®); and fingolimod (Gilenya®).

Academic experts recognized in related pharmacological or biostatistical areas are also regularly sought by the Company for specific issues linked to clinical development.

### **5.7.4 Regulatory Expertise**

GeNeuro has one senior consultant in regulatory affairs with extensive experience in regulatory matters. She has substantial knowledge of regulatory development for pharmaceutical products, which is reflected in the regulatory activities of the Company. GeNeuro focuses its regulatory activities on strategic planning and decisions, and uses

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57 Sources: Curtin F, Lang AB, Perron H, Laumonier M, Vidal V, Porchet HC, Hartung HP. "Temelimab, a Humanized Monoclonal Antibody Against the Envelope Protein of Multiple Sclerosis-Associated Endogenous Retrovirus: A First-in-Humans Randomized Clinical Study". *Clin Ther* 2012, 34:2268-78.  
Derfuss T, Curtin F, Guebelin C, Bridel C, Rasenack M, Matthey A, Du Pasquier R, Schlupe M, Desmeules J, Lang AB, Perron H, Faucard R, Porchet H, Hartung HP, Kappos L, Lalive PH. "A phase IIa randomized clinical study testing Temelimab, a humanized monoclonal antibody against the envelope protein of multiple sclerosis associated endogenous retrovirus in multiple sclerosis patients — a twelve month follow-up". *J Neuroimmunol*. 2015 Aug. 15; 285:68-70.  
Derfuss T, Curtin F, Guebelin C, Bridel C, Rasenack M, Matthey A, Du Pasquier R, Schlupe M, Desmeules J, Lang AB, Perron H, Faucard R, Porchet H, Hartung HP, Kappos L, Lalive PH. "A phase IIa randomised clinical study of Temelimab, a humanised monoclonal antibody against the envelope protein of multiple sclerosis-associated endogenous retrovirus in multiple sclerosis patients". *Mult Scler*. 2015 Jun; 21(7):885-93.  
Curtin F, Vidal V, Bernard C, Lang AB, Porchet H. "Serum and Cerebrospinal Fluid Pharmacokinetics of the new IgG4 Monoclonal Antibody Temelimab to treat multiple sclerosis: a Phase I Study". *MAbs*. 2016 Jul; 8(5): 854–860.



highly regarded industry consultants as required to assist it. Some of the regulatory matters successfully conducted by the Company include:

- Organization of scientific advice meetings/requests with the following Health Authorities: Paul-Ehrlich Institute (PEI) Germany in 2010 and in 2014 (with respect to Quality, Non-Clinical and Clinical aspects); and Swissmedic in 2012 (with respect to Non Clinical and Clinical aspects) and the European Medicines Agency (EMA), London, UK in 2013. The scientific advice sought from PEI and Swissmedic concerned development of temelimab in MS and from EMA relating to quality, non-clinical and clinical issues with respect to another intended indication (chronic inflammatory demyelinating polyneuropathy).
- SME status with the EMA: GeNeuro Innovation SAS, a subsidiary of GeNeuro SA, has obtained SME status from the EMA (EMA SME number: EMA/SME/080/10/R3).
- Approval by the EMA of the Pediatric Investigation Plan for temelimab in MS in 2017
- Orphan Drug Designation for temelimab for CIDP by the FDA in 2018.

## **5.8 Material Events having an Impact on the Information set forth in Sections 5.1 to 5.3**

None.

## **5.9 Degree of the Company's Dependence on Patents, Licenses, Manufacturing and Commercial or Financial Agreements or new Manufacturing Processes**

For a description of the risk factors relating to manufacturing agreements with CROs and CMOs, and patent licenses with bioMérieux and INSERM, please see Section 3.4, "Risks Related To The Company's Dependency on Third Parties Risks" and Section 3.5, "Risks Relating To The Company's Intellectual Property Rights of this Universal Registration Document.

## **5.10 Factual Basis for any Statement by the Company about its Competitive Position**

Except for estimates made by the Group as of the date of this Universal Registration Document, the facts on which statements about the Group's competitive position are derived come principally from the following sources:

- Atlas Multiple Sclerosis 2013; UK Multiple Sclerosis Trust; US National MS Society
- Sorensen S. "New Management Algorithms in Multiple Sclerosis", Current Opinion Neurology 2014
- [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- Scientific publications about clinical trial results
- Annual reports of companies active in the field; and
- BioMed tracker.

## **5.11 Investments**

### **5.11.1 Historical Investments**

Investments in tangible fixed assets have historically been limited to specific laboratory equipment as well as information technology equipment. The first-time application of IFRS 16 as of January 1, 2019 using the modified retrospective approach resulted in a € 913 thousand increase in the Company's financial liabilities and an increase in property, plant and equipment for the same amount. Intangible property investments include the cost of exclusive licenses to bioMérieux patents in 2006 and the 2016 milestone payment, the cost of the exclusive license to NIH for the jointly owned patent in 2018 as well as the acquisition costs of various software programs. Please see Notes 3 and 4 to the consolidated financial statements for the year ended 31 December 2021 set forth in CHAPTER 18 of this Universal Registration Document.

### **5.11.2 Pending Investments**

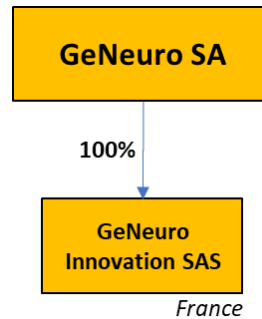
None.

### **5.11.3 Future Investments**

The Group does not expect at this stage to have to undertake investments over €250 thousand, to keep its computer equipment and its laboratories in line with its growth and development.

## **CHAPTER 6.** **ORGANIZATION CHART**

### **6.1 Organization**



### **6.2 Subsidiaries And Equity Stakes**

The Company has one 100%-owned subsidiary (shares and voting rights) in France, based in Lyon. GeNeuro Innovation SAS, organized in December 2009 and registered in 2010, is a French société par actions simplifiée (simplified stock company) with its registered office at 60 avenue Rockefeller (69008) in Lyon, France. The purpose of GeNeuro Innovation is research and development, especially involving experiments on models and products used, in particular, for therapeutic purposes in the healthcare field as well as providing services in connection with its research and development.

### **6.3 Restructurings**

None.

## **CHAPTER 7.**

### **ANALYSIS OF FINANCIAL CONDITION AND RESULTS**

Readers are urged to read the following information and comments relating to the financial condition and results of the Company and of its subsidiaries together with this entire Universal Registration Document and especially the Group's consolidated financial statements and the notes thereto prepared in accordance with IFRS for the years ended December 31, 2023 and 2022, reproduced with the notes thereto in CHAPTER 18 of this Universal Registration Document.

The discussion of the financial statements set forth in this CHAPTER 7, "Analysis of Financial Condition and Results" and CHAPTER 8, "Cash and Equity" of this Universal Registration Document has been prepared solely on the basis of the consolidated financial statements prepared in accordance with IFRS, as issued by the IASB, included in CHAPTER 18, "Information Regarding the Company's Assets, Financial Situation and Results" of this Universal Registration Document.

#### **7.1 Financial Condition**

##### **7.1.1 General Discussion**

GeNeuro is a clinical-stage biopharmaceutical company focused on the development of novel treatments of Human Endogenous Retroviruses (or HERV)-mediated diseases, including diseases or disorders of the central nervous system and other diseases induced by HERVs. Since its formation, GeNeuro has devoted its resources primarily to the development of novel treatments for MS. GeNeuro's most advanced candidate, temelimab, is a humanized monoclonal antibody that neutralizes a HERV protein called W-ENV which has been identified as a potential key factor fueling the inflammatory and neurodegenerative components of MS. The Company believes that temelimab is the first treatment against a suspected causal factor of MS and, as such, temelimab has the potential to offer a safe and effective treatment that does not affect the patient's immune system, and which could slow or even stop disease progression in all major forms of MS. In addition, W-ENV has been found at high levels in the blood of about a third of patients suffering from severe neuropsychiatric consequences of COVID-19, (PASC, post-COVID or Post-COVID). W-ENV is known to have a direct pathogenic effect on nervous system cells, translating into neuropsychological (impaired cognitive functions), psychiatric (depression, anxiety) and neurological symptoms (dysautonomia, sleep disorders), often observed in Post-COVID patients more than three months after the acute phase Post-COVID has become a major public-health concern worldwide, affecting millions of individuals. While most patients recover over time, there is a part of the population whose symptoms remain severe and are deeply affected in their quality of life and ability to work.

The Company was formed on February 6, 2006 and, in 2009, formed a French subsidiary, GeNeuro Innovation, to pursue research, then in 2016 formed an Australian subsidiary, GeNeuro Australia Pty Ltd, to conduct a clinical trial in that country starting in 2017. Following completion of trial activities in Australia, this latter subsidiary was liquidated during 2021.

At this stage, research and development has absorbed the majority of the resources of the Group, which has devoted approximately 81% of its financial resources in 2023, and 75% in 2022, to research and development.

Since its formation, the Group has been financed primarily by successive capital increases, including the €33 million capital increase completed in 2016 in connection with the Company's initial public offering (IPO) on Euronext's regulated market in Paris, the €17.5 million capital increase completed in January 2020 through a private placement, the €6.0 million capital increase completed in July 2021 through a private placement, the €7.7 million capital increase completed in May 2022 through a private placement and the €5 million capital increase completed in February 2024 through a private placement and a public offering via the PrimaryBid platform. The Group has also received limited research subsidies, particularly from Bpifrance and the European Union in connection with the Psych-Aid program, as well as research tax credits for work conducted by its French and Australian subsidiaries. Finally, the Group has been selected as one of the four projects retained by the Swiss FOPH within the framework of the CHF 50 million "Federal Funding Programme for COVID-19 Medicines" incentive to receive a grant of 6.7 million Swiss francs (€6.4 million) to co-fund (up to 50%) a Phase II clinical trial to treat patients with long-standing COVID who exhibit neuropsychiatric symptoms, and has in March 2023 entered into a credit agreement for a total amount of up to EUR 25 million with the European Investment Bank ("EIB"), supported by the InvestEU programme, including a first tranche of €7 million, which was drawn in March 2023 and is intended to support the Phase 2 clinical trial in Post-COVID.

Since the Group is active only in research and development, its operations during the various periods discussed are organized under a single segment, "Research and Development of Pharmaceutical Products."

### **7.1.2 Principal Factors Having an Impact on the Group's Business and Profit (Loss)**

In light of the Group's stage of development, historical results principally reflect the research and development expenses of its product, temelimab.

The principal factors having an impact on the Group's business and operations, financial condition, profit and loss, growth and development, and prospects are:

- the scale of the Group's research and development programs, adherence to their development schedule, and opportunities for developing new indications;
- the generation of new pre-clinical and clinical data making it possible to confirm the therapeutic potential of treatments based on the neutralization of HERVs;
- the ability of the Group to finance its operations, including by equity increases and research subsidies.

### **7.1.3 Summary of Key Accounting Principles and Methods**

The Group's financial statements for the financial years ended December 31, 2023 and 2022, which are reproduced with the notes thereto in CHAPTER 18, "Information Regarding the Company's Assets, Financial Situation and Results" of this Universal Registration Document, have been prepared in accordance with IFRS, as issued by the IASB. Such financial statements have been prepared in accordance with historical cost convention, except for certain financial instruments which are measured at fair value and the plan assets included in the calculation of the defined benefit pension plan liability, which are also measured at fair value.

In connection with the preparation of the Group's financial statements in accordance with IFRS, the Company has exercised judgments and made estimates that could influence the amounts presented in respect of assets and liabilities on the date of preparation of the financial statements and of revenue and expense for the period. Such estimates have been made by the Company on a going concern basis in accordance with information available at the time when such judgments and estimates were made. Such estimates are continuously evaluated and are based on past experience as well as various other factors that have been deemed reasonable and that constitute the basis for analyzing the book value of assets and liabilities. These estimates may be revised, if the circumstances on the basis of which they were made change, or if new information becomes available. The Company's actual results of operations may differ significantly from such estimates if the assumptions or conditions should change.

The Company believes that the most significant estimates or judgments involved in the preparation of the financial statements are described below. For a more detailed description of the accounting principles and methods applied by the Group, please see Note 2 of the consolidated financial statements included in CHAPTER 18 of this Universal Registration Document.

#### **Recognition of Revenue from Collaborative Agreements**

There were no revenues from Collaborative Agreements recognized in 2023 or 2022.

#### **Intangible Assets**

##### **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 it or sell it;
- there is an ability to use or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits;
- 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.

In the opinion of management, due to uncertainties inherent in the development of the Group's products, the criteria for development costs to be recognized as an asset, as prescribed by IAS 38, "Intangible Assets," are not met. As a result, internal development expenses incurred (mainly consisting of the cost of pre-clinical experiments, clinical trials, and the production cost of temelimab) are recognized under "research and development expenses" when they are incurred.

#### **Licenses**

Licenses acquired by the Company to access intellectual property are recognized under intangible assets. The amortization of such licenses over their useful lives shall start upon marketing approval of the related products (please see Notes 19.3 and 19.4 of the Notes to the Group's consolidated financial statements set forth in CHAPTER 18, "Information Regarding the Company's Assets, Financial Situation and Results" of the Universal Registration Document).

### **Subsidies and Grants**

Grants received from public entities to subsidize certain types of expenditure are recognized when there is reasonable assurance that the entity will comply with the conditions attached to obtaining the grants. They are recognized as a reduction in the related expenditure, in this case research and development ("R&D") expenses.

Contributions received from academic institutions are recognized as a reduction in R&D expenses, in a constant proportion to the corresponding expenditure so as to maintain the principle of matching income with related expenses.

### **Research Tax Credits**

The Group receives certain specific project-related research tax credits ("RTC") that are granted to companies incorporated in France as an incentive for technical and scientific research. Companies with expenses that meet the eligibility criteria receive a tax credit that (i) can offset against corporate income tax due in the year in which it is granted, as well as in the following three financial years, or, (ii) under certain circumstances, can be paid to the Company.

Until 2019, the Group has also benefited from research tax credits for its activities in Australia for the research of new treatments against Type 1 diabetes linked to endogenous retroviruses. This research tax credit scheme provided a tax credit of 43.5% of admissible research expenses.

The Group considers the research tax credits received from French and Australian tax authorities as government grants as the tax credits are received independently from tax payments of the Group. The Group recognizes these credits in the consolidated statement of financial position within other current receivables given the expected time of collection, and in the consolidated income statement under research and development subsidies. The credits are recognized in the year in which the eligible expenses giving rise to the tax credit are incurred.

### **Bpifrance repayable advance**

A repayable advance was granted to the Company's subsidiary, GeNeuro Innovation, by Bpifrance in September 2011 to provide financial support to the Group in conducting a clinical trial and developing a diagnostic test for CIDP subject to a 70% waiver in case of failure of the program. In January 2023, Bpifrance acceded to GeNeuro Innovation's request to consider the program a failure and confirmed the debt waiver of the 70% balance, representing a gross amount of € 140K. Accordingly, the Bpifrance advance was presented as a non-current liability at December 31, 2022 for €139K. The advance is described in Note 10.1 of the Notes to the Group's consolidated financial statements set forth in CHAPTER 18 of the Universal Registration Document.

### **Forgivable loan**

On December 13, 2021, GeNeuro entered into a subsidy contract with the FOPH for the financing of its Post-COVID project testing temelimab in Post-COVID (or "Post-COVID") patients with neuro-psychiatric symptoms. Pursuant to this contract, GeNeuro issued an invoice to the FOPH of CHF 3,090K (€ 2,991K) for the first instalment payment, which amount is included within the "Other" receivables as of December 31, 2021 (see Note 6). The subsidy contract allows the FOPH, in case of success of the project leading to a marketing authorization for the Company's drug in Post-COVID, to apply the amount of the subsidy to the purchase price, at market levels, of temelimab for the Post-COVID indication. Due to this component of the contract, GeNeuro considers that it has received a forgivable conditional loan from the FOPH, as defined in IAS 20, and that it has accordingly benefitted from a government loan at a below-market rate and the amount to be received as of Dec. 31, 2021 was therefore considered as a liability. Under IAS 20, since the conditional loan does not bear annual interest, it is treated as an interest-free loan for the Company (i.e. under conditions more favorable than market rates), and the difference between the amount of the advance at historical cost and the advance discounted at market rates is considered as a public grant, in an amount of € 467.8K for 2021. The first instalment payment was received in January 2022; in addition, a second instalment payment of CHF 2,289.7K (€ 2,325.3K) was received in September 2022.

### **Evaluation of Purchase Options Granted to Employees, Executives, and Outside Service Providers**

The determination of the fair value of payments made to employees, executives, and outside service providers based on shares is based on the Black & Scholes option valuation model which makes assumptions about complex and subjective variables. Such variables include notably the value of the Company's shares, the expected volatility in 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 fair value of the options is thus measured by taking into consideration the following valuation assumptions, which are set forth in Note 9 of the consolidated financial statements:

- the price of the underlying shares is deemed to be equal to the investor's subscription price, or is calculated by reference to internal valuations;
- the risk-free rate is selected by reference to on the average lifetime of the instruments; and
- volatility is estimated by reference to a sample of listed companies in the biotechnology sector, at the date when instruments are granted and over a period equivalent to the lifetime of the option.

The table below sets forth the assumptions used to calculate the fair value of the share purchase options in accordance with IFRS 2 for the financial years ended December 31, 2023 and 2022:

Grants	Number of options issued	Exercise price and currency	Exercise period	Volatility	Non-risk rate	Fair value on the date of grant in accordance with IFRS 2 (Black & Scholes) in EUR
Stock Purchase Options 04/2010 (1)	123,000	CHF 4.00	5 years	50.5%	1.11%	1.46
Stock Purchase Options 04/2013 (1)	3,000	CHF 4.00	5 years	50.3%	0.05%	1.41
Ordinary C shares granted to directors 11/2015 (2)	45,000	N/A	N/A	N/A	N/A	27.99
Performance Share Option Units (PSOU) 06/2016	624,282	€ 13.00	5 years	58.8%	-1.09%	2.29
Performance Share Option Units (PSOU) 01/2017	35,000	€ 13.00	5 years	53.6%	-0.86%	2.48
Performance Share Option Units (PSOU) 02/2017	15,000	€ 13.00	5 years	53.6%	-0.87%	1.74
Performance Share Option Units (PSOU) 02/2018	20,000	€ 13.00	5 years	50.0%	-0.77%	0.14
Stock-Options 02/2017	42,500	€ 13.00	5 years	53.6%	-0.94%	2.50
Stock-Options 02/2017 (plan 2)	7,500	€ 13.00	5 years	53.60%	-0.94%	2.35
Stock-Options 02/2018	22,500	€ 13.00	5 years	50.0%	-0.75%	0.80
Stock-Options 09/2018	158,540	€ 2.73	10 years	50.0%	0.00%	1.74
Stock-Options 03/2020	151,500	€ 3.34	10 years	49.4%	-0.58%	0.97 (2)
Stock-Options 12/2020	30,000	€ 2.95	10 years	53.6%	-0.71%	1.09 (2)
Stock-Options 02/2021	184,800	€ 3.19	10 years	63.0%	-0.57%	1.19 (2)
Stock-Options 03/2022	203,627	€ 3.48	10 years	56.0%	-0.23%	1.64 (2)
Stock-Options 04/2023	237,694	€ 2.86	10 years	63.0%	0.65%	0.82 (2)

(1) Reflects the number of PSOUs granted originally; the actual number of stock options granted in February 2019, at the end of the PSOU Plan, is 602,335 for the 2016 Plan, 36,400 and 15,000, respectively, for the 2017 Plans and 18,500 for the 2018 Plan.

(2) Average fair value.

Stock options are valued on the basis of management assumptions on the likely exercise horizons for each option, which are in certain cases split in two parts (1 and 2), with different volatility and risk-free rates used to value the stock options using the Black & Scholes model.

## **7.1.4** Presentation of Principal Items of Consolidated Profit and Loss Statement

### **7.1.4.1** Revenue and Operating Profit and Loss

Given the stage of clinical development of its most advanced product, the Group has not earned any revenue from product sales as of the date hereof.

The Group's research and development activities, given the significant financial resources involved, have generated operating losses and have not generated operating revenue other than that resulting from the execution of partnering and licensing agreements providing for lump-sum payments and royalties.

### **7.1.4.2** Research and Development

The Company conducts research and development on therapies associated with the presence of HERVs with first indications for MS and for neuropsychiatric symptoms of Post-COVID.

During the years under review, the Company has devoted a significant part of its resources to the development of such therapies. Research and development expenses are set forth in Note 14 of the annual financial statements, which are reproduced set forth in CHAPTER 18 of the Universal Registration Document.

In accordance with IAS 38, development expenses may be recorded as intangible assets only if the Company can show that the six criteria (described in Section 7.1.3 of the Universal Registration Document) for recording an asset have been met. The Company has determined that these criteria are not met at this stage. Accordingly, internal development expenses, consisting principally of expenses for pre-clinical and clinical studies, are recorded as expenses in the line item Research and Development, when incurred.

Principal research and development expenses are:

- the cost of research and conducting pre-clinical and clinical studies on temelimab for MS and Post-COVID;
- the cost of developing and manufacturing the monoclonal antibody temelimab in accordance with GMP;
- personnel expenses for members of the research and development team; and
- expenses for protection of intellectual property.

Product candidates at advanced stages of clinical development generally have higher development costs than those in the initial stages of clinical development, principally because of the increase in the size and duration of such clinical trials. The Company expects that its research and development expense will continue to increase inasmuch as it intends to initiate clinical trials for various product candidates while pursuing the later stages of clinical development for temelimab for MS and Post-COVID.

#### 7.1.4.3 General and Administrative Expenses

General and administrative expenses consist principally of:

- compensation for administrative staff;
- the fees of outside advisors; and
- overhead costs for the rental of office space and the general expenses of the management of the Company, including travel expense.

The Company applies a strict policy for incurring expenses, particularly for general and administrative expense, so that it can devote its resources primarily to pre-clinical and clinical development.

#### 7.1.4.4 Financial Income and Expenses

Net financial income and expenses consist essentially of:

- interest on time deposits; and
- currency exchange gains and losses in connection with payments made to foreign service providers in local currencies.

## **7.2 Comparison Of The Financial Statements For The Two Years Ended December 31, 2023 and 2022**

### **7.2.1 Constitution of Operating Loss and Net Loss**

<b>SIMPLIFIED INCOME STATEMENT (in thousands of EUR)</b>	<b>31 Dec. 2023 Audited 12 months</b>	<b>31 Dec. 2022 Audited 12 months</b>
Income	-	-
Research and development expenses	(12,492.1)	(9,833.2)
Subsidies	1,143.4	1,825.8
General and administrative expenses	(3,008.6)	(3,221.8)
Operating expenses	(14,357.3)	(11,229.2)
<b>Operating loss</b>	<b>(14,357.3)</b>	<b>(11,229.2)</b>
<b>Net loss</b>	<b>(14,757.0)</b>	<b>(12,199.8)</b>

### 7.2.1.1 Revenue

Given that its product is still at an early stage of development, the Company did not earn any revenue from product sales during the financial years ended December 31, 2023 and 2022.

<b>INCOME (in K of EUR)</b>	<b>31 Dec. 2023 Audited 12 months</b>	<b>31 Dec. 2022 Audited 12 months</b>
Income	-	-
<b>Total Income</b>	<b>-</b>	<b>-</b>

There was no revenue in 2023 or 2022.

### 7.2.1.2 Operating Expenses by Function

#### **Research and development expenses**

Research and development expenses during the financial years presented were as follows:

<b>RESEARCH AND DEVELOPMENT (in thousands of EUR)</b>	<b>31 Dec. 2023 Audited 12 months</b>	<b>31 Dec. 2022 Audited 12 months</b>
Studies and research	(9,622.8)	(6,984.3)
Intellectual property	(305.2)	(267.1)
Travel and assignments expenses	(64.0)	(64.5)
Raw materials and consumables	(28.1)	(29.0)
Rental expenses	(46.6)	(41.5)
Professional fees	(146.3)	(178.5)
Payroll expense	(2,032.4)	(1,992.1)
Amortization and depreciation	(186.7)	(157.9)
Share based payment expense	(57.3)	(60.7)
Other	(2.7)	(57.6)
<b>Research and Development expenses</b>	<b>(12,492.1)</b>	<b>(9,833.2)</b>
Research tax credit	555.9	1,316.4
Other subsidies	587.5	509.4
<b>Subsidies</b>	<b>1,143.4</b>	<b>1,825.8</b>
<b>Net research and development expense</b>	<b>(11,348.7)</b>	<b>(8,007.4)</b>

Research and development expenses increased by €2.7 million in 2023 compared to 2022, due to the expenses incurred in connection with the Post-COVID program, which led to an increase of €2.6 million in studies and research in connection with the GNC-501 clinical trial.

Research & development payroll expense increased by €0.1 million, as the Company increased its clinical team to manage the Post-COVID trial.

Other costs remained broadly in line with the levels observed in 2022.

Despite the higher level of studies and research expenses, subsidies (under the form of research tax credits linked to R&D activities) decreased by €0.8 million in 2023 over 2022 as the bulk of the Company's GNC-501 Phase 2 clinical trial activities are conducted out of the Swiss parent and are therefore not eligible for French Research Tax Credit; other subsidies increased from K€ 509 to K€ 588; these other subsidies include K€ 140 of debt cancellation from Bpifrance in connection with the K€ 200 reimbursable advance that had been granted to GeNeuro Innovation SAS in 2011, K€ 182 from the European Union HERVCOV grant and K€ 265 of subsidies accounted for in connection with the Swiss FOPH grant.



### **General and administrative expenses**

General and administrative expenses during the financial years presented were as follows:

<b>GENERAL AND ADMINISTRATIVE EXPENSES (in thousands of EUR)</b>	<b>31 Dec. 2023 Audited 12 months</b>	<b>31 Dec. 2022 Audited 12 months</b>
Travel and assignments expenses	(199.1)	(146.2)
Office expenses	(40.4)	(36.7)
Rental expenses	(36.1)	(39.3)
Professional fees	(864.0)	(876.8)
Payroll expense	(1,482.2)	(1,702.3)
Tax expense	(1.5)	(12.7)
Insurance expense	(69.1)	(69.2)
Postal and telecom expenses	(29.5)	(27.4)
Amortization and depreciation	(107.1)	(130.6)
Share based payment expense	(188.1)	(174.5)
Other	8.5	(6.1)
<b>General and administrative expenses</b>	<b>(3,008.6)</b>	<b>(3,221.8)</b>

In 2023, general and administrative expenses decreased by €0.2 million, as GeNeuro cancelled the cash bonuses for all and management, resulting in a reduction of payroll expense by €0.2 million in 2023 compared to 2022.

#### 7.2.1.3 Financial Income (Expenses)

<b>FINANCIAL INCOME (EXPENSES), NET (Amounts in thousands of EUR)</b>	<b>31 Dec. 2023 Audited 12 months</b>	<b>31 Dec. 2022 Audited 12 months</b>
Change in fair value of derivatives	806.9	-
Other financial income	75.8	7.6
Share based expense related to capital increase at discount to market	-	(589.2)
Other financial expenses	(952.6)	(269.3)
Foreign exchange gains (losses)	(325.6)	(117.6)
<b>Financial income (expenses), net</b>	<b>(395.5)</b>	<b>(968.5)</b>

In 2023, in connection with drawdown of the first €7 million tranche from the EIB Credit Facility, the Company issued to the EIB a total of 642,031 share purchase warrants at an exercise price of €2.58 per share and an initial aggregate valuation of K€ 1,106. Due to the decrease at December 31, 2023 of the Company's share price compared to the exercise price, these warrants were valued at December 31, 2023 at K€ 299, leading to the above K€ 807 change in fair value of the derivatives.

Other financial expenses increased due to the drawdown of the first €7 million tranche from the EIB Credit Facility, which carries interest of 9% p.a. (of which 2% p.a. payable in cash and 7% p.a. to be capitalized until maturity).

In 2022, the share-based expense is related to the capital increases completed in May 2022 and July 2021 through private placements. Because both capital increases were not open to all existing shareholders but were restricted to certain selected institutional investors, pursuant to IFRS 2 the discount between the share price prior to the capital increase and the actual issue price (€3.75 vs €3.48 for the 2021 capital increase, and €3.08 per share vs €2.86 per share for the 2022 capital increase) is considered a share based payment, resulting in a charge of € 467K for 2021 and € 589K for 2022, accounted within financial expenses, with a corresponding amount added to reserves within shareholders' equity.

The Group's financial income derives essentially from interest earned on its euro cash balances.

#### 7.2.1.4 Income Tax

<b>INCOME TAX (EXPENSE) / INCOME (Amounts in K of EUR)</b>	<b>31 Dec. 2023 Audited 12 months</b>	<b>31 Dec. 2022 Audited 12 months</b>
Deferred tax	-	-
Withholding tax	-	-
<b>Income tax (expense) / income</b>	<b>-</b>	<b>-</b>

Deferred tax assets are recorded when it is probable that the Company will have future taxable earnings against which cumulative tax loss carryforwards may be used. In application of this principle, in light of the Group's earnings prospects, no deferred tax assets were recorded as of December 31, 2023 or 2022. The amount of € 4.2K in tax expense shown in the income statement is a Swiss tax on capital and is therefore excluded from the table above which relates to taxes on income.

#### 7.2.1.5 Earnings Per Share

<b>RESULT PER SHARE</b>	<b>31 Dec. 2023</b> Audited <b>12 months</b>	<b>31 Dec. 2022</b> Audited <b>12 months</b>
Weighted average number of outstanding shares	24,843.4	23,898.3
Net result for the period (in K of EUR)	(14,757.0)	(12,198.8)
<b>Basic losses per share (EUR/share)</b>	<b>(0.59)</b>	<b>(0.51)</b>
<b>Diluted losses per share (EUR/share)</b>	<b>(0.59)</b>	<b>(0.51)</b>

During the 2022 financial year, the Group recorded an increase of €5.4 million in its net loss, resulting primarily from a €4.8 million increase in its operating loss, and from a €0.5 million increase in its financial expenses. Losses per share were also impacted by the increase in the weighted average number of shares due to the capital increase completed in May 2022.

### 7.2.2 Analysis of Statement of Financial Position

#### 7.2.2.1 Non-currents Assets

<b>NON-CURRENT ASSETS</b> (in thousands of EUR)	<b>31 Dec. 2023</b> Audited	<b>31 Dec. 2022</b> Audited
Intangible assets	1,152.3	1,139.8
Property, plant and equipment	742.1	992.9
Non-current financial assets	260.8	249.5
Non-current receivables	1,872.3	-
<b>Total non-current assets</b>	<b>4,027.5</b>	<b>2,382.2</b>

Intangible assets consist essentially of license rights acquired from bioMérieux in 2006, upon the formation of the Company, and of milestone payments related thereto and due at the time of launching clinical trials.

Property, plant and equipment consist principally of laboratory equipment specific to the Group's research operations and reflects the application of IFRS 16 as of January 1, 2019.

Non-current financial assets include the cash reserve related to the liquidity contract (described in Note 8 of the financial statements for the year ended 31 December 2023) and security deposits related to the leases of the Company's premises. Non-current receivables consist of the French research tax credit receivables (€1.3 million with respect to 2022 and €0.6 million with respect to 2023); the 2022 French research tax credit receivable was pre-financed through a bank financing of €1 million in January 2024.

#### 7.2.2.2 Current Assets

<b>CURRENT ASSETS</b> (in thousands of EUR)	<b>31 Dec. 2023</b> Audited	<b>31 Dec. 2022</b> Audited
Other current assets	507.0	3,495.0
Cash and cash equivalents	1,827.4	5,593.3
<b>Total current assets</b>	<b>2,334.4</b>	<b>9,088.3</b>

Other current assets in 2022 consisted essentially of the French research tax credit receivables of €1.3 million, of advance payments comprise payments made to service providers involved with the Company's clinical trials (€1.3 million at December 31, 2022).

Cash and cash equivalents consist of excess cash in bank accounts.

### 7.2.2.3 Equity

<b>EQUITY</b> <b>(in thousands of EUR)</b>	<b>31 Dec. 2023</b> <b>Audited</b>	<b>31 Dec. 2022</b> <b>Audited</b>
Capital	1,100.2	1,100.2
Additional paid-in capital	33.6	27,157.0
Cumulative translation adjustments	202.2	202.2
Accumulated comprehensive income (loss)	(100.0)	628.7
Treasury shares	(796.1)	(794.7)
Accumulated deficit attributable to owners of the parent	(14,217.9)	(26,829.7)
<b>Equity attributable to owners of the parent</b>	<b>(13,778.0)</b>	<b>1,463.7</b>
<b>Total Equity</b>	<b>(13,778.0)</b>	<b>1,463.7</b>

The Company's capital as of December 31, 2023 was CHF 1,249,951.40 (€ 1,100K) divided into 24,999,028 fully paid shares each with a nominal value of CHF 0.05 (unchanged from December 31, 2022). At the 14 June 2023 Annual General Meeting of Shareholders, shareholders decided to allocate €30 million from the additional paid-in capital to "other reserves", included within accumulated deficit attributable to owners of the parent.

Net changes in the Group's net equity during the dates presented result principally from the annual losses for the periods under review, reflecting research and development expenses incurred by the Group.

### 7.2.2.4 Non-current Liabilities

<b>NON-CURRENT LIABILITIES</b> <b>(in thousands of EUR)</b>	<b>31 Dec. 2023</b> <b>Audited</b>	<b>31 Dec. 2022</b> <b>Audited</b>
Employee benefit obligations	928.3	153.8
Non-current financial liabilities	12,509.3	6,517.9
Non-current derivative liabilities	299.4	-
Other non-current liabilities	42.6	26.0
<b>Total non-current liabilities</b>	<b>13,779.6</b>	<b>6,697.7</b>

Obligations to employees include a provision for retirement obligations for GeNeuro's employees located in Switzerland as well as retirement indemnities for employees of its French subsidiary, GeNeuro Innovation (please see CHAPTER 18 of the Universal Registration Document). Employee benefit obligations increased in 2023 largely due to actuarial changes in financial assumptions resulting from the change in market conditions, which led to an increase of gross employee benefit obligations of €0.8 million compared to December 31, 2022.

Non-current financial liabilities include, at December 31, 2022, a repayable advance granted by Bpifrance to GeNeuro Innovation, the balance of which was forgiven in January 2023. In addition, they include:

- the long-term portion of a three-year non-secured bank loan for €0.5 million at December 31, 2022 and €0.2 million at December 31, 2023;
- the long-term portion of the lease liabilities pursuant to IFRS 16 for €0.7 million at December 31, 2022 and €0.5 million at December 31, 2023;
- the EIB Venture Debt loan, for € 6,319K at December 31, 2023 (IFRS value of a gross €7 million amount); this loan was drawn in March 2023;
- for € 5,630K at December 31, 2023 and € 5,136K at 31 December 2022, the FOPH subsidy deemed to be a forgivable loan from FOPH for the financing of its Long-COVID project. The subsidy contract allows the FOPH, in case of success of the project leading to a marketing authorization for the Company's drug in Post-COVID, to apply the amount of the subsidy to the purchase price, at market levels, of temelimab for the Long-COVID indication. Due to this component of the contract, GeNeuro considers that it has received a forgivable conditional loan from the FOPH, as defined in IAS 20, and that it has accordingly benefitted from a government loan at a below-market rate and the amount to be received as of Dec. 31, 2021 was therefore considered as a liability. Under IAS 20, since the conditional loan does not bear annual interest, it is treated as an interest-free loan for the Company (i.e. under conditions more favorable than market rates), and the difference between the amount of the advance at historical cost and the advance discounted at market rates is considered as a public grant, in an amount of € 115K and € 148K, respectively for 2022 and 2023. The first instalment payment was received in January 2022; in addition, a second instalment payment of CHF 2,289.7K (€ 2,325.3K) was received in September 2022. Refer to Section 8.1.4, "Funding Through Repayable Advances and Subsidies" of the Universal Registration Document.

#### 7.2.2.5 Current Liabilities

CURRENT LIABILITIES (in thousands of EUR)	31 Dec. 2023 Audited	31 Dec. 2022 Audited
Current financial liabilities	858.1	601.8
Trade payables	2,459.6	764.8
Other current liabilities	3,042.6	1,942.5
<b>Total current liabilities</b>	<b>6,360.3</b>	<b>3,309.1</b>

Current financial liabilities include the current portion of the bank loan and of lease liabilities; other current liabilities include primarily accrued liabilities in connection with the GNC-501 study.

### 7.3 Group's Market Risks

GeNeuro strives to implement measures in line with the Company's size to minimize the potentially adverse effects of market risks on its financial performance.

#### 7.3.1 Interest Rate Risk

The Company does not have any significant exposure to interest rate risk. Please see Note 20 of the consolidated financial statements for the year ended 31 December 2022 for additional information.

#### 7.3.2 Foreign Currency Exchange Rate Risk

The Company is exposed to foreign currency exchange rate risk with respect to changes in the exchange rate between the euro and the Swiss franc, and the U.S. dollar. Please see Section 3.2.6 "Exchange Rate Risk" and Note 20 of the consolidated financial statements for the year ended 31 December 2023.

#### 7.3.3 Key Performance Indicators

The Company has not defined key performance indicators.

## **CHAPTER 8.**

### **CASH AND EQUITY**

Readers are urged to review Notes 6, 7, 8 and 10 of the Notes to the Group's consolidated financial statements prepared in accordance with IFRS for the financial years ended December 31, 2023 and 2022 set forth in CHAPTER 18 of this Universal Registration Document.

#### **8.1 Information About Equity, Liquidity, And Sources Of Funds**

As of December 31, 2023 and 2022, the net amount of cash and cash equivalents owned or held by the Group (consisting of excess cash assets) as well as liquid investments (in the form of short-term deposits) was €5.6 million and €5.5 million, respectively.

<b>CASH AND LIQUID INVESTMENTS (in thousands of EUR)</b>	<b>31 Dec. 2023 Audited</b>	<b>31 Dec. 2022 Audited</b>
Cash and cash equivalents	1,827.4	5,593.3
<b>Total cash and liquid investments</b>	<b>1,827.4</b>	<b>5,593.3</b>

Since its formation, the Group has been financed primarily by successive capital increases. Please see Section 3.2.1 for further details of the Company's cash strategy, its financing and funding strategy, and its exposure to risks linked to financial instruments and securities.

The Group has also received research subsidies, particularly from Bpifrance and the European Union in connection with the Psych-Aid program, as well as research tax credits for work conducted by its French subsidiary. In addition, the Group has been selected as one of the four projects retained by the Swiss FOPH within the framework of the CHF 50 million "Federal Funding Programme for COVID-19 Medicines" incentive to receive a grant of 6.7 million Swiss francs (€6.4 million) to co-fund (up to 50%) a Phase II clinical trial to treat patients with long-standing COVID who exhibit neuropsychiatric symptoms (refer to sub-section 8.1.4) and in March 2023 has entered into a credit agreement for a total amount of up to EUR 25 million with the European Investment Bank ("EIB"), supported by the InvestEU programme, including a first tranche of €7 million, available immediately, which is intended to support the Phase 2 clinical trial in Post-COVID.

##### **8.1.1 Financing by Equity Capital**

Until 2015, the Group had raised, by contributions from the founders and successive capital increases, a total of CHF 28.7 million (€23.4 million at the applicable historical exchange rates between 2006 and 2014). Capital increases from 2008 to 2015 have been fully subscribed by the Group's two historical shareholders, Ecllosion2 & Cie SCPC and Institut Mérieux. In 2016, in the context of its initial public offering on Euronext's regulated market in Paris, the Group completed a new capital increase of €33 million, increasing the total amount of funds raised from capital increases to €56.4 million.

On February 4, 2020, the Group completed a €17.5 million capital increase through an international private placement open only to certain qualified and institutional investors (the "2020 Offering") at an issue price of €2.95 per share, determined through a book-building process. After deduction of the loan set-off (see below) and issuance expenses and taxes, the net amount raised by the Company was € 9 million.

On July 13, 2021, the Group completed a €6.0 million capital increase through an international private placement open only to certain qualified and institutional investors (the "Offering") at an issue price of €3.48 per share, determined through a book-building process. After deduction of issuance expenses and taxes, the net amount raised by the Company was € 5.4 million.

On May 13, 2022, the Group completed a €7.7 million capital increase through an international private placement open only to certain qualified and institutional investors (the "Offering") at an issue price of €2.86 per share, determined through a book-building process. After deduction of issuance expenses and taxes, the net amount raised by the Company was € 7.0 million.

On February 2, 2024, GeNeuro completed a €5 million capital increase with cancellation of the preferential subscription rights through an international private placement reserved for specialized or strategic investors of (the "Private Placement") 4,666,901 new ordinary bearer shares of GeNeuro and through a public offering for retail investors in France via the PrimaryBid platform (the "PrimaryBid Offer", and together with the Private Placement, the "Offering") of 95,004 new ordinary bearer shares of GeNeuro. After deduction of issuance expenses and taxes, the net amount raised by the Company was € 4.5 million.

### **8.1.2 Debt Financing**

At December 31, 2023, the Company had the following debt financings:

- An unsecured bank loan of €0.5 million, repayable over three years until June 2025;
- An unsecured Venture Debt loan from the EIB, for a gross amount of €7 million, issued with warrants, repayable at maturity in 2028;
- The FOPH “forgivable loan” resulting from the IFRS treatment of the FOPH subsidy.

Refer to Section 8.1.4, “Funding Through Repayable Advances and Subsidies” of the Universal Registration Document.

### **8.1.3 Financing by Leases**

The first-time application of IFRS 16 as of January 1, 2019 using the modified retrospective approach resulted in a € 913 increase in the Company's financial liabilities and an increase in property, plant and equipment for the same amount (see Note 7 and Note 4, respectively). 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 between 1.5% to 2% for property leases and 5% for the other leases

### **8.1.4 Funding Through Repayable Advances and Subsidies**

#### **Bpifrance Repayable Advance**

A repayable advance was made to the Company's subsidiary, GeNeuro Innovation, by Bpifrance on September 16, 2011 to support the Group financially in conducting a clinical trial and for development of a diagnostic test for CIDP.

The following table shows the changes in such repayable advance during the periods discussed.

<b>(in thousands of EUR)</b>	<b>Bpifrance reimbursable advance</b>
<b>At 31 December 2021</b>	<b>149.8</b>
Reimbursement	(12.5)
Financial expenses	1.8
<b>At 31 December 2022</b>	<b>139.1</b>
Subsidies	(140.0)
Financial expenses	0.9
<b>At 31 December 2023</b>	<b>-</b>

On January 13, 2023, Bpifrance acceded to GeNeuro Innovation's request to consider the program a failure and confirmed the debt waiver of the 70% balance, representing a gross amount of € 140K. Accordingly, the Bpifrance advance is presented as a non-current liability at December 31, 2022. Refer to Note 10.1 of the Notes to the Group's consolidated financial statements prepared in accordance with IFRS for the year ended 31 December 2023 set forth in CHAPTER 18 of this Universal Registration Document.

#### **FOPH Forgivable loan**

On December 13, 2021, GeNeuro entered into a subsidy contract with the FOPH for the financing of its Post-COVID project testing temelimab in Post-COVID (or “Post-COVID”) patients with neuro-psychiatric symptoms. Pursuant to this contract, GeNeuro issued an invoice to the FOPH of CHF 3,090K (€ 2,991K) for the first instalment payment, which amount is included within the “Other” receivables as of December 31, 2021 (see Note 6). The subsidy contract allows the FOPH, in case of success of the project leading to a marketing authorization for the Company's drug in Post-COVID, to apply the amount of the subsidy to the purchase price, at market levels, of temelimab for the Post-COVID indication. Due to this component of the contract, GeNeuro considers that it has received a forgivable conditional loan from the FOPH, as defined in IAS 20, and that it has accordingly benefitted from a government loan at a below-market rate. Under IAS 20, since the conditional loan does not bear annual interest, it is treated as an interest-free loan for the Company (i.e. under conditions more favorable than market rates), and the difference between the amount of the advance at historical cost and the advance discounted at market rates is considered as a public grant. The first instalment payment was received in January 2022; in addition, a second instalment payment of CHF 2,289.7K (€ 2,325.3K) was received in September 2022.

(in thousands of EUR)	FOPH FORGIVABLE LOAN
<b>At December 31, 2021</b>	<b>2,534.5</b>
Addition	2,659.1
Subsidies	(115.4)
Financial expenses	233.1
Impact of exchange rate difference	(175.0)
<b>At December 31, 2022</b>	<b>5,136.3</b>
Addition	-
Subsidies	(148.1)
Financial expenses	308.0
Impact of exchange rate difference	333.4
<b>At December 31, 2023</b>	<b>5,629.6</b>

### **8.1.5** Financing by Research Tax Credits

The Company's French subsidiary has benefitted from research tax credits ("RTC") for its research and development work. The amount of the RTC reported for financial year 2021 was repaid during the second half of 2022. Payment of the amount of RTC accrued as at December 31, 2022 is expected in 2026 and the Company implemented a bank prefinancing of the 2022 RTC for €1 million in January 2024; the amount of RTC accrued for the financial year 2023 is expected to be reimbursed in 2027 and the Company also intends to implement a bank prefinancing for this amount.

## **8.2** Description Of The Group's Cash Flows

As of December 31, 2023, cash and cash equivalents were €1.8 million, compared to €5.5 million as of December 31, 2022.

### **Cash flow from operating activities**

Cash flows from operating activities were negative in 2023 and 2022, as a result of the still significant expenses of the Company's research and development activities and despite the decrease in general and administrative expenses and, for 2023, the favorable impact of the change in working capital as the Company slowed down the pace of supplier payment. These cash outflows from operating activities amounted to -€10.1 million and -€13.1 million for the years ended December 31, 2023 and 2022, respectively. The decrease in cash outflows from operating activities during 2023 was due primarily to the positive €3.9 million impact from the change in working capital in 2023 compared to a negative impact of €1.9 million in 2022, as a result of higher trade payables and accrued liabilities and the reduction of other current assets.

### **Cash flow from investing activities**

Cash flows from investing activities were positive by €51 K in 2023 and negative by €50 K in and 2022, respectively.

The Group's operations generally do not require investments in tangible assets given that the Company subcontracts the major part of production to third parties. Acquisitions of tangible assets are not significant and relate essentially to laboratory equipment and office equipment.

### **Cash flow from financing activities**

Cash flow from financing activities was positive by €6.3 million and €13.1 million, respectively, for the years ended December 31, 2023 and 2022, resulting for 2023 from the EIB Venture Debt financing implemented and for 2022 from the capital increases completed in 2022 and from the proceeds from the bank loan and from the proceeds from the FOPH subsidy forgivable loan..

### **Cash burn**

The Group considers its cash burn to approximate its cash outflow from operating activities, given its low level of capital expenditures and investment in intangible assets. Accordingly, its cash burn for 2023 was €10.1 million, compared to €13.1 million for 2022.

During 2022, the Company has completed its Karolinska Trial in March 2022 and accordingly continued only certain related costs during 2022, a year during which it also launched the manufacturing of a new batch of temelimab and incurred start-up expenses of the Post-COVID trial. With the ramp-up of the GNC-501 clinical trial and the approximate 6-month delay in patient recruitment, until completion in November 2023, cash consumption increased in 2023 (offset by a favorable impact of working capital) but with the study completion planned for June 2024, cash

consumption is expected to decrease significantly during 2024. With the recent €5 million capital increase of February 2024, the Company considers its operations to be funded until the end of 3Q 2024. The Company continues to be actively engaged in seeking a new partner for temelimab in the MS indication, but will also seek other sources of financing, such as capital increases, debt or non-dilutive funding, such as grants or subsidies, to allow it to continue its program in indications such as MS, ALS and Post-COVID.

In addition, the following factors will continue to contribute to the Company's cash burn:

- some of the Company's other products move beyond the stage of pre-clinical development to clinical development;
- the Company is confronted with increased regulatory requirements for manufacturing and trials for its product candidates (including temelimab for MS, which is its only product in an advanced stage of development);
- the Company begins to pay fees in connection with applications for product licenses from regulatory bodies;
- it increases its product portfolio by adding new products for future development;
- it makes milestone payments to third parties (such as bioMérieux) which have already licensed their technologies to it;
- it develops its research and development activities and buys new technologies, products or licenses, as the case may be;
- it develops its business; and
- it finances structural expenses consistent with the growth of its business.

### **8.3 Borrowing Conditions And Financing Structure**

With respect to the year ended December 31, 2023, the Group's financial debts consisted of:

- lease liabilities for a total amount of €1,005 K;
- research subsidies received in the form of a reimbursable advance granted by Bpifrance amounting to €139 K on the date hereof (as mentioned above, this balance was cancelled by Bpifrance in January 2023);
- an unsecured bank loan of €840 K, repayable over three years until June 2025;
- the FOPH "forgivable loan" resulting from the IFRS treatment of the FOPH subsidy, for €5,136 K

(amounts in thousands of EUR)	December 31, 2023			
	Total amount	Less than 1 year	1 to 5 years	More than 5 yrs
FOPH COVID-19 forgivable loan	5,629.6	-	5,629.6	-
Lease liabilities	796.4	298.2	498.2	-
Unsecured bank loan	511.4	338.3	173.1	-
EIB Venture Debt loan	6,430.0	110.8	6,319.2	-
Derivative liabilities	299.4	-	-	-
<b>Total financial liabilities</b>	<b>13,666.8</b>	<b>747.3</b>	<b>12,126.8</b>	<b>-</b>
<i>Current financial liabilities</i>	<i>747.3</i>			
<i>Non-current derivative liabilities</i>	<i>299.4</i>			
<i>Non-current financial liabilities</i>	<i>12,620.1</i>			
<b>Trade liabilities</b>	<b>2,459.6</b>	<b>2,459.6</b>	-	-
<b>Other current liabilities</b>	<b>3,042.6</b>	<b>3,042.6</b>	-	-

Please see Notes 7, 10 and 12 to the audited consolidated financial statements as at and for the year ended December 31, 2023 reproduced in CHAPTER 18 of this Universal Registration Document, for further details.

### **8.4 Information About Any Restriction On The Use Of Funds Significantly Influencing, Or Potentially Influencing, The Group's Business, Directly Or Indirectly**

None.



## **8.5 Sources Of Funds Expected For Future Investments**

To cover the Company's future needs, the Company listed its shares in Euronext's regulated market in Paris in April 2016 and at the same time completed a capital increase.

Since it began operations, the Company has sustained operating losses, except for the 2014 financial year. Such losses reflect both the significance of the expenses incurred in research and development and the weakness of the Company's revenues. The Company foresees that such losses will continue over the next few years, at least until the marketing and sale of its products (should that occur), because of the significant investments required for research, development, manufacture, quality control, distribution of its products, pre-clinical and clinical trials, administrative activities, and activities linked to the development of intellectual property, as well as license agreements for new products and for the acquisition of new technologies that may become necessary, as the case may be. The Company may never market or sell any products and, as a result, may never become profitable. Its operating loss was €11.2 million in 2022 compared to €14.4 million in 2023.

Following the positive results from the Karolinska Trial, which confirmed the positive results from the CHANGE-MS and ANGEL-MS trials, the Company has reactivated partnership discussions for the MS indication. The Company has also succeeded in seeking subsidies or "venture debt", under the form of the EIB financing, for its Post-COVID program and will also continue to seek other sources of financing, such as capital increases, debt or non-dilutive funding, such as grants or subsidies, to allow it to continue its programs.

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

- some of its products move beyond the stage of pre-clinical development to clinical development;
- it is confronted with increased regulatory requirements for manufacturing and trials for its product candidates (including temelimab for MS, which is its only product in an advanced stage of development);
- it begins to pay fees in connection with applications for product licenses from regulatory bodies;
- it increases its portfolio of products by adding new products for future development;
- it makes milestone payments to third parties (such as bioMérieux or the NIH) which have already licensed their technologies to it;
- it develops its research and development activities and buys new technologies, products or licenses, as the case may be;
- it develops its business in different parts of the world; 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 pre-clinical developments and clinical trials;
- the calendar 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; and
- other factors, a great number of which are beyond the Company's control.

## **8.6 Off-Balance Sheet Commitments**

Off-balance sheet commitments consist of individual rights to training, commercial leases, covenants under the license agreement with bioMérieux and the NIH, and put option commitments under the warrant agreement with the EIB. These off-balance sheet commitments are described in Note 19 to the consolidated financial statements prepared in accordance with IFRS for the year ended 31 December 2023. prepared in accordance with IFRS, set forth in CHAPTER 18 of this Universal Registration Document.

## **CHAPTER 9.**

### **REGULATORY ENVIRONMENT**

Governmental authorities in Europe, the United States and other countries, at the federal, state and local levels extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and the export and import of drug and biological products, or biologics, such as the Company's product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review, and approved by the regulatory authority.

#### **9.1 In the United States**

##### **9.1.1 U.S. Biological Product Development**

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act (the "**FDCA**"), and the Public Health Service Act, and their implementing regulations. Biologics are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process, or after approval, may subject an applicant to administrative or legal sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, the withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market, product seizures, the total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on the Company.

The Company's product candidates must be approved by the FDA through the Biologics License Application (the "**BLA**") process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- the completion of extensive non-clinical (sometimes referred to as "pre-clinical") laboratory tests, pre-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("**GLP**") regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- the performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations (sometimes referred to as good clinical practices ("**GCPs**")), to establish the safety and efficacy of the proposed product candidate for its proposed indication;
- submission of a BLA to the FDA;
- the satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practices ("**cGMP**"), requirements to assure that the facilities, methods, and controls are adequate to preserve the product's identity, strength, quality, purity, and potency;
- a potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The data required to support a BLA are generated in two distinct development stages: pre-clinical and clinical. The pre-clinical development stage generally involves laboratory evaluations of drug chemistry, formulation, and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the pre-clinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical protocol to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or noncompliance. Accordingly, the Company cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board ("IRB"), at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose specified clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase I, Phase II and Phase III clinical trials. Phase I clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability, and safety of the product candidate and, if possible, to gain early evidence on effectiveness. Phase II clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as the identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase III clinical trials generally involve large numbers of patients at multiple sites, in multiple countries (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use and its safety in use, to establish the overall benefit/risk relationship of the product, and to provide an adequate basis for product approval. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse reactions, findings from other studies suggesting a significant risk to humans exposed to the drug, and findings from animal or in vitro testing suggesting a significant risk to humans. Phase I, Phase II, and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial if the clinical trial is not being conducted in accordance with the IRB's requirements, or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. The company may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality, and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

### **9.1.2** BLA and FDA Review Process

Following trial completion, trial data are analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and

information about the manufacturing process and facilities that will be used to ensure product quality, the results of analytical testing conducted on the chemistry of the product candidate, and other relevant information. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity, potency, and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes both negative or ambiguous results of the pre-clinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act (the “PDUFA”), as amended, each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. The PDUFA also imposes an annual product fee for human drugs and an annual establishment fee on facilities used to manufacture prescription drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Once a BLA has been accepted for filing, which occurs, if at all, 60 days after the BLA’s submission, the FDA’s goal is to review BLAs within ten months of the filing date for standard review or six months of the filing date for priority review, if the application is for a product intended for a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness. The review process is often significantly extended by FDA requests for additional information or clarification.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether it is being manufactured in accordance with cGMP to ensure and preserve the product candidate’s identity, strength, quality, purity, and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the company during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming, and may take longer than originally planned to complete, and the company may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, the manufacturing process, and the manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies, or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials is not always conclusive and the FDA may interpret data differently from the way the Company interprets the same data.

There can be no assurance that the FDA will ultimately approve a product for marketing in the United States, and the Company may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, the development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase IV testing, which involves clinical trials designed to assess the product’s safety and effectiveness further and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals, including the requirement for a Risk Evaluation and Mitigation Strategy (“REMS”), to ensure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any

of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of products. Product approvals may be withdrawn for noncompliance with regulatory standards or if problems occur following initial marketing.

### 9.1.3 Orphan Drug Designation

The FDA may grant an orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and marketing the drug for this type of disease or condition will be recovered from sales in the United States. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product status, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure sufficient quantities of the approved orphan-designated product. Competitors, however, may receive approval for different products, the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of the Company's products for seven years, if a competitor obtains approval of the same biological product as defined by the FDA. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than that so designated, it may not be entitled to orphan product exclusivity.

### 9.1.4 Expedited Development and Review Programs

The FDA has a Fast-Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast-track designation if they are intended to treat a serious or life-threatening condition and non-clinical or clinical data demonstrate the potential for addressing an unmet medical need. Fast-Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast-Track product concurrently with the submission of an IND or at any time before a pre-BLA meeting, and the FDA must determine if the product qualifies for Fast-Track designation within 60 days of receipt of the sponsor's request. Unique to a fast-track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast-Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review, or review within a six-month time-frame from the date a complete BLA is accepted for filing, if it treats a serious condition and has the potential to provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate end point that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical end point other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials.

If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions as it deems necessary to assure the safe use of the drug, or elements to assure safe use ("ETASU"), such as:

- distribution being restricted to certain facilities or physicians with special training or experience; or
- distribution being conditioned on the performance of specified medical procedures.

The limitations imposed would be commensurate with the specific safety concerns presented by the product. In addition, the FDA currently requires as a condition for accelerated approval the pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast-track designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process.

#### **9.1.5 Breakthrough Designation**

The Food and Drug Administration Safety and Innovation Act (the “**FDASIA**”) amended the FDCA to require the FDA to expedite the development and review of a Breakthrough Therapy. A product can be designated as a Breakthrough Therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant end points. A sponsor may request that a product candidate be designated as a Breakthrough Therapy concurrently with the submission of an IND or any time thereafter, and the FDA must determine if the product candidate qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor’s request. If so designated, the FDA must act to expedite the development and review of the product’s marketing application, including by meeting with the sponsor throughout the product’s development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project head for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable.

#### **9.1.6 Pediatric Trials**

Under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, a new indication, a new dosage form, new dosing regimen or a new route of administration submit an initial Pediatric Study Plan (“**PSP**”) within 60 days of an end-of-Phase II meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant end points, and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from non-clinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers.

#### **9.1.7 Post-Marketing Requirements**

Following approval of a new product, a manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, the reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product’s approved labeling (known as “off-label use”), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation, and provide an obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort on production and quality control in order to maintain cGMP compliance. These regulations also impose



certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed, or tested by them. The discovery of problems with a product after approval may result in restrictions on the product, manufacturer, or holder of an approved BLA, including, among other things, the recall or withdrawal of the product from the market.

The FDA also may require post-approval testing (sometimes referred to as Phase IV testing), risk minimization action plans, and post-marketing surveillance in order to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. The discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. New government requirements, including those resulting from new legislation, may also be established, or the FDA's policies may change, which could delay or prevent the regulatory approval of products under development.

#### **9.1.8 Other Regulatory Matters**

Manufacturing, sale, promotion, and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. In the United States, sales, marketing, and scientific or educational programs must also comply with state and federal fraud and abuse laws, data privacy and security laws, transparency laws, and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion, and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Failure to comply with regulatory requirements can subject firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, the recall or seizure of products, the total or partial suspension of production, the denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or the withdrawal of future products marketed by the Company could materially adversely affect its business.

Changes in regulations, statutes, or the interpretation of existing regulations could impact the Company's business in the future by requiring, for example: (i) changes to its manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuance of its products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of the Company's business.

#### **9.1.9 U.S. Patent Term Restoration and Marketing Exclusivity**

Depending upon the timing, duration, and specifics of the FDA approval of the Company's product candidates, some of its U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (also called the Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of

the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, the Company may apply for the restoration of the patent term for its currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 (“**BPCIA**”). Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times, the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. A reference biological product is granted twelve years of exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification changes its safety, purity, or potency. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

## **9.2 In the European Union**

### **9.2.1 European Union Drug Development**

In the European Union, the Company’s future product candidates may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

As in the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, Regulation No. 536/2014 on clinical trials of medicinal product candidates for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. This Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. The Regulation entered into force on June 16, 2014 and became applicable six months after the full functionality of the IT portal, called the Clinical Trials Information System (CTIS) went live with a searchable public website, on 31 January 2022. CTIS supports the flow of information between clinical trial sponsors, European Union (EU) Member States, European Economic Area (EEA) countries and the European Commission.

### **9.2.2 European Union Drug Review and Approval**

In the European Economic Area (the “EEA”) (which is now comprised of the 27 Member States of the European Union plus Norway, Iceland, Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization (“**EU MA**”). There are two types of MAs:

- the EU MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (“**CHMP**”), of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products that contain a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, or autoimmune and viral diseases. The Centralized Procedure is optional for products that contain



a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the European Union; and

- national MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territories, are available for products that do not fall within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another member state through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (“RMS”). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (“SmPC”), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member State (the “CMSs”) for their approval. If the CMSs raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all Member States (i.e., in the RMS and the CMSs).

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk–benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

### **9.3 Registration procedures outside of Europe and the United States**

In addition to regulation in the United States and Europe, a variety of foreign regulations govern clinical trials, commercial sales and distribution of drugs. Pharmaceutical firms who wish to market their medicinal drugs outside the European Union and the United States must submit marketing authorization application to the national authorities of the concerned countries, such as the Pharmaceutical and Medical Device Agency, or PMDA in Japan. The approval process varies from jurisdiction to jurisdiction and the time to approval may be longer or shorter than that required by the FDA or European Commission.

### **9.4 Reimbursement**

Sales of the Company’s products will depend, in part, on the extent to which the Company’s products, once approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance, and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list (also known as a formulary) which might not include all the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product candidate that might be approved for sale, the Company may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of the product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not the Company conducts such studies, its product candidates may not be considered medically necessary or cost effective. A third-party payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not ensure that other payors will also provide coverage, and adequate reimbursement, for the product. Third-party reimbursement may not be sufficient to enable the Company to maintain price levels high enough to realize an appropriate return on its investment in product development.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for the substitution of generic products. The adoption of price controls and cost-containment measures, and the adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit the Company’s net revenue and results. Decreases in third-party reimbursement for the Company’s product candidate or a decision by a third-party payor not to cover the Company’s product candidate could reduce physician usage of the product candidate and have a material adverse effect on the Company’s sales, results of operations, and financial condition.

In addition, in some countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. In Europe, the requirements governing drug pricing vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its Member States to restrict the range of medicinal

products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. For example, in France, effective access to the market assumes that the Company's future products will be supported by a hospital (through an agreement for local communities) or reimbursed by a healthcare or social security administration and the price of medications is negotiated with the Economic Committee for Health Products.

There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of the Company's product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the "**ACA**") enacted in the United States in March 2010, has already had, and is expected to continue to have, a significant impact on the healthcare industry. The ACA has expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program.

Since its enactment there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. While the Texas U.S. District Court Judge, as well as the Trump Administration and CMS, have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least USD 1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction of several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, begun in April 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the "**ATRA**") which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. . Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Additionally, on January 31, 2019, Office of Inspector General of the U.S. Department of Health and Human Services proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the

cost of drug products to consumers. Although a number of these, and other proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

## **9.5 Other Healthcare Laws and Compliance Requirements in the United States**

Business operations in the United States and arrangements with clinical investigators, healthcare providers, consultants, third-party payors and patients may expose the Company to broadly applicable federal and state fraud and abuse and other healthcare laws. These laws may impact, among other things, the Company's research, proposed sales, marketing, and education programs for the Company's product candidates that obtain marketing approval. The laws that may affect the Company's ability to operate include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item, good, facility, or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated;
- federal, civil and criminal false claims laws and civil monetary penalty laws, which impose penalties and provide for civil whistleblower or qui tam actions against individuals and entities for, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to the payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters, knowingly and willfully embezzling or stealing from a healthcare benefit program, or willfully obstructing a criminal investigation of a healthcare offense;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies to track and annually report to the CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH"), and its implementing regulations, which impose certain requirements on covered entities and their business associates relating to the privacy, security, and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing, and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

The ACA broadened the reach of the federal fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable federal criminal healthcare fraud statutes.

Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil U.S. False Claims Act or the civil monetary penalties statute.

Efforts to ensure that the Company's business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that the Company's business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws. If the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, the Company may be subject to significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, (such as Medicare and Medicaid), and the curtailment or restructuring of its operations. If the physicians or other healthcare providers or entities with whom or which the Company expects to do business are found to be not in compliance with applicable laws, they may be subject to administrative, civil, and/or criminal sanctions, including exclusions from government-funded healthcare programs.

## **9.6 Data protection Rules in Europe**

European Union Regulation (EU) 2016/679, known as the General Data Protection Regulation (GDPR), which entered into force on 25 May 2018, as well as EU Member States implementing legislations, apply to the collection and processing of personal data, including health-related information, by companies located in the EU, or in certain circumstances, by companies located outside of the EU and processing personal information of individuals located in the EU. These laws impose strict obligations on the ability to process personal data, including health-related information, in particular in relation to their collection, use, disclosure and transfer.

## **CHAPTER 10.** **INFORMATION ON TRENDS**

### **10.1 Recent Changes Since The End Of Financial Year 2022**

#### **February 2024 Capital Increase**

On February 2, 2024, GeNeuro announced the successful completion of a €5 million capital increase with cancellation of the preferential subscription rights through an international private placement reserved for specialized or strategic investors of (the “Private Placement”) and through a public offering for retail investors in France via the PrimaryBid platform.

#### **Post-COVID 19 Project**

In March 2023, the Company announced it had entered into a “venture debt” credit facility with the European Investment Bank (EIB) for a total amount of up to €25 million, supported by the InvestEU program, of which a first tranche of €7 million was immediately available and was drawn down in March 2023.

#### **Cash Position as at March 31, 2024**

On April 30, 2024, the Company reported on its unaudited cash and cash equivalent position for the first quarter of 2024 of €2.9 million. The Company considered that on the filing date of this Universal Registration Document its available cash resources provide GeNeuro with visibility until end of Q3 2024 in terms of financing its activities, which are currently focused on the Post-COVID trial and the continuation of partnership discussions for MS.

For Q1 2024, the cash consumption related to GeNeuro’s operating and investing activities was €2.9 million, compared to €3.0 million for the same period of 2023. The Q1 2024 cash consumption included the reduction of working capital in connection with trade payables for the Phase 2 clinical trial in Post-COVID. The Company expects its quarterly cash consumption to decrease during 2024 as the post-COVID clinical trial will be completed in June 2024.

### **10.2 Known Trends, Uncertainties, Requests For Commitment Or Event Reasonably Likely To Influence The Company’s Prospects**

Given the high costs of Phase III clinical trials in MS, likely to exceed to €100 million, GeNeuro has reactivated partnership discussions following the results from the Karolinska ProTECT-MS trial.

The Company’s current clinical trial in Post-COVID has completed patient recruitment in November 2023 and the topline results are planned for June 2024.

**CHAPTER 11.**  
**FORECASTS OR ESTIMATES OF PROFIT OR LOSS**

The Company does not plan to make forecasts or estimates of profits and losses.

**CHAPTER 12.**  
**ADMINISTRATIVE, MANAGEMENT, SUPERVISORY, AND SENIOR MANAGEMENT BODIES**

**12.1 Members Of The Administration, Management, And Supervisory Bodies**

**12.1.1 Board of Directors**

12.1.1.1 Membership of the Board of Directors

On the filing date of this Universal Registration Document, the members of the Company's Board of Directors were as follows:

Name	Position	First appointment	Expiration
Jesús Martin-Garcia	Chairman of the Board of Directors	Feb. 6, 2006	General Shareholders' Meeting to consider and act on the financial statements for FY 2023
Philippe Archinard	Independent* Director	May 27, 2021	General Shareholders' Meeting to consider and act on the financial statements for FY 2023
Hedi Ben Brahim	Independent* Director	May 27, 2020	General Shareholders' Meeting to consider and act on the financial statements for FY 2023
Michel Dubois	Independent* Director	July 16, 2008	General Shareholders' Meeting to consider and act on the financial statements for FY 2023
Giacomo Di Nepi	Independent* Director	July 21, 2015	General Shareholders' Meeting to consider and act on the financial statements for FY 2023
Sandrine Flory	Independent* Director	March 18, 2024	General Shareholders' Meeting to consider and act on the financial statements for FY 2023
Gordon S. Francis	Independent* Director	March 17, 2015	General Shareholders' Meeting to consider and act on the financial statements for FY 2023
Pascal Lemaire	Independent* Director	March 18, 2024	General Shareholders' Meeting to consider and act on the financial statements for FY 2023

\* Independent directors for purposes of the Swiss Code of Good Practices for company governance organized in Switzerland (economiesuisse).

Since the 2023 AGM, one former director, Mr Eric Falcand, who had been proposed to the Board by Servier, resigned from the Company's Board following his departure from Servier, and two new directors, Mrs Sandrine Flory (proposed by GNEH/Institut Mérieux), and Mr Pascal Lemaire (proposed by Servier) were elected at the extraordinary shareholders' meeting of March 18, 2024. There has been no other change in the members of the Company's Board of Directors nor is there is any family relationship between any of them.

- Other offices or positions presently held

Companies that are not part of the Group in which members of the Company's Board of Directors have served as a member of the board of directors or a supervisory body, or are general partners of a limited partnership during the last five years are as follows:

Name	Position	Company/Entity
Jesús Martin-Garcia	Managing Director Director	Eclosion2 & Cie SCPC Netris Pharma SA
Philippe Archinard	Director Chief Operating Officer Chief Executive Officer Director Chairman  Director	Transgene SA* Institut Mérieux TSGH SA Erytech Pharma* Institut de Recherche Technologique BIOASTER NH Theraguix
Hedi Ben Brahim	Chief Executive Officer	One BioSciences SA
Giacomo Di Nepi	Director Chairman of the Board Chairman of the Board Chairman of the Board Senior Advisor and Director Senior Advisor Health Care	Zambon SpA, Zambon Biotech Peptomyc SA NTC Srl, Handicap International (Suisse) KKR Inc.
Michel Dubois	Chairman	GeNeuro Innovation SAS
Sandrine Flory	Chief Financial Officer Director (employee representative) Director	Institut Mérieux Institut Mérieux Financière de Tubize
Gordon S. Francis	-	-
Pascal Lemaire	Chief Financial Officer	Servier

\* : listed company

- Offices held during the last five fiscal years and which have terminated as of the date hereof

Companies that are not part of the Group in which members of the Company's Board of Directors served as member of an administration, management, or supervisory body or were partners in a limited partnership during the last five years are as follows:

Name	Office	Company/Entity
Jesús Martin-Garcia	Director Director	Fondation Eclosion Genkyotex SA*
Philippe Archinard	CEO	Transgene SA*
Hedi Ben Brahim	-	-
Michel Dubois	-	-
Giacomo Di Nepi	CEO Director	Polyphor SA* Kuros Biosciences AG *
Sandrine Flory	-	-
Gordon S. Francis	-	-
Pascal Lemaire	-	-

\* : listed (or previously listed) company

For purposes of Company directorships, the members of the Board of Directors are domiciled at the Company's registered and principal office.

During the last five years, no member of the Company's Board of Directors:

- was convicted of fraud, perjury, or any other official sanction or penalty against him/her/it by governmental or regulatory authorities;
- was involved in an insolvency, bankruptcy, receivership, or liquidation as an executive or officer; or
- has been prevented by a court from acting as a member of an administration, management, or supervisory body or from being involved in the management or conduct of the business and affairs of an issuer.



#### 12.1.1.2 Biographies of Members of the Board of Directors

**Jesús Martin-Garcia** – Chairman of the Board of Directors and Chief Executive Officer, Swiss national, 61 years old

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, the largest retail company in Switzerland. He was also an initial equity investor and participated in the development of other start-ups such as Silverwire and VTX, during more than 10 years.

In 2003, he organized Ecllosion, 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, of which Jesús took the leadership in 2006.

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.

**Philippe Archinard – Director**, French national, 64 years old

Philippe Archinard is a graduate of the Ecole Nationale Supérieure de Chimie in Montpellier and holds a PhD in biochemistry from the University of Lyon. He has also completed the PMD management program from the Harvard Business School. He was the Chief Executive Officer of Innogenetics (Belgium) from 2000 to 2004. He was appointed Chief Executive Officer of Transgene in 2004 and Chief Executive Officer in 2010. Since 2014, Philippe Archinard has been Chairman of BIOASTER (Foundation for scientific cooperation), a technology research institute focusing on infectious diseases and microbiology. He chaired the Lyon competitiveness cluster, Lyon Biopôle, for 11 years. He has terminated his operational functions at Transgene while continuing to be a director of this company. He has also been Chief Operating Officer of Institut Mérieux since 2021.

**Hedi Ben Brahim – Director**, French national, 43 years old

Hedi Ben Brahim became Chief Executive Officer of One BioSciences in 2023, after having been Chairman & Chief Executive Officer of Transgene SA since January 1st, 2021. Prior to that he was Vice-President for Immunotherapy at Institut Mérieux since September 2018. Prior to joining the Institut Mérieux, he was General Manager at a subsidiary of Vallourec, a solutions provider to the energy sector. Hedi began his career in the public sector at the Ministry of the Economy, Action and Public Accounts, then at the Ministry of Social Affairs and Health. He is a graduate of the École Polytechnique and the École Nationale Supérieure des Mines de Paris.

**Giacomo Di Nepi – Director**, Italian national, 71 years old

Mr. Giacomo Di Nepi, Director of the Company, has very broad experience in the pharmaceutical industry, having been an executive both in large companies and in successful start-ups.

He is currently Senior Advisor to KKR, a leading global investment firm, focusing on Healthcare investment opportunities. He is also Chairman of Peptomyc, NTC, and Zambon Biotech, a Director of Zambon S.p.A., and Advisor and Board Member of Handicap International (Suisse), a leading charity. He was previously Chief Executive Officer of Polyphor, a clinical stage Swiss biotechnology company, where he led a CHF 150m IPO on the SIX Swiss Exchange.

From 2009 to 2015, Mr. Giacomo Di Nepi was Executive Vice President and Chief Executive Officer for Europe at InterMune Inc., until its acquisition by Roche. Prior, he was Head of Europe at Takeda, was Executive Committee Member of Novartis Pharma – where he had several leading roles in Switzerland, Italy and the US - and a Partner with McKinsey&Co.

Mr. Di Nepi is the Chair of the Nomination and Remuneration Committee.

**Michel Dubois – Director**, French national, 80 years old

Michel Dubois spent 25 years with Institut Mérieux, with increasing responsibility until he became the Chief Executive Officer of the Institut Mérieux holding company. He began his career as a consultant with McKinsey & Company and with Arthur Andersen.



Michel Dubois is Chairman of GeNeuro Innovation, the French subsidiary of GeNeuro.

**Sandrine Flory – Director**, French national, 53 years old

Mrs Sandrine Flory has been a Director of the Company since March 18, 2024. She holds a DESCF (Diplôme d'études supérieures comptables et financières) and a Master 2 Évaluation et Transmission d'Entreprises from Lyon 2 University.

**Gordon S. Francis – Director**, Canadian national, 74 years old

Dr. Gordon Francis, Director of the Company, is a recognized neurologist in the field of MS.

Gordon Francis has dedicated most of his career to developing treatments for multiple sclerosis and has played a key part in marketing three important treatments against this condition.

Dr. Gordon Francis served as Vice President and Chief of the Neurological division at Novartis and was in charge of developing and registering Gilenya®, the first oral treatment for MS to be registered in the United States in 2010 and in Europe in 2011. Prior to that, he managed the group responsible for the marketing of Tysabri® with Elan from 2004 to 2006 and, before then, the group responsible for the approval procedure for Rebif® in the United States for Serono in 2002.

He has a degree from the Medical School of Queen's University in Kingston and completed his training in internal medicine and neurology at McGill University. In addition, he undertook post-doctoral research in neuro-immunology at the University of California at San Francisco. He has published more than 100 articles in the field of neurology.

Dr. Gordon Francis also managed the clinic for clinical research on MS at McGill and the clinical research center of the *Institut neurologique* (neurological institute) of Montréal.

**Pascal Lemaire – Director**, Swiss national, 50 years old

Mr. Pascal Lemaire is a Director of the Company since March 18, 2024. Pascal has over 25 years' international experience in corporate finance, notably in the consumer goods and pharmaceutical industries. Pascal Lemaire began his international career with Nestlé. For over 17 years, he held various positions of responsibility in all areas of corporate finance and Global Business Services. In 2015, he was appointed Executive Director Finance and Business Planning at Celgene for all business outside the United States. Pascal Lemaire joined Servier in 2020 and is a member of the Executive Committee, as Executive Vice President Finance.

Pascal Lemaire holds a Bachelor's degree in Business Administration and a Master's degree in Banking and Finance from HEC Lausanne.

### **12.1.2 Management**

Members of management are appointed by the Board of Directors and are responsible for the management and direction of the Company's business and affairs, subject to the inalienable authority of the Board of Directors (please see Section 19.2.2.1, of this Universal Registration Document) in accordance with the Articles of Association, the internal rules and procedures of management.

Management performs its responsibilities under the supervision of the Board of Directors, assists the Board of Directors in the performance of its responsibilities, and carries out its decisions.

The authority of management and its members is set forth in a Table showing the division of roles and responsibilities approved by the Board of Directors.

The members of the management are registered at the Geneva Commercial Register, and any of them signing together with the Chief Executive Officer or the CFO of the Company have authority to bind the Company.

Management itself determines the procedures applicable to the performance of their responsibilities, in compliance with relevant laws, the Company's Articles of Association and internal rules and procedures.

#### **12.1.2.1 Members of Management**

On the filing date of this Universal Registration Document, the members of the Company's management were as follows:

- **Jesús Martin-Garcia**, Chief Executive Officer (CEO)

- **Alois B Lang**, Chief Development Officer (CDO)
- **Anke Post**, Chief Medical Officer (CMO)
- **Miguel Payró**, Chief Financial Officer (CFO)
- **Hervé Perron**, Chief Scientific Officer (CSO)

Dr. Anke Post joined the Company on January 1, 2024 following the full retirement of Dr. David Leppert, the former CMO. There has been no other change in 2023 and until the filing date of this Amendment. There are no family ties or relationships between the members of Management and the Company.

- Other outstanding positions

Companies that are not members of the Group in which members of the Company's management and directors have served as members of an administration, management, or supervisory body or are general partners in a French limited partnership during the last five years are as follows:

Name	Position	Company/Entity
Alois B Lang	-	-
Anke Post	-	-
Miguel Payró	-	-
Hervé Perron	-	-

- Offices held during the last five fiscal years and that have terminated as of the date hereof

Companies not members of the Group in which members of the Company's management have served as a member of an administration, management or supervisory body or have been general partners in a French limited partnership during the last five years are as follows:

Name	Position	Company/Entity
Alois B Lang	-	-
Anke Post	-	-
Miguel Payró	-	-
Hervé Perron	-	-

#### 12.1.2.2 Biographies of Members of Management

##### **Alois B. Lang – Chief Development Officer**, Swiss national, 72 years old

Dr. Alois B. Lang has been the Company's Chief Development Officer from 2007 to 2017 before rejoining GeNeuro in September 2021. Dr Lang holds a doctorate from the Ecole Polytechnique of Zurich and did postdoctoral work at the Zurich University Hospital and with the Immunology Department of Cetus Inc. in Palo Alto, United States. Dr. Alois B. Lang was also a professor of immunology at the Faculté de médecine (medical school) of the University of Berne.

He held the position of Chief of Research and Immunology and Project Director for Berna Biotech, in Berne. He was also co-founder and Scientific Director of Kenta Biotech in Zurich.

Mr. Alois B. Lang is involved in various working groups with scientific experts and regularly participates in major scientific conferences.

##### **Miguel Payró – Chief Financial Officer**, French and British national, 61 years old

Mr. Miguel Payró has been the Company's Chief Financial Officer since November 2015 and holds a degree from the University of Geneva in Economics and Social Science/Company Management.

Previously, he was Chief Financial Officer of the Swiss Franck Muller watch group, for which he completed a number of mergers and acquisitions and the formation of subsidiaries as well as a restructuring of its shareholders. He was a partner in Value Management Group, a strategic management advisory company, and was responsible for the IPO on the Swiss stock exchange of Unilabs and numerous development projects, including in the field of clinical trials, as well as investor relations. He also worked in the fields of capital markets and acquisition finance for various Swiss banks.

##### **Hervé Perron – Chief Scientific Officer**, French national, 65 years old

Dr. Hervé Perron is co-founder and Chief Scientific Officer of the Company.

His research for 15 years at Université Joseph Fourier and INSERM, and his role as research director at bioMérieux led to the discovery of the impact of HERVS on MS. This research served as a basis for the setting up of GeNeuro, which he joined at its formation in 2006.

Hervé is internationally known as a leader in the area of endogenous retroviruses. GeNeuro's research unit, which he directs together with an international network of academic collaborators, is attempting to exploit the enormous potential opened by endogenous retroviruses for understanding and treating serious diseases.

Dr. Hervé Perron holds a doctorate in virology and wrote his doctoral dissertation on neuro-immunology. He is author of more than 120 publications and patents and works as a reference expert for various scientific journals.

##### **Anke Post – Chief Medical Officer (CMO)**, German national, 58 years old

Dr. Anke Post, MD, PhD, joined Geneuro in January 2024 as Chief Medical Officer and will steer the development of Geneuro's clinical development strategy and lead execution of its clinical programs. Dr. Post has in-depth academic and medical knowledge and training in the field of Neurosciences, Psychiatry and Neurology as well as broad pharmaceutical industry experience after holding positions as senior physician and leader with more than 25 years of academic and Pharmaceutical R&D activity in major multinational pharmaceutical organizations as well as in biotech and medical device companies.

Dr. Post, who is a board-certified psychiatrist and psychotherapist, has a degree from the Medical Faculty of the Westfälische Wilhelmsuniversität in Münster, Germany, with a specialization degree in Psychiatry and Psychotherapy. From 2005 to 2011, she was Global Program Medical Director for the Neuroscience Franchise at Novartis in Basel, where she was, amongst other functions, Global Program Medical Director for a Phase III program in a psychiatric indication. In 2011, she moved to Eli Lilly & Cop, where she worked as Senior Medical Director in Discovery, Research and Clinical Investigation Neuroscience. From 2017 to 2019 she was Head Translational Medicine/Neurology at Roche, then Head Clinical development/ Therapeutic Area Neurosciences at Idorsia. Most recently Dr. Post was Senior Vice-President at UniQure where she managed the development and execution of the clinical programs.

Dr. Post has authored over 25 peer reviewed publications and holds an MD from the University of Münster, Germany. She completed research fellowships in neurology and psychiatry at the Humboldt-University in Berlin, Germany, at the Salk Institute of Biological Studies (post-doctoral fellowship), La Jolla, California, attended the Harvard Medical Course of Neurology and Psychiatry and from 1996 to 2004, was Associate Professor and Senior

Physician at the Max-Planck Institute of Psychiatry in Munich, Germany; Dr. Post has also worked from 2008 to 2011 as senior neuropsychiatrist consultant at the Psychiatric Hospital of the University of Basel, Switzerland.

### **12.1.3 Committees of the Board of Directors**

The Nominations Committee and the Remuneration Committee consist of:

- Mr. Giacomo Di Nepi, Chairman of the committee;
- Mr. Hedi Ben Brahim, member; and
- Mr. Philippe Archinard, member.

The Audit and Control Committee consists of:

- Mr. Michel Dubois, Chairman of the committee;
- Mrs. Sandrine Flory, member; and
- Mr. Pascal Lemaire, member.

Mr Archinard was elected as member of the Remuneration Committee at the 2023 AGM; Mrs Flory and Mr Pascal Lemaire were appointed by the Board to the Audit and Control Committee following their election to the Board on March 18, 2024..

For further information about the responsibilities and modus operandi, please see Section 14.3, “Operation of Committees” of this Universal Registration Document.

## **12.2 Conflicts Of Interest In The Administration, Management, And Supervisory Bodies**

Mr. Martin-Garcia, Dr. Lang, Mr. Di Nepi, Mr. Dubois, Dr. Francis, Dr. Post, Mr. Payró and Dr. Perron are shareholders, directly or indirectly, of the Company and/or owners of securities carrying the right to acquire the Company's shares (please see Section 16.1, “Identification of Shareholders” of this Universal Registration Document).

Furthermore, Messrs. Martin-Garcia and Guichard are also Directors of Ecllosion2 SA, a general partner without limited liability of Ecllosion2 & Cie SCPC (Société en Commandite - Swiss limited partnership), which is one of the Company's shareholders.

Mr. Philippe Archinard is Chief Operating Officer of Institut Mérieux, and Mrs Sandrine Flory is Chief Financial Officer of Institut Mérieux. Mr Pascal Lemaire is Executive Vice-President, Finance, with Servier. Both Servier and Institut Mérieux are shareholders (in the case of Institut Mérieux through GNEH SAS) of the Company.

### **Agreements between related parties are described in Section 17.2 of this Universal Registration Document.**

To the Company's knowledge and subject to the relationships described above and the personal interests involved in the agreements set forth in Section 17.2 of this Universal Registration Document, there is no present or potential conflict of interest between their responsibility to the Company and the private interests and/or obligations of the persons constituting the management and administration committees of the Company.

The Board of Directors has adopted a set of internal rules and procedures that contain an article relating to conflicts of interest that requires an obligation for a member of the Board of Directors in a conflict of interest situation or in a situation that gives the appearance of a conflict of interest, to inform the Chairman of the Board of Directors thereof. In the event of a conflict of interest, or in the event of an appearance of a conflict of interest (and only at the Chairman's request), the Director may not participate in the discussion or the vote. A person with a conflict of interest may not serve as a member of the Board of Directors.

The agreements or arrangements between the Company and members of the Company's governance bodies or their family or close relations thereof have been made on arm's-length terms and conditions and approved without the involvement of the persons concerned. If necessary, an expert fact-finding may be ordered.

To the Company's knowledge, there is no agreement, arrangement, or contract of any kind between the Company and its shareholders, customers, suppliers, or others pursuant to which any member of management or of the Board of Directors of the Company has been appointed.

## CHAPTER 13. COMPENSATION AND BENEFITS

### **13.1 Compensation And Benefits Of Any Kind Granted To Executive Officers And Members Of The Administrative, Management, And Supervisory Bodies**

As provided in the Swiss Code of Obligations, the Company is required to submit directors' and management's compensation to the approval of its general shareholders' meeting; this approval concerns the maximum global (i.e. collective) fixed and variable compensation of the members of the Board of Directors and of management, respectively. There is no vote on the individual remuneration of each member. The maximum global remuneration is approved ex ante (until the next general shareholders' meeting for the Board of Directors and for the next annual financial years for the members of management). In addition, the Company's Board of Directors is responsible for preparing each year a written compensation report, that must be made available to the shareholders in advance of the general shareholders' meeting in the same manner as the annual financial statements. Pursuant to Swiss law and the Company's articles of incorporation, as amended, the GeNeuro compensation report is submitted to the consultative vote of the general shareholders' meeting; this vote does not affect any global compensation that was approved ex ante by the general shareholders' meeting.

Also as provided in the Swiss Code of Obligations, the Company hereby discloses the overall compensation of members of the Board of Directors and executive management as well as the amount granted to each of the members of the Board of Directors (for more details, see the 2023 Remuneration Report presented in section 13.5 of this Universal Registration Document) and the amount granted to the highest paid member of management, Mr. Jesús Martin-Garcia in 2023.

The total amount of overall annual compensation (including social security benefits) for the 2023 financial year paid to members of the Board of Directors was €43 thousand (2022: €87 thousand).

The total amount of overall compensation (including cash compensation, accruals for variable compensation, share-based payments, benefits in kind and social security and pension charges) for 2023 paid (or accrued) to members of management (including the CEO) was €1,631 thousand (2022: €2,104 thousand), including nil amount (2022: €246 thousand) of bonus accrual and €189 thousand (2022: €301 thousand) of accounting value attributable to stock options granted to members of management. The total amount paid to the CEO in 2023, including social charges and non-cash equity incentives, was € 630 thousand (2022: €805 thousand), including nil amount (2022: €117 thousand) of cash bonus paid in the following year and €108 thousand (2022: €153 thousand) of accounting value attributable to the stock options granted to the CEO at an exercise price of €2.86 per share (2022: €3.48 per share).

#### **13.1.1 Compensation of Any Kind Granted to the Highest-Paid Member of Management**

##### **Compensation Table 1: Summary of compensation and stock options granted to the highest-paid member of management**

<b>Table summarizing compensation, options, and shares granted to the highest-paid member of management</b>		
Amounts in thousands	2023 financial year	2022 financial year
<b>Jesús MARTIN-GARCIA – CEO <sup>(1)</sup></b>		
Compensation in respect of the year <i>(detailed in Table 2)</i>	€ 440	€ 545
Valuation of multi-year variable compensation granted during the year	-	-
Valuation of options granted during the year <i>(detailed in Table 4)</i>	€ 108	€ 153
Valuation of shares granted without consideration during the year	-	-
<b>Total</b>	<b>€ 548</b>	<b>€ 698</b>

(1) Appointed CEO (*directeur général*) with effect from January 1<sup>st</sup>, 2016.

**Compensation Table 2: Compensation of highest-paid member of management**

Table summarizing compensation of the highest-paid member of management				
	2023		2022	
Amounts in thousands	Amounts due <sup>(1)</sup>	Amounts paid <sup>(2)</sup>	Amounts due <sup>(1)</sup>	Amounts paid <sup>(2)</sup>
<b>Jesús MARTIN-GARCIA – CEO <sup>(3)</sup></b>				
Base compensation	€ 435 <sup>(4)</sup>	€ 435 <sup>(4)</sup>	€ 410 <sup>(4)</sup>	€ 410 <sup>(4)</sup>
Annual variable compensation	€ 0	€ 117 <sup>(5)</sup>	€ 117	€ 124 <sup>(5)</sup>
Multi-year variable compensation	-	-	-	-
Exceptional compensation	-	-	-	-
Director's fee	-	-	-	-
Fringe benefits (vehicle)	€ 17	€ 17	€ 17	€ 17
<b>TOTAL</b>	<b>€ 452</b>	<b>€ 569</b>	<b>€ 534</b>	<b>€ 551</b>

(1) For the year.

(2) During the year, including payment in the year of variable compensation attributed for the prior year

(3) Appointed CEO with effect from January 1st, 2016. Mr MARTIN-GARCIA's variable compensation is defined in connection with the annual performance appraisal with a specific objectives plan (qualitative and quantitative criteria, such as the progress of clinical trials). The bonus is decided by the Board of Directors.

(4) The base compensation is paid in CHF and has been increased by 3% in 2023 compared to 2022, to partly offset inflation; the 10.8%% increase in the EUR amount is due for 7.8% to the unfavorable evolution of the EUR/CHF exchange rate in 2022.

(5) The variable compensation is paid in CHF in the following year. No variable compensation was attributed for 2023.

**13.1.2 Compensation and benefits of any kind paid to members of the Board of Directors**

The compensation and benefits paid to members of the Board of Directors during the financial years ended December 31, 2023 and December 31, 2022 consist of the following.

**Compensation Table 3: Table of directors' fees and other compensation received by members of the Board of Directors**

Table of directors' fees and other compensation received by members of the Board of Directors (in thousands of Euros)			
Directors		Amounts paid in 2023	Amounts paid in 2022
Jesús Martin-Garcia	Director's fees	n.a.	n.a.
	Other compensation	n.a.	n.a.
Michel Dubois	Director's fees	12.9	24.9
	Other compensation	-	-
Eric Falcand	Director's fees	-	-
	Other compensation	-	-
Hedi Ben Brahim	Director's fees	-	-
	Other compensation	-	-
Gordon S. Francis	Director's fees	17.2	34.4
	Other compensation	-	-
Giacomo Di Nepi (1)	Director's fees	12.9	25.3
	Other compensation	5.9	6.1

(1) Other compensation relates to additional consulting services provided.

**13.1.3 Stock Options and Grants of Free Shares**

As mentioned in the Compensation Report included in Section 13.4.3, the compensation during 2023 of the members of the Board of Directors, other than the CEO, Mr. Jesús Martin-Garcia, consists exclusively of a fixed annual monetary compensation per term from one general meeting of shareholders to the next. At the March 18, 2024, extraordinary shareholders' meeting, shareholders also approved a variable compensation for directors.

**Compensation Table 4: Rights convertible into shares of the Company granted by the Group to the CEO during the year ended December 31, 2023**

Mr Martin-Garcia received 135,300 stock options during 2023, with an exercise price of €2.86 and a duration of 10 years. During 2022, Mr Martin-Garcia received 93,110 stock options, with an exercise price of €3.48 and a duration of 10 years



**Compensation Table 5: Rights convertible into shares of the Company exercised by the CEO during the year ended December 31, 2023**

None.

**Compensation Table 6: Shares granted without consideration to each Board member during the year ended December 31, 2023**

None.

**Compensation Table 7: Shares granted without consideration becoming available for each Board member during the year ended December 31, 2023**

None.



**Compensation Table 8: History of grants of rights convertible into shares of the Company**

Type of Plan	Plan 1	Plan 2	Plans 3-4-6 PSOU 2016- 2018 <sup>58</sup>	Plan 5 Stock Options <sup>59</sup>	Plan 7 Stock Options <sup>135</sup>	Plan 8 Stock Options <sup>60</sup>	Plan 9 Stock Options <sup>61</sup>	Plan 10 Stock Options	Plan 11 Stock Options	Plan 12 Stock Options	Plan 13 Stock Options
Date of Board decision	Apr. 16, 2010	Nov. 10, 2015	Jun. 22, 2016, Feb. 23, 2017 Feb. 8, 2018	Feb. 23, 2017	Feb. 8, 2018	July 4, 2018	Mar. 5, 2020 Dec. 11, 2020	Feb. 25, 2021	Mar. 18, 2022	Mar. 20, 2023	Mar. 14, 2024
<b>Total number of shares to be subscribed for or purchased of which by Directors*:</b>	111,000	45,000	672,335 <sup>134</sup>	49,000	22,500	158,540	181,500	178,000	203,627	237,694	1,885,118
<i>Gordon S. Francis</i>	-	30,000	-	-	-	-	-	-	-	-	37,500
<i>Giacomo di Nepi</i>	-	15,000	-	-	-	-	-	-	-	-	54,000
<i>Michel Dubois</i>	-	-	-	-	-	-	-	-	-	-	37,500
Point of departure for exercising options	Apr. 16, 2013	Election to the Board	Jan. 1, 2019	Feb. 23, 2018	Feb. 8, 2019	Feb. 27, 2020	Mar. 5 /Dec. 11, 2021	Feb. 25, 2022	Mar. 18, 2023	Mar. 20, 2024	Oct. 1, 2024
Expiration date of exercise rights	Apr. 16, 2022	Duration of Board mandate	5 years after option grant	5 years after option grant	5 years after option grant	10 years after option grant	10 years after option grant	10 years after option grant	10 years after option grant	10 years after option grant	2 years after option grant
Subscription or purchase price	CHF 4	CHF 0.5	€13	€13	€13	€2.73	€3.34 and €2.95	€3.19	€3.48	€2.86	€1.17 - €2.04
Terms and conditions of exercise (when the plan has several tranches)	In one time	In one time	-	-	-	-	-	-	-	-	-
Cumulative number of exercised subscription and purchase options	5,000	45,000	-	-	-	-	-	-	-	-	-
Subscription or purchase options remaining at the end of the year	-	-	-	-	-	89,853	164,000	178,000	183,627	237,694 <sup>62</sup>	1,885,118 <sup>63</sup>
Parity	1 : 1	1 : 1	1 : 1	1 : 1	1 : 1	1:1	1:1	1:1	1:1	1:1	1:1

\*: as defined under French law, i.e. excluding the CEO ("Directeur général")

<sup>58</sup> Includes Plan 3 (approved June 22, 2016, with grant without consideration of 606,400 Performance Share Option Units (PSOUs), which are contingent rights to receive, after a maximum of 3 years and under certain performance conditions, a variable number of options to acquire shares of the Company); Plan 4 PSOU 2017 (approved on February 23, 2017, with a grant of 50,000 PSOUs, and Plan 6 PSOU 2018 (approved on February 8, 2018 with a grant of 20,000 PSOUs), all PSOUs having the same terms. The final number of options granted at the expiry of the three-year period was decided by the Board of Directors on February 27, 2019, based on the achievement of personal and social goals. Of the total of 676,400 PSOUs initially awarded, a total of 672,235 stock options were granted. All stock options expired on February 23, 2024.

<sup>59</sup> The Plan 5 Stock Options was approved by the Board of Directors of February 23, 2017, and the Plan 7 Stock Options was approved by the Board of Directors on February 8, 2018. Options vest over three years, with one third vesting after one year, then one-sixth vesting every six months thereafter.

<sup>60</sup> The Plan 8 "Loyalty Stock Options" were approved by the Board on July 4, 2018, with final determination as to the terms and numbers of options granted on February 27, 2019.

<sup>61</sup> The Plan 9 Stock Options were approved by the Board on March 5, 2020, with an additional award to new executives on December 11, 2020.

<sup>62</sup> Awarded on March 20, 2023

<sup>63</sup> Awarded on March 14, 2024; 440,000 stock options were awarded to employees, with an exercise price of €1.17 per share, with the balance of 1,445,818 stock options awarded to directors and members of management, with an exercise price of €2.04 per share.

**Compensation Table 9: Options to subscribe for or purchase shares granted during 2023 to the top 10 non-officer\*/director employee grantees and options exercised by them**

Options to subscribe for or purchase shares granted to the top 10 non-officer/director employee grantees and options exercised by them	Total number of options granted / shares acquired
Number of options granted in 2023 by the Company and any other company of the Group to the ten non-officer employees of the Company or any company of the Group outstanding on the filing date of this Universal Registration Document	-
Total number of shares available for subscription upon exercise of the options on the filing date of this Universal Registration Document (including 440,000 options granted in 2024)	479,631
Subscription price for one share	EUR 1.17 to EUR 3.34, with a weighted average price of EUR 1.32
Number of options exercised during the last financial year	0

**Compensation Table 10: History of grants of free shares**

None.

**13.1.4 Specifics on Terms and Conditions of Compensation and Other Benefits Granted to Executive Officers**

**Compensation Table 11: Specifics on terms and conditions of compensation and other benefits granted to executive officers\***

Executive officers	Employment agreement (permanent)		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
Jesús Martin-Garcia – Chairman of the Board of Directors and Chief Executive Officer	X		X (1)			X		X
Beginning date of term of office	January 1, 2016, for Mr Martin-Garcia							
Ending date of term of office	Indefinite							

\*: as defined under French law, being the CEO (“*Directeur général*”)?

(1): pursuant to the Swiss pension fund system, the Company contributes to an old age retirement and pension plan for its Swiss-based employees consisting of two pillars: the minimum State old age retirement insurance (*Assurance Vieillesse et Survivants*, “**AVS**”, the first pillar) and a compulsory company-wide defined benefit scheme (“**LPP**”, the second pillar), pursuant to which the Company has made contributions of K€ 81 for the benefit of Mr Martin-Garcia.

**13.2 Amounts Provisioned By The Company And Its Subsidiary For Payment Of Pensions, Retirement, Or Other Benefits To Executives**

The Company made provisions for the purpose of paying pensions and retirement benefits to certain Directors and executives under State-mandated compulsory plans; such amounts are calculated on the same basis as for the Group’s other employees, which bases are set forth in Note 2.19 of the consolidated financial statements for the year ended 31 December 2023 set forth in CHAPTER 18, “Information Regarding the Company’s Assets, Financial Situation and Results” of this Universal Registration Document.

**13.3 Loans And Guarantees Granted To Executives**

None.

## **13.4 Legal Framework Relating To Compensation**

### **13.4.1 Swiss Ordinance against Excessive Compensation**

Since January 1, 2023, the Swiss Code of Obligations, art. 626.2, requires listed companies to set out in their Articles of Association the principles for the determination of the compensation of the Board of Directors and the Executive Management. These principles have been included in the Articles which are available on the Company's web site in the French language original under <https://geneuro.com/data/documents/Statuts-GeNeuro-14-juin-2023.pdf>), together with the organizational rules and policies provided the basis for the principles of compensation.

- ***Termination indemnities, premature indemnities, and provisions for the transfer or acquisition of a company***

Swiss law prohibits the payment of certain types of indemnities or compensation to members of a board of directors, management, or consultative council of a publicly traded Swiss company, including, among others, termination indemnities, premature indemnities, and provisions for the transfer or acquisition of a company, just as for certain other types of compensation or benefits that may not be expressly contemplated by the articles of association.

Swiss law broadly prohibits termination indemnities, regardless of their form, termination notice periods greater than one year, and agreements providing for compensation the maximum time period of which exceeds one year. However, non-competition clauses taking effect after the end of the employment relationship or consulting agreement are not subject to the prohibition against termination indemnities, unless, by their language, they can be considered to be disguised termination indemnities.

Swiss law also prohibits or limits certain types of premature indemnities. The determining point making it possible to distinguish prohibited termination indemnities ("golden parachutes") from certain other types of premature indemnities, such as signing bonuses, is the time when payment is made. Accordingly, a signing bonus the purpose of which is to compensate for benefits and other rights that an executive agrees not to receive from his/her preceding employer remain authorized, whereas an advance against salary is not authorized.

Swiss law also prohibits compensation for the transfer or acquisition of a company or companies that are controlled by it, directly or indirectly.

- ***Approval by the shareholders of compensation for the board of directors, for management, or for advisory board***

Swiss law also requires that compensation for the board of directors, for management, or, in the case of Swiss publicly traded companies, for the advisory board, be approved annually by the company's shareholders. Swiss publicly traded companies must state the terms and conditions of voting in their articles of association, while meeting certain minimum conditions:

- the vote must occur annually;
- the vote must be mandatory; and
- the vote must occur separately for the maximum global amounts granted to the Board of Directors, the consultative council (if any), and management, respectively.

Swiss law allows companies to determine in their Articles of Association whether the compensation is to be approved ex ante or ex post.

The compensation that must be covered by the approved maximum global amounts includes all compensation granted in relation to the position of the recipients of the relevant corporate bodies (Board of Directors, consultative council, if any, and management) for their services to the company. It includes (without limitation) all fees, salaries, bonuses, overtime compensation, credit notes, revenue and profit participation rights, equity and debt securities, as well as the value of option rights for, or conversion rights into such securities. It comprises all types of compensation, whether in cash or in kind through the provision of services or the delivery of any goods, or through any voluntary pension contributions. It further comprises the value of any suretyship, guarantee or security for, or the waiver of, any obligations of the members of the relevant corporate body.

- ***Compensation Report***

Swiss law requires that the board of directors prepare an annual compensation report that indicates any and all indemnities that a company has paid, directly or indirectly.

In substance, the compensation report must contain any and all compensation, loans, or credit paid during the financial year just ended to members of the board of directors, management, and consultative council as well as to former members of the board, management, and consultative council and to close relatives of present and past members of the board of directors, management, and consultative council.

The compensation report must also indicate compensation, loans, and credit granted to members of the board of directors overall and individually, while compensation, loans, and credit to members of management must only

indicate in a general manner the amount granted to the member of management who is the highest paid, mentioning his/her name and position.

- **Articles of Association**

Swiss companies that are publicly traded companies (in Switzerland or elsewhere) must generally ensure that their articles of association and governance rules conform to the Ordinance against excessive compensation.

A Swiss publicly traded company must, at a minimum, include in its articles of association provisions relating to:

- the number of permitted positions occupied by members of the board of directors, management, and advisory board on senior management bodies or on the board of directors of legal entities that are not controlled by the company, or that do not control the company;
- the maximum term and maximum notice period of agreements that provide for compensation of members of the board of directors and management (which may not exceed a year);
- the principles applicable to tasks and abilities of the Remuneration Committee; and
- terms and conditions of votes at general shareholders' meetings on compensation.

- **Election of members of the board of directors, chairman of the board of directors, members of the Remuneration Committee, and of the independent representative**

Swiss law requires that members of the board of directors, its chairman, members of the Remuneration Committee (which may be selected only from members of the board of directors) and the independent representative must be elected individually at the general shareholders' meeting for a term ending at the end of the following ordinary general shareholders' meeting. Re-election is possible.

- **Independent Representative**

Swiss law prohibits representation of shareholders by a member of the company's governance body or by a custodian.

Swiss law also states that the board of directors must ensure that shareholders have the right to:

- issue instructions to the independent representative on a proposal mentioned in the notice of meeting and relating to the matters on the agenda;
- issue general instructions to the independent representative on unannounced proposals relating to matters on the agenda; and
- grant authority and instructions to the independent representative also by electronic means.

When the independent representative has not received any instructions, the independent representative may not vote.

- **Criminal provisions**

Swiss law punishes members of the board of directors, management, and the consultative council who knowingly receive or have been granted illegal compensation. Swiss law also provides for criminal liability for certain prohibited actions performed by a member of the board of directors. Intentional violation of Swiss law may give rise to a maximum of three years' imprisonment and a fine of up to six times the annual compensation agreed by the perpetrator with the Company at the time of the document.

#### **13.4.2 Adoption of Rules Relating to Compensation**

The Company was subject to the Swiss Ordinance against excessive compensation since the date of initial admission of the Company's shares on Euronext's regulated market in Paris, and is subject to the provisions of Swiss law that replaced the Swiss Ordinance against excessive compensation since January 1, 2023.

The Articles of Association provide that the members of the Board of Directors receive fixed, or base, compensation and may also receive variable compensation and that members of management are to receive fixed, or base, and variable compensation. Variable compensation may be based, among other things, on the individual performance of the individual involved, of the company, of certain business divisions, or on the trading price of the shares.

The Company may make loans to members of management. The loans may not exceed three months' salary. They are to be repayable no later than the end of the employment relationship.

Compensation may be paid by the Company or its subsidiaries for services rendered thereto.

In accordance with the Ordinance against excessive compensation, the Company's Articles of Association provide for an annual vote at a general shareholders' meeting on:

- the maximum global amount of compensation for the members of the Board of Directors until the next ordinary general shareholders' meeting; and

- the maximum global amount of compensation for the members of management for the following annual financial year.

The compensation submitted to the approval of the general shareholders' meeting is the maximum global (i.e. collective) compensation of the members of the Board of Directors and of management, respectively. There is no vote on the individual remuneration of each member. The maximum global remuneration is approved *ex ante* (until the next general shareholders' meeting for the Board of Directors and for the next annual financial years for the members of management).

The Board of Directors, however, may decide to submit the fixed (base) and the variable compensation to two separate votes. In connection therewith, the Board of Directors may further decide to submit the variable compensation, or a part thereof, to a retrospective approval (*ex post*) of the general meeting, which shall be only consultative.

The proposals concerning the compensation of the Board of Directors and the management are submitted to the general shareholders' meeting by the Board of Directors. The general shareholders' meeting has only the competency to approve or reject the proposals made by the Board of Directors. The shareholders are not entitled to make proposals in this respect. In the event of a negative vote on the Board of Directors' proposals, the Board of Directors may immediately submit one or more amendment proposals at the shareholders' meeting until it obtains approval, or organize a new general shareholders' meeting.

In line with the above, the Company's 2024 general shareholders' meeting to be called to approve the 2023 financial year accounts, to be held on a date to be confirmed and published in the official notice of meeting, will be required to vote, pursuant to article 35 of the articles of association, on the Board of Directors' proposals on:

- The maximum global compensation for members of the Board of Directors until the next general shareholders' meeting (i.e. for the period from the 2024 AGM to the 2025 AGM approving the 2024 financial statements); and
- The maximum global compensation for members of the Executive Management for the next financial year (i.e. for the period from January 1, 2025, to December 31, 2025).

In addition, the compensation report for the 2023 financial year will be submitted to a consultative vote (please see the relevant resolutions to be submitted to the shareholders' meeting as described in **Erreur ! Source du renvoi introuvable.** of this Universal Registration Document).

If new members of management are appointed after the vote on compensation, and the total amount of compensation already approved at a shareholders' meeting is insufficient to cover the compensation of such new members, their additional compensation not exceeding 40% of the total amount of compensation already approved shall be deemed approved until the next ordinary general shareholders' meeting.

For the purpose of Swiss law and the related provisions of the Articles of Association, the members of the Board of Directors are the persons formally elected by the general shareholders' meeting to the Board of Directors. The members of management are the persons to whom the executive management is delegated and who report directly to or are at the next level below the Board of Directors (see Section 12.1.2.1).

As provided in the Articles of Association, contracts providing for the compensation of members of the Board of Directors are limited to a maximum term of the pending term of office, while contracts that provide compensation to members of management, theoretically, are made for an indefinite term with a maximum termination period of one year. Short-term, or definite-term, agreements may also be made, for no more than one year.

In respect of external offices and positions, the Articles of Association provide that members of the Board of Directors may not serve in more than five additional positions in privately held companies, while members of management may not serve in more than one additional office in publicly traded companies and more than five positions in privately held companies.

### **13.4.3 Compensation Report pursuant to Swiss law**

The Company's Board of Directors is responsible for preparing each year a written compensation report (with the support of the Remuneration Committee, see below Section 14.3.2).

The Board of Directors must make the compensation report available to the shareholders in advance of the general shareholders' meeting in the same manner as the annual financial statements.

The compensation report may be submitted to the consultative vote of the general shareholders' meeting. This vote does not affect any global compensation that was approved *ex ante* by the general shareholders' meeting (see above Section 13.4.2).

The auditors ensure that this compensation report is in conformity with applicable law. The auditors prepare a report to the board of directors and to the shareholders' general meeting.

# GeNeuro SA

## Plan-les-Ouates

Report of the statutory auditor to the  
General Meeting

on the remuneration report 2023



# Report of the statutory auditor

to the General Meeting of GeNeuro SA

## Plan-les-Ouates

We have audited the accompanying remuneration report of GeNeuro SA for the year ended 31 December 2023.

### Board of Directors' responsibility

The Board of Directors is responsible for the preparation and overall fair presentation of the remuneration report in accordance with Swiss law and the Ordinance against Excessive Compensation in Stock Exchange Listed Companies (Ordinance). The Board of Directors is also responsible for designing the remuneration system and defining individual remuneration packages.

### Auditor's responsibility

Our responsibility is to express an opinion on the remuneration report. We conducted our audit in accordance with Swiss Auditing Standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the remuneration report complies with Swiss law and articles 14–16 of the Ordinance.

An audit involves performing procedures to obtain audit evidence on the disclosures made in the remuneration report with regard to compensation, loans and credits in accordance with articles 14–16 of the Ordinance. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatements in the remuneration report, whether due to fraud or error. This audit also includes evaluating the reasonableness of the methods applied to value components of remuneration, as well as assessing the overall presentation of the remuneration report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Opinion

In our opinion, the remuneration report of GeNeuro SA for the year ended 31 December 2023 complies with Swiss law and articles 14–16 of the Ordinance.

PricewaterhouseCoopers SA



Luc Schulthess  
Audit expert  
Auditor in charge



Adelina Todorova

Geneva, 30 April 2024

Enclosure:

- Remuneration report

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## **2023 REMUNERATION REPORT**

### **1. INTRODUCTION**

This Remuneration Report provides the information required by the Swiss Code of Obligations, art. 734.

The Swiss Code of Obligations, art. 626.2, requires the Company to set out in its Articles of Association the principles for the determination of the compensation of the Board of Directors and the Executive Management. These principles have been included in the Articles which are available on the Company's web site in the French language original under <https://geneuro.com/data/documents/Statuts-GeNeuro-14-juin-2023.pdf>), together with the organizational rules and policies provided the basis for the principles of compensation.

### **2. COMPENSATION POLICY AND GUIDING PRINCIPLES**

The key priorities for GeNeuro in 2023 were the completion of the recruitment of its new clinical trial in Post-COVID, resulting from the research by GeNeuro and its academic collaborators, and the conduct of partnership discussions related to multiple sclerosis, following the completion in March 2022 of its last Phase 2 clinical trial (the "Karolinska Trial") in this indication.

In Post-COVID, GeNeuro launched at the end of 2022 a Phase 2 trial, called GNC-501, that is evaluating the clinical efficacy of a six-month treatment with temelimab, the anti-W-ENV antibody developed by GeNeuro, on the improvement of fatigue and cognitive impairment in Post-COVID patients who are positive for the presence of W-ENV protein in their blood.

The trial "Temelimab as a Disease Modifying Therapy in Patients With Neuropsychiatric Symptoms in Post-COVID 19 or PASC Syndrome" is a randomized, placebo-controlled, biomarker-based, Phase 2 clinical trial assessing the effect of the treatment with temelimab on the clinical course of these symptoms. The trial has completed in November 2023 the recruitment of 203 patients across 14 clinical centres in Switzerland, Spain and Italy and the topline results from the study will be available in June 2024. All enrolled patients receive 6 intravenous infusions of temelimab or placebo (1 to 1 randomization) over 24 weeks. The clinical endpoints will assess the efficacy and the safety of the treatment with temelimab on the improvement in fatigue and cognitive impairment measures. The recruitment of the trial has already demonstrated that the expression of the pathogenic W-ENV protein, triggered by the SARS-CoV-2 infection, may continue long after the acute phase has been resolved. 36% of the patients presenting post-COVID syndromes who were screened were positive to the presence of W-ENV in their blood. W-ENV is suspected to have a major role in the persistence of inflammation and in the neurological symptoms affecting these patients, and temelimab is a highly specific neutralizing anti-W-ENV-antibody. GeNeuro's precision medicine approach allows to identify, within the millions of patients affected by post-COVID, those for whom the treatment may be relevant.

GeNeuro's Post-COVID program is supported both by the Swiss FOPH, which selected GeNeuro to receive a grant of 6.7 million Swiss francs (€7.2 million), and by the EIB, with which GeNeuro entered into a credit agreement for a total amount of up to €25 million, supported by the InvestEU program, of which a first tranche of €7 million was drawn down in March 2023.

Patient recruitment in this study has suffered a delay of 3 quarters compared to the initial plan, due both to regulatory and administrative reasons in this complex new indication without established regulatory paths, and to the high level of co-morbidities amongst W-ENV positive patients, that have led to the need to screen 1'092 patients to recruit the 203 patients enrolled in the study.

The results from the Karolinska Trial, which were presented atECTRIMS 2022 in Amsterdam, in October 2022, show that temelimab is a safe add-on to anti-CD20 treatment, as the drug was well tolerated with no treatment related discontinuations, no serious or severe treatment emergent adverse events, and no differences in overall clinical or laboratory safety findings, which meets the primary endpoint of the study. The primary endpoint of the ProTECT-MS study was met, with results confirming the excellent safety profile and tolerability of higher doses of temelimab administered concomitantly with a high-efficacy anti-inflammatory drug. Efficacy data, obtained in this patient group already effectively treated against inflammation, showed that temelimab has a favorable impact on key MRI parameters measuring neurodegeneration; the observed effect sizes in this new patient population were consistent with the ones shown in the previous CHANGE-MS and ANGEL-MS studies without an anti-inflammatory treatment. New exploratory data on soluble biomarkers also showed favorable impact on measures of neurodegeneration at one year: the study showed a reduction of GFAP biomarkers in cerebrospinal fluid (CSF). GFAP is a biomarker for astrocytic activation associated with diffuse neuroaxonal damage leading to MS disease progression. The results on these CSF biomarkers confirm the synergistic potential to treat neurodegeneration with temelimab in addition to a high-efficacy anti-inflammatory therapy in MS. GeNeuro continues to hold discussions with potential partners to define the best development pathway combining temelimab and anti-inflammatory treatments.

The ambition of GeNeuro to expand into new indications leveraging the biology of human endogenous retroviruses and the academic discoveries in this field remains intact but follows the pace of the limited resources of the company



which are concentrated today on post-COVID and MS, with the pre-clinical program against ALS remaining largely on hold.

GeNeuro remains committed to having a compensation policy that is designed to attract, motivate and retain its employees and promote the delivery of outstanding individual performance. Nevertheless, the tight financial condition under which the Company operates has led it to the need to cancel all cash bonuses for 2023 and to convert them into stock options, in order to conserve liquidity. The award of variable, performance-related compensation, and in particular share-based compensation components, is intended to promote an entrepreneurial mindset and approach whilst aligning long-term employee and shareholder interests. In addition, given the need to preserve cash, the Independent Directors proposed to receive only 50% of their 2023 compensation in cash and the Board of Directors proposed to convert this reduction into stock options, which was approved at the extraordinary general meeting of shareholders in March 2024.

### **3. ORGANISATION AND COMPETENCIES**

For further details on the organization of the Company, please refer to Chapter 14 of the 2023 Universal Registration Document which provides more information on the Company's governance.

#### **3.1. Remuneration Committee**

The Remuneration Committee supports the Board of Directors in establishing and reviewing the compensation strategy and guidelines. Further, the Remuneration Committee supports the Board of Directors in preparing the proposals to the ordinary annual general meeting ("AGM") of shareholders regarding the compensation of the Board of Directors and the Executive Management.

#### **3.2. The Role of the Board of Directors and the Remuneration Committee**

Following are the key matters on which the Remuneration Committee provides recommendations to the Board of Directors:

- Compensation strategy, system and guidelines
- Definition of performance criteria (for cash bonus and equity-based incentives)
- Assessment of performance and decision on vesting multiple for equity-based incentive plan
- Compensation of the Board of Directors
- Compensation of the Executive Management (base salary and variable incentive)
- Grant of equity-based incentives to staff other than to the Executive Management
- Proposals to the AGM for maximum compensation of Executive Management and Board of Directors
- Proposals on other compensation-related issues
- Compensation report to the shareholders

#### **3.3. Description of Benchmarks Used, Salary Comparisons and Support from External Consultants**

A new benchmark review of the total compensation of the Executive Management was performed in 2023 by Mercer Switzerland Inc., an independent external consulting firm, to assess market competitiveness of GeNeuro's compensation levels. In order to compare GeNeuro's compensation with the market, 2 different peer groups have been used:

- Selection of 11 Swiss headquartered and publicly listed companies : This first peer group comprises Swiss headquartered companies of similar size and industry that are publicly listed
- Mercer Life Science Surveys in Switzerland and France: This second peer group comprises companies of Mercer's Life Science Surveys (MLS) in both Switzerland and France.

The benchmark data source is ( i ) disclosed data as per the peer companies' 2022 compensation reports, and (ii) 2022 Mercer Life Science Surveys in Switzerland and France (with data effective date 1 April 2022).

To be able to compare GeNeuro's positions with similar roles in other organizations, each role was matched to a standard Mercer Job Library position which is underpinned with a standard job evaluation. These evaluations have been reviewed with GeNeuro to arrive at a Mercer level/grade, a so called "Position Class". Both the job match (which reflects a role's tasks and responsibilities), and the size of each role are key elements for the benchmarking.

Mercer reviewed the following compensation components:

- Annual Base Salary: Includes only annualized base salary;
- Total Annual Cash Compensation (Target): includes the annual base salary, any guaranteed cash and the annualized value of any target short term incentive (STI);
- Total Direct Compensation (Target): Includes total annual cash compensation at target plus the annualized target value of any long term incentive (LTI) awards, valued using Black Scholes methodology for appreciation based awards.

Each Executive Management position was evaluated by Mercer, which found that compensation was generally well aligned with peer group 1, both in terms of Annual Base Salary and Total Cash at Target, and that Total Direct Compensation at Target was below the peer group 1 for all roles.

Except for the CEO and CDO, compensation is generally positioned in the higher range of peer group 2 (Swiss market).

For the CEO, the Annual Base Salary and Target Total Cash is positioned at the median of both peer groups while his Total Direct Compensation at Target is positioned below the 25th percentile of peer group 1 and between the median and 75th percentile of peer group 2.

For the CFO and the CMO, the Annual Base Salary and Target Total Cash is positioned at the 75th percentile of both peer groups while their Total Direct Compensation at Target is positioned below the 25th percentile of peer group 1 and above the 75th percentile (CFO) and at the 75<sup>th</sup> percentile (CMO) of peer group 2.

The CSO and CDO compensation is in the low range of peer group 1 for all compensation elements (and, for the CSO, in the upper range of the peer group 2 (French market) which can be explained by the fact that a comparison is made between a compensation package aligned with the French market and the peer group 1 representing the Swiss market. In comparison with peer group 2 (French market), compensation is aligned with the 75th percentile of the market for the CSO.

The Remuneration Committee foresees to revise the management compensation to bring it in line with the benchmark as appropriate in 2024, after the results of the post-COVID study.

### 3.4. Shareholders' Vote

As a Swiss legal entity listed on a major foreign stock exchange, the Company is subject to the Swiss Compensation Ordinance, which requires a "say on pay" approval mechanism for the compensation of the Board of Directors and the Executive Management, under which shareholders must vote on the compensation of the Board of Directors and the Management Board on an annual basis.

### 3.5. Compensation approval process

Beneficiaries	Proposal	Decision <sup>a</sup>	AGMs (Binding approval by shareholders)
Members of the Board of Directors	Remuneration Committee	Board of Directors	<i>Maximum total compensation:</i> for the period between two consecutive AGMs
Members of the Executive Management <sup>b</sup>	Remuneration Committee	Board of Directors	<i>Maximum aggregate compensation:</i> for the period from January 1 to December 31 of the same year

a: subject to shareholders' binding vote

b : the Executive Management (EM) is defined as the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Scientific Officer (CSO), Chief Development Officer (CDO) and Chief Medical Officer (CMO)

## 4. COMPENSATION COMPONENTS

### 4.1. Board of Directors

The compensation of the members of the Board of Directors may, as per the Company's Articles of Association, consist of fixed and variable compensation. On December 13, 2023 and February 16, 2024, the Board decided to allow the compensation of the members of the Board of Directors to include variable compensation in order to conserve cash, reversing its decision of December 7, 2016 to set board compensation exclusively on the basis of a fixed annual monetary compensation per term from one general meeting of shareholders to the next. Accordingly, at the March 18, 2024 extraordinary shareholders' meeting, shareholders approved a change to the maximum compensation for board members for the period from the 2023 AGM to the 2024 AGM, from a maximum aggregate fixed compensation (including social security payments and pension fund contributions) of EUR 160'000 (as initially approved on June 14, 2023) to a maximum aggregate fixed compensation of EUR 80'000 and a maximum aggregate variable compensation (including the fair value of equity incentive grants and social security payments) of EUR 80'000. At present only directors who are not linked to one of the large shareholders are remunerated by the Company.

In addition, the Company pays social security contributions where applicable and reimburses members of the Board of Directors for out-of-pocket expenses incurred in relation to their services on an on-going basis. For further

information on the compensation for members of the Board of Directors, please refer to the section “Disclosure of 2023 Compensation Paid to the Board of Directors” on page 6.

#### 4.2. **Executive Management**

The compensation of the members of the Executive Management includes a base salary, variable compensation, pension plan contributions and other benefits such as disability insurance and car allowances. Variable compensation comprises performance-related bonus and equity-based incentives (described in the Universal Registration Document under section 19.1.4 “Conditional capital”). The contractual notice period for members of the Executive Management does not exceed six months.

The variable compensation elements may be subject to the attainment of performance targets (annual corporate and individual targets) that may take into account the achievement of annual operational, strategic, financial or other objectives.

##### 4.2.1. **Fixed base salary**

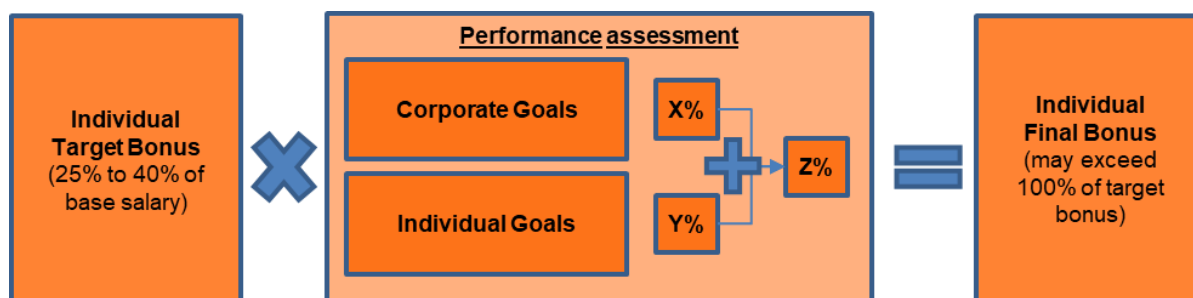
The fixed base salary is reviewed based on the position, responsibilities, experience and skills of each member of the Executive Management and takes into account individual performance. The Remuneration Committee reviews the fixed base salaries at the beginning of each year to ensure the Company remains an attractive employer.

##### 4.2.2. **Indirect benefits**

The Company contributes to the corporate pension plan and provides car allowances and representation allowances for the members of its Executive Management.

##### 4.2.3. **Performance-related bonus**

Performance-related cash bonuses are reviewed annually and are based on individual and corporate performance. Potential bonuses range from 25 % to 40 % of fixed compensation depending on position and are assessed based on individual and corporate performance.



*Corporate goals:* Given the current development stage of GeNeuro, the corporate goals for 2023 were closely linked to the execution of the GNC-501 post-COVID trial. Corporate development and other goals are also set by the Board of Directors during the last quarter of each year.

*Individual goals* relate to the roles and responsibilities of the members of the Executive Management and are aligned with the corporate strategy and annual corporate goals. Individual goals are set by the CEO (except in the case of the CEO, where they are set by the Board of Directors) during the first quarter of each year.

For the financial year 2023, due to the delay in the completion of recruitment for the GNC-501 post-COVID clinical trial and the need to conserve cash, the Board of Directors decided, at its December 13, 2023 and January 19, 2024, meetings to cancel all cash bonuses for executive management and employees, and to replace cash bonuses by stock option awards to be effected in 2024.

##### 4.2.4. **Equity Incentive Plans**

In addition to the Equity Incentive Plans that have been disclosed in prior remuneration reports, the Board of Directors made option awards in 2023 on the basis of the new 4-year Stock Option Incentive Plan approved in March 2020 with the objective of aligning the equity incentive plan to the strategy and to the value creation timeline and framework for the Company. Pursuant to this new Plan, as tool for retention and motivation, the Board decided to increase stock options awards for 2023 to 237,694 new Stock Options to executive management.

For more information about the underlying Plans, see note 9 “Stock Option Plans” in the consolidated financial statements.

#### 4.3. Structure of compensation

The compensation strategy and split for the period from January 1, 2023 to Dec. 31, 2023 was structured as follows:

- Board of Directors: 50% fixed cash fee and 50% variable compensation through stock options (awarded in 2024);
- Executive Management: due to the cancellation of cash bonuses, the compensation structure for the CEO was 80% fixed cash salary (base salary), and 20% equity-based incentives; for the other executive management positions, the compensation structure was 90% fixed cash salary (base salary), and 10% equity-based incentive.

Compared to 2022, base salaries for the executive management team have been slightly increased (+2.5%) in local currency terms to partly offset inflation, but have increased in EUR due to the continued weakening of the EUR vs CHF in 2023, whereas cash bonuses were, as mentioned above, altogether cancelled together with 50% of the Independent Directors compensation for 2023. Both have been substituted by Stock Options.

#### 5. COMPENSATION DISCLOSURE

##### 5.1. Disclosure of 2023 Compensation to the Board of Directors

The total compensation of the members of the Board of Directors is as follows:

**For the period from January 1, 2023 to December 31, 2023 (audited):**

<b>in EUR thousands</b>	<b><u>Annual Fixed Cash fee</u></b>	<b><u>Annual Variable Compensation (4)</u></b>	<b><u>Social security</u></b>	<b><u>Total compensation</u></b>
Jesús Martin Garcia (1) Chairman and CEO	-	-	-	-
Philippe Archinard	-	-	-	-
Hedi Ben Brahim	-	-	-	-
Giacomo Di Nepi	12.9	-	0.0	12.9
Michel Dubois	12.9	-	0.0	12.9
Eric Falcand (2)	-	-	-	-
Sandrine Flory (3)	-	-	-	-
Gordon Francis	17.2	-	0.0	17.2
Pascal Lemaire (3)	-	-	-	-
<b>Total</b>	<b>43.0</b>	<b>-</b>	<b>0.0</b>	<b>43.0</b>

<b>in CHF thousands</b>	<b><u>Annual Fixed Cash fee</u></b>	<b><u>Annual Variable Compensation (4)</u></b>	<b><u>Social security</u></b>	<b><u>Total compensation</u></b>
Jesús Martin Garcia (1) Chairman and CEO	-	-	-	-
Philippe Archinard	-	-	-	-
Hedi Ben Brahim	-	-	-	-
Giacomo Di Nepi	12.5	-	0.0	12.5
Michel Dubois	12.5	-	0.0	12.5
Eric Falcand (2)	-	-	-	-
Sandrine Flory (3)	-	-	-	-
Gordon Francis	16.7	-	0.0	16.7
Pascal Lemaire (3)	-	-	-	-
<b>Total</b>	<b>41.7</b>	<b>-</b>	<b>0.0</b>	<b>41.7</b>

(1) The compensation for Mr. Martin Garcia, chairman and CEO, is disclosed within the Executive Management

(2) Resigned on December 13, 2023

(3) [Elected on March 18, 2024]

(4) Variable compensation approved at the March 18, 2024, extraordinary shareholders' meeting; share options awarded in 2024 will be included in the 2024 remuneration report.

For the period from January 1, 2022 to December 31, 2022 (audited):

<b>in EUR thousands</b>	<b>Annual Fixed Cash Fee</b>	<b>Social security</b>	<b>Total compensation</b>
Jesús Martin Garcia <sup>(1)</sup> Chairman and CEO	-	-	-
Philippe Archinard	-	-	-
Hedi Ben Brahim	-	-	-
Giacomo Di Nepi	25.3	0.7	26.0
Michel Dubois	24.9	0.7	25.5
Eric Falcand	-	-	-
Gordon Francis	34.4	1.4	35.9
Christophe Guichard	-	-	-
<b>Total</b>	<b>84.7</b>	<b>2.8</b>	<b>87.4</b>

<b>in CHF thousands</b>	<b>Annual Fixed Cash Fee</b>	<b>Social security</b>	<b>Total compensation</b>
Jesús Martin Garcia <sup>(1)</sup>	-	-	-
Philippe Archinard	-	-	-
Hedi Ben Brahim	-	-	-
Giacomo Di Nepi	25.5	0.7	26.2
Michel Dubois	25.0	0.7	25.7
Eric Falcand	-	-	-
Gordon Francis	34.6	1.4	36.0
Christophe Guichard	-	-	-
<b>Total</b>	<b>85.1</b>	<b>2.8</b>	<b>87.9</b>

(1) The compensation for Mr. Martin Garcia, chairman and CEO, is disclosed within the Executive Management

For the financial year 2023, the three directors entitled to an annual compensation offered to waive 50% of their cash fee, and the Board decided to convert the remaining 50% into stock options during 2024. Total fixed compensation of KEUR 43.0 paid to members of the Board of Directors in 2022 is 46% below the maximum amount of KEUR 80 approved at the March 18, 2024 extraordinary shareholders' meeting, which also approved a maximum variable compensation amount of KEUR 80 for the period from the ordinary General Meeting 2023 until the ordinary General Meeting 2024. As mentioned above, the options to be awarded in 2024 to directors, in conversion of the 50% cash fee waiver, will be disclosed in the 2024 compensation report.

## 5.2. Disclosure of 2023 Compensation to the Executive Management

The total compensation of the members of the Executive Management is as follows:

For the period from January 1, 2023 to December 31, 2023 (audited):

<b>In EUR</b>	<b>Base salary</b>	<b>Cash bonus<sup>(1)</sup></b>	<b>Social Security, pension &amp; others</b>	<b>Total Cash Compensation</b>	<b>Non-Cash Equity incentives<sup>(2)</sup></b>	<b>Total Compensation</b>	<b>Number of stock options granted</b>
Jesús Martin Garcia Chairman and CEO	434,554	0	102,444	536,998	110,946	647,944	135,300
Other 4 members of the Executive Management	774,414	0	171,953	946,367	83,963	1,030,330	102,394
<b>Total</b>	<b>1,208,968</b>	<b>0</b>	<b>274,397</b>	<b>1,483,365</b>	<b>194,909</b>	<b>1,678,274</b>	<b>237,694</b>

<b>In CHF</b>	<b>Base salary</b>	<b>Cash bonus<sup>(1)</sup></b>	<b>Social Security, pension &amp; others</b>	<b>Total Cash Compensation</b>	<b>Non-Cash Equity incentives<sup>(2)</sup></b>	<b>Total Compensation</b>	<b>Number of stock options granted</b>
Jesús Martin Garcia Chairman and CEO	422,300	0	99,555	521,854	107,817	629,672	135,300
Other 4 members of the Executive Management	752,576	0	167,104	919,680	81,595	1,001,275	102,394
<b>Total</b>	<b>1,174,875</b>	<b>0</b>	<b>266,659</b>	<b>1,441,534</b>	<b>189,413</b>	<b>1,630,947</b>	<b>237,694</b>

(1): No cash bonus related to 2023.

(2): Based on the value of the entirety of the Stock Options awarded in March 2023. Social charges on the equity incentives will be due only at the time of exercise of the stock options, and will be calculated on the gain realized at that time.

For the period from January 1, 2022 to December 31, 2022 (audited):

<u>In EUR</u>	<u>Base salary</u>	<u>Cash bonus<sup>(1)</sup></u>	<u>Social Security, pension &amp; others</u>	<u>Total Cash Compensation</u>	<u>Non-Cash Equity Incentives<sup>(2)</sup></u>	<u>Total Compensation</u>	<u>Number of stock options granted</u>
Jesús Martin Garcia Chairman and CEO	410,069	117,151	125,374	652,594	152,700	805,294	93,110
Other 4 members of the Executive Management	784,614	129,236	236,235	1,150,086	148,448	1,298,534	90,517
<b>Total in EUR</b>	<b>1,194,683</b>	<b>246,388</b>	<b>361,609</b>	<b>1,802,680</b>	<b>301,148</b>	<b>2,103,828</b>	<b>183,627</b>

<u>In CHF</u>	<u>Base salary</u>	<u>Cash bonus<sup>(1)</sup></u>	<u>Social Security, pension &amp; others</u>	<u>Total Cash Compensation</u>	<u>Non-Cash Equity Incentives<sup>(2)</sup></u>	<u>Total Compensation</u>	<u>Number of stock options granted</u>
Jesús Martin Garcia Chairman and CEO	411,996	117,702	125,963	655,661	153,418	809,079	93,110
Other 4 members of the Executive Management	788,302	129,844	237,345	1,155,491	149,146	1,304,637	90,517
<b>Total in CHF</b>	<b>1,200,298</b>	<b>247,546</b>	<b>363,308</b>	<b>1,811,152</b>	<b>302,564</b>	<b>2,113,716</b>	<b>183,627</b>

(1): cash bonus has been paid in March 2023.

(2): Based on the value of the entirety of the Stock Options awarded in March 2022. Social charges on the equity incentives will be due only at the time of exercise of the share option, and will be calculated on the gain realized at that time.

Aggregate cash compensation for the 2023 financial year paid to members of the Executive Management, including social security, pension and other charges, was KEUR 1,483, i.e. 18% below the 2022 amount of KEUR 1,803, and was 20% below the 2022 amount in CHF, the difference being attributable to the weakening of the EUR vs. the CHF during 2022. Fixed executive compensation was increased at most 2.5% during 2022, to partly offset inflation. For the fixed compensation, the aggregate amount (including related social security payments and pension fund contributions) was KEUR 1,483, i.e. 26% below the total fixed executive management compensation for 2023 of KEUR 2,000 approved at the AGM held on May 31, 2022.

The variable compensation paid to members of Executive Management decreased in EUR by 100% for the cash portion (nil, vs KEUR 305 including related social security payments and pension fund contributions in 2022), as the Company cancelled all cash bonuses. As for the equity incentive component, which is the accounting valuation of the options granted, this amounted to KEUR 195 for 2023 vs KEUR 301 for 2022, due to the lower valuation of the options granted. Option grants for 2023 were made at an exercise price of €2.86 per share, vs. a closing price of €1.09 on December 31, 2023. The variable compensation in 2023 was thus entirely non-cash (accounting valuation of the granted options), compared to a 50% cash/50% non-cash mix in 2022), further reinforcing the Board of Directors' wish to align management compensation with shareholder value. The 2023 total variable compensation was 90% below the maximum amount of KEUR 2,000 for 2023 approved at the AGM held on May 31, 2022.

## LOANS AND CREDITS

As of December 31, 2024, the Company has no outstanding loans, credit lines or post-retirement commitments beyond the occupational benefit schemes to members of the Board of Directors or the Management Board. Furthermore, the Company has not paid any compensation to nor granted any loans or credit lines to former members of the Board of Directors or related persons.

## SHARE OWNERSHIP INFORMATION

**Disclosure of share awards in the Company to members of the Board of Directors or Executive Management in the year ended**

<u>Beneficiaries</u>	<u>Dec. 31, 2023</u>		<u>Dec. 31, 2022</u>	
	<u>Shares</u>	<u>Stock options</u>	<u>Shares</u>	<u>Stock options</u>
Jesús Martin Garcia	-	135,300	-	93,110
David Leppert	-	20,179	-	26,518
Miguel Payró	-	54,810	-	42,294
Hervé Perron	-	27,405	-	21,705
<b>Total</b>	<b>-</b>	<b>237,694</b>	<b>-</b>	<b>183,627</b>

## CHAPTER 14.

### **OPERATION OF ADMINISTRATION AND MANAGEMENT BODIES OF THE COMPANY**

The running of the Company's Board of Directors is determined by Swiss law and regulations, by the Company's Articles of Association and by the organizational rules and procedures of the Board of Directors, the principal provisions of which are described in this CHAPTER 14.

The Articles of Association as well as the organizational rules and procedures of the Board of Directors described in this Universal Registration Document are available on the Company's website [www.geneuro.com](http://www.geneuro.com).

#### **14.1 Organization And Operation Of The Company's Management And Administrative Bodies**

##### **14.1.1 Organization and Operation of the Board of Directors**

Membership and information on members of the Board of Directors are subject to the developments set forth in Section 12.1.1, "Board of Directors" of this Universal Registration Document.

##### **Membership**

In accordance with the Articles of Association, the Board of Directors may consist of between five and ten members elected at a general shareholders' meeting. The chairman of the Board of Directors is also chosen at a general shareholders' meeting.

At the filing date of this Universal Registration Document, the Board of Directors comprises eight members. The names and biographies of such members are set forth in Section 12.1.1 of this Universal Registration Document.

The Board of Directors believes that it has seven independent members for purposes of Article III7 of its organizational rules and procedures and Article 14, section 1, of the Swiss Code of Good Company Governance Practices of *economiesuisse* to which the Company intends to refer (please see Section 14.4, "Statement Regarding Company Governance" of this Universal Registration Document).

The independent members are Messrs. Philippe Archinard, Hedi Ben Brahim, Michel Dubois, Giacomo Di Nepi, Sandrine Flory, Gordon S. Francis, and Pascal Lemaire, inasmuch as these individuals:

- do not serve in management, nor have they served in management in the last three years; and
- do not have a significant business relationship with the Company or its subsidiaries.

##### **Authority**

In accordance with the Swiss Code of Obligations and the Articles of Association and the organizational rules and procedures of the Board of Directors, the Board of Directors exercises the highest authority and supervision of the Company's business and affairs.

The decision-making authority of the Board of Directors applies principally to the following items:

- i. exercising the highest levels of management of the Company and issuing necessary instructions, especially to define the Company's strategy and general resources for achieving it, the ultimate supervision of management and of the persons to whom it is delegated, decisions on developing, terminating, acquiring or selling strategic activities, and withdrawal from strategically important court cases;
- ii. setting the basic principles in respect of the organization of the Company's administration and management;
- iii. appointment and removal of the persons responsible for management and representation;
- iv. fixing the compensation of the Directors and management, particularly the compensation strategy and structure of the compensation of Directors and management within the framework provided by law, regulations, and the Articles of Association, guidelines relating to the occupational pensions of members of the Board of Directors and management, proposals at the general shareholders' meeting to consider and act on approving the total compensation of the Board of Directors and management, fixing the individual compensation of the Directors and members of management, and preparing a report on compensation to be submitted at a general meeting of shareholders;
- v. creating a system for identifying and handling risks and internal controls and of compliance with law and the Articles of Association;
- vi. fixing the principles applicable to bookkeeping and accounting, financial controls, and the strategic financing plan, especially the establishment of the accounting function, and determination of the

- accounting reference, and the establishment of an appropriate system of financial planning, including, especially, the annual budget;
- vii. preparing the management report (which includes the annual report, annual financial statements, and consolidated financial statements);
  - viii. organizing and giving notice of general shareholders' meetings and preparing proposals by the Board of Directors for the general shareholders' meeting;
  - ix. carrying out decisions approved at general shareholder meetings taken in compliance with law and the Articles of Association;
  - x. adopting the rules relating to the Company's communications and public relations strategy; and
  - xi. informing a court in the event of over-indebtedness.

In addition, the Board of Directors is responsible for ensuring that appropriate measures (such as embargoes or black-out periods) are taken for purchases and sales of the Company's shares or relevant rights at critical moments, such as in connection with an acquisition proposal or prior to a press conference or disclosure of the Group's results.

Finally, on November 19, 2015, the Board of Directors approved organizational rules and procedures by which it delegates management of the Company to members of management.

### **Terms and conditions of operation**

The Board of Directors meets as often as the Company's business and affairs require, but at least four times per year.

Notice of Board meetings or decisions is given by the Chairman in writing (letter, fax, email, or any other similar, form of notice). In the event the Chairman is unable to act, notice of a Board of Directors meeting may also be given by the Vice Chairman.

Any member of the Board of Directors may ask the Chairman at any time to hold a meeting of the Board of Directors for a specific agenda matter, or request that points be included on the agenda.

Notices of meetings are sent 10 days prior to the meeting. In the event of an emergency, the Chairman may fix a shorter period. The notice is to contain the agenda as well as the documents, presented clearly and concisely, needed for the Board of Directors to transact business. If documentation cannot be provided before the meeting, the Chairman is to give the members of the Board of Directors sufficient time to familiarize themselves therewith prior to the commencement of the meeting.

As a general rule, the persons responsible for an item added to the agenda are present at the meeting. The persons who are indispensable for responding to questions for the purpose of illuminating various points must be available. The chairman of the Board of Directors may invite members of management, employees, or third parties to participate in Board of Directors' meetings for all or part of the agenda.

For major matters, the Board of Directors may consult independent outside experts, at the Company's expense.

Action of the Board of Directors may be taken in the form of a meeting, telephone conference, video-conference, or any other means making it possible to transact business.

If the Board of Directors consists of several members, its decisions are to be taken at a meeting by a majority of the votes cast by members present: provided, however, that they form a quorum of a majority of the Board (an attendance quorum).

Actions by the Board of Directors may also be taken by a majority of the votes of the Board members in the form of a written consent (letter, fax, or email) to a proposal by the Chairman, as long as the proposal is submitted to all members, and none of them demands a meeting.

In the event of a tie vote, the Chairman's vote shall be decisive.

Actions relating to formalities in connection with capital increases, future payments for new shares, or an issue of warrants may be taken by a single Director, and no quorum will be required.

Minutes of the deliberations and discussions of the Board of Directors are to be prepared, even when only a single Director takes part, and must be signed by the Chairman and the secretary of the meeting. The minutes must mention the members present. The Chairman shall be responsible for the content and retention of Board minutes.

Each member of the Board of Directors has the right to obtain information about the Company's business and affairs. During meetings, each Board member may ask for information from the other members, as well as from members of management. Outside meetings, Directors are to send their requests for information to the Chairman.



### **Rate of participation**

During the 2023 financial year, the Company's Board of Directors met nine times, and the average attendance of Board members was 97%.

#### **14.1.2 Organization of Management**

The membership and information about members of management are set forth in Section 12.1.1.1 "Membership of the Board of Directors" of this Universal Registration Document.

### **14.2 Agreements Between Members Of Administration Or Management Bodies And The Company Or Any Of Its Subsidiaries**

#### **14.2.1 Employment Agreements**

Pursuant to Swiss law, Messrs. Martin-Garcia and Payró and Mrs Post hold employment agreements with the Company. Dr. Lang is employed pursuant to a consulting agreement with the Company. Dr. Perron is party to an employment agreement with GeNeuro Innovation.

#### **14.2.2 Consulting Contracts**

Mr. Gordon S. Francis is a consultant to the Company who assists in connection with clinical development projects in the field of neurology.

On February 25, 2015, Mr. Gordon S. Francis and the Company entered into a consulting agreement for a term of three years, terminable at any time upon 30 days' prior notice. For his consulting work, Mr. Gordon S. Francis is paid compensation of CHF 2,000 per day of work. His travel expenses are also reimbursed, in accordance with the Company's internal rules.

### **14.3 Operation Of Committees**

The Board of Directors has delegated to certain of its members, organized in committees, the responsibility for preparing, supervising, or carrying out decisions and actions within the scope of its authority.

Article II.3 of the Company's organizational rules and procedures provides that the Board of Directors will include the following permanent committees:

- a Nominations Committee;
- a Remuneration Committee; and
- an Audit and Control Committee.

In connection with its responsibilities, the Board of Directors may appoint other committees on the basis of ad hoc rules or decisions/actions.

As of the filing date of this Universal Registration Document, the Board of Directors has not used this authority.

#### **14.3.1 Nomination Committee**

On November 19, 2015, the Board of Directors approved the rules and procedures for the Nominating Committee, the principal terms of which are set forth below.

#### **Membership**

The Nominations Committee has three members. The Board of Directors chooses the Chairman and members of the Nomination Committee.

The members of the Nominations Committee are:

- Mr. Giacomo Di Nepi, Chairman of the committee;
- Mr. Hedi Ben Brahim, member; and
- Mr. Philippe Archinard, member.

### **Responsibilities**

The Nominations Committee has the following responsibilities:

1. it prepares for the action to be taken by the Board of Directors in respect of candidates for the Board of Directors proposed at a general shareholders' meeting;
2. it ensures, taking account of the Company's situation and interests, that, over time, the members of the Board of Directors comply with the recommendations of the Swiss Code of Best Practice for Corporate Governance; and
3. it develops and submits proposals to the Board of Directors in respect of:
  - a. planning and scheduling the succession of Directors,
  - b. the criteria for selecting candidates for the Board of Directors,
  - c. the program to initiate new Directors in their responsibilities, and
  - d. continuous training and education of the Directors.

### **Terms and conditions of operation**

The relevant rules and procedures of the organizational rules and procedures are to apply mutatis mutandis to proceedings of the Nominations Committee (please see Section III of the organizational rules and procedures set forth in Section 14.1, "Organization and Operation of the Company's Management and Administrative Bodies" of this Universal Registration Document).

### **Reports**

The Nominations Committee reports to the Board of Directors.

#### **14.3.2 Remuneration Committee**

On November 19, 2015, the Board of Directors approved the rules and procedures of the Remuneration Committee, the principal terms of which are set forth below.

### **Membership**

The Remuneration Committee is a body that is mandatory for any Swiss company publicly traded in Switzerland or elsewhere.

As provided in the Articles of Association, the Remuneration Committee has three members.

To the extent possible, the Board of Directors is to propose that at least two independent members be elected, at a general shareholders' meeting, to the Remuneration Committee. If it proposes members that are not independent, the Board of Directors shall so report at the general shareholders' meeting.

The Board of Directors has not proposed that at a general shareholders' meeting there be elected members who are interdependent (i.e., who are under the control or orders of other members of the Board of Directors or management).

The members of the Remuneration Committee are:

- Mr. Giacomo Di Nepi, Chairman of the committee;
- Mr. Hedi Ben Brahim, member; and
- Mr. Philippe Archinard, member.

### **Responsibilities**

The Remuneration Committee has the following responsibilities:

1. it assists the Board of Directors in establishing and periodically revising the Company's compensation policy, as follows:
  - (a) it reports periodically to the Board of Directors on the status of the compensation process in light of applicable law, the Articles of Association, and decisions taken at a general shareholders' meeting,
  - (b) it ensures that the Company offers a package of services and benefits consistent with the market and its performance in order to attract and retain persons with the skills and personalities required, and

- (c) it ensures that the compensation system does not contain undesired or undesirable incentives, and that it does not contain items that could be influenced on a targeted basis in a way that is contrary to the objective sought;
2. it assists the Board of Directors in the preparation of proposals for compensation that the Board of Directors is to submit for approval at a general shareholders' meeting;
  3. it prepares and submits to the Board of Directors a report on compensation to be submitted at a general shareholders' meeting;
  4. at the time of a general shareholders' meetings, acting by and through its Chairman, it provides explanations on the report and the compensation system and answers questions;
  5. it chooses outside advisors on compensation and mandates them, determines their fees, and critically assesses their conclusions; and
  6. it submits to the Board of Directors any proposal on compensation that it believes is in the Company's interest.

### **Terms and conditions of operation**

The Chairman of the Board of Directors, the Chief Executive Officer and the Chief Financial Officer may be invited to meetings, except when the issue is their own compensation.

The Remuneration Committee is authorized to obtain necessary specialized knowledge, by consulting outside advisors, if necessary.

If the compensation practices of other companies are used for comparison, the Remuneration Committee is to review the membership of the comparison group and the relevance of the comparisons made.

If the Remuneration Committee asks Company employees to undertake comparisons, they shall follow the instructions of the Chairman of the Remuneration Committee for such purpose.

As to other matters, the relevant rules of procedures of the organizational rules and procedures are to apply mutatis mutandis to proceedings of the Remuneration Committee (please see Section III of the organizational rules and procedures set forth in Section 14.1, "Organization and Operation of the Company's Management and Administrative Bodies" of this Universal Registration Document).

### **Reporting**

The Remuneration Committee reports to the Board of Directors.

#### **14.3.3 Audit and Control Committee**

On November 19, 2015, the Board of Directors approved the rules and procedures of the Audit and Control Committee, the principal terms of which are set forth below.

### **Membership**

The Audit and Control Committee is composed of three members. The Board of Directors chooses the Chairman and the members of the Audit and Control Committee. The majority of the members of the Audit and Control Committee must be independent.

The members of the Audit and Control Committee are:

- Mr. Michel Dubois, Chairman of the committee;
- Mrs Sandrine Flory, member; and
- Mr. Pascal Lemaire, member.

All members are considered independent under the economiesuisse Code and have particular competences in finance and accounting.

### **Responsibilities**

The Audit and Control Committee has the following responsibilities:

1. it ensures the establishment of a risk management and internal control system appropriate to the size, complexity, and risk profile of the Company and submits necessary proposals to the Board of Directors;
2. it supervises the internal audits;
3. it prepares a report at least once a year containing recommendations to the Board of Directors on:

- (a) the adequacy of the control system with regard to the recognized rules of good practices; and
- (b) the extent of effective implementation of the Company's compliance system;
- 4. it reviews the effectiveness of the external auditors (auditing firm);
- 5. it assists the Board of Directors, prepares decisions and makes recommendations in respect of any and all responsibilities of the Board of Directors in respect of financial accounting and planning;
- 6. it exercises critical control and verification of the Company's financial statements, the consolidated financial statements, and the interim financial statements intended to be published or disclosed;
- 7. it discusses the financial statements with finance managers as well as separately, as the case may be, with the head of the outside auditing firm;
- 8. it decides whether to recommend to the Board of Directors that the Company's financial statements and consolidated financial statements be presented at a general shareholders' meeting;
- 9. it evaluates the performance and fees of the outside auditors, ensures their independence, and verifies, in particular, whether the audit engagement is compatible with any other engagements by the Board; and
- 10. if the Chairman of the Board of Directors is also a member of management, it takes necessary measures to ensure the control and verification of the management activities of the Chairman of the Board of Directors.

### **Terms and conditions of operation**

The relevant rules and procedures of the organizational rules and procedures are to apply mutatis mutandis to proceedings of the Audit and Control Committee (please see Section III of the organizational rules and procedures set forth in Section 14.1, "Organization and Operation of the Company's Management and Administrative Bodies" of this Universal Registration Document).

### **Reporting**

The Audit and Control Committee reports to the Board of Directors.

### **14.4 Statement Regarding Company Governance**

There are no requirements under Swiss law for a company to present a specific report on corporate governance.

Since the listing of the Company's shares on Euronext Paris, the Company refers to all recommendations of the Swiss Code of Best Practice for Corporate Governance of *economiesuisse* (the "economiesuisse Code").

The applicable *economiesuisse* Code to which the Company refers to may be consulted on the Internet at: [www.economiesuisse.ch](http://www.economiesuisse.ch). The Company keeps copies of this Code permanently available to the members of its governance bodies.

The table below presents the Company's position vis-à-vis the recommendations made by the *economiesuisse* Code:

<b>Recommendations of the Code of Good Practices</b>	<b>Compliance</b>	<b>Noncompliance</b>
<b>I. Shareholders</b>		
R1: As providers of capital, the shareholders have the last word	X	
R2: The Company works to facilitate exercise by the shareholders of their legal rights	X	
R3: The Company ensures that general meetings of shareholders are a venue of communication so that they may discharge their responsibilities as members of a company's supreme governance body on an informed basis	X	
R4: The Company works to facilitate participation of the shareholders at general shareholders' meetings by setting the dates clearly and with sufficient lead time	X	
R5: General shareholders' meetings are to be organized so that shareholders can express themselves factually and concisely on the items set forth in the agenda	X	
R6: The organizational structure ensures the right of the shareholders to obtain information and consult documents	X	
R7: At a general shareholders' meeting, the majority must make its wishes known clearly	X	
R8: The Board of Directors is also to maintain contact with the shareholders between general meetings	X	

Recommendations of the Code of Good Practices	Compliance	Noncompliance
<b>II. Board of Directors and Management</b>		
<b>a. Tasks of the Board of Directors</b>		
R9: The board of directors, elected by the shareholders, exercises high-level management and supervision of the Company or group	X	
R10: The principal inalienable and nontransferable tasks of the Board of Directors are set forth in Swiss company law	X	
R11: The Board of Directors in the Articles of Association defines the responsibilities of persons responsible for management	X	
<b>b. Membership</b>		
R12: The membership of the Board of Directors must be balanced (male/female representation, diversity of members and majority of independent members)		Partially <sup>64</sup>
R13: The board of directors plans and schedules the renewal of offices and ensures continuing training and education of its members	X	
<b>c. Independence</b>		
R14: The independence of members of the Board of Directors must meet specific criteria	X	
<b>d. Operation and chairmanship of the Board of Directors</b>		
R15: The Board of Directors defines procedures appropriate to its business	X	
R16: The Chairman is responsible for preparing and presiding at meetings; he/she ensures and vouches for information	X	
<b>e. Management of conflicts of interest and inside information</b>		
R17: Each member of the Board of Directors and of management must manage his or her personal affairs so as to avoid as much as possible conflicts of interest with the Company	X	
R18: The Board of Directors is to adopt very precise principles relating to any disclosure of events and is to take steps to prevent violations of law on insider trading	X	
<b>f. Chairmanship of the Board of Directors and of management</b>		
R19: The principle of the balanced relationship to be reached between the responsibilities of management and control is also valid for the head of the Company		Partially <sup>65</sup>
<b>g. Risk management, compliance with rules, and system of internal controls</b>		
R20: The Board of Directors is responsible for ensuring that management of risks and the system of internal controls are appropriate for the company. Risk management relates to financial, operational, and reputational risks	X	
R21: The Board of Directors is to take steps to ensure compliance with applicable standards	X	
<b>h. Committees of the Board of Directors</b>		
R22: The Board of Directors may appoint committees responsible for specific tasks	X	
<b>1. Audit Committee</b>		
R23: The Board of Directors is to create an Audit Committee	X	
R24: The Audit Committee reaches its own opinion on internal and external audits, the internal control system, and the annual financial statements	X	
<b>2. Remuneration Committee</b>		
R25: The Board of Directors is to propose to the shareholders non-executive and independent parties to be appointed to a Remuneration Committee	X	
<b>3. Nomination Committee</b>		

<sup>64</sup> In accordance with the *economiesuisse* Code, the Board of Directors is to consist of men and women: at present the Board of Directors consists solely of men. This results from the Company's development and the active role of its founders and historical investors. The Company and its subsidiary promote equality between men and women within the Group. The Board of Directors, however, is opposed to the introduction of quotas in its membership. The Board of Directors should target appropriate diversity among its members: the Board of Directors aims to develop diversity of its members in the Company's interests. The Board of Directors should consist of a majority of independent members: six Directors out of seven are independent.

<sup>65</sup> According to the *economiesuisse* Code, the chairmanship of the Board of Directors and management should be entrusted to two different persons. The Chairman of the Board of Directors, Mr. Jesús Martin-Garcia, also holds the position of Chief Executive Officer. The Board of Directors believes that this organization is presently best suited to the Company, given the human competences currently available. Supervision of management actions by Mr. Jesús Martin-Garcia is ensured by the Audit and Control Committee.

<b>Recommendations of the Code of Good Practices</b>	<b>Compliance</b>	<b>Noncompliance</b>
R26: The Board of Directors shall create a Nomination Committee	X	
<b>i. Specific cases</b>		
R27: The rules of the Swiss Code, depending on the structure of the shareholders and the size of the Company, may be adapted to the circumstances	X	
<b>III. Audit</b>		
R28: Outside audits are conducted by the audit firm appointed by the shareholders	X	
<b>IV. Disclosure</b>		
R29: The Company is to supply in its management report information about corporate governance	X	
<b>ANNEX 1</b>		
<b>I. Recommendations about compensation for members of the Board of Directors and management</b>		
<b>a. Role of the shareholders at a general meeting</b>		
R30: The Board of Directors is to ensure that shareholders at a general meeting are able to exercise their rights and competence	X	
<b>b. Role of the Board of Directors and Remuneration Committee</b>		
R31: The Board of Directors is to decide on the compensation system for the highest-level managers of the Company and the compensation to be proposed at a general shareholders' meeting	X	
R32: With a view to appointment of the Remuneration Committee, the Board of Directors is to propose at the general meeting of shareholders non-executive and independent persons	X	
R33: The Remuneration Committee plays a key part in implementing the requirements of the law, the Articles of Association, and the shareholders' meetings, which require, in the Company's interests, specialized skills	X	
R34: On the basis of indications by the Board of Directors relating to compensation strategy, the Remuneration Committee is to develop a proposal for the creation of a compensation system intended for Company executives	X	
<b>c. Details of system of compensation</b>		
R35: As a general matter, the compensation system is based on fixed and variable components. It rewards service leading to success over the long and medium term through compensation available in the future	X	
R36: The compensation system is organized so as to avoid granting benefits that are not materially justified and negative incentives	X	
R37: The Remuneration Committee critically appraises compensation paid by other companies and the conclusions of internal and external advisors	X	
<b>d. Reporting on compensation and transparency</b>		
R38: The Board of Directors prepares a report each year on compensation and ensures transparency of the compensation for members of the Board of Directors and management	X	

## **14.5 Internal Control And Company Governance**

Since the listing of the Company's shares on Euronext Paris, the Company has adopted an internal control system in accordance with Article 728a of the Swiss Code of Obligations.

The Company has thus adopted several internal control procedures relating to accounting and financial information:

- it maintains internal separation between the production and supervision of its financial statements;
- it uses an independent expert to evaluate its retirement obligations for Swiss employees;
- it has outsourced the preparation of its payroll as well as having a specialized firm handle accounting for its subsidiary, GeNeuro Innovation; and
- it has adopted a procedure for delegating authority regarding the approval of purchase orders and purchase invoices.



In accordance with the internal organizational rules and procedures approved on November 19, 2015, the Audit and Control Committee is responsible for creating a risk management and internal control system appropriate to the size, complexity, and risk profile of the Company.

Furthermore, an independent auditor that is responsible for verifying the internal control system is appointed annually at a general shareholders' meeting.

Finally, since the listing of the Company's shares on Euronext Paris, the Company has continued to improve its internal control practices and its adherence to the *économiesuisse* Code.

## **CHAPTER 15.** **EMPLOYEES**

### **15.1 Human Resources**

#### **15.1.1 Headcount**

As of December 31, 2023, the Group employed a total of 19 persons. An operational organization chart is presented in Section 5.7.1, “Operating Organization Chart” of this Universal Registration Document. At the filing date of this Universal Registration Document, the number of employees is 19.

#### **15.1.2 Distribution by Department**

As of December 31, 2022, 20 professionals (including consultants and temporary workers) worked for the Group, distributed as follows:

<b>Department</b>	<b>Number of employees</b>
Management and administration	5
Research and development	14
<b>TOTAL</b>	<b>19</b>

#### **15.1.3 Geographic Distribution**

The table below presents the geographic distribution of the 19 professionals working for the Group as of December 31, 2023:

<b>Country</b>	<b>Number of employees</b>
France	9
Switzerland	10
<b>TOTAL</b>	<b>19</b>

#### **15.1.4 Structure and Evolution of Employees Within the Group**

The tables below present the structure and recent evolution of employees within the Group during the last two years.

#### **15.1.5 Overall Evolution of the Number of the Group’s Employees**

	<b>December 31, 2023</b>	<b>December 31, 2022</b>
Number of Group employees	19	20

#### **15.1.6 Distribution of Employees by Type of Employment**

The table below shows the distribution of the Group’s employees by type of employment during the past two years:

<b>(in percentage)</b>	<b>December 31, 2023</b>	<b>December 31, 2022</b>
Permanent	89%	95%
Non-permanent	11%	5%

### **15.2 Profit Sharing And Participation Of Employees**

#### **15.2.1 Profit Sharing and Participation Agreements**

None.

#### **15.2.2 Employee Shareholders – Options for the Acquisition of the Company’s Shares**

Please see Section 13.1.3, “Stock Options and Grants of Free Shares” and Section 16.1.1, “Distribution of Share Capital and Voting Rights” of this Universal Registration Document.



## CHAPTER 16. PRINCIPAL SHAREHOLDERS

### 16.1 Identification Of Shareholders

#### 16.1.1 Distribution of Share Capital and Voting Rights

As of December 31, 2022 and December 31, 2021, and based on the latest publicly available information, the Company's shareholders were the following:

Shareholders	At December 31, 2022			At December 31, 2023			At March 31, 2024 (1)		
	Number of shares and voting rights*	% of capital	% of voting rights	Number of shares and voting rights*	% of capital	% of voting rights	Number of shares and voting rights*	% of capital	% of voting rights
GNEH SAS (2)	9,768,695	39.08%	39.32%	9,768,695	39.08%	39.34%	11,973,646	40.23%	40.44%
Eclosion2 & Cie SCPC	6,367,608	25.47%	25.63%	6,228,041	24.91%	25.07%	6,228,041	20.93%	21.03%
Invesco Ltd	2,471,017	9.88%	9.95%	2,471,017	9.88%	9.95%	-	-	-
Citigroup Global Markets Limited	-	-	-	-	-	-	2,139,917	7.19%	7.23%
Servier International BV	1,365,659	5.46%	5.50%	1,365,659	5.46%	5.50%	2,500,729	8.40%	8.44%
Treasury shares	157,672	0.63%	0.00%	164,739	0.66%	0.00%	148,334	0.50%	0.00%
Free float	4,719,377	18.88%	19.00%	4,851,877	19.41%	19.54%	6,621,266	22.25%	22.36%
Employees & directors	149,000	0.60%	0.60%	149,000	0.60%	0.60%	149,000	0.50%	0.50%
<b>TOTAL</b>	<b>24,999,028</b>	<b>100.00%</b>	<b>100.00%</b>	<b>24,999,028</b>	<b>100.00%</b>	<b>100.00%</b>	<b>29,760,933</b>	<b>100.00%</b>	<b>100.00%</b>

\* Shares held in treasury have their voting rights suspended in accordance with Swiss law.

(1): GNEH SAS is held 81.1% by Institut Mérieux and 18.9% by bioMérieux.

Eclosion2 SCPC & Cie is an investment fund under the authority of FINMA (Swiss Financial Markets Surveillance Federal Authority) and is structured according to the Swiss Federal Act on Collective Investment Schemes. Its main investors are either institutional investors (mainly pension funds) or industrial groups or private individuals investing individually or as part of family offices. According to the partnership agreement between Eclosion2 & Cie SCPC and its investors, they delegate to the general partner, Eclosion2 SA, the management of investments. The largest investor in Eclosion2 SCPC & Cie represents less than 12% of the partnership.

Mr. Martin-Garcia is one of Eclosion2 S.A.'s three managing partners and takes part in decisions regarding that company. However, under the organizational regulations of Eclosion2 S.A., all decisions relating to investment policies are made unanimously by the managing partners.

#### 16.1.2 Significant Shareholders Not Represented on the Board of Directors

None.

### **16.1.3 Changes in Distribution of Equity Capital and Votes During the Last Two Financial Years\***

<b>Shareholders</b>	<b>At December 31, 2022</b>			<b>At December 31, 2023</b>			<b>At March 31, 2024 (1)</b>		
	Number of shares and voting rights*	% of capital	% of voting rights	Number of shares and voting rights*	% of capital	% of voting rights	Number of shares and voting rights*	% of capital	% of voting rights
GNEH SAS (2)	9,768,695	39.08%	39.32%	9,768,695	39.08%	39.34%	11,973,646	40.23%	40.44%
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Invesco Ltd	2,471,017	9.88%	9.95%	2,471,017	9.88%	9.95%	-	-	-
Citigroup Global Markets Limited	-	-	-	-	-	-	2,139,917	7.19%	7.23%
Servier International BV	1,365,659	5.46%	5.50%	1,365,659	5.46%	5.50%	2,500,729	8.40%	8.44%
Treasury shares	157,672	0.63%	0.00%	164,739	0.66%	0.00%	148,334	0.50%	0.00%
Free float	4,719,377	18.88%	19.00%	4,851,877	19.41%	19.54%	6,621,266	22.25%	22.36%
Employees & directors	149,000	0.60%	0.60%	149,000	0.60%	0.60%	149,000	0.50%	0.50%
<b>TOTAL</b>	<b>24,999,028</b>	<b>100.00%</b>	<b>100.00%</b>	<b>24,999,028</b>	<b>100.00%</b>	<b>100.00%</b>	<b>29,760,933</b>	<b>100.00%</b>	<b>100.00%</b>

\* Shares held in treasury have their voting rights suspended in accordance with Swiss law.

(1): GNEH SAS is held 81.1% by Institut Mérieux and 18.9% by bioMérieux.

As mentioned in section 3.3, in so far as the Company's registered office is in Switzerland whilst its shares are listed only on Euronext Paris's regulated market, neither French regulations on mandatory public tender offers and buyouts, nor Swiss regulations on public takeover offers (purchase or exchange offer) are applicable to public tender offers concerning the Company's shares.

Under these conditions, a person might acquire shares in the Company to an extent representing a controlling stake as defined under Swiss or French law without a legally enforceable obligation to file a public tender offer to all the shareholders.

Similarly, because of the unenforceability of French and Swiss law on compulsory public tender offers, a person could issue a public tender offer to some, but not all, shareholders.

### **16.2 Shareholder Voting Rights**

On the filing date of this Universal Registration Document, each shareholder's votes equal the number of shares each owns. There is no double-voting right, bearing in mind that under Swiss law, each share may carry only one voting right. Furthermore, under Swiss law, voting rights on treasury shares are suspended.

### **16.3 Shareholders' Agreements, Lock-Up Obligations, And Concerted Action**

To the Company's knowledge, there is no shareholders' agreement, retention agreement, or concerted action involving the Company's shares.

### **16.4 Control Of The Company**

On the filing date of this Universal Registration Document, no shareholder holds control over the Company, the main shareholder, GNEH SAS, holding 40.2% of the Company's shares and 40.4% of the votes.

### **16.5 Agreements That Could Cause A Change Of The Company's Control**

None. To the Company's knowledge, there is no agreement that might cause a change of control of the Company.

## **CHAPTER 17.**

### **TRANSACTIONS WITH RELATED PARTIES**

#### **17.1 Intragroup Agreements**

GeNeuro and GeNeuro Innovation have entered into various agreements:

- A subcontracting agreement and a mutual services agreement, both dated December 19, 2009: pursuant to the subcontracting agreement, GeNeuro mandates a certain number of studies to GeNeuro Innovation among which is the development of animal models to improve the comprehension of the mechanisms causing, and the development of, diseases and disorders linked to endogenous retroviruses, the development of antibodies, and the development of a diagnostic test for the detection of the envelope protein in serum. In consideration of such services, GeNeuro is to pay GeNeuro Innovation a price equal to the sum of the costs incurred by it plus 4%. The agreement provides that GeNeuro has the option of deciding whether or not to extend the term of the studies during a period of three months preceding the end thereof. This agreement has been tacitly renewed since its expiry. The mutual services agreement provides for GeNeuro and GeNeuro Innovation to each make their employees available to the other and bill each other for such services, which reflects the Group's mode of organization, which assigns internal "research and development costs" to GeNeuro Innovation and the remaining expenses to GeNeuro. In consideration of such services, each company is to pay to the other a price equal to the amount of the costs and expense incurred plus 3%. Each party may terminate this agreement at any time upon one month's notice.
- A "Development Collaboration And Option For A License Agreement", dated April 2023, pursuant to which GeNeuro Innovation contributes to the costs of the Post-COVID Phase 2 trial in exchange for an option for a license on temelimab for the Post-COVID indication for the European Community. In the case of positive results from the Phase 2 trial, GeNeuro Innovation may exercise its option for a license, pursuant to which it would have to pay development and regulatory milestones as well as royalties on sales.

#### **17.2 Transactions With Related Parties**

Agreements with related parties are discussed in Note 18, "Related Parties", to the Group's consolidated financial statements for the year ended 31 December 2023 set forth in CHAPTER 18 of this Universal Registration Document.

#### **17.3 Special Reports Of Auditors**

None. Under Swiss law, there is no obligation to submit transactions with related parties to the auditors' review.

**CHAPTER 18.**  
**INFORMATION REGARDING THE COMPANY'S ASSETS,**  
**FINANCIAL SITUATION AND RESULTS**

**18.1 Historical Financial Information**

The consolidated financial statements as of and for the years ended December 31, 2022 and 2023 have been prepared in conformity with IFRS standards as issued by the International Accounting Standards Board.

**18.2 Pro Forma Financial Information**

Not applicable.

**18.3 Financial Statements**

**18.3.1** Independent Auditors' Report on the Consolidated Financial Statements as of and for the year ended December 31, 2023

# GeNeuro SA

## Plan-les-Ouates

Report of the statutory auditor  
to the General Meeting

on the consolidated financial statements 2023



# Report of the statutory auditor to the General Meeting of GeNeuro SA

## Plan-les-Ouates

### Report on the audit of the consolidated financial statements

#### Opinion

We have audited the consolidated financial statements of GeNeuro SA and its subsidiaries (the Group), which comprise the consolidated statement of financial position as at 31 December 2023, and the consolidated income statement, the consolidated statement of comprehensive income, the consolidated statement of changes in equity, the consolidated cash flow statement for the year then ended, and notes to the consolidated financial statements, including material accounting policy information.

In our opinion, the accompanying consolidated financial statements give a true and fair view of the consolidated financial position of the Group as at 31 December 2023 and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with IFRS Accounting Standards and comply with Swiss law.

#### Basis for opinion

We conducted our audit in accordance with Swiss law, International Standards on Auditing (ISAs) and Swiss Standards on Auditing (SA-CH). Our responsibilities under those provisions and standards are further described in the 'Auditor's responsibilities for the audit of the consolidated financial statements' section of our report. We are independent of the Group in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, as well as the International Code of Ethics for Professional Accountants (including International Independence Standards) issued by the International Ethics Standards Board for Accountants (IESBA Code), and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Material uncertainty related to going concern

We draw your attention to notes 2 and 20 to these consolidated financial statements, which state that the Group has incurred recurring losses since inception, is experiencing liquidity shortage, and therefore is dependent on additional future funding. This, along with other matters as described in the aforementioned notes, indicates the existence of a material uncertainty which may cast significant doubt about the ability of the Group to continue as a going concern. If it is not possible for the Group to continue as a going concern, the consolidated financial statements need to be prepared on a liquidation basis. Our opinion is not modified in respect of this matter.

#### Our audit approach

##### Materiality

The scope of our audit was influenced by our application of materiality. Our audit opinion aims to provide reasonable assurance that the consolidated financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the consolidated financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall Group materiality for the consolidated financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate, on the consolidated financial statements as a whole.

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Téléphone: +41 58 792 91 00, [www.pwc.ch](http://www.pwc.ch)

PricewaterhouseCoopers SA is a member of the global PricewaterhouseCoopers network of firms, each of which is a separate and independent legal entity.

<b>Overall Group materiality</b>	EUR 736'000
<b>Benchmark applied</b>	Pre-tax loss
<b>Rationale for the materiality benchmark applied</b>	We chose pre-tax loss as the benchmark because, in our view, it is the benchmark against which the performance of the Group is most commonly measured.

We agreed with the Audit Committee that we would report to them misstatements above EUR 73'000 identified during our audit as well as any misstatements below that amount which, in our view, warranted reporting for qualitative reasons.

#### **Audit scope**

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the consolidated financial statements as a whole, taking into account the structure of the Group, the accounting processes and controls, and the industry in which the Group operates.

The Group is comprised of two entities in Switzerland and in France. The Group financial statements are a consolidation of these two entities comprising the Group's operating business and centralised functions. Based on the client's operations we have performed full-scope audit work on the Swiss entity and specified procedures on the French entity.

#### **Key audit matters**

Except for the matter described in the 'Material uncertainty related to going concern' section, we have determined that there are no key audit matters to communicate in our report.

#### **Other information**

The Board of Directors is responsible for the other information. The other information comprises the information included in the annual report, but does not include the financial statements, the consolidated financial statements and our auditor's reports thereon.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

#### **Board of Directors' responsibilities for the consolidated financial statements**

The Board of Directors is responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with IFRS Accounting Standards and the provisions of Swiss law, and for such internal control as the Board of Directors 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, the Board of Directors is responsible for assessing the Group'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 the Board of Directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

#### **Auditor's responsibilities for the audit of the consolidated financial statements**

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with

Swiss law, ISAs and SA-CH 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 part of an audit in accordance with Swiss law, ISAs and SA-CH, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our 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.
- Obtain 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 Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.
- Conclude on the appropriateness of the Board of Directors' 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 Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain 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. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the Board of Directors or its relevant committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Board of Directors or its relevant committee with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them regarding all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

From the matters communicated with the Board of Directors or its relevant committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

## Report on other legal and regulatory requirements

In accordance with article 728a para. 1 item 3 CO and PS-CH 890, we confirm the existence of an internal control system that has been designed, pursuant to the instructions of the Board of Directors, for the preparation of the consolidated financial statements.

We recommend that the consolidated financial statements submitted to you be approved.



PricewaterhouseCoopers SA



Luc Schulthess  
Licensed audit expert  
Auditor in charge



Adelina Todorova

Genève, 30 April 2024

Enclosure:

- Consolidated financial statements (consolidated statement of financial position, consolidated income statement, consolidated statement of comprehensive income, consolidated statement of changes in equity, consolidated cash flow statement and notes)

**18.3.2 Consolidated Financial Statements prepared in accordance with IFRS standards as of and for the Years Ended December 31, 2023 and December 31, 2022**

**Consolidated Statement of Financial Position**

GENEURO		12/31/2023	12/31/2022
Consolidated Statement of Financial Position	Notes		
(in thousands of EUR)			
<b>ASSETS</b>			
Intangible assets	3	1,152.3	1,139.8
Property, plant and equipment	4	742.1	992.9
Non-current financial assets	5, 7	260.8	249.5
Non-current receivables	6	1,872.3	-
<b>Total non-current assets</b>		<b>4,027.5</b>	<b>2,382.2</b>
Other current assets	6	507.0	3,495.0
Cash and cash equivalents	7	1,827.4	5,593.3
<b>Total current assets</b>		<b>2,334.4</b>	<b>9,088.3</b>
<b>Total Assets</b>		<b>6,361.9</b>	<b>11,470.5</b>
<b>LIABILITIES AND EQUITY</b>			
<b>Equity</b>			
Share Capital	8	1,100.2	1,100.2
Additional paid-in capital		33.6	27,157.0
Other reserves from capital		42,750.0	42,750.0
Net income (loss) attributable to owners of the parent		(14,757.0)	(12,199.8)
Accumulated deficit attributable to owners of the parent		(42,210.9)	(57,379.9)
Treasury shares		(796.1)	(794.7)
Cumulative translation adjustments		202.2	202.2
Accumulated other comprehensive loss		(100.0)	628.7
<b>Equity attributable to owners of the parent</b>		<b>(13,778.0)</b>	<b>1,463.7</b>
<b>Total equity</b>		<b>(13,778.0)</b>	<b>1,463.7</b>
<b>Non-current liabilities</b>			
Employee benefit obligations	11	928.3	153.8
Non-current financial liabilities	7, 10	12,620.1	6,517.9
Non-current derivative liabilities	10	299.4	-
Other non-current liabilities		42.6	26.0
<b>Non-current liabilities</b>		<b>13,890.4</b>	<b>6,697.7</b>
<b>Current liabilities</b>			
Current financial liabilities	7, 10	747.3	601.8
Trade payables	12	2,459.6	764.8
Other current liabilities	12	3,042.6	1,942.5
<b>Current liabilities</b>		<b>6,249.5</b>	<b>3,309.1</b>
<b>Total Liabilities and Equity</b>		<b>6,361.9</b>	<b>11,470.5</b>

The accompanying notes form an integral part of these consolidated financial statements

## Consolidated Income Statement

GENEURO Consolidated Income Statement (in thousands of EUR)	Notes	12/31/2023 12 months	12/31/2022 12 months
Income	13	-	-
Research and development expenses			
Research and development expenses	14	(12,492.1)	(9,833.2)
Subsidies	14	1,143.4	1,825.8
General and administrative expenses	14	(3,008.6)	(3,221.8)
<b>Operating loss</b>		<b>(14,357.3)</b>	<b>(11,229.2)</b>
Financial income	15	75.9	7.6
Financial expenses	15	(952.6)	(858.5)
Change in fair value of financial derivatives	15	806.9	-
Foreign exchange gains (losses)	15	(325.7)	(117.6)
<b>Financial income (expenses), net</b>		<b>(395.5)</b>	<b>(968.5)</b>
<b>Pre-tax loss</b>		<b>(14,752.8)</b>	<b>(12,197.7)</b>
Income tax (expense)	16	(4.2)	(2.1)
<b>Net loss for the period</b>		<b>(14,757.0)</b>	<b>(12,199.8)</b>
		<b>12/31/2023</b>	<b>12/31/2022</b>
<b>Basic loss per share (EUR/share)</b>	17	<b>(0.59)</b>	<b>(0.51)</b>
<b>Diluted loss per share (EUR/share)</b>		<b>(0.59)</b>	<b>(0.51)</b>

## Consolidated Statement of Comprehensive Income

GENEURO Consolidated Statement of Comprehensive income (in thousands of EUR)		12/31/2023 12 months	12/31/2022 12 months
<b>Net loss for the period</b>		<b>(14,757.0)</b>	<b>(12,199.8)</b>
Actuarial gains - employee benefits	11	(728.7)	1,020.7
<b>Net other comprehensive income that will not be reclassified to profit or loss in subsequent periods</b>		<b>(728.7)</b>	<b>1,020.7</b>
Currency translation differences		-	-
<b>Net other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods</b>		<b>-</b>	<b>-</b>
<b>Total other comprehensive income</b>		<b>(728.7)</b>	<b>1,020.7</b>
<b>Comprehensive loss</b>		<b>(15,485.7)</b>	<b>(11,179.1)</b>

The accompanying notes form an integral part of these consolidated financial statements

## Consolidated Statement of Changes in Equity

GENEURO		Capital	Share Capital Ordinary shares at nominal value	Additional paid-in capital	Other reserves from capital	Accumulated deficit and net loss attributable to owners of the parent	Treasury Shares	Cumulative translation adjustments	Other comprehensive income (loss)	Shareholders' equity attributable to owners of the parent
Consolidated Changes in Equity	Notes	Number of shares						In thousands of EUR		
<b>At December 31, 2021</b>		<b>22,320,777</b>	<b>972.0</b>	<b>20,243.7</b>	<b>42,750.0</b>	<b>(58,204.3)</b>	<b>(726.5)</b>	<b>202.2</b>	<b>(392.0)</b>	<b>4,845.1</b>
Net loss 2022/12			-	-	-	(12,199.8)	-	-	-	(12,199.8)
Other comprehensive income			-	-	-	-	-	-	1,020.7	1,020.7
<b>Comprehensive income (loss)</b>			-	-	-	<b>(12,199.8)</b>	-	-	<b>1,020.7</b>	<b>(11,179.1)</b>
Split of the nominal value			-	-	-	-	-	-	-	-
Shares issued	8	2,678,251	128.2	7,531.6	-	-	-	-	-	7,659.8
Share capital increase costs			-	(618.3)	-	-	-	-	-	(618.3)
Share-based payments	9		-	-	-	824.4	-	-	-	824.4
Treasury shares			-	-	-	-	(68.2)	-	-	(68.2)
<b>At December 31, 2022</b>		<b>24,999,028</b>	<b>1,100.2</b>	<b>27,157.0</b>	<b>42,750.0</b>	<b>(69,579.7)</b>	<b>(794.7)</b>	<b>202.2</b>	<b>628.7</b>	<b>1,463.7</b>
Net loss 2023/12			-	-	-	(14,757.0)	-	-	-	(14,757.0)
Other comprehensive income			-	-	-	-	-	-	(728.7)	(728.7)
<b>Comprehensive income (loss)</b>			-	-	-	<b>(14,757.0)</b>	-	-	<b>(728.7)</b>	<b>(15,485.7)</b>
Reclassification pursuant to shareholders' meeting			-	(30,000.0)	-	30,000.0	-	-	-	-
Reclassification of currency impact from change of functional currency on Jan. 1, 2016	8		-	2,876.6	-	(2,876.6)	-	-	-	-
Share-based payments	9		-	-	-	245.4	-	-	-	245.4
Treasury shares			-	-	-	-	(1.4)	-	-	(1.4)
<b>At December 31, 2023</b>		<b>24,999,028</b>	<b>1,100.2</b>	<b>33.6</b>	<b>42,750.0</b>	<b>(56,967.9)</b>	<b>(796.1)</b>	<b>202.2</b>	<b>(100.0)</b>	<b>(13,778.0)</b>

The accompanying notes form an integral part of these consolidated financial statements

## Consolidated Cash Flow Statement

GENEURO Consolidated Cash Flow Statement (in thousands of EUR)	Notes	12/31/2023 12 months	12/31/2022 12 months
<b>Cash flow from operating activities</b>			
<b>Net loss for the period</b>		<b>(14,757.0)</b>	<b>(12,199.8)</b>
Adjusted by the reversal of:			
Amortization of intangible assets	3	-	2.4
Depreciation of property, plant and equipment	4	293.8	286.0
Change in provision for defined benefit obligation	11	131.6	49.6
Share-based payment expense	9	245.4	824.4
Subsidies recognized on reimbursable advances		(405.0)	(452.2)
Financial expense, net	15	86.6	74.5
Unwinding of advances		308.9	234.9
<b>Net cash outflow from operating activities</b>		<b>(14,095.7)</b>	<b>(11,180.2)</b>
<b>Change in working capital</b>			
Decrease in Deposits	5	(0.7)	0.1
Increase in Other non-current receivables		(1,872.3)	-
(Increase) / Decrease in Other current assets	6	2,697.5	(2,224.7)
Increase / (Decrease) in Trade payables and related accounts	10.1	1,757.5	160.5
Increase in Other non-current liabilities	10.2	16.6	14.9
Increase in Other current liabilities	10.2	1,350.1	168.0
<b>Income tax paid</b>		-	-
<b>Cash outflow from operating activities</b>		<b>(10,147.0)</b>	<b>(13,061.4)</b>
<b>Cash flow from investing activities</b>			
Acquisitions of intangible assets	3	(12.5)	-
Acquisitions of property, plant and equipment	4	(12.5)	(57.4)
Interest received on short term deposits		75.8	7.5
<b>Cash outflow from investing activities</b>		<b>50.8</b>	<b>(49.9)</b>
Capital increase	8	-	7,659.8
Proceeds from borrowings	10	6,925.0	6,463.1
Interest paid		(34.8)	(18.6)
Share capital increase costs paid	8	-	(618.3)
Repayment of lease liabilities	10	(238.8)	(214.4)
Repayment of advances		-	(12.5)
Repayment of borrowings		(328.2)	(160.4)
<b>Cash flow from financing activities</b>		<b>6,323.2</b>	<b>13,098.7</b>
<b>Increase / (Decrease) in cash</b>		<b>(3,773.0)</b>	<b>(12.6)</b>
Cash & cash equivalents - beginning of period		5,593.3	5,479.5
Impact of exchange rate fluctuations		7.1	126.4
<b>Cash &amp; cash equivalents - end of period</b>		<b>1,827.4</b>	<b>5,593.3</b>
		-	-
<b>Decrease in cash</b>		<b>(3,773.0)</b>	<b>(12.6)</b>

The accompanying notes form an integral part of these consolidated financial statements

## Notes to the Consolidated Financial Statements

*(Unless indicated otherwise, the amounts mentioned in these Notes are in thousands)*

### Note 1: Company overview

The following information constitutes the Notes to the consolidated financial statements and forms an integral part of the consolidated financial statements presented for the financial years ended December 31, 2023 and 2022.

Each of these years covers a 12-month period from January 1 to December 31.

Incorporated on January 31, 2006, GeNeuro SA (“GeNeuro”) is a clinical-stage biopharmaceutical Swiss limited company (société anonyme) which develops therapies and companion-diagnostic tools. GeNeuro’s mission is to develop safe and effective treatments against neurological disorders and autoimmune diseases, such as multiple sclerosis, by neutralizing causal factors encoded by human endogenous retroviruses (“HERV”), which represent 8% of the human DNA. This represents a novel therapeutic approach pioneered by GeNeuro since 2006, based on 15 years of R&D at Institut Mérieux and INSERM. GeNeuro’s lead therapeutic candidate, temelimab, is a humanized monoclonal antibody that neutralizes a pathogenic HERV protein of the W family called HERV-W ENV that has been identified as a potential key factor in the onset and development of autoimmune diseases such as MS, where it has already completed Phase II clinical trials with an excellent tolerability and safety, or of Post-Acute Sequelae of COVID-19 (PASC, long-COVID or post-COVID), where the Company has launched at the end of 2022 a Phase II clinical trial. The Company has been listed on Euronext in Paris since April 18, 2016. The Company’s registered office is at 3, chemin du Pré-Fleuri - CH-1228 Plan-les-Ouates - Geneva – Switzerland. It has one subsidiary, GeNeuro Innovation SAS, which was established in France in 2009.

GNEH SAS, a subsidiary of Institut Mérieux in France, is the largest shareholder of the Company as at December 31, 2023, with a stake of 39.55% in the Company, compared to 38.08% at December 31, 2022.

GeNeuro is hereinafter referred to as “GeNeuro”, the “Company” or the “Group”.

### Note 2: Significant accounting policies

#### 2.1 Basis of preparation

##### Compliance with International Financial Reporting Standards

GeNeuro has prepared its financial statements, approved by the Board of Directors on 29 April 2024, in accordance with International Financial Reporting Standards (IFRS) published by the International Accounting Standards Board (IASB) as at the preparation date of the financial statements, for all the periods presented.

##### New standards, updates and interpretations adopted by the Group

There were no new standards or amendments adopted by the Group in 2023 which had a material impact on its consolidated financial statements. In addition, there are no new standards and amendments published but not yet effective that are expected to have a material impact on the consolidated financial statements of the Group.

##### Historical cost convention

The Group’s financial statements have been prepared in accordance with the historical cost convention, except with respect to the plan assets included in the calculation of the defined benefit pension plan liability, which are measured at fair value.

##### Material uncertainty and ability to continue as a going concern

The accompanying audited consolidated financial statements have been prepared on the basis that the Group will continue as a going concern. The consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

GeNeuro SA is a biopharmaceutical company at the clinical stage developing innovative therapeutics. The Group is exposed to risks and uncertainties inherent in establishing and developing a business that are common to development-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Group’s product development efforts are successful, it is uncertain when, if ever, the Group will realize significant revenue from product sales.

The Group’s success may also depend on its ability to:

- establish and maintain strong patent position and protection;
- enter into collaborations with partners in the pharmaceutical industry;
- acquire and retain key personnel;
- acquire additional funding to support its operations.

The Group has sustained operating losses since its formation, except for the 2014 financial year. Such losses, which amounted to €46 million for the last five financial years, reflect both the significance of the expenses incurred in research and development and the absence of revenues. In addition, for the year ended December 31, 2023, the Group incurred a net loss of €14.7 million (2022: €12.2 million) and negative cash flows from operations of €10.1 million (2022: €13.1 million). Since its incorporation, the Group has primarily funded its growth through issuances of shares, including the capital increases conducted at the time of its initial public offering in 2016 and the subsequent capital increases completed in January 2020, July 2021, May 2022 and February 2024; additional funds have been provided by research collaborations, research grants and research tax credits in France. In addition, the Group was one of the four projects selected by the Swiss Federal Office for Public Health (FOPH)'s Federal Funding Programme for COVID-19 Medicines, pursuant to which it is entitled to receive a grant of 6.7 million Swiss francs (€7.2 million) to co-fund up to 50% of a Phase II clinical trial to treat patients with long-standing COVID who exhibit severe neurological and psychiatric ("neuropsychiatric") symptoms. In 2022, the Group received the first two instalments from the FOPH grant for its post-COVID program, of €3.0 million and €2.3 million. In addition, in March 2023, the Group, through its French subsidiary, entered into a credit agreement for a total amount of up to EUR 25 million with the European Investment Bank ("EIB"), supported by the InvestEU programme. The first tranche of EUR 7 million, which was immediately available and was drawn in March 2023, is intended to support the Phase 2 clinical trial in long-COVID. The other tranches of EUR10 million and EUR8 million are intended for the preparation and launch of Phase 3 respectively.

The Group has no revenues and cannot predict when, if at all, one of its drugs under development will reach commercial stage; future business activities are highly dependent on the outcome of the currently ongoing Phase 2 clinical trial with temelimab, its leading drug candidate, in the post-COVID indication, with results expected by the end of June 2024. The costs for this clinical program are such that the Group's operations will continue to require significant amounts of capital. The Group determined that there are currently insufficient financial resources to fund its operations for at least twelve months from when the 2023 financial report is approved on 29 April 2024, based on the funds available as of December 31, 2023 in the amount of €1.8 million (cash and cash equivalents) together with the €1 million bank pre-financing of its French Research Tax Credit, received in January 2024, and the net proceeds of the February 2024 capital increase and the expected negative cashflow for the next twelve months based on the Group's current business plan. Furthermore, the Group considers that from the date when the 2023 financial report is approved on 29 April 2024, its net working capital is sufficient only over the next five months taking into account the last payment of €1.4 million expected from the FOPH, which is conditional upon submitting to Swissmedic a marketing authorization application and submitting to the FOPH the preliminary final material & financial report. Without the FOPH payment, the net working capital is sufficient until mid-August 2024. Based on the Group's available cash and cash equivalents on the date when the 2023 financial report is approved on 29 April 2024 (which takes into account the cash available at December 31, 2023 and the net proceeds from the February 2024 capital increase), the Group estimates that the amount of insufficient working capital that would allow it to fund its operations for at least twelve months from when the 2023 financial report is approved on 29 April 2024 amounts to approximately €3.5 million.

In order to remedy such insufficient net working capital, the Group continues to be engaged in discussions with investors, suppliers and lenders, including ongoing negotiations with the EIB, with the objective to secure further additional or earlier financing or than envisioned earlier, or cost cuts. The Company is over-indebted as per article 725b CO as of December 31 2023 which could lead the Company to initiate a debt restructuring moratorium or enter into bankruptcy proceedings in the short term. In case the outcome of actions would not be fruitful, the Company may not be able to continue as a going concern. There is material uncertainty that may cast significant doubt on the Company's ability to continue as a going concern. The Company may not be able to realize its assets and settle its liabilities in an orderly manner. While the Group is actively seeking to raise additional funding, there can be no assurance that the necessary financing will be available.

Shareholders should note that whilst Management and Board of Directors consistently continue to apply best efforts to evaluate and execute all available options, there is no guarantee that any transaction can be realized or that such transaction would generate sufficient funds to finance operations for twelve months from when the 2023 financial report is approved. If the Company is unable to obtain adequate capital resources to fund the operations, it will need to substantially modify its operations by significantly reducing spending as well as seeking to monetize assets under development through outlicensing transactions. This may impact the ability to complete the current Phase 2 clinical trial. If such measures are not sufficient, and/or additional funding is not obtained in due course, the Group may be forced to discontinue its operations entirely.

Liquidity risk management is assessed in Note 20.

## **Consistency of accounting policies**

The accounting policies applied are consistent with those applied for the preparation of the annual financial statements as at December 31, 2022. There are no new standards, amendments or interpretations mandatory from the beginning of the 2023 financial year that could have a significant impact on the financial statements of the Group.

## **2.2 Consolidation methods**

Subsidiaries are all the entities over which the Company has control. The Company controls an entity when it 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. Subsidiaries are fully consolidated from the date on which the Company acquires control. They are deconsolidated from the date on which control ceases.

Intra-group transactions and balances are eliminated. The accounting policies of the subsidiaries have been aligned with those of the Company.

As of the date of the publication of these consolidated financial statements, the Company had one subsidiary:

- GeNeuro Innovation SAS, 100% of the voting rights and interests held throughout the periods presented.

Therefore, GeNeuro SA (parent company based in Switzerland) presents consolidated financial statements that include the financial statements of its subsidiary GeNeuro Innovation SAS for the fiscal years ended on December 31, 2023 and 2022.

## **2.3 Use of judgments and estimates**

To prepare the financial statements in accordance with IFRS, the Company has made judgments and estimates that could affect the amounts presented under assets and liabilities as at the reporting date, and the amounts presented under income and expenses for the period.

Such estimates are made by the Company's management based on the assumption of going concern and on the information available at the time. These estimates are ongoing and are based on past experience as well as diverse other factors judged to be reasonable and form the basis for the assessments of the book value 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 such estimates if assumptions or conditions change.

The significant estimates or judgments made by the Company relate to the following in particular:

- Measurement of stock-options issued 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 Company's 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 9.
- Defined benefit plans:
  - Defined benefit schemes are recognized in the statement of financial position based on an actuarial valuation of the obligations at period-end, minus the fair value of the scheme assets. This valuation is determined using the projected unit credit method, taking into account staff turnover, mortality probability and actuarial assumptions based on management estimates.
  - The valuation assumptions adopted are disclosed in Note 11.

## **2.4 Foreign currency translation**

### **Functional currency**

Items included in the financial statements of each of the group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency').

The consolidated financial statements are presented in Euros, which is the presentation currency of the group and the functional currency of GeNeuro SA.

### **Reporting currency**

The Group uses the euro (EUR or €) as the reporting currency for its consolidated financial statements.



## Transactions and balances

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

### 2.5 Distinction between current and non-current

In its statement of financial position, the Group makes a distinction between current and non-current assets and liabilities.

The following rules were applied to distinguish current from non-current items:

- assets and liabilities constituting working capital circulating in the normal course of business are classified as "current";
- assets and liabilities not being turned over in the normal course of business are presented as "current" or "non-current" depending on whether their maturity is longer or shorter than one year from the balance sheet date.

### 2.6 Intangible assets

#### 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;
- there is an ability to use or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits;
- adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available;
- the expenditure attributable to the intangible asset during its development can be reliably measured.

The development projects undertaken by the Group are subject to technical, regulatory and other uncertainties, such that, in the opinion of management, the criteria for capitalization as intangible assets are not met prior to obtaining marketing approval by the regulatory authorities in major markets.

As a result, internal development expenses incurred (mainly consisting of the cost of preclinical experiments, clinical trials and production cost of temelimab) are recognized under research and development ("R&D") expenses at the point that they are incurred.

#### Licenses

Licenses acquired by the Company to access intellectual property are recognized under intangible assets. The amortization of such licenses over their useful lives shall start upon marketing approval of the related products.

#### Contingent payments

The acquisition of certain intangible assets, mainly licenses, may involve additional payments contingent on the occurrence of specific events or milestones. Unless the Group already has a present obligation to make the payment at a future date, the initial measurement of the intangible asset does not include such contingent payments. Instead, such payments are subsequently capitalized as intangible assets when the contingency or milestone occurs.

#### Software

Software license acquisition costs are recognized as assets on the basis of the costs incurred in acquiring them and in making the software concerned operational.

#### Amortization

Amortization is calculated using the straight-line method to spread the cost over the estimated useful life, specifically:

Items	Amortization period
Software	1 to 5 years

Amortization expense is recognized in the income statement under "General and administrative expenses".

### 2.7 Property, plant and equipment

Property, plant and equipment are stated at their acquisition cost less accumulated depreciation.

Depreciation is calculated on a straight-line basis over the estimated useful life of the asset. The following depreciation periods are used:

Items	Depreciation period
Office and computer equipment	3 to 5 years
Laboratory equipment	3 to 5 years
General facilities, fixtures and fittings	5 years
Buildings (Right of use)	Duration of lease

The depreciation expense for property, plant and equipment is recognized in the income statement under:

- “General and administrative expenses” for depreciation of general facilities, fixtures and fittings; office and computer equipment;
- “Research and development expenses” for laboratory equipment.

## **2.8 Lease agreements**

Since January 1, 2019, the Group applies IFRS 16 “Leases” for lease agreements and has elected to use the exemption proposed by the standard on lease contracts for which the lease terms end within 12 months as of the date of initial application; and to exclude the low-value assets (with an individual value in USD of less than 5'000 when new). In applying the new standard, a lessee determines each lease’s term including any lessee’s extension or termination option that is deemed reasonably certain. The assessment of such options is performed as of the commencement of each lease and requires judgment by management.

As per IFRS 16, lessees must remeasure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee generally recognizes the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset.

At the inception of the lease a right-of-use asset and a lease liability are recognized in the balance sheet. The asset is initially measured at the amount of the lease liability plus any initial direct costs incurred.

The lease liability is initially measured at the present value of the lease payments payable over the lease term, including variable lease payments depending on an index at the commencement date and the exercise price of purchase options if it is reasonably certain that the option will be exercised. The lease liability is discounted at the rate implicit in the lease. If that rate cannot readily be determined the incremental borrowing rate is used. Lease liabilities are subsequently re-measured to reflect possible changes in the lease terms. Right-of-use assets are depreciated over of the duration of the lease contract including contractually agreed optional extension periods, whose exercise are deemed to be reasonably certain. The depreciation is recognized in operating income. The unwinding of the discounting effect is included in the financial expense. Lease payments are accounted for as a repayment of the lease liability. Expenses for lease contracts for objects with a value of less than USD 5'000 and lease contracts with a duration of up to twelve months are recognized directly in the income statement.

## **2.9 Recoverable value of non-current assets**

Non-current assets that are not yet being amortized or depreciated, such as licenses, are tested for impairment at the end of the period in which they are acquired and subsequently annually, and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Non-current assets that are subject to amortization or depreciation are subjected to an impairment test whenever an internal or external factor indicates that an asset may have lost value.

Impairment is recognized when the book value of an asset exceeds its estimated recoverable value. The recoverable value of an asset is its fair value less selling costs, or its value in use, whichever is higher.

Any impairment charge is recognized in the income statement under the same category as the amortization or depreciation of the same asset.

## **2.10 Financial assets**

The Group’s financial assets are classified into two categories depending on their nature and the purpose for which they are held:

- financial assets at fair value through profit or loss;
- financial assets at amortized cost.

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset.

All purchases and sales of financial assets are recognized on the settlement date.

Financial assets are derecognized when the rights to receive cash flows from the investments have expired or have been transferred and the Group has transferred substantially all risks and rewards of ownership.

### **Financial assets at fair value through profit or loss**

Financial assets at fair value through profit or loss consist of currency derivatives and are presented in current financial assets.

Gains or losses arising from changes in the fair value of the “financial assets at fair value through profit or loss” category are presented in the income statement within “Financial income (loss)” in the period in which they arise.

The Group may opt to classify other assets within this category.

### **Financial assets at amortized cost**

This category includes other assets (refer to Note 6) and financial assets (refer to Notes 5 and 7).

Other assets are initially recognized at fair value and subsequently measured at amortized cost using the effective interest rate method. A provision for impairment of receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of the invoice. The amount of the provision is the difference between the carrying amount and the recoverable amount and is recognized in the income statement.

Non-current financial assets include the cash reserve linked to the liquidity contract (Refer to Note 5). These are non-derivative financial assets with fixed or determinable payments that are not listed on an active market.

## **2.11 Cash and cash equivalents**

Cash and cash equivalents recognized in the statement of financial position include cash positions at banks and cash at hand.

Term deposits with an initial maturity of less than three months are classified as cash equivalent. Cash equivalents are held for trading purposes, easily convertible into a known amount of cash and exposed to negligible risk that they will change in value.

For cash flow statement purposes, net cash consists of cash and cash equivalents as defined above.

## **2.12 Fair value of financial instruments**

The nominal values of trade receivables and trade payables are considered to approximate to their fair values, given the very short payment maturities of these receivables. The same principle applies to other receivables and other current liabilities.

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 or on observable market data on the valuation date.

At December 31, 2023 and December 31, 2022, there were no instruments held by the Company recognized at fair value through profit and loss.

## **2.13 Public subsidies receivable**

The Company benefits from public subsidies and grants as disclosed below.

### **Subsidies and grants**

Grants received from public entities to subsidize certain types of expenditure are recognized when there is reasonable assurance that the entity will comply with the conditions attached to obtaining the grants. They are recognized as a reduction in the related expenditure, in this case research and development (R&D) expenses.

### **Research tax credits**

The Group receives certain specific project-related research tax credits that are granted to companies incorporated in France as an incentive for technical and scientific research. Companies with expenses that meet the eligibility criteria receive a tax credit that (i) can offset against corporate income tax due in the year in which it is granted, as well as in the following three financial years, or, (ii) under certain circumstances, can be paid to the Company.

The Group considers the research tax credits received from the French tax authorities as government grants as the tax credits are received independently from tax payments of the Group. The Group recognizes these credits in the consolidated statement of financial position within other current receivables given the expected time of collection and reasonable assurance of the collectability, and in the consolidated income statement under research and development subsidies. The credits are recognized in the year in which the eligible expenses giving rise to the tax credit are incurred.

### **Forgivable loan**

Based on the terms of the subsidy contract entered into with the FOPH, GeNeuro considers that it has received a forgivable conditional loan from the FOPH, as defined in IAS 20, and that it has accordingly benefitted from a government loan at a below-market rate. Accordingly, it considers the amounts received during 2022 under the first two instalments of the FOPH subsidy as a liability. Under IAS 20, since the conditional loan does not bear annual interest, it is treated as an interest-free loan for the Company (i.e. under conditions more favorable than market rates), and the difference between the amount of the advance at historical cost and the advance discounted at market rates is considered as a public grant.

### **2.14 Receivables and other current assets**

Receivables are initially recognized at fair value and subsequently measured at amortized cost.

A provision for impairment is established when there is objective evidence that the Company will not be able to collect all amounts due according to the original terms of the invoice. The amount of the provision is the difference between the carrying amount and the recoverable amount and is recognized in the income statement.

Other receivables include the nominal values of research tax credits, which are recognized in assets in the year when the eligible expenses giving rise to the tax credit are incurred.

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables and contract assets.

### **2.15 Capital**

Classification as equity depends on specific analysis of the characteristics of each instrument issued. Ordinary shares are classified under Shareholders' Equity.

Costs directly attributable to the issue of shares in a capital increase or in a capital increase as part of an initial public offering project, are recognized, net of tax, as a deduction from equity. Refer to Note 8.

### **2.16 Treasury shares**

In accordance with IAS 32, GeNeuro treasury shares are deducted from equity, irrespective of the purpose for which they are held. No gain or loss is recognized in the income statement on the purchase, sale or cancellation of treasury shares.

### **2.17 Share-based payments**

Since its incorporation, the Company has implemented a compensation plan settled in equity instruments in the form of stock-options allocated to certain employees.

In accordance with IFRS 2, the cost of transactions settled in equity instruments is charged to expenses in the period in which the rights to benefit from the equity instruments are acquired, and a corresponding amount is credited to equity. The Company has applied IFRS 2 in accounting for all equity instruments granted to employees and Board members, as well as for all capital increases not open to all existing shareholders.

The fair value of the stock-options granted to employees is measured using the Black & Scholes option valuation model.

All assumptions used in measuring the value of such plans are disclosed in Note 9.

## **2.18 Provisions**

Provisions are recognized for litigation and other risks when the Group has an obligation to a third party resulting from a past event, it is probable that there will be an outflow of resources to settle the obligation and the future outflow of resources can be reliably estimated. The amount recognized in provisions is the estimated expense necessary to extinguish the obligation, discounted if necessary at period-end.

## **2.19 Employee benefit obligations**

The Group provides retirement, death and disability benefits to its employees in line with local customs and requirements through pension payments to Social Security bodies, which are funded by Company and employee contributions in Switzerland and France, the two countries where the Company operates.

The Group also provides retirement, death and disability benefits to its Swiss and French employees through the following defined benefit scheme plans as follows:

- Swiss employees of the Company are members of a compulsory company-wide defined benefit scheme through a plan which is funded through employer (50%) and employee (50%) contributions to “La Bâloise”, a Switzerland-based multi-employer plan (foundation). For the purpose of calculating contributions under this plan, salaries are capped at CHF 150K (approximately € 150K). This company-wide plan has been in place since the inception of the Company and all Swiss employees of the Company are eligible for its benefits. In addition, from January 1, 2018, the Company has implemented an additional pension benefit plan for its executive management to cover the portion of their salary in excess of CHF 150K (approximately € 150K). All Swiss executive managers of the Company are eligible for its benefits; this plan is funded through employer (60%) and employee (40%) contributions to “La Bâloise”. On retirement, each 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, at a rate which is fixed by the law up to a certain minimum level and at the discretion of the Council of the Foundation thereafter. At the age of retirement, the plan participant has the right to choose between a lump-sum payment or an annuity, or a combination thereof.
- For French employees, the Company provides a retirement indemnity, through the payment by the Company of a lump sum upon retirement.

Pension plans, similar compensation and other employee benefits that qualify as defined benefit schemes (in which the Company guarantees an amount or defined level of benefits) are recognized in the statement of financial position on the basis of an actuarial valuation of the scheme obligations at period-end, minus the fair value of the scheme assets.

The defined benefit obligations are calculated annually by independent actuaries using the projected unit credit method, taking into account staff turnover and mortality probability. The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using the interest rate of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid and that have terms to maturity approximating the terms of the related pension liability.

Current and past services as well as the net interest on the defined benefit obligation are recognized in the income statement in the period in which they are incurred, and are presented as part of payroll expenses in the income statement. Re-measurements of the defined benefit pension plans are recognized in other comprehensive income.

## **2.20 Financial liabilities**

Financial liabilities are split into two categories and include:

- financial liabilities recognized at amortized cost;
- financial liabilities recognized at fair value through profit or loss.

### **Financial liabilities recognized at amortized cost**

The Group's financial liabilities consist of other payables and accruals which are classified as liabilities at amortized cost according to IFRS 9.

Borrowings and other financial liabilities are initially recognized at fair value and subsequently measured at amortized cost using the effective interest rate method. The “less than 1 year” component of financial liabilities is presented under “current financial liabilities”.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortization is included within finance costs in the income statement.

This category generally applies to interest-bearing loans and borrowings.

## **2.21 Income tax**

Current income tax assets and liabilities are amounts expected to be recovered from or paid to the tax authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

### **Deferred taxes**

Deferred taxes are calculated using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

The main temporary differences relate to losses carried forward.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry forward of unused tax credits and unused tax losses can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

### **Withholding taxes**

Withholding taxes which are estimated to be not recoverable are recognized as an expense in the income statement. No amounts have been expensed due to non-recoverability in the years ended December 31, 2022 and December 31, 2023.

## **2.22 Information by segment**

The Group operates in only one activity segment, the research and development of pharmaceutical products, with the objective to market such products subject to the success of the development phases and the obtention of the required regulatory approvals. The Chief Executive Officer ("CEO") of the Company reviews the consolidated statement of operations of the Group on an aggregated basis and manages the operations of the Group as a single operating segment.

The Group currently generates no revenue from the sales of pharmaceutical products.

The geographical analysis of non-current assets is as follows:

(Amounts in thousands of EUR)	As at December 31,	
	2023	2022
Switzerland	3,955.3	2,273.1
France	72.2	109.1
<b>Total non-current assets</b>	<b>4,027.5</b>	<b>2,382.2</b>

The geographical analysis of operating expenses and subsidies is as follows:

(Amounts in thousands of EUR)	Operating expenses		Subsidies	
	As at December 31,		As at December 31,	
	2023	2022	2023	2022
Switzerland	7,801.6	7,200.2	265.0	452.2
France	7,699.1	5,854.8	878.4	1,373.6
<b>Total operating expenses</b>	<b>15,500.7</b>	<b>13,055.0</b>	<b>1,143.4</b>	<b>1,825.8</b>

## **2.23 Presentation of the Income Statement**

The Group presents its income statement by function. The nature of the expenses presented in the income statement by function is disclosed in Note 14 of the Notes to the financial statements.

Financial income (expenses), net, includes mainly:

- expenses related to the financing of the Group;
- foreign exchange gains or losses.

## **2.24 Earnings per share**

Basic earnings per share are calculated by dividing the net income attributable to Company shareholders by the weighted average number of shares outstanding during the financial year.

Diluted earnings per share are calculated by adjusting the net income attributable to the holders of ordinary shares and the weighted average number of the ordinary shares in circulation by the effects of all the potential dilutive ordinary shares.

If, when calculating diluted earnings per share, the inclusion of instruments giving deferred access to capital (stock-options) creates an anti-dilutive effect, those instruments are not taken into account. Refer to Note 17.

### Note 3: Intangible assets

Intangible assets consist of license and software assets.

INTANGIBLE ASSETS (Amounts in thousands of EUR)	License	Software	Total
<b>GROSS VALUE</b>			
<b>Statement of financial position at 31 December 2021</b>	<b>1,139.8</b>	<b>62.9</b>	<b>1,202.7</b>
Additions	-	-	-
Disposals	-	-	-
<b>Statement of financial position at 31 December 2022</b>	<b>1,139.8</b>	<b>62.9</b>	<b>1,202.7</b>
Additions	-	12.5	12.5
Disposals	-	-	-
<b>Statement of financial position at 31 December 2023</b>	<b>1,139.8</b>	<b>75.4</b>	<b>1,215.2</b>
<b>ACCUMULATED AMORTIZATION</b>			
<b>Statement of financial position at 31 December 2021</b>	-	<b>60.5</b>	<b>60.5</b>
Increase	-	2.4	2.4
Decrease	-	-	-
<b>Statement of financial position at 31 December 2022</b>	-	<b>62.9</b>	<b>62.9</b>
Increase	-	-	-
Decrease	-	-	-
<b>Statement of financial position at 31 December 2023</b>	-	<b>62.9</b>	<b>62.9</b>
<b>NET BOOK VALUE</b>			
<b>At 31 December 2021</b>	<b>1,139.8</b>	<b>2.4</b>	<b>1,142.2</b>
<b>At 31 December 2022</b>	<b>1,139.8</b>	-	<b>1,139.8</b>
<b>At 31 December 2023</b>	<b>1,139.8</b>	<b>12.5</b>	<b>1,152.3</b>

Pursuant to the Exclusive License Agreement entered into with bioMérieux in 2006 and to the Exclusive License Agreement on Companion Diagnostic signed with bioMérieux in 2015, the Group became liable in 2016 to make milestone payments of € 957K relating to the launch of a phase IIb clinical trial, of which € 907K was paid during 2016 and € 50K was paid during 2017.

Pursuant to an Exclusive License Agreement entered into with the National Institute of Neurological Disorders and Stroke (NINDS), part of the U.S. National Institutes of Health (NIH), in October 2018, the Company made an up-front payment of USD 50K (€ 44.2K).

Neither of these licenses is currently amortized as the marketing approval for the relevant products has not yet been obtained.

The Group performed an assessment of its licenses in the context of its annual impairment test. Given the stage of the Group's development activities, the Group concluded that there was no appropriate manner to assess the "Value in use" (VIU) of the intangible assets, as the future cash flows that could be derived from the intangible assets cannot at this stage be reliably assessed.

Given this early stage, the group has performed the impairment test collectively on the basis of the market capitalization for the entire group of €27 million at December 31, 2023, less the value of its tangible assets of €5.2 million. The valuation is considered to be Level 1 in the fair value hierarchy. The Group concluded that no impairment was required under the provisions of IAS 36.

The Group's product candidates related to these licenses were additionally assessed for impairment by considering their probability of success. This assessment included reviews of the following:

- Historic investments on the clinical trials, future contractual commitments and internal budgets approved by the Board of Directors for ongoing and future trials;
- Consideration of progress of clinical trials, including obtaining primary endpoint readout data, discussions with regulatory authorities for new trials and enrolment status for ongoing clinical trials;
- Consideration of market potential supported where available by external market studies, and assessments of competitor products and product candidates.



#### Note 4: Property, plant and equipment

Property plant and equipment consist mainly of laboratory equipment, leasehold improvements and IT equipment.

PROPERTY, PLANT AND EQUIPMENT (Amounts in thousands of EUR)	Buildings (right of use)	Machinery and equipment	Fixtures and fittings	Office and computer equipment, furniture	Office and computer equipment (right of use)	Vehicles (right of use)	Total
<b>GROSS VALUE</b>							
<b>Statement of financial position at 31 December 2021</b>	<b>1,873.0</b>	<b>252.0</b>	<b>55.8</b>	<b>212.5</b>	<b>8.2</b>	<b>18.8</b>	<b>2,420.3</b>
Additions	3.1	2.7	-	54.7	-	-	60.5
Disposals	-	-	-	-	-	-	-
<b>Statement of financial position at 31 December 2022</b>	<b>1,876.1</b>	<b>254.7</b>	<b>55.8</b>	<b>267.2</b>	<b>8.2</b>	<b>18.8</b>	<b>2,480.8</b>
Additions	30.5	10.6	-	1.9	-	-	43.0
Disposals	-	-	-	-	-	-	-
<b>Statement of financial position at 31 December 2023</b>	<b>1,906.6</b>	<b>265.3</b>	<b>55.8</b>	<b>269.1</b>	<b>8.2</b>	<b>18.8</b>	<b>2,523.8</b>
<b>ACCUMULATED DEPRECIATION</b>							
<b>Statement of financial position at 31 December 2021</b>	<b>756.9</b>	<b>214.4</b>	<b>28.9</b>	<b>201.3</b>	<b>-</b>	<b>0.4</b>	<b>1,201.9</b>
Increase	240.4	13.9	8.5	17.2	0.5	5.5	286.0
Disposals	-	-	-	-	-	-	-
<b>Statement of financial position at 31 December 2022</b>	<b>997.3</b>	<b>228.3</b>	<b>37.4</b>	<b>218.5</b>	<b>0.5</b>	<b>5.9</b>	<b>1,487.9</b>
Increase	250.1	12.3	7.0	20.3	-	4.1	293.8
Disposals	-	-	-	-	-	-	-
<b>Statement of financial position at 31 December 2023</b>	<b>1,247.4</b>	<b>240.6</b>	<b>44.4</b>	<b>238.8</b>	<b>0.5</b>	<b>10.0</b>	<b>1,781.7</b>
<b>NET BOOK VALUE</b>							
<b>At 31 December 2021</b>	<b>1,116.1</b>	<b>37.6</b>	<b>26.9</b>	<b>11.2</b>	<b>8.2</b>	<b>18.4</b>	<b>1,218.4</b>
<b>At 31 December 2022</b>	<b>878.8</b>	<b>26.4</b>	<b>18.4</b>	<b>48.7</b>	<b>7.7</b>	<b>12.9</b>	<b>992.9</b>
<b>At 31 December 2023</b>	<b>659.2</b>	<b>24.7</b>	<b>11.4</b>	<b>30.3</b>	<b>7.7</b>	<b>8.8</b>	<b>742.1</b>

No impairment was required under the provisions of IAS 36.

#### Note 5: Financial assets

FINANCIAL ASSETS (Amounts in thousands of EUR)	12/31/2023	12/31/2022
Liquidity contract	49.0	50.4
Deposits	211.8	199.1
<b>Non-current financial assets</b>	<b>260.8</b>	<b>249.5</b>

Non-current financial assets include the cash reserve related to the liquidity contract entered into following the initial public offering of the Company in April 2016 (refer to Note 7), and a bank security deposit related to the lease of the Company's premises. No impairment was required under the provisions of IAS 36.

## Note 6: Other assets

OTHER CURRENT AND NON-CURRENT ASSETS (Amounts in thousands of EUR)	12/31/2023	12/31/2022
Research Tax Credits (1)	1,872.3	-
<b>Total other non-current receivables</b>	<b>1,872.3</b>	<b>-</b>
Research Tax Credits (1)	-	1,316.4
Value Added Tax	162.1	108.8
Social and tax receivables	-	56.6
Prepaid expenses	64.8	34.2
Invoices to be issued	-	-
Income tax	-	-
Advance payments (2)	45.8	1,362.6
Other	234.3	616.4
<b>Total other current assets</b>	<b>507.0</b>	<b>3,495.0</b>

### (1) Research tax credits (RTC)

GeNeuro Innovation SAS has been granted RTCs pursuant to the provisions of articles 244 quater B and 49 septies F of the French General Tax Code. Amounts due from RTCs are recognized as receivables and result in a corresponding reduction in expense in the period that the qualifying expenses were made. Until 2021, RTCs were settled in cash in the following year; since 2022, the RTCs are eligible for repayment three years after the claim has been filed with the French tax authorities. In 2022, the Group recognized € 1,316K in French RTCs, which were expected to be reimbursed in the third quarter of 2023 but which, due to the change in repayment process now applicable to GeNeuro Innovation SAS, is now expected to be reimbursed in 2026. In January 2024, the Group implemented a bank pre-financing of this 2022 RTC, pursuant to which it collected an amount of € 990K, with a residual amount of € 132K expected to be received in 2026 and the balance comprising interest charge and bank fees. In 2023, the Group recognized € 556K in French RTCs, which are expected to be reimbursed in 2027. Accordingly, the RTCs for 2022 and 2023 are accounted for as non-current receivables.

### (2) Advance payments

Advance payments comprise payments made to service providers involved with the Company's clinical trials.

## Note 7: Financial assets and liabilities and impact on income statement

The Group's assets and liabilities are measured as follows for each year:

(Amounts in thousands of EUR)	12/31/2023		Value - Statement of financial position as per IFRS 9		
	Carrying Amount of Financial Position	Fair value	Fair value through profit and loss	Fair value through OCI	Amortized cost
Other non-current financial assets	260.8	260.8			260.8
Cash and cash equivalents	1,827.4	1,827.4	1,827.4		-
<b>Total Financial Assets</b>	<b>2,088.2</b>	<b>2,088.2</b>	<b>1,827.4</b>	-	<b>260.8</b>
Non-current financial liabilities	12,620.1	12,620.1			12,620.1
Current financial liabilities	747.3	747.3			747.3
Non-current derivative liabilities	299.4	299.4	299.4		
<b>Total Financial &amp; Derivative Liabilities</b>	<b>13,666.8</b>	<b>13,666.8</b>	<b>299.4</b>	-	<b>13,367.4</b>

(Amounts in thousands of EUR)	12/31/2022		Value - Statement of financial position as per IFRS 9		
	Carrying Amount of Financial Position	Fair value	Fair value through profit and loss	Fair value through OCI	Amortized cost
Other non-current financial assets	249.5	249.5			249.5
Cash and cash equivalents	5,593.3	5,593.3			5,593.3
<b>Total Financial Assets</b>	<b>5,842.8</b>	<b>5,842.8</b>	-	-	<b>5,842.8</b>
Non-current financial liabilities	6,517.9	6,517.9			6,517.9
Current financial liabilities	601.8	601.8			601.8
<b>Total Financial Liabilities</b>	<b>7,119.7</b>	<b>7,119.7</b>	-	-	<b>7,119.7</b>

## Note 8: Capital

COMPOSITION OF SHARE CAPITAL (number of shares)	12/31/2023	12/31/2022
Common bearer shares	24,999,028	24,999,028
<b>Total</b>	<b>24,999,028</b>	<b>24,999,028</b>
Nominal value (in CHF)	0.05 CHF	0.05 CHF
Approximate nominal value (in EUR)	0.05 €	

This number of shares excludes stock options granted to certain employees, directors and consultants that have not yet been exercised.

### Share capital

On May 13, 2022, the Company completed a €7.7 million capital increase through an international private placement only to certain qualified and institutional investors. Accordingly, at December 31, 2022, the Company's share capital amounted to € 1,100.2K (CHF 1,250.0K, converted into euros at the applicable historical exchange rates) and was divided into 24,999,028 common bearer shares with a nominal value of CHF 0.05. All shares are fully paid up.

Because the May 2022 capital increase was not open to all existing shareholders but was restricted to certain selected institutional investors, pursuant to IFRS 2 the difference (discount) between the share price prior to the capital increase (€3.08 per share) and the actual issue price (€2.86 per share) is considered a share based payment, resulting in a charge of €589K, accounted for within financial expenses (see Note 15), with a corresponding amount added to reserves within shareholders' equity.

### Capital band

The June 14, 2023 shareholders' meeting approved a new capital band allowing to issue up to 12,499,514 bearer shares of CHF 0.05 nominal value each. The approval for this authorized capital lapses on June 14, 2028.

On 18 March 2024, the Company held an extraordinary shareholders' meeting at which a new capital band was approved, allowing to increase the capital by up to 50% to CHF 2,232,069.95 through the issuance of new fully paid-up shares. The approval for this capital band lapses on 18 March 2029.

### Conditional capital

Following the May 31, 2022, shareholders' meeting, the "part I" conditional capital includes 3,348,116 bearer shares of CHF 0.05 nominal value, to be issued upon exercise of stock options granted to employees, directors and consultants in the context of an incentive plan.

Following the May 31, 2022, shareholders' meeting, the "part II" conditional capital comprises 7,812,271 bearer shares of CHF 0.05 nominal value, to be issued upon exercise of stock options or conversion rights granted to shareholders or strategic partners or linked to loans or similar bond issues.

On 18 March 2024, the Company held an extraordinary shareholders' meeting at which the "part I" conditional capital was amended to 4,464,139 bearer shares of CHF 0.05 nominal value, to be issued upon exercise of stock options granted to employees, directors and consultants in the context of an incentive plan, whereas the "part II" conditional capital was amended to 10,416,326 bearer shares of CHF 0.05 nominal value, to be issued upon exercise of stock options or conversion rights granted to shareholders or strategic partners or linked to loans or similar bond issues.

## Capital management

Following its initial public offering on Euronext Paris, the Company entered in May 2016 into a liquidity contract with the Gilbert Dupont brokerage house in Paris, in order to reduce the share price's intra day volatility.

In this context, in 2016 the Company provided € 750K to this broker to enable it to buy and sell the Company's shares. The share of the contract that is invested in treasury shares by this broker is accounted for as a reduction in the Company's consolidated equity. The Company can terminate the contract at any time. Pursuant to this contract, 118,739 treasury shares were accounted for as a reduction in shareholders' equity as of December 31, 2023 (111,672 shares as of December 31, 2022). Results from the sale of such treasury shares are also directly applied to shareholders' equity.

<b>MOVEMENT OF LIQUIDITY ACCOUNT</b>	<b>12/31/2023</b>	<b>12/31/2022</b>
Initial balance (thousands of shares)	111.7	80.0
Shares purchased (thousands of shares)	184.7	194.0
Shares sold (thousands of shares)	(177.6)	(162.3)
<b>Year-end balance (thousands of shares)</b>	<b>118.8</b>	<b>111.7</b>
Purchases of shares (thousands of EUR)	312.6	492.2
Sales of shares (thousands of EUR)	(311.2)	(424.0)
<b>Net movement of liquidity contract (thousands of EUR)</b>	<b>1.4</b>	<b>68.2</b>

## Reclassification of currency impact from change of functional currency on Jan. 1, 2016

On January 1, 2016, the Company decided to adopt the euro (EUR) as functional currency, instead of the Swiss franc (CHF) which had heretofore been its functional currency. All items were converted into the new functional currency by using the exchange rate at the time of the change (rate as of December 31, 2015: 1,0835 CHF for 1 EUR), except for shareholders' equity which was converted at the applicable historical rates. This resulted in a negative currency impact of K€ 61.6 to share capital and K€ 2,876.6 to additional paid-in capital, which was offset by a positive impact of K€2,736.0 to accumulated deficit and of K€ 202.2 to cumulative translation adjustments. This led to a difference in additional paid-in capital as reported in the consolidated financial statements compared to additional paid-in capital as reported in the Company's statutory financial statements. Given the decision approved at the June 14, 2023's shareholders' meeting, to allocate EUR 30 million from additional paid-in capital to the accumulated deficit, the Company has decided to reclassify the K€ 2,876.6 currency impact booked in 2016 from additional paid-in capital to accumulated deficit, in order to present a positive value for the additional paid-in capital.

## Dividends

The Company has paid no dividends in the financial years ended December 31, 2023 and 2022.

## Note 9: Stock options and common shares granted as part of an incentive plan

### Share awards to directors

Holders of ordinary shares that were obtained as part of an incentive plan created for two board members (11/2015 plan) were subject to a restriction period during which the shares could not be transferred, this restriction being lifted by 25% every twelve months; as a result, this restriction was fully lifted on November 18, 2019.

Upon termination of each director's service, the Company has no present obligation to repurchase or settle the shares in cash.

### Stock options

The Company has issued stock options as part of an equity incentive plan. In 2023, the Company granted a total of 237,694 stock options with an exercise price of €2.86 per share. All vested options not exercised in the 12 month-period following the departure (within the validity period of the options) are cancelled. The Group has no legal or constructive obligation to repurchase or settle any of the stock options in cash.

The following tables summarize the assumptions adopted in the IFRS 2 valuation:

Allocation date	Number of options issued / Shares granted with a restriction period	Exercise price	Market price at time of grant	Exercise period	Vesting period	Volatility	Risk-free rate	Fair value at grant date per option / share
Stock-options 04/2010	123,000	4.00 CHF	N/A	12 years		50.5%	1.11%	1.46
Stock-options 04/2013	3,000	4.00 CHF	N/A	5 years		50.3%	0.05%	1.40
Shares granted to Board members 11/2015	45,000	N/A	N/A	N/A		N/A	N/A	27.99
PSOU 06/2016 (1)	606,400	13.00 €	9.28 €	5 years		58.8%	-1.09%	2.29
PSOU 01/2017 (1)	35,000	13.00 €	10.19 €	5 years	3 years	53.6%	-0.86%	2.48
PSOU 02/2017 (1)	15,000	13.00 €	9.29 €	5 years	2 years	53.6%	-0.87%	1.74
PSOU 02/2018 (1)	20,000	13.00 €	6.28 €	5 years	2 years	50.0%	-0.77%	0.14
Stock-options 02/2017 - part 1	42,500	13.00 €	9.67 €	5 years	3 years	53.6%	-0.94%	2.50
Stock-options 02/2017 - part 2	7,500	13.00 €	9.39 €	5 years	3 years	53.6%	-0.94%	2.35
Stock-options 02/2018	22,500	13.00 €	6.20 €	5 years	3 years	50.0%	-0.75%	0.80
Stock-options 09/2018	158,540	2.73 €	3.66 €	10 years	4 years	50.0%	0.00%	1.74
Stock-options 03/2020 - part 1	75,750	3.34 €	3.07 €	10 years	4 years	49.4%	-0.63%	0.73
Stock-options 03/2020 - part 2	75,750	3.34 €	3.07 €	10 years	4 years	45.8%	-0.52%	1.20
Stock-options 12/2020 - part 1	15,000	2.95 €	2.82 €	10 years	4 years	59.6%	-0.78%	0.86
Stock-options 12/2020 - part 2	15,000	2.95 €	2.82 €	10 years	4 years	53.6%	-0.64%	1.32
Stock-options 02/2021 - part 1	87,400	3.19 €	3.08 €	10 years	4 years	70.0%	-0.78%	0.81
Stock-options 02/2021 - part 2	87,400	3.19 €	3.08 €	10 years	4 years	63.0%	-0.57%	1.57
Stock options 03/2022 - part 1	91,859	3.48 €	3.74 €	10 years	4 years	67.5%	-0.20%	1.45
Stock options 03/2022 - part 2	91,858	3.48 €	3.74 €	10 years	4 years	62.3%	0.18%	1.83
Stock options 04/2023 - part 1	118,847	2.86 €	2.32 €	10 years	4 years	66.9%	1.06%	0.59
Stock options 04/2023 - part 2	118,847	2.86 €	2.32 €	10 years	4 years	65.8%	0.96%	1.03

(3) Reflects the number of PSOU's granted originally; the actual number of stock options granted in February 2019, at the expiry of the PSOU Plan, is 602,335 for the 2016 Plan, 36,400 and 15,000, respectively, for the 2017 Plans and 18,500 for the 2018 Plan.

Stock options are valued on the basis of management assumptions on the likely exercise horizons for each option, which are in certain cases split in two parts (1 and 2), with different volatility and risk-free rates used to value the stock options using the Black & Scholes model.

### Evolution of the number of outstanding options

Number of options	Stock options 04/2010	PSOU Plans 2016-2018	Stock options 02/2017- parts 1&2	Stock options 02/2018	Stock options 09/2018	Stock options 03/ & 12/2020	Stock options 02/2021	Stock options 03/2022	Stock options 04/2023	Total
<b>December 31, 2021</b>	45,000	493,694	30,000	14,167	102,679	166,812	178,000	-	-	1,030,352
Issued		-	-				183,627			183,627
Forfeited / cancelled (1)	(45,000)	-	(30,000)	(4,167)	(11,799)	(2,812)				(93,778)
<b>December 31, 2022</b>	-	493,694	-	10,000	90,880	164,000	178,000	183,627	-	1,120,201
Issued		-	-	-	-	-	-	237,694		237,694
Forfeited / cancelled (1)		-	-	(10,000)	(1,027)					(11,027)
<b>December 31, 2023</b>	-	493,694	-	-	89,853	164,000	178,000	183,627	237,694	1,346,868
<b>Number of shares to be issued</b>	-	493,694	-	-	89,853	164,000	178,000	183,627	237,694	1,346,868
<b>Number of options vested as at December 31, 2023</b>	-	493,694	-	-	89,853	141,001	111,250	68,859	-	904,657

(1) Forfeited following resignation or cancelled at maturity or following expiry of employee departure exercise period.

### Valuation of stock options and common shares granted as part of an incentive plan

The fair value of the options was measured using an adjusted Black & Scholes option pricing model, with included the following factors:

- The price of the underlying shares was deemed to be equal to the investor subscription price or was calculated by reference to internal valuations;
- The risk-free rate was selected by reference to the average lifetime of the instruments;

- Volatility was estimated by reference to a sample of biotechnology companies listed on Euronext and SIX (Switzerland), at the date when the instruments were granted, and over a period equivalent to the lifetime of the option.

The fair value of the common shares granted under an incentive plan is equal to the share price at the grant date less the purchase price paid by the allottee.

#### Breakdown of charges recognized in accordance with IFRS 2 for the relevant periods

(Amounts in thousands of EUR)	12/31/2022			12/31/2023		
	Grant date	Accumulated expense at opening	Expense	Accumulated expense at 12/31/2022	Expense	Accumulated expense at 12/31/2023
Stock options 2011— extension granted 2020		22.8	-	22.8	-	22.8
Shares granted to board members 11/2015		614.4	-	614.4	-	614.4
PSOUs 06/2016		1,381.6	-	1,381.6	-	1,381.6
PSOUs 01/2017		89.6	-	89.6	-	89.6
PSOUs 02/2017		27.0	-	27.0	-	27.0
Stock options 02/2017- part 1		96.2	-	96.2	-	96.2
Stock options 02/2017- part 2		16.1	-	16.1	-	16.1
Stock options 02/2018		14.1	-	14.1	-	14.1
PSOUs 02/2018		3.0	-	3.0	-	3.0
Stock options 09/2018		164.7	12.8	177.5	4.5	182.0
Stock options 03/2020		94.7	25.8	120.5	15.9	136.4
Stock options 12/2020		10.4	5.4	15.8	3.7	19.5
Stock options 02/2021		76.7	77.9	154.6	57.3	211.9
Stock options 03/2022		-	113.3	113.3	93.5	206.8
Stock options 04/2023		-	-	-	70.5	70.5
<b>Total</b>		<b>2,611.3</b>	<b>235.2</b>	<b>2,846.5</b>	<b>245.4</b>	<b>3,091.9</b>

#### Note 10: Financial liabilities

Financial liabilities include the lease liabilities related to lease agreements; research grants received in the form of reimbursable advances (refer to Note 10.1); and the FOPH forgivable loan (refer also to Notes 2.13 and 10.2).

CURRENT AND NON-CURRENT FINANCIAL LIABILITIES (Amounts in thousands of EUR)	12/31/2023	12/31/2022
Reimbursable advance (Note 10.1)	-	139.10
FOPH Covid-19 contract (Note 10.2)	5,629.6	5,136.27
Unsecured bank loan	173.1	511.40
EIB Venture Debt Loan (Note 10.3)	6,319.2	-
Lease liabilities	498.2	731.1
<b>Non-current financial liabilities</b>	<b>12,620.1</b>	<b>6,517.9</b>
<b>Non-current derivative liabilities</b>	<b>299.4</b>	<b>-</b>
Unsecured bank loan	338.3	328.2
EIB Loan (Note 10.3)	110.8	-
Lease liabilities	298.2	273.6
<b>Current financial liabilities</b>	<b>747.3</b>	<b>601.8</b>
<b>Total financial liabilities</b>	<b>13,666.8</b>	<b>7,119.7</b>

<b>Net debt</b> <b>(amounts in thousands of EUR)</b>	<b>12/31/2023</b>	<b>12/31/2022</b>
Cash and cash equivalents	1,827.4	5,593.3
Borrowings (including reimbursable advance)	(511.4)	(978.7)
EIB Venture Debt Loan	(6,430.0)	-
Derivative liabilities on EIB warrants	(299.4)	-
FOPH Covid-19 Contract	(5,629.6)	(5,136.3)
Lease liabilities	(796.4)	(1,004.7)
<b>Net (debt) / cash</b>	<b>(11,839.4)</b>	<b>(1,526.4)</b>
Cash and cash equivalents	1,827.4	5,593.3
Gross debt - fixed interest rates (1)	(13,666.8)	(7,119.7)
<b>Net debt</b>	<b>(11,839.4)</b>	<b>(1,526.4)</b>

(1) Gross debt includes the FOPH COVID-19 forgivable loan at gross amount, excluding the effect of the grant subsidy – refer to Note 10.2

This section sets out an analysis of net debt and the movements in net debt for each of the periods presented.

#### CHANGE IN LOANS AND BORROWINGS

<b>(Amounts in thousands of EUR)</b>	<b>Lease Liabilities</b>	<b>Reimbursable Advance</b>	<b>FOPH Forgivable Loan under COVID-19 Contract (2)</b>	<b>Bank Loan</b>	<b>EIB Venture Debt Loan</b>	<b>Derivative Liabilities</b>	<b>TOTAL LOANS AND BORROWINGS</b>
<b>At December 31, 2021</b>	<b>1,216.0</b>	<b>149.8</b>	<b>2,534.5</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>3,900.3</b>
Additions	3.1	-	2,472.3	1,000.0	-	-	3,475.4
Cash flows	(214.4)	(12.5)	-	(160.4)	-	-	(387.3)
Interest expense	-	1.8	233.1	-	-	-	234.9
(+/-) Other (1)	-	-	(103.6)	-	-	-	(103.6)
<b>At December 31, 2022</b>	<b>1,004.7</b>	<b>139.1</b>	<b>5,136.3</b>	<b>839.6</b>	<b>-</b>	<b>-</b>	<b>7,119.7</b>
Additions	30.5	-	-	-	7,000.0	-	7,030.5
Derivative instruments	-	-	-	-	(1,106.3)	1,106.3	-
Transaction costs	-	-	-	-	(75.0)	-	(75.0)
Cash flows	(238.8)	-	-	(328.2)	-	-	(567.0)
Interest expense	-	0.9	308.0	-	611.3	-	920.2
Subsidies	-	(140.0)	(265.0)	-	-	-	(405.0)
(+/-) Other (1)	-	-	450.3	-	-	(806.9)	(356.6)
<b>At December 31, 2023</b>	<b>796.4</b>	<b>-</b>	<b>5,629.6</b>	<b>511.4</b>	<b>6,430.0</b>	<b>299.4</b>	<b>13,666.8</b>

(1): others include foreign exchange difference on lease liabilities, subsidies on reimbursable advance and forgivable loan and the change in fair value of financial derivatives.

(2): see Note 10.2.

#### 10.1 Reimbursable advance

<b>CHANGE IN REIMBURSABLE ADVANCE</b> <b>(Amounts in thousands of EUR)</b>	
<b>At December 31, 2022</b>	<b>139.1</b>
(-) repayment	-
Subsidies	(140.0)
Financial expenses	0.9
<b>At December 31, 2023</b>	<b>-</b>

A reimbursable advance was granted to GeNeuro Innovation SAS by Bpifrance on September 16, 2011 in the form of an interest-free, reimbursable innovation loan facility to develop a diagnostic test and a therapeutic solution for polyradiculoneuropathies, subject to a 70% waiver in case of failure of the program. This reimbursable advance did not bear annual interest and, as a result, has been treated under IFRS as an interest-free loan for the company. As the conditions were more favorable than market rates, the difference between the amount of the advance at historical cost and the advance discounted at market rates was considered as a public grant. On January 13, 2023,

Bpifrance acceded to GeNeuro Innovation's request to consider the program a failure and waived the 70% outstanding balance, representing a gross amount of € 140K.

## **10.2 FOPH Forgivable loan**

On December 13, 2021, GeNeuro entered into a Subsidy Contract with the FOPH for the financing of its Post-COVID project testing temelimab in Post-COVID (or "Long-COVID") patients with neuro-psychiatric symptoms. Pursuant to this contract, GeNeuro issued an invoice to the FOPH of CHF 3,090K (€ 2,991K) for the first instalment payment, which amount is included within the "Other" receivables as of December 31, 2021 (see Note 6). The Subsidy Contract allows the FOPH, in case of success of the project leading to a marketing authorization for the Company's drug in Post-COVID, to apply the amount of the subsidy to the purchase price, at market levels, of temelimab for the Long-COVID indication. Due to this component of the Subsidy Contract, under IAS 20 GeNeuro accounted for the amounts received from the FOPH as a forgivable conditional loan from the FOPH, , treated as a government loan at a below-market rate, and the amount to be received as of Dec. 31, 2021 was therefore considered as a liability. Under IAS 20, since the conditional loan does not bear annual interest, it is treated as an interest-free loan for the Company (i.e. under conditions more favorable than market rates), and the difference between the amount of the advance at historical cost and the advance discounted at market rates is considered as a public grant, in an amount of € 467.8K for 2021. The first instalment payment was received in January 2022; in addition, a second instalment payment of CHF 2,289.7K (€ 2,325.3K) was received in September 2022.

<b>CHANGE IN FOPH FORGIVABLE LOAN</b>	
<b>(Amounts in thousands of EUR)</b>	
<b>At December 31, 2021</b>	<b>2,534.5</b>
Addition	2,659.1
Subsidies	(115.4)
Financial expenses	233.1
Impact of exchange rate difference	(175.0)
<b>At December 31, 2022</b>	<b>5,136.3</b>
Addition	-
Subsidies	(265.0)
Financial expenses	308.0
Impact of exchange rate difference	450.3
<b>At December 31, 2023</b>	<b>5,629.6</b>

## **10.3 EIB Venture Debt Loan**

In March 2023, the Company announced that its French subsidiary had entered into a €25 million Venture Debt Loan facility with the European Investment Bank ("EIB"), designed to finance the GeNeuro Group's Post-COVID development program, of which €7 million were immediately available as a first Tranche A and were drawn in March 2023.

The amount of € 7 million shown for the EIB Venture Debt Loan is the first tranche this EIB unsecured credit agreement; the derivative instruments relate to the IFRS valuation of the 642,031 share purchase warrants issued to the EIB (at an exercise price of €2.58 per share).

The € 25 million credit facility is divided into three tranches: 7 million euros for the first tranche ("Tranche A"), 10 million euros for the second tranche ("Tranche B") and 8 million euros for the third tranche ("Tranche C"). 8 million for the third tranche ("Tranche C"). The disbursement of the remaining two tranches is subject to certain conditions, the main ones of which are detailed below:

Tranche B:

- Full run of Tranche A,
- Issue of the warrants relating to Tranche B,
- Positive results from the Phase 2b clinical trial in long COVID,
- 30 million in cash, in the form of equity, license revenues or customer advances.

Tranche C:

- Full run of Tranche B,
- Issue of the warrants relating to Tranche C,
- Production contracts with two companies specialized in Contract Manufacturing



- Organization for the commercial production of temelimab,
- Enrollment of the first patient in a Phase III clinical trial in long COVID, or conditional marketing authorization of temelimab in this indication granted by Swissmedic, the EMA or the FDA,
- 60 million (in addition to the above-mentioned 30 million euros) in the form of equity, licensing revenues or customer advances.

The last two tranches will be available for 24 months from the signing of the Financing Agreement, i.e. until December 2024.

Interest rate: The credit agreement will have a fixed annual interest rate of 2% for each tranche as well as a declining capitalized interest rate per tranche, 7% for Tranche A, 5% for Tranche B and 2.5% for Tranche C, with a maturity of five years for each tranche. This interest will be capitalized annually, payable at maturity and incorporated in the nominal amount of the loan, and will therefore bear interest.

In certain circumstances, the credit may be prepaid, in whole or in part, at a fee, at the request of the Company or EIB following certain prepayment events, including a change of control or change of management of the Company.

Subject to certain conditions, upon the occurrence of standard events of default (e.g., payment default, misrepresentation, cross default), the EIB may require the Company to immediately repay all or part of the outstanding loan and/or cancel any undisbursed portion.

The credit agreement is complemented by a warrant agreement between GeNeuro SA and the EIB, representing 2.4% of GeNeuro SA's fully diluted share capital for Tranche A, 2.0% of GeNeuro SA's fully diluted share capital for Tranche B, and 1.3% of GeNeuro SA's fully diluted share capital for Tranche C. In connection with the drawdown of the first €7 million tranche from the EIB Credit Facility, the Company issued to the EIB a total of 642,031 share purchase warrants at an exercise price of €2.58 per share and an initial aggregate valuation of K€ 1,106. Due to the decrease at December 31, 2023 of the Company's share price compared to the exercise price, these warrants were valued at December 31, 2023 at € 299K, leading to the above € 807K favorable change in fair value of the derivatives.

The warrants will have a maturity of 7 years, renewable once. Each warrant will entitle EIB to acquire one common share of the Company in exchange for the exercise price (subject to anti-dilution provisions). The exercise price for each warrant will be equal to 95% of the volume-weighted average of the price of the Company's ordinary shares over the last twenty trading days preceding the decision of the competent body of the Company to issue such warrants. The EIB will have a put option, as soon as the warrants become exercisable, to request GeNeuro SA to repurchase all or part of the exercisable but not yet exercised warrants at their intrinsic value (within the limit of a ceiling equal to the amount drawn under the credit facility).

## Note 11: Defined benefit obligation

EMPLOYEE BENEFIT OBLIGATIONS Amounts in thousands of EUR	France	Switzerland	Total
At December 31, 2023	150.0	778.3	928.3
At December 31, 2022	122.7	31.1	153.8

### 11.1 French Employees

Defined benefit obligations for French employees result in a provision for a retirement indemnity to be paid by the Group at the date of retirement, measured in accordance with the applicable collective bargaining agreement of the pharmaceutical industry.

The main actuarial assumptions used to measure retirement packages are as follows:

ACTUARIAL ASSUMPTIONS	12/31/2023	12/31/2022
Age at retirement	Voluntary retirement age 65 to 67	
Collective agreements	Pharmaceutical industry	
Discount rate (IBOXX Corporates AA )	3.17%	3.75%
Mortality table	INSEE 2017	INSEE 2017
Salary revaluation rate	1.50%	1.50%
Turnover rate*	High	High
Social security expense ratio		
Management	43%	43%
Non-management	41%	41%

\* Turnover rates assumptions are summarized as follows:

- From 20 to 30 years old : from 18.3% to 10.9%
- From 30 to 40 years old : from 10.9% to 6.3%
- From 40 to 50 years old : from 6.3% to 4.2%
- From 50 to 65 years old : from 4.2% to 0%
- From 65 to 67 years old : 0%

The following shows the change in retirement indemnity:

POST EMPLOYMENT BENEFIT OBLIGATION (Amounts in thousands of EUR)	Post-employment benefit obligations
<b>At December 31, 2021</b>	<b>120.6</b>
Service costs	12.6
Financial costs	1.2
<b>Sub-total included in profit or loss</b>	<b>13.8</b>
Actuarial (gains) losses	(11.7)
<b>At December 31, 2022</b>	<b>122.7</b>
Service costs	16.3
Financial costs	4.6
<b>Sub-total included in profit or loss</b>	<b>20.9</b>
Actuarial (gains) losses	6.4
<b>At December 31, 2023</b>	<b>150.0</b>

### Sensitivity analysis as at December 31, 2023

(Amounts in thousands of euros)	Turnover		
Sensitivity analysis	Low	Medium	<b>Selected assumption : high</b>
Post employment benefit obligation	156.8	155.7	<b>150.0</b>
	<b>Salary revaluation rate</b>		
Sensitivity analysis	1%	<b>Selected assumption: 1.5%</b>	2%
Post employment benefit obligation	152.3	<b>150.0</b>	147.7
	<b>Discount rate</b>		
Sensitivity analysis	2.67%	<b>Selected assumption: 3.17%</b>	3.67%
Post employment benefit obligation	152.3	<b>150.0</b>	147.7

## Sensitivity analysis as at December 31, 2022

(Amounts in thousands of euros)	Turnover		
Sensitivity analysis	Low	Medium	Selected assumption : high
Post employment benefit obligation	128.3	127.5	122.7
Salary revaluation rate			
Sensitivity analysis	1%	Selected assumption: 1.5%	2%
Post employment benefit obligation	119.9	122.7	125.6
Discount rate			
Sensitivity analysis	3.25%	Selected assumption: 3.75%	4.25%
Post employment benefit obligation	125.0	122.7	120.5

The Group estimates that changes in other assumptions would cause no significant impact on liabilities.

### 11.2 Swiss Employees

The defined benefit obligation related to the so-called "Second Pillar" Swiss pension scheme is assessed using the following assumptions:

ACTUARIAL ASSUMPTIONS	12/31/2023	12/31/2022
Age at retirement	Voluntary retirement age : 65 female / 65 male	Voluntary retirement age : 64 female / 65 male
Discount rate	1.45%	2.30%
Demographic basis	LPP 2020 generation	LPP 2020 generation
Salary increase	2.00%	1.00%
Pension increase	1.00%	1.00%
Interest credited on saving accounts	1.50%	1.00%
Turnover rate	10.00%	10.00%

The assumption regarding the age at retirement for female employees was revised at December 31, 2023, due to the change in the legal retirement age approved by the Swiss population in September 2022 and implemented by the Swiss government as of January 1, 2024. Assumptions regarding the discount rate, the rates of salary increase and interest credit were revised at December 31, 2023 due to market conditions.

#### Mortality rate

Assumptions regarding future mortality are set based on advice, published statistics and experience. The weighted average duration of the defined benefit obligation included in the statement of financial position date is as follows:

	12/31/2023	12/31/2022
Weighted average duration of the defined benefit obligation	15.8	14.8

Changes in the defined benefit obligation and in the fair value of the plan assets are as follows:

Amounts in thousands of EUR	Defined benefit obligation	Fair value of plan assets	Benefit liability
<b>At December 31, 2021</b>	<b>3,431.1</b>	<b>2,474.7</b>	<b>956.4</b>
Service	211.9	-	211.9
Financial interests	12.5	9.7	2.8
Employee Contribution	130.1	130.1	-
Currency effects	175.9	128.0	47.9
<b>Sub-total included in profit or loss</b>	<b>530.4</b>	<b>267.8</b>	<b>262.6</b>
<b>Benefits (paid) / received</b>	<b>111.6</b>	<b>111.6</b>	<b>-</b>
Return on plan assets (excluding financial interests)	-	15.1	(15.1)
Actuarial changes arising from changes in financial assumptions	(1,106.8)	-	(1,106.8)
Other actuarial gain	112.9	-	112.9
<b>Sub-total included in "Other Comprehensive Income"</b>	<b>(993.9)</b>	<b>15.1</b>	<b>(1,009.0)</b>
<b>Contributions by employer</b>	<b>-</b>	<b>178.9</b>	<b>(178.9)</b>
<b>At December 31, 2022</b>	<b>3,079.2</b>	<b>3,048.1</b>	<b>31.1</b>
Service	274.0	-	274.0
Financial interests	75.7	78.3	(2.6)
Employee Contribution	123.0	123.0	-
Currency effects	140.0	225.8	(85.8)
<b>Sub-total included in profit or loss</b>	<b>612.7</b>	<b>427.1</b>	<b>185.6</b>
<b>Benefits (paid) / received</b>	<b>(346.9)</b>	<b>(346.9)</b>	<b>-</b>
Return on plan assets (excluding financial interests)	-	(50.2)	50.2
Actuarial changes arising from changes in financial assumptions	810.0	-	810.0
Other actuarial gain / (loss)	1.1	-	1.1
Plan amendment	(139.0)	-	(139.0)
<b>Sub-total included in "Other Comprehensive Income"</b>	<b>672.1</b>	<b>(50.2)</b>	<b>722.3</b>
<b>Contributions by employer</b>	<b>-</b>	<b>160.7</b>	<b>(160.7)</b>
<b>At December 31, 2023</b>	<b>4,710.9</b>	<b>3,932.6</b>	<b>778.3</b>

Assumptions regarding the discount rate, the rates of salary increase and interest credit were revised at December 31, 2023 due to market conditions for CHF corporate bond yields, resulting in actuarial changes of €810 K.

The "other actuarial gain" of €1.1K is due to the impact of changes in salaries.

During 2023, the Bâloise Swiss multi-employer plan decreased the conversion rate (i.e., the rate at which the retirement assets can be converted into an annual retirement pension) and applied the new retirement age for female employees, leading to a plan amendment of € 139K.

#### Sensitivity analysis as at December 31, 2023 and as at December 31, 2022

Changes in certain actuarial assumptions could result in substantial changes in the post-employment benefit obligation.

They can be summarized as follows on December 31, 2023 and 2022:

(Amounts in thousands of EUR)	on December 31, 2023			on December 31, 2022		
	Salary revaluation rate			Salary revaluation rate		
Sensitivity analysis	1.50%	<b>Selected assumption: 2.0%</b>	2.50%	0.50%	<b>Selected assumption: 1%</b>	1.50%
Post employment benefit obligation	4,698.7	<b>4,710.9</b>	4,724.1	3,069.4	<b>3,079.2</b>	3,089.8
	Discount rate			Discount rate		
Sensitivity analysis	0.95%	<b>Selected assumption: 1.45%</b>	1.95%	1.80%	<b>Selected assumption: 2.30%</b>	2.80%
Post employment benefit obligation	5,102.5	<b>4,710.9</b>	4,364.6	2,941.0	<b>3,079.2</b>	3,231.5
	Rate of pension increase			Rate of pension increase		
Sensitivity analysis	0.50%	<b>Selected assumption: 1.00%</b>	1.50%	0.50%	<b>Selected assumption: 1.00%</b>	1.50%
Post employment benefit obligation	4,624.6	<b>4,710.9</b>	4,800.3	3,020.3	<b>3,079.2</b>	3,140.4

The estimated Company contributions to pension plans for the financial year 2024 amount to € 176K (based on the closing rate at December 31, 2023).

The categories of plan assets, based on an asset/liability matching analysis, and their respective allocation, are as follows:

Allocation in K€	12/31/2023	12/31/2022
Cash	98.3	79.3
Bonds	2,288.9	1,774.1
Shares	98.3	73.2
Real estate	676.4	524.3
Mortgages	491.6	381.0
Alternative investments	279.2	216.4
<b>Total</b>	<b>3,932.7</b>	<b>3,048.3</b>

The benefit payments for the next ten years (in euros) are broken down as follows:

2024	€ 87.9K
2025	€ 61.3K
2026	€ 53.2K
2027	€ 460.6K
2028	€ 599.7K
2029-2033	€ 959.5K

## Note 12: Other current liabilities

### 12.1 Trade payables

The amount of trade payables is consistent with the expenses incurred by the Group as part of its clinical trials program and the payment terms agreed by the suppliers and service providers.

### 12.2 Other current liabilities

OTHER CURRENT LIABILITIES (Amounts in thousands of EUR)	12/31/2023	12/31/2022
Personnel and related accounts	153.6	393.4
Social security and other social institutions	151.0	248.4
Other	20.9	28.8
Prepaid income (1)	-	138.3
Accrued liabilities	2,717.1	1,018.2
Deferred grant (2)	-	115.4
<b>Total other current liabilities</b>	<b>3,042.6</b>	<b>1,942.5</b>

(1) Corresponds to prepaid subsidies.

(2) Refer to Note 10.2.

## Note 13: Income

No income was recognized during 2023 or 2022.

## Note 14: Breakdown by nature of expenses and income

### 14.1 Research and development expenses

RESEARCH AND DEVELOPMENT EXPENSES (Amounts in thousands of EUR)	12/31/2023	12/31/2022
Studies and research	(9,622.8)	(6,984.3)
Intellectual property	(305.2)	(267.1)
Travel, assignments, entertainment and marketing expenses	(64.0)	(64.5)
Raw materials and consumables	(28.1)	(29.0)
Rental expenses	(46.6)	(41.5)
Professional fees	(146.3)	(178.5)
Payroll expense	(2,032.4)	(1,992.1)
Postal and telecom expenses	-	(57.6)
Amortization and depreciation	(186.7)	(157.9)
Share-based payment expense	(57.3)	(60.7)
Other	(2.7)	-
<b>Research and Development Expenses</b>	<b>(12,492.1)</b>	<b>(9,833.2)</b>
Research tax credits	555.9	1,316.4
Other subsidies	587.5	509.4
<b>Subsidies</b>	<b>1,143.4</b>	<b>1,825.8</b>

The "Other subsidies" relate:

- For 2023: to the BPIFrance debt waiver of € 140K (see Note 10.1), to the FOPH subsidy for €265K and to a European Union subsidy of € 182K for the HERVCOV research program, which is funded with a €6.8 million grant from the European Union under the HORIZON-HLTH-2021-DISEASE call (Personalised medicine and infectious disease: understanding the individual host response to viruses) of the European Commission under the Horizon Europe Framework Program. The Company's French subsidiary is the industrial R&D partner of the HERVCOV project and its share of the overall grant is estimated at less than 10% of the total grant;
- For 2022: to the FOPH subsidy for € 452K and to a European Union subsidy of € 57K for the HERVCOV research program.

The increase in 2023 in expenses for studies and research is primarily due to the Company's Phase 2 clinical trial in Post-COVID, leading to the completion of patient recruitment in November 2023, whereas this trial was only launched at the end of 2022 and the Company's prior Phase 2 trial of temelimab in multiple sclerosis (MS) at the Karolinska Institutet's Academic Specialist Center (ASC), in Stockholm, Sweden, was completed in the first half of 2022. Intellectual property costs increased by € 38K, reflecting the Company's patent filing activities; payroll expense increased by € 40K despite the full-year effect of new hires from 2022 in the Company's clinical operations, as the Group cancelled all cash bonuses for all employees and management

Subsidies under the form of research tax credits decreased from € 1,316K in 2022 to € 556K in 2023, as the bulk of the Group's clinical trial activities were conducted by the parent company in Switzerland.

## 14.2 General and administrative expenses

GENERAL AND ADMINISTRATIVE EXPENSES (Amounts in thousands of EUR)	12/31/2023	12/31/2022
Travel and assignments expenses	(199.1)	(146.2)
Office expenses	(40.4)	(36.7)
Rental expenses	(36.1)	(39.3)
Professional fees	(864.0)	(876.8)
Payroll expense	(1,482.2)	(1,702.3)
Tax expense	(1.5)	(12.7)
Insurance expense	(69.1)	(69.2)
Postal and telecom expenses	(29.5)	(27.4)
Amortization and depreciation	(107.1)	(130.6)
Share-based payment expense	(188.1)	(174.5)
Other	8.5	(6.1)
<b>General and administrative expenses</b>	<b>(3,008.6)</b>	<b>(3,221.8)</b>

The Company continued its cost control during 2023, with the payroll expense decrease of €220K being attributable to the cancellation of cash bonuses for all employees, offset by € 47K of the negative effect of the lower EUR rate vs. the Swiss franc, in which currency more than 90% of the General and Administrative payroll expense is incurred. Investor relations were continued at a lower pace during 2023, with travel and assignments expenses increasing by €53K but investor relations expenses (within professional fees) decreasing by € 171K. The remaining increase in professional fees is primarily attributable to higher legal fees. Share-based payment expense increased by € 13K as the Company increased stock option awards to executive management offsetting reduced cash executive management variable compensation.

### Note 15: Financial income (expenses), net

Net financial income (expenses) are broken down as follows:

FINANCIAL INCOME (EXPENSES), NET (Amounts in thousands of EUR)	31/12/2023	12/31/2022
Change in fair value of derivatives	806.9	-
Other financial income	75.9	7.6
<b>Financial income</b>	<b>882.8</b>	<b>7.6</b>
Share based expense related to capital increase at discount to market	-	(589.2)
Other financial expenses	(952.6)	(269.3)
Foreign exchange (losses) gains	(325.7)	(117.6)
<b>Financial expenses</b>	<b>(1,278.3)</b>	<b>(976.1)</b>
<b>Financial income (expenses), net</b>	<b>(395.5)</b>	<b>(968.5)</b>

In connection with drawdown of the first €7 million tranche from the EIB Credit Facility, the Company issued to the EIB a total of 642,031 share purchase warrants at an exercise price of €2.58 per share and an initial aggregate valuation of € 1,106K. Due to the decrease at December 31, 2023 of the Company's share price compared to the exercise price, these warrants were valued at December 31, 2023 at € 299K, leading to the above € 807K favorable change in fair value of the derivatives.

In 2022, the Company completed a capital increase which was not open to all existing shareholders but was restricted to certain selected institutional investors; accordingly, pursuant to IFRS 2 the discount between the share price prior to the capital increase and the actual issue price (€3.08 per share vs €2.86 per share) is considered a share based payment, resulting in a charge of € 589K for 2022, accounted within financial expenses, with a corresponding amount added to reserves within shareholders' equity.

Other financial expenses increased due to the drawdown of the first €7 million tranche from the EIB Credit Facility, which carries interest of 9% p.a. (of which 2% p.a. payable in cash and 7% p.a. to be capitalized until maturity).

## Note 16: Income tax

### Group income tax (expense) / income

INCOME TAX (EXPENSE) / INCOME (Amounts in thousands of EUR)	12/31/2023	12/31/2022
Deferred tax	-	-
<b>Income tax (expense)</b>	<b>-</b>	<b>-</b>

The amount of € 4.2K in tax expense shown in the income statement is a Swiss tax on capital and is therefore excluded from the tables above and below which relate to taxes on income.

#### Income tax rates and losses carried forward

Although the Group's functional currency is the euro, the parent company, GeNeuro SA, must establish its Swiss tax returns in CHF, converting the euro amounts in CHF at the 2023 average rate determined by the Swiss tax authorities, which is CHF 0.97165 per EUR for 2023. Accordingly, carried-forward tax losses are denominated in CHF and are converted for information purposes hereunder in euros at the average rate for 2023 determined by the Swiss tax authorities.

At December 31, 2023, taking into account the decision taken at the 2023 annual shareholders' meeting of GeNeuro SA to apply EUR 30 million of additional paid-in capital to carried-forward losses, GeNeuro SA had carried-forward tax losses of € 51,607 (CHF 50,394K converted at the 2023 average rate), compared with € 62,559 at December 31, 2022, split as follows:

€	9,610.2	originated in 2023 and expiring in 2031
€	9,673.4	originated in 2022 and expiring in 2030
€	7,783.8	originated in 2021 and expiring in 2029
€	10,827.7	originated in 2020 and expiring in 2028
€	4,318.9	originated in 2019 and expiring in 2027
€	5,478.8	originated in 2018 and expiring in 2026
€	3,913.8	originated in 2017 and expiring in 2025
€	nil	originated in 2016 and expiring in 2024

The income tax rate applicable to the Company is the rate currently applicable in the Canton of Geneva, Switzerland, which is 14% (14% in 2022).

GeNeuro Innovation SAS had carried forward tax losses of € 10,249K as at December 31, 2023. The income tax rate applicable to GeNeuro Innovation SAS is the French income tax rate of 25%.

### Reconciliation between theoretical tax and effective tax

(Amounts in thousands of EUR)	12/31/2023	12/31/2022
Net loss	(14,757.0)	(12,199.8)
Income tax expense	-	-
<b>Loss before tax</b>	<b>(14,757.0)</b>	<b>(12,199.8)</b>
Current tax rate in Geneva	14.00%	14.00%
<b>Theoretical income tax at current tax rate in Geneva</b>	<b>2,066.0</b>	<b>1,708.0</b>
Items not subject to tax	138.3	328.4
Share-based payments <sup>(1)</sup>	(36.7)	(117.5)
Carry forward tax losses used	-	-
Unrecognized tax losses	(2,786.5)	(2,131.7)
Effect of different tax rates	618.9	200.1
<b>Income tax (expense)</b>	<b>-</b>	<b>(12.7)</b>
<i>Effective tax rate</i>	<b>0.00%</b>	0.02%

(1) *Deferred tax asset is not recognized because it is not probable that future profits would arise that would allow the deferred tax asset to be recovered.*

Items not subject to tax include mainly research tax credits (non-taxable operating income in France).



## Nature of deferred taxes

NATURE OF DEFERRED TAX (Amounts in thousands of EUR)	12/31/2023	12/31/2022
Temporary differences	10.1	46.6
<i>Swiss defined benefit obligation</i>	115.4	14.9
<i>Other</i>	(105.3)	31.7
Loss carryforward France	2,562.2	1,022.0
Loss carryforward Switzerland	7,581.1	8,937.5
<b>Total of items with a nature of deferred tax assets</b>	<b>10,153.4</b>	10,006.1
Unrecognized deferred tax assets	(10,154.3)	(9,976.4)
<b>Net total of deferred tax assets</b>	<b>0.9</b>	29.8
Temporary differences	(0.9)	(29.8)
<b>Total of deferred tax liabilities</b>	<b>(0.9)</b>	(29.8)
<b>Net total of deferred tax assets (liabilities)</b>	<b>-</b>	-

Given the uncertainty related to the Company's ability to generate profits against which it would be able to apply the carried forward losses, management did not recognize any deferred tax assets on the Group's carried forward losses.

## Note 17: Losses per share

### Basic losses

"Basic losses per share" is calculated by dividing the net income attributable to the Company's shareholders by the weighted average number of ordinary shares issued during the financial year.

Diluted losses per share are calculated by adjusting basic losses per share for the dilutive effect of instruments giving deferred rights to share capital (warrants, bonds, options). When the Group is in a loss-making position, these instruments are not treated as dilutive since they would reduce the loss per share. For the periods reported, diluted losses per share are therefore identical to basic losses per share.

BASIC LOSS PER SHARE	12/31/2023 12 months	12/31/2022 12 months
Weighted average number of shares outstanding	24,843,355	23,898,317
Number of potentially dilutive shares from exercise of options <sup>(1)</sup>	-	-
Net loss for the period (in thousands of EUR)	(14,757.0)	(12,199.8)
<b>Basic loss per share (EUR/share)</b>	<b>(0.59)</b>	<b>(0.51)</b>
<b>Diluted loss per share (EUR/share)</b>	<b>(0.59)</b>	<b>(0.51)</b>

(1): there were no potentially dilutive shares from options outstanding at December 31, 2023; all 1,346,868 stock options, with a weighted average exercise price of €6.75 per share, and all 642,031 EIB warrants, with an exercise price of €2.58, were "out of the money". The shares resulting from the exercise of "in the money" options are not taken into account in the calculation of diluted loss per share as these shares would have an anti-dilutive effect and would decrease the loss per share.

The loss per share in 2022 includes € 0.02 per share of the share based expense of the capital increase of May 2022 (see notes 8 and 15).

## Note 18: Related parties

### 18.1 Compensation due to members of the Board and Officers

One executive officer of the Company is also a member of the Board of Directors. Aggregate compensation of the members of the Board and Officers was as follows:

<b>COMPENSATION DUE TO MEMBERS OF THE BOARD AND OFFICERS (Amounts in thousands of EUR)</b>	<b>12/31/2023</b>	<b>12/31/2022</b>
Fixed compensation due	1,164.9	1,153.7
Variable compensation due	36.8	247.8
Benefits in kind	38.1	36.6
Employer contribution to pension scheme and other social contributions	274.4	364.4
Share-based payments	240.0	222.3
Attendance fees	42.9	84.7
<b>TOTAL</b>	<b>1,797.1</b>	<b>2,109.5</b>

*Note : variable compensation due is paid in March of the following year.*

The above table includes compensation for executive officers who have left the Company during the respective periods.

The Company has signed contracts with three members of its Board of Directors; two of the contracts were entered into in 2015 and one in 2016. In accordance with these contracts and as compensation for services rendered, the Company recorded attendance fees of € 85K in 2022 and € 43K in 2023, as the three directors offered to waive half of their attendance fees.

No post-employment benefits were granted to members of the Board or Officers, with the exception of the mandatory and additional defined benefit scheme applicable for Swiss employees and executives under the second pillar of the Swiss social security system, as described in Note 2.19.

All compensation components were fully paid in the year, except for the share-based payments compensation, which is not due to be settled in cash, and the variable compensation which was paid in each case in the subsequent year. For 2023, no variable compensation will be paid in cash; the amount shown in the 2023 column above refers to the difference between the actual amounts paid out in March 2023 and the amounts accrued at December 31, 2022.

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 9.

### **18.2 Related party transaction with bioMérieux**

The Company signed an exclusive licensing contract with bioMérieux in 2006. BioMérieux is a French listed company, majority-owned by Institut Mérieux; bioMérieux and Institut Mérieux are the sole shareholders of GNEH SAS, which owns 39.08% of GeNeuro SA. The key elements of the licensing contract are disclosed in Note 19.2.

### **18.3 Related party transaction with GNEH SAS**

In May 2022 the Company completed a capital increase of €7.7 million through a private placement reserved to selected institutional investors, to which GNEH SAS participated to in the amount of €4.0 million. The difference to market price at which the private placement was completed led to the recognition of share-based payments in 2022 – refer to Note 15.

## **Note 19: Off-balance-sheet commitments**

### **19.1 Contingent liabilities and commitments in respect to the licensing Agreement with bioMérieux**

In 2006, the Company signed an exclusive license agreement with bioMérieux, France (the “2006 Agreement”), for the sole purpose of developing, manufacturing and selling products covered under bioMérieux patents, with bioMérieux retaining the rights pertaining to diagnostics.

This 2006 Agreement provides for payments in Swiss francs. Amounts in euros presented below are provided for information only, using the average foreign exchange rate of the related year.

Under this 2006 Agreement, the Company is committed to make the following payments:

- An up-front payment of CHF 150K, paid in 2006 (€ 138K);
- An annual contribution towards patent maintenance fees of CHF 50K (approximately € 51K);
- Milestone payments up to a total sum of CHF 72.6 million (approximately € 73.7 million):
  - On commencement of the Phase IIa clinical trial in 2012, the first milestone was reached, triggering a payment by the Company of CHF 200K (€ 185K);
  - The start of the Phase IIb clinical trial in 2016 triggered a payment by the Company of CHF 1,000K (€ 925K).

- The start of a Phase IIa clinical trial in Type 1 diabetes triggered a contingent payment of CHF 200K (approximately € 203K), to be paid only if certain conditions (such as entering a Phase III clinical trial, or being sub-licensed for that indication) are met.
- Royalties based on GeNeuro net licensing revenues and GeNeuro net sales.

In 2015, pursuant to an exclusive license agreement on companion diagnostics (the “Diagnostics Agreement”), bioMérieux also granted an exclusive license on companion diagnostics. This Diagnostics Agreement commits the Company to make milestone payments of up to € 100K.

On the commencement of the Phase IIb clinical trial in 2016, a first milestone was reached, triggering an amount of € 50K paid by the Group to bioMérieux. The balance of € 50K will be due in the event of the start of a Phase III trial. No royalties are due to bioMérieux under the Diagnostics Agreement.

### **19.2 Contingent liabilities and commitments in respect to the licensing Agreement with the US National Institutes of Health (NIH).**

In October 2018, the Company has entered into an Exclusive License Agreement with the National Institute of Neurological Disorders and Stroke (NINDS), part of the U.S. National Institutes of Health (NIH). The agreement covers the development of an antibody program to block the activity of pHERV-K Env (pathogenic envelope protein of the HERV-K family of Human Endogenous Retroviruses), a potential key factor in the development of ALS. Pursuant to this agreement, the Company made an up-front payment of USD 50K (€ 44K), and is committed to annual minimum payments of USD 25K (approximately € 23K) and milestone payments up to a total sum of USD 11.6 million (approximately € 10.9 million) subject to clinical development achievements; in addition, GeNeuro will have to pay the NIH royalties based on its net licensing revenues and net sales.

### **19.3 Contingent liabilities and commitments in respect to the EIB Venture Debt Loan Agreement**

In connection with the drawdown of Tranche A of the EIB Venture Debt Loan, the Company issued to the EIB 642,031 share purchase warrants representing 2.4% of GeNeuro SA's diluted share capital. Each warrant entitles the EIB to acquire one common share of the Company in exchange for the exercise price of €2.58 per share; the warrants are exercisable at any time after March 2028 and until their expiration date in March 2030. The EIB holds a put option, as soon as the warrants become exercisable, to request GeNeuro SA to repurchase all or part of the exercisable but not yet exercised warrants at their intrinsic value (within the limit of a ceiling equal to the amount drawn under the credit facility). Because the warrants are not yet exercisable and because the exercise price of €2.58 is significantly above the €1.09 December 31, 2023, closing price for GeNeuro shares, the Company has not recognized this put option contingent liability.

## **Note 20: Financial risk management and assessment**

GeNeuro may find itself exposed to various types of financial risk: market risk, liquidity risk and credit risk. GeNeuro is implementing measures consistent with the size of the Group to minimize the potentially adverse effects of those risks on its financial performance.

GeNeuro's policy prohibits the use of financial instruments for speculative purposes.

### **Market risk**

#### Interest rate risk

Interest rate risk reflects the Group's exposure to fluctuations in interest rates in the market. As the Group has no floating-rate debt, the Group is not at risk of increases in debt servicing costs (refer to Note 10 for extent and nature of fixed rate debt obligations). Changes in interest rate could affect returns achieved on cash and fixed term deposits but this risk is not considered material given the current low returns on deposits held by the Group.

#### Foreign exchange risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Group's exposure to the risk of changes in foreign exchange rates relates primarily to the Group's operating activities in Switzerland (when expense is denominated in a different currency from the Group's presentation currency).

No currency derivatives were outstanding at December 31, 2023.

Any major development in the Group activity may result in an increase of its exposure to exchange rate risk. Should such increase materialize, the Group would consider adopting an appropriate policy to hedge such risks.

### Equity risk

The Company does not hold long or short-term tradable equities on any regulated market.

### Liquidity risk

Since its incorporation, the Group has primarily funded its growth through capital increase and additional funds provided by research collaborations. Since 2022, the Group has also had recourse to bank loans, including the EIB Venture Debt credit facility entered into in 2023. As a result, the Group is now exposed to liquidity risk through requests for early repayment of loans.

Significant R&D expenses have been incurred from the start of the Group's activities, generating negative cash flows from operating activities.

As at December 31, 2023, the Group's cash & cash equivalents amounted to € 1,827 K (December 31, 2022: € 5,593 K). In addition, in January 2024 the Group received € 990K from a bank pre-financing of its 2022 French Research Tax Credit, and completed in February 2024 a €5 million capital increase.

Refer to Note 2 "Material uncertainty and ability to continue as a going concern" of the Notes to the financial statements.

### Breakdown of financial liabilities, trade payable and other current liabilities by maturity

The following table shows the breakdown of financial liabilities, trade payable and other current liabilities in the period presented:

Contractual maturities of financial liabilities at 31 December 2023 (Amounts in thousands of EUR)				Total contractual cash flows	Carrying amount of liabilities
	< 1 year	1 ≥ 5 years	> 5 years		
Amounts due under lease contracts	305.8	503.4	-	809.2	796.4
EIB loan	140.0	8,307.4	-	8,447.4	6,430.0
Derivative instruments of EIB loan contract	-	299.4	-	299.4	299.4
FOPH Covid-19 Contract	-	5,809.4	-	5,809.4	5,629.6
SG Loan	349.2	174.6	-	523.8	511.4
<b>Sub-total</b>	<b>795.0</b>	<b>15,094.2</b>	<b>-</b>	<b>15,889.2</b>	<b>13,666.8</b>
Trade payables	2,459.6	-	-	2,459.6	2,459.6
Other current liabilities	3,042.6	-	-	3,042.6	3,042.6
<b>Sub-total</b>	<b>5,502.2</b>	<b>-</b>	<b>-</b>	<b>5,502.2</b>	<b>5,502.2</b>
<b>Total</b>	<b>6,297.2</b>	<b>15,094.2</b>	<b>-</b>	<b>21,391.4</b>	<b>19,169.0</b>

(Amounts in thousands of EUR)	12/31/2022			
	Gross amount	< 1 year	1 ≥ 5 years	> 5 years
Reimbursable advance	140.0	-	140.0	-
Amounts due under lease contracts	1,003.3	271.3	732.0	-
FOPH Covid-19 Contract	5,463.1	-	5,463.1	-
Bank Loan	839.6	328.2	511.4	-
<b>Sub-total</b>	<b>7,446.0</b>	<b>599.5</b>	<b>6,846.5</b>	<b>-</b>
<i>Discounted interest on reimbursable advance</i>	<i>(0.9)</i>			
<i>Interest component of lease contracts</i>	<i>(19.6)</i>			
<i>Discounted interest on FOPH Covid-19 contract</i>	<i>(326.8)</i>			
<b>Net financial liabilities</b>	<b>7,098.7</b>			
<i>Current financial liabilities</i>	<i>601.8</i>			
<i>Non-current financial liabilities</i>	<i>6,517.9</i>			
<b>Trade payables</b>	<b>764.8</b>	<b>764.8</b>	-	-
<b>Other current liabilities</b>	<b>1,942.5</b>	<b>1,942.5</b>	-	-

The Group will continue to have major funding requirements in the future to fuel its strategy to develop temelimab and new compounds through clinical trials. The precise extent of funding required is difficult to predict accurately and will largely depend in part on factors outside the Group's control.

Areas subject to significant uncertainty include but are not limited to:

- the ability to conduct successful clinical trials in multiple sclerosis, type 1 diabetes and other indications, including the capacity to recruit in a timely manner patients for those studies,
- the change in the regulatory landscape,
- the approval for other drugs on the market that would potentially reduce the attractiveness for the approach developed by GeNeuro.

Should the Group find itself unable to finance its own growth through partnership agreements, the Group would be dependent on other sources of financing, including equity funding or research grants. See also Note 22.

### Credit risk

The Group's credit risk is associated with deposits at banks and financial institutions and with other receivables. The Group seeks to minimize the risk related to banks and financial institutions by placing cash deposits with highly rated financial institutions. The maximum amount of credit risk is the carrying amount of the financial assets. As outstanding receivables include mainly research tax credits granted by France and amounts to be received from the Swiss government under the FOPH Subsidy Contract, the Group does not carry significant credit risk.

Cash balances held at December 31, 2023	Short-term credit rating of financial institution		
	% of cash balances	Standard & Poors	Moody's
Bank 1	59.0%	A-1	P-1
Bank 2	41.0%	A-1+	n.a.
Total	100.0%		

### Note 21: Auditors' fees

Audit fees due by the Group to its auditors, PricewaterhouseCoopers SA, were the following:

Audit fees (Amounts in thousands of EUR)	2023 Financial Year	2022 Financial Year
Audit Fees	259.3	250.8
Assurance services related to share issuance	-	69.2

### Note 22: Post balance sheet events

On 2 February 2024, the Company announced that it had completed a €5 million capital increase through an international private placement reserved for specialized or strategic investors of 4,666,901 new ordinary bearer shares and through a public offering for retail investors in France via the PrimaryBid platform of 95,004 new ordinary bearer shares.

On March 18, 2024, the Company held an extraordinary shareholders' meeting that approved a new capital band with an upper limit of CHF 2,232,069.95 through the issuance of new, fully paid-up bearer shares (Capital Band).

## **CHAPTER 19.** **ADDITIONAL INFORMATION**

### **19.1 Equity Capital**

#### **19.1.1 Amount of the Equity Capital**

Following the February 2, 2024, capital increase, the Company's equity capital is CHF 1,488,046.65 divided into 29,760,933 bearer shares, each with a nominal value CHF 0.05, all fully paid.

#### **19.1.2 Securities Not Representing Equity**

None.

#### **19.1.3 Buy-back by the Company of its Own Shares**

Since May 4, 2016, the Company has entered into a liquidity contract with Gilbert Dupont, a Paris based investment services provider. The main purposes of a liquidity contract on shares, where implemented pursuant to the accepted market practice established by the French Financial Markets Authority (Autorité des marchés financiers - the "AMF"), are to improve liquidity of share transactions and regularity daily traded prices of the Company's shares and thus to avoid price swings that would not be justified by the market trend.

During the 2023 financial year, through the liquidity contract the Company purchased 184,656 (2022: 193,990 ) GeNeuro common shares (of CHF 0.05 nominal value) and sold 177,589 (2022: 162,341 ) GeNeuro common shares (of CHF 0.05 nominal value), at an average weighted purchase price of €1.69 per share (2022: €2.54) and an average weighted sale price of €1.75 per share (2022: €2.61 ).

At December 31, 2023, the Company held, through the liquidity contract, 118,739 (December 31, 2022: 111,672 ) GeNeuro common shares (i.e., 0.475% of its equity at December 31, 2023; 2022: 0.447%).

On December 31, 2023, the Company owned 164,739 (December 31, 2022: 157,672 ) of its own shares, including shares owned through the liquidity contract and other treasury shares.

Under Swiss law, a company may acquire its own shares only if it has free equity available to it equivalent to the amount of the expense necessary to acquire the shares and if the nominal value (paid-in capital) of all such shares does not exceed 10% of the equity capital.

Voting rights related to treasury shares and the rights attaching to them are suspended as long as the Company owns or holds the shares. In addition, the Company must credit to a special reserve (a reserve for treasury shares) an amount equal to the acquisition value of the treasury shares. This reserve may be reduced only to the extent of the acquisition value of the treasury shares if the shares are sold or cancelled.

Furthermore, when the Company holds or owns a majority stake in a subsidiary, acquisition of the Company's shares by such subsidiary is subject to the same limitations and the same consequences as acquisition by the Company of its own shares.

The Company's Board of Directors has the authority to implement a program to buy back the Company's shares subject to Swiss law, applicable EU regulations, the accepted market practice established by the AMF and the General Rules and Regulations of the AMF.

#### **19.1.4 Conditional Equity Capital**

The Company's share capital may be increased by a maximum amount of 4,464,139 shares, equivalent to 15% of the existing share capital, through the exercise of options granted (and to be granted) to the Company's managers, employees, and consultants, as based on rules approved by the Board of Directors. The shareholders' pre-emptive rights do not apply to the new shares issued.

In this connection, the Company's Board of Directors, approved various incentive plans for management and employees, as follows:

- Stock options with an exercise price of €13 per share : these include options under a Performance Share Option Units (PSOU) Plan, for the Company's top management, which matured on December 31, 2018; on February 27, 2019, the Board of Directors reviewed the service condition and the achievement of the performance condition and made a final determination as to the number of options to be granted; as a result, the total of 676,400 PSOU's granted were replaced by a total of 672,235 stock options, with an exercise price of €13 per share and a term of 5 years. The Board also approved an incentive plan for stock options on February 23, 2017, when it granted 7,500 stock options to certain executive managers; on February 4, 2018, it also granted 22,500 stock options to executive managers. All these options have a

- term of five years from award date; the options under the PSOU Plan are fully vested whereas the others vest over four years (25% after one year, then 12.% every six months).
- Stock options with an exercise price of €2.73 per share: on July 4, 2018, the Board of Directors approved a Loyalty Bonus Option Plan and on February 27, 2019 made the final determination under this plan and granted a total of 158,540 to the Group's employees; these Loyalty Bonus Options have a 10-year term and vest over four years (25% after one year, then 12.% every six months).
  - Stock options with an exercise price of €3.34 per share: on March 5, 2020, the Board of Directors approved a new Option Plan and granted a total of 75,750 to management and certain employees; these options have a 10-year term and vest over four years (25% after one year, then 12.5% every six months).
  - Stock options with an exercise price of €2.95 per share: on December 11, 2020, the Board of Directors granted a total of 15,000 to certain managers; these options have a 10-year term and vest over four years (25% after one year, then 12.5% every six months).
  - Stock options with an exercise price of €3.19 per share: on February 25, 2021, the Board of Directors approved a new Option Plan and granted a total of 184,800 to management and certain employees; these options have a 10-year term and vest over four years (25% after one year, then 12.5% every six months). Following forfeiture of certain options following the departure of employees, a total of 178,000 was outstanding at December 31, 2021.
  - Stock options with an exercise price of €3.48 per share: on March 18, 2022, the Board of Directors approved a new Option Plan and granted a total of 203,627 to management and certain employees; these options have a 10-year term and vest over four years (25% after one year, then 12.5% every six months).
  - Stock options with an exercise price of €2.86 per share: on March 20, 2023, the Board of Directors approved a new Option Plan and granted a total of 237,694 to management; these options have a 10-year term and vest over four years (25% after one year, then 12.5% every six months).
  - Stock options with an exercise price of €1.17, respectively €2.04, per share: on March 14, 2024, the Board of Directors approved a new Option Plan and granted a total of 440,000 stock options to employees and 1,445,118 stock options to directors and executive management; these options have a 2-year term and are fully vested.

Furthermore, the share capital of the Company may also be increased by a maximum amount of 10,416,326 shares equivalent to 35% of the existing share capital by exercising options and conversion rights attaching to the issuance of debt securities or similar securities of the Company or other financial instruments by the Company, as defined in Swiss law. The preferential subscription rights will not apply to the shares so issued. In connection with the Company's drawdown of Tranche A under the EIB Financing, the Company issued 642,031 warrants to the EIB, each warrant entitling to subscribe to one new share of GeNeuro at an exercise price of €2.5833 initially, adjusted to €2.17 per share following the February 2024 capital increase pursuant to certain anti-dilution provisions.

In the case of debt securities or other similar securities, the preferential subscription right of shareholders may be restricted or eliminated by the Board of Directors, if the issuance is made with a view to financing an acquisition of companies, parts of companies, or equity stakes.

In the event of the elimination of preferential subscription rights, debt securities and similar securities or any other financial instrument will be offered at market conditions. The exercise date for options may not be later than five years from the issue date and for conversion rights 10 years from the issuance of debt or similar securities. The exercise price for the acquisition of new shares will correspond to the market price on the date of issuance.

### **19.1.5** Securities Convertible into Equity Capital

On the filing date of this Universal Registration Document, the securities and other instruments still outstanding and carrying a right to be converted into equity capital consisted of stock options granted to certain executives and consultants of the Company (such options are described in detail in Section 13.1.3, "Stock Options and Grants of Free Shares" of this Universal Registration Document) as well as of the EIB Tranche A stock options described above. In the event of the full exercise of the instruments carrying a right to equity capital granted and issued on this day, this would lead to the issuance and subscription of 3,380,323 shares, resulting in a dilution of 10.2% based on the existing number of shares of the Company on the filing date of this Universal Registration Document.

### **19.1.6** Authorized but Unissued Shares, Undertakings to Increase Equity Capital

Under Swiss law and pursuant to the resolutions of the extraordinary shareholders' meeting of March 18, 2024 approving a new Capital Band, the Board of Directors was authorized to increase the Company's equity securities by a maximum of 50% to CHF 2,232,069.95. The Board of Directors may implement this capital increase entirely or in installments. This authorization, which is recorded in the Company's articles of incorporation, as amended, lapses on March 18, 2029.

Under Swiss law, in the case of a capital band, the Board of Directors determines freely the issue price, the types of capital contributions, and the date from and after which the new shares will have dividend rights as well as other terms and conditions of the share issue that are not reserved to the shareholders.

The Board of Directors decides on the allocation of the preferential subscription rights of shareholders that are not exercised. However, the Board of Directors may eliminate or limit the preferential subscription right only:

- for warrants granted in the usual way to financial institutions that are firm acquirers involved with the Company's IPO (firm underwriting) (overallotment option);
- to acquire companies, parts of companies, and equity stakes; or
- to place new shares on international capital markets by a public offering or private placement with institutional investors at the price that results from book-building.

### 19.1.7 Equity Capital of Any Group Company Subject to an Option or Conditional or Unconditional Agreement Placing it Under Option

The Company has granted options or warrants to various executive officers and employees that give them the right to acquire the Company's shares. Such options are described in detail in Section 13.1.3 of this Universal Registration Document. In addition, the Company has granted warrants to the EIB as described in Section 19.1.5 of this Universal Registration Document.

### 19.1.8 Changes to Equity Capital

The Company was registered at the commercial register of Geneva, Switzerland on February 6, 2006, with an initial equity capital of CHF 100,000, fully paid up.

The equity capital was thereafter increased, on several occasions, the last time on February 2, 2024, to reach CHF 1,488,046.65 as of the filing date of this Universal Registration Document.

Other than the capital increase described under section 8.1.1 of this Universal Registration Document, there was no change to the Equity Capital in 2023 or until the filing date of this Universal Registration Document.

### 19.1.9 Pledges

The Company is not aware of any pledge on its share capital.

## 19.2 Articles Of Association

Amended provisions of Swiss Company law have entered into force on 1 January 2023, pursuant to which companies were granted a transition period of two years to amend their articles of association.

In accordance with the new provisions, the Board of Directors submitted to its 14 June 2023 annual general meeting of shareholders a proposal to partially amend the Articles of Association of GeNeuro SA, in order to implement most of the provisions of the new Swiss Company law. A more in-depth amendment of the Articles of Association will be organized at a later stage. The change related to the new "Capital Band" is disclosed in **Erreur ! Source du renvoi introuvable.** above.

As a result, the following Articles of Association were amended:

### 19.2.1 Inalienable powers of the General Meeting (Art. 9, amended)

The General Meeting has the inalienable and non-transferable right:

1. to adopt and amend the articles of association;
2. to appoint and dismiss the members of the Board of Directors, the Chairman of the Board of Directors, the members of the Compensation Committee, the Independent Proxy and the auditors, and, where required by law, the auditors of the consolidated financial statements;
3. to approve the annual accounts, the annual report and the consolidated financial statements;
4. to decide on the appropriation of available earnings, in particular with regard to dividends and the shares of profits paid to board members;
5. to determine the interim dividend and approve the interim financial statements required therefor;
6. to decide on the repaying the statutory capital reserves;
7. to grant discharge the members of the board of directors;
8. to delist the shares of the company;
9. to approve the compensation of the Board of Directors, the Management and the advisory board;
10. to pass resolutions concerning matters reserved to the general meeting by law or the articles of association.



### **19.2.2 Venue (Art. 12bis, new)**

The Board of Directors shall decide on the venue for the General Meeting. The choice of the venue shall not, for any shareholder, result in an unduly burdensome exercise of their rights at the General Meeting.

The General Meeting may be held in various locations at the same time. In such case, the oral contributions of participants must be transmitted directly by audiovisual means to all venues. The General Meeting may be held abroad if the Board of Directors designates an Independent Proxy in the convening notice.

### **19.2.3 Use of electronic means (Art. 12ter, new)**

The Board of Directors may provide that shareholders who are not present at the venue for the General Meeting can exercise their voting rights electronically. A General Meeting may be held with no venue by electronic means if the Board of Directors designates an Independent Proxy in the convening notice.

The Board of Directors shall regulate the use of electronic means and ensure that:

1. the identity of the participants is established;
2. the oral contributions at the General Meeting are directly transmitted;
3. each participant can table motions and participate to the debate;
4. the result of the vote cannot be falsified.

If the General Meeting cannot be duly conducted because of technical problems, the meeting must be reconvened, it being specified that the resolutions that the General Meeting has approved before the technical problems arose remain valid.

### **19.2.4 Representation (Art. 15 para. 1, amended)**

A shareholder may have their shares represented by a third-party representative, by means of a written proxy.

### **19.2.5 Independent proxy (Art. 16, new para. 4, current para. 4 amended and becomes para. 5)**

para. 4: The Independent Proxy shall treat the instructions from individual shareholders as confidential until the general meeting. They may provide the company with general information on the instructions received. They shall not provide information earlier than three working days before the General Meeting and must disclose to the General Meeting which information they have provided to the company.

para. 5: The representation of shareholders by another shareholder, a member of a corporate body or by a depositary is prohibited.

### **19.2.6 Resolutions of the General Meeting (Art. 19 para. 1 and 2, amended)**

Para. 1: If the law or the articles of association do not provide otherwise, the General Meeting takes its decisions and proceeds to the elections by a majority of the votes attributed to the shares represented. If a second ballot is necessary, a relative majority is sufficient.

Para. 2: However, a resolution by the General Meeting requires at least two-thirds of the votes represented and a majority of the nominal value of shares represented for each of the following:

1. any amendment of the company's purpose or corporate form;
2. the consolidation of shares, unless the consent of all concerned shareholders is required;
3. a capital increase from equity capital, against a contribution in kind or by offset with a claim, and the granting of special privileges;
4. the restriction or withdrawal of preferential subscription right;
5. the introduction of contingent capital, the introduction of a capital band;
6. the conversion of participation certificates into shares;
7. any restriction on the transferability of registered shares;
8. the introduction of shares with preferential voting rights;
9. any change in the currency of the share capital;
10. the introduction of a casting vote for the person chairing the General Meeting;
11. the introduction of a statutory provision on the holding of General Meetings abroad;
12. the delisting of the shares of the company;
13. the relocation of the seat of the company;
14. the introduction of an arbitration clause in the articles of association;

15. the waiver on the designation of an Independent Proxy for a virtual General Meeting (in the case the company's shares are no longer listed);
16. the dissolution of the company.

#### **19.2.7 Minutes, resolution by written or electronic approval of the Board of Directors (Art. 25 para. 3, amended)**

Resolutions of the Board of Directors may also be taken in form of a written approval to a proposal or in electronic form unless a discussion is requested by one of its members. Such resolutions must be recorded in the minutes of the next meeting.

#### **19.2.8 Company Purposes (Article 3 of the Articles of Association)**

The Company's principal purpose is the research, development, manufacture, and sale of products used, in particular, for therapeutic purposes, especially in the field of healthcare.

The Company may engage in any activity linked, directly or indirectly, to its company purpose or that could promote it.

#### **19.2.9 Management and Administration of the Company**

The Company is managed and administered by a Board of Directors.

##### **19.2.9.1 Board of Directors (Section 4 of the Articles of Association)**

The Company is managed and administered by a Board of Directors consisting of a minimum of five directors and up to 10 directors elected individually at a general shareholders' meeting.

The Swiss Code of Obligations does not allow legal entities to act or serve as members of the Board of Directors, but legal entity's representatives are eligible in its place and stead.

The Board of Directors includes a chairman, and may include a vice chairman and a secretary, who may but need not be members of the Board. If applicable, the vice chairman and secretary are appointed by the Board of Directors.

The Directors' term of office is one year. The term of office of a Director ends at the end of the next ordinary general shareholders' meeting considering and voting on the financial statements for the year just ended.

Directors are eligible for re-election; they may be removed at any time by action taken at a general shareholders' meeting.

The Chairman of the Board of Directors is elected at a general shareholders' meeting.

The term of his/her responsibilities as Chairman is one year. The Chairman's term of office ends at the end of the next ordinary general shareholders' meeting considering and voting on the financial statements for the year just ended.

The Chairman is eligible for re-election; he/she may be removed at any time by action taken at a general shareholders' meeting.

In the event of a vacancy during a term of office, the Chairman shall be appointed by the Board of Directors.

Subject to the responsibilities of the committees and the management delegation set forth in the Company's internal organizational rules and procedures, the Chairman manages and directs the work of the Board of Directors on which he/she reports at a general shareholders' meeting. She/he is responsible for the operation of the Company's management bodies and, in particular, ensures that the Directors are able to perform their responsibilities.

Together with management, the Chairman shall transmit to the Board of Directors, on a timely basis, information on all aspects of the Company that could influence its decisions, actions, and supervision.

The Board of Directors meets as often as the Company's business and affairs require, but at least four times a year.

Meetings of the Board of Directors are called by the Chairman in writing (letter, fax, email, or any other similar notice). If the Chairman is unable to act, meetings of the Board of Directors may also be called by the Vice Chairman.

Each member of the Board of Directors may ask the Chairman at any time to call a meeting of the Board of Directors to consider and act on a special agenda or ask that certain items be placed on the agenda sent with the notice.

Notices of meetings are to be sent upon 10 days' prior notice. In the event of an emergency, the Chairman may set a shorter period. The notice of meeting will contain the agenda items as well as the documents necessary for the Board of Directors to transact business, presented clearly and concisely. If it is not possible to provide the documents before the meeting, the Chairman is to give members of the Board of Directors sufficient time to familiarize themselves therewith before beginning the meeting.

As a general matter, persons responsible for an agenda item are to be present at the meeting. It should be possible to contact persons who are indispensable for answering questions and in a position to provide a better

understanding of various points. The Chairman may invite members of management, employees, or third parties to take part in meetings of the Board of Directors for all, or any part, of the agenda.

For important matters, the Board of Directors may consult independent outside experts at the Company's expense.

Decisions by the Board of Directors may be taken at a meeting, telephonic conference, videoconference, or any other means allowing for a discussion.

If the Board of Directors has several members, its actions are to be taken at a meeting by a majority of the votes cast by the members present; provided, however, that they represent a majority of the Board (quorum).

Decisions of the Board of Directors may also be taken by a majority vote of members of the Board of Directors in the form of a written consent (by letter, fax, or email) to a proposal by the Chairman, as long as the proposal is submitted to all members, and none of them requests a discussion.

In the event of a tie vote, the Chairman's vote shall prevail.

Actions relating to formalities linked to capital increases, future payments of paid-in capital, or an issuance of coupons may also be taken by a single Director, and no quorum will be necessary.

Minutes of the deliberations and discussions of the Board of Directors are to be prepared, even when only a single Director takes part, and must be signed by the Chairman and the secretary of the meeting. The minutes must list the members present. The Chairman shall be responsible for the content and retention of Board minutes.

Each member of the Board of Directors has the right to obtain information about the Company's business and affairs. During meetings, each Board member may ask for information from the other members, as well as from members of management. Outside of meetings, Directors are to send their requests for information to the Chairman.

The Board of Directors may take decisions on any and all matters not reserved by law or the Articles of Association to shareholders at a general meeting and manage the Company's business and affairs to the extent there has been no delegation to management.

The Board of Directors represents the Company vis-à-vis third parties. The Board of Directors may give signature authority to its members, on a case-by-case basis, by registration with the commercial register. To the extent a Director is a member of management, management's internal rules will determine his/her authority.

The Board of Directors has the following nontransferable and inalienable attributions:

- i. exercising the highest-level management of the Company and issuing necessary instructions, especially for determining the Company's strategy and general resources for achieving it, the ultimate supervision of management and of the persons to whom it is delegated, decisions to develop, terminate, acquire or sell strategic activities, and the initiation of and withdrawal from strategically important litigation;
- ii. setting the basic principles in respect of the organization of the Company's administration and management;
- iii. appoint and remove the persons responsible for management and representation;
- iv. setting the compensation of the Directors and management, particularly the compensation strategy and structure of the compensation of Directors and management within the framework provided by law and regulations and the Articles of Association, by guidelines relating to the workplace pensions of members of the Board of Directors and management, and by proposals at the general shareholders' meeting to consider and act on approving the total compensation of the Board of Directors and management, setting the individual compensation of the Directors and members of management and preparing a report on compensation to be submitted to a general meeting of shareholders;
- v. creating a system for identifying and handling risks and internal controls in compliance with law and the Articles of Association;
- vi. setting the principles applicable to bookkeeping and accounting, financial controls, and the strategic financing plan, especially the establishment of the accounting principles, and determination of the accounting reference, and the establishment of an appropriate system of financial planning, including, especially, the annual budget;
- vii. preparing the management report for the shareholders at an ordinary general meeting including approval of the financial statements);
- viii. exercising the highest-level supervision of persons responsible for management to ensure, among other things, compliance with law, the Articles of Association, rules, regulations, and instructions given;
- ix. calling and giving notice of general shareholders' meetings and preparing proposals by the Board of Directors;
- x. carrying out decisions approved at general shareholders' meetings taken in compliance with law and the Articles of Association;
- xi. adopting the rules relating to the Company's communications and public relations strategy; and
- xii. informing a court in the event of over-indebtedness.

In addition, the Board of Directors is responsible for ensuring that appropriate measures (such as embargoes or black-out periods) are taken for purchases and sales of the Company's shares or relevant rights at critical moments, such as in connection with an acquisition proposal or prior to a press conference or disclosure of the Group's results (please see the rules and regulations relating to the obligations of Directors linked to the listing of the Company).

Each year the Board of Directors will report on its activity, on the activity of its committees, and on the principles applicable to the organization and delegation of management. On that occasion it will review the relevance of the Board of Directors' organizational rules and procedures and other rules and regulations that it has issued and, if appropriate, adapt them to new requirements.

### 19.2.9.2 Management<sup>66</sup>

The Company's executive management consists of the following, appointed by the Board of Directors:

- Chief Executive Officer (CEO) ("Directeur Général");
- Chief Financial Officer (CFO) ("Directeur financier");
- Chief Medical Officer (CMO) ("Directeur en charge des affaires médicales");
- Chief Scientific Officer (CSO) ("Directeur en charge des affaires scientifiques");
- Chief Development Officer (CDO) ("Directeur en charge du développement").

Subject to any management roles attributed to members of the Company's Board of Directors, management of the Company is entirely delegated to management. Management, moreover, assists the Board of Directors in discharging its responsibilities and, to the extent provided by law and the Articles of Association, carries out the decisions taken by the Board of Directors.

Management's authority is limited by the allocation of roles and responsibilities approved by the Board of Directors (approval requirements, consultation, or prior information of the Board of Directors, its Chairman or the chairs of various committees) or by any ad hoc action or decision of the Board of Directors reserving the right to grant prior approval.

Management may sub-delegate authority to its members or to others in accordance with an organization chart that establishes the principles and limits of the sub-delegation.

The CEO reports to the Board of Directors, while the other members of management report to the CEO or the COO. Management provides appropriate periodic and special reports on events. Management provides the Board of Directors each month with a brief report which contains key numbers that make it possible for the Board of Directors to monitor the evolution of the business, its affairs, and changes in the cash position.

Members of management may represent the Company vis-à-vis third parties and are registered at the commercial register, with signing authority requiring two signatures — those of the CEO and CFO.

### 19.2.10 Rights, Privileges, Restrictions and Obligations Attaching to the Shares (Articles 5, 7, and 14 of the Articles of Association)

The Company's shares are in bearer form. Each share is indivisible vis-à-vis the Company, which recognizes only one owner for each share. Since November 1, 2019, pursuant to the Federal Act on Implementation of Recommendations of Global Forum on Transparency and Exchange of Information for Tax Purposes and to the related Guidance, bearer shares are only allowed for Swiss companies if the issuing company has securities that are listed on a stock exchange (and in the case of a foreign stock exchange, that this exchange is subject to principles of transparency that are equivalent to those provided for under Swiss law) or if they are intermediated securities pursuant to the Swiss federal law of 3 October 2008 on intermediated securities and deposited with a Swiss depository. The Company has provided the required evidence that (i) its shares are listed on Euronext Paris and (ii) that Euronext Paris is subject to principles of transparency that are equivalent to those provided for under Swiss law, and is therefore allowed to continue having bearer shares. So long as GeNeuro's bearer shares remain listed on Euronext Paris or another stock exchange and, in the case of listing on a non-Swiss stock exchange, as long as the Company can demonstrate that this foreign stock exchange is regulated by principles of transparency that are equivalent to those of Swiss law, there will be no requirement to change their form to registered shares.

All the Company's shareholders shall have voting rights proportional to the nominal value of all the shares belonging to them.

Each shareholder has the right to at least one vote, even if the shareholder has only one share.

Distribution of earnings under the Articles of Association (Article 7 of the Articles of Association)

Each shareholder shall have the right to a portion of the earnings reflected on the balance sheet in proportion to contributions to equity capital.

Any dividend that has not been claimed within five years of its availability is time-barred automatically and by operation of law ("de plein droit") in favor of the Company.

#### 19.2.10.1 Form of securities issued by the Company (Article 6 of the Articles of Association)

Shares shall be dematerialized and issued in the form of value rights ("droits-valeurs"). The value rights of the shareholders will be recorded in the principal registry and the rights corresponding thereto will be recorded to

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<sup>66</sup> This description of the role and authority of the Company's management, which is provided for information in this Section 19.2.2.2, is not a summary of the Articles of Association of the Company which do govern such role or authority.

securities accounts with banks. The Company's shares held as indirectly held securities may be transferred or pledged or put into beneficial ownership ("remises en usufruit") by notice in accordance with the terms and conditions provided under applicable Swiss federal law.

#### 19.2.10.2 Preferential subscription right

The Company's shareholders shall have a preferential right to subscribe for capital increases on the terms and conditions provided by the Swiss Code of Obligations and the Articles of Association.

As provided for under the Swiss Code of Obligations and Article 5b of the Company's Articles of Association (see also Section 19.1.6), the Board of Directors may limit or cancel the shareholders' preferential subscription rights:

- In the case of over-allotment options granted in the usual course of business to banks in the context of a public share issue;
- In the case of shares issued during acquisitions of firms or parts of other firms;
- In the case of the issuance of new shares on international equity markets through a bookbuilding process with institutional shareholders.

#### 19.2.10.3 Limitations on voting rights

No provision of the Articles of Association will restrict the right to vote attaching to shares.

#### 19.2.10.4 Changes to Shareholder Voting Rights

Shareholders' rights as set forth in the Company's Articles of Association may be changed or amended only at a general shareholders' meeting.

### **19.2.11 General Shareholder Meetings (Section 3 of the Articles of Association)**

General shareholders' meetings shall include all shareholders regardless of the number of shares the shareholder owns or possesses.

Ordinary general shareholders' meetings are held in principle each year within six months following the end of the financial year. An extraordinary general meeting may be held as often as necessary.

#### 19.2.11.1 Notices of meetings and holding of general shareholders' meetings (Articles 11 seq. of the Articles of Association)

Notice of meetings for a general shareholders' meeting ("GSM") is given by the Board of Directors or, if needed, by the statutory auditors, liquidators, or representative of debt securities.

One or more shareholders representing together at least a tenth of the equity capital may require that a GSM be called or that an item be put onto the agenda. The notice of meeting and inclusion of an item on the agenda must be requested in writing, indicating the subjects of the discussion and proposals.

The Board of Directors is to communicate the date of the GSM at the earliest possible time. A GSM is called by a notice inserted into the *Feuille Officielle Suisse du Commerce* (official Swiss business gazette) at least 20 days prior to the date of the meeting.

The Company will announce the date until which shareholders may send their requests for inclusion of items on the agenda and their proposals relating thereto. This date should not be more in advance of the date of the GSM than is necessary.

The notice of meeting must indicate the matters on the agenda as well as proposals by the Board of Directors and of shareholders who have sought that a meeting be called and held or who have requested inclusion of a matter on the agenda.

The notice of a GSM must inform the shareholders that the management report, the compensation report, and reports of the auditors are available to them at the registered / principal office of the Company and subsidiaries, if any, no later than 20 days prior to the GSM. Each shareholder may demand that a copy of such documents be provided to the shareholder promptly.

The owners or representatives of all the shares may hold a GSM, if there is no opposition, without using the forms prescribed for the notice of meeting. For as long as they are present, such shareholders have the right to conduct business and validly act with respect to any and all matters within the scope of the GSM.

In order to obtain their admission card and vote at the GSM, the shareholders or their representatives must submit to the Company a bank certificate certifying that the securities are deposited and blocked at the bank. The securities must be blocked until the day after the GSM.

The Board of Directors is free to determine the reference date until which shareholders may request from the Company their admission and voting card, taking into account practical constraints.

A shareholder may request that the shareholder's shares be represented by another person who is not a shareholder, or by an independent proxy. Representation of shareholders by a member of a committee of the Company or by a custodian is prohibited.

At a GSM an independent representative will be elected, and the term of office of such person will terminate at the end of the next ordinary general shareholders' meeting. In the event of a vacancy, the Board of Directors will appoint an independent representative for the next GSM.

The independent representative is to vote on the basis of general or specific instructions given by the shareholders. If no instruction is received, the independent representative is to abstain.

Voting by mail is not a form of vote allowed under Swiss law.

GSMs are chaired by the Chairman of the Board of Directors or, in the Chairman's absence, by another member thereof. If there is none, the shareholders at the general meeting will elect a chairman.

The chairman of the GSM will appoint a secretary who may, but need not, be a shareholder.

The chairman answers questions about the Company or asks competent persons or chairs of committees of the Board of Directors to answer them. Complex matters must be submitted in writing to the Board of Directors sufficiently in advance for it to prepare its answers.

The Board of Directors oversees the preparation of the minutes of GSMs. The minutes shall state (i) the number, type, par value and class of shares represented by shareholders and the independent representative, (ii) the decisions and the outcome of elections, (iii) requests for information and answers given, and (iv) declarations or statements which the shareholders ask to have recorded.

The minutes are signed by the chairman and the secretary of the meeting. The shareholders have the right to consult the minutes. Excerpts thereof that are issued are certified true and correct by a member of the Board of Directors.

#### 19.2.11.2 Quorum (Article 19 of the Articles of Association)

An ordinary or extraordinary shareholders' meeting may be validly held regardless of the number of shares represented.

The Chairman organizes the terms and conditions of voting so that it is possible to determine the will of the majority as clearly and efficiently as possible. If a vote is held with raised hand, the shareholders may require any refusals to vote or abstentions from voting to be recorded; the number of votes is to be disclosed.

The shareholders at a general meeting take decisions and hold elections on the basis of an absolute majority of all of votes attributable to the votes represented.

If, in connection with an election, the first round of voting does not make it possible to secure an absolute majority, a second round is to be held during which a relative majority will be decisive.

In the event of a tie vote the chairman's vote prevails.

On the basis of the requirements of the Swiss Code of Obligations, the Articles of Association provide that it is necessary to secure at least two-thirds of the votes attributable to the shares represented and an absolute majority of the paid-in capital amount in order to (i) change or amend the Company's purposes or legal form, (ii) issue shares with preferred voting rights, (iii) make any change in the clause limiting in percentage terms the registration of a shareholder with the right to vote in the share records, (iv) increase the equity capital by an authorized or conditional increase, or an ordinary increase through equity, contributions in kind or for the purposes of acquiring assets, or a grant of special benefits, (v) limit or eliminate the preferential subscription right, (vi) change the Company's registered and principal office, and (vii) dissolve the Company.

#### 19.2.12 Committees

The Board of Directors has three permanent committees formed pursuant to rules approved by the Board of Directors:

- the Remuneration Committee;
- the Nomination Committee; and
- the Audit and Control Committee.

In connection with its authority, the Board of Directors may create other committees or give various tasks to members on the basis of rules or ad hoc decisions.

#### 19.2.13 Clauses in the Articles of Association that could have an impact on the occurrence of a change of control

The Company's Articles of Association do not contain any provision that would make it possible to delay, defer, or prevent a change of control.

As mentioned in section 3.3.3, insofar as the Company's registered office is in Switzerland whilst its shares are listed only on Euronext's regulated market in Paris, neither French regulations on mandatory public tender offers and buyouts, nor Swiss regulations on public takeover offers (purchase or exchange offer) are applicable to public tender offers concerning the Company's shares.

#### **19.2.14 Requirements for holdings exceeding certain percentages**

Since the listing of the Company's shares on Euronext Paris, the Company, as a third-country issuer of shares with securities admitted to trading on a regulated market in France and, therefore, having chosen France as an initial member, is subject to applicable French law and regulations requiring reporting when investment thresholds are crossed.

Thus, any individual or legal entity that may possess a number of shares representing more than 5%, 10%, 15%, 20%, 25%, 30%, 33.33%, 50%, 66.66%, 90%, or 95% of the Company's equity capital and voting rights must inform the Company and the AMF thereof before the end of trading no later than on the fourth trading day following the crossing of the investment threshold, and the total number of shares and voting rights it possesses.

This information is also to be provided, in the same time frame, when the equity stake or right to vote falls below the thresholds mentioned above.

The person or entity responsible for providing this information must also specify in the report: (i) the number of shares it possesses convertible into, or carrying the right to acquire, shares and the number of votes attaching thereto, and (ii) the shares already issued that such person or entity may acquire under an agreement or security. The same applies to voting rights that such person or entity may acquire on the same terms and conditions.

A threshold crossing reporting form is available on the AMF's website.

#### **19.2.15 Special provisions applicable to changes in the equity capital**

Equity capital and rights attaching to shares constituting equity may be changed on the conditions provided by law and the Articles of Association, although the Company's Articles of Association do not contain specific provisions.

For information, the Swiss Code of Obligations provides that the general shareholders' meeting decision to increase the capital may only cancel the preferential subscription rights for valid reasons. The following are considered as valid reasons: the acquisition of a company, or of parts of a company or of a stake in a company, as well employee incentives. No shareholder must be unfairly advantaged or disadvantaged by the cancellation of preferential subscription rights (art. 652b CO).

#### **19.2.16 Financial year (Article 38 of the Articles of Association)**

Each financial year begins on January 1 and end on December 31 of each calendar year.

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## **CHAPTER 20.**

### **MATERIAL AGREEMENTS**

#### **License Agreements with bioMérieux**

On January 31, 2006, the Company entered into a license agreement with bioMérieux, amended on October 27, 2010 to cover additional indications. The initial agreement granted an exclusive license to GeNeuro for any therapeutic application of the patents involving HERV-W belonging to bioMérieux, whilst leaving to bioMérieux any and all rights to the same patents in the field of diagnostics. However, in connection with the license agreement relating to companion diagnostics, dated October 14, 2015, bioMérieux agreed to waive its rights to develop companion diagnostics linked thereto to temelimab and granted to GeNeuro a non-exclusive license to its rights for which the Company agreed to pay it a maximum of €100,000 (excluding taxes).

As of the date hereof, GeNeuro has paid €1,194 thousand to bioMérieux in respect of milestone payments for the clinical development of temelimab. Other milestone payments as well as royalties are also contemplated.

#### **Exclusive License Agreement with the NIH**

In October 2018, GeNeuro announced it had signed an exclusive worldwide license with the National Institute of Neurological Disorders and Stroke (NINDS), part of the U.S. National Institutes of Health (NIH). The agreement covers the development of an antibody program to block the activity of pHERV-K Env (pathogenic envelope protein of the HERV-K family of Human Endogenous Retroviruses), a potential key factor in the development of ALS. Pursuant to this agreement, the Company made an up-front payment of KUSD 50 (K€ 44), and is committed to make annual minimum payments of KUSD 25 (approximately K€ 21) and milestone payments up to a total sum of USD 11.6 million (approximately € 9.7 million) subject to clinical development achievements; in addition, GeNeuro will have to pay the NIH royalties based on its net licensing revenues and net sales.

#### **Contract Development and Manufacturing Agreement with Polymun Scientific GmbH**

On December 1, 2012, GeNeuro entered into a contract development and manufacturing agreement with Polymun. Pursuant to amendments to the contract, the latest being dated January 17, 2022, Polymun has produced additional batches of temelimab for use in Phase II trials. Under the contract, GeNeuro owns all improvements concerning the manufacturing of temelimab developed during the execution of the agreement while Polymun retains the right to use any improvements to manufacture other proteins. A purchase of the manufacturing process and a transfer of the technology to third parties, as needed, are possible under the contract with Polymun.

#### **Venture Debt Credit Agreement with the European Investment Bank**

On March 7, 2023, GeNeuro announced the signature by its wholly-owned French subsidiary GeNeuro Innovation SAS of a credit agreement for a total amount of up to EUR 25 million with the European Investment Bank ("EIB"), supported by the InvestEU programme (the "EIB Credit Facility Agreement"). The first tranche of EUR 7 million, which was immediately available and was drawn in March 2023, is intended to support the Phase 2 clinical trial in Post-COVID. The other tranches of EUR10 million and EUR8 million are intended for the preparation and launch of Phase 3 respectively. The Company is negotiating with the EIB for the early availability of part of the second tranche of €10 million.

The debt resulting from the first tranche of € 7 million drawn down in March 2023 is unsecured, has a maturity of 5 years and carries interest of 9% p.a. (of which 2% p.a. payable in cash and 7% p.a. to be capitalized until maturity). In addition, in connection with the drawdown of the first €7 million tranche from the EIB Credit Facility, the Company issued to the EIB a total of 642,031 share purchase warrants at an exercise price of €2.58 per share.



## **CHAPTER 21.**

### **DOCUMENTS AVAILABLE TO THE PUBLIC**

Copies of this Universal Registration Document are available, free of charge, from the Company (3 chemin du Pré-Fleuri – 1228 Plan-les-Ouates – Geneva – Switzerland – Tel.: +41 22 552 48 00).

This Universal Registration Document is also available on the websites of the Company (<http://www.geneuro.com/en/investors/documentation-2/regulated-information> or <http://www.geneuro.com/fr/investisseurs-fr/documentation/information-reglementee>) and of the AMF ([www.amf-france.org](http://www.amf-france.org)).

During the period of validity of this Universal Registration Document, the following documents (or copies of such documents) may be consulted at the Company's registered and principal office:

- the Company's Articles of Association;
- any and all reports, correspondence, and other documents, historical financial information, valuations and estimates, and statements or reports prepared by an expert at the Company's request, some of which are included or referred to in this Universal Registration Document; and
- historical financial information included in this Universal Registration Document.

All legal and financial documents relating to the Company and required to be made available to shareholders in accordance with applicable law and regulations may also be consulted at the Company's principal and registered office.

The regulated information under the meaning of the AMF's General Rules and Regulations is also available on the Company's website.

## **CHAPTER 22.**

### **INFORMATION ON INVESTMENTS**

The information about the company in which the Company owns or holds a fraction of the equity capital that could have a material impact on an analysis of its assets and liabilities, financial condition, or profit and loss is set forth in Section 6.2, "Subsidiaries and Equity Stakes" of this Universal Registration Document and Note 2.2, "Consolidation Methods" to the Group's financial statements for the two years ended 31 December 2021 and 2022 set forth in CHAPTER 18, "Information Regarding the Company's Assets, Financial Situation and Results" of this Universal Registration Document.

CHAPTER 23.  
ANNUAL ACCOUNTS FOR THE YEAR ENDED DECEMBER 31, 2023

**GeNeuro SA**  
**Plan-les-Ouates**

Report of the statutory auditor  
to the General Meeting

on the financial statements 2023



# Report of the statutory auditor

to the General Meeting of GeNeuro SA

Plan-les-Ouates

## Report on the audit of the financial statements

### Opinion

We have audited the financial statements of GeNeuro SA (the Company), which comprise the balance sheet as at 31 December 2023, and the income statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying financial statements comply with Swiss law and the Company's articles of incorporation.

### Basis for opinion

We conducted our audit in accordance with Swiss law and Swiss Standards on Auditing (SA-CH). Our responsibilities under those provisions and standards are further described in the 'Auditor's responsibilities for the audit of the financial statements' section of our report. We are independent of the Company in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Material uncertainty related to going concern

We draw your attention to note 1 to these annual financial statements, which states that the Company has incurred recurring losses since inception, is experiencing a liquidity shortage, and is therefore dependent on the availability of future funding. This, along with other matters as described in the aforementioned notes, indicates the existence of a material uncertainty which may cast significant doubt about the ability of the Company to continue as a going concern. The Company's liabilities exceed its assets, as defined in article 725b CO. If it is not possible for the Company to continue as a going concern, compliance with the provisions of article 725b CO is required. Our opinion is not modified in respect of this matter.

### Our audit approach

#### Materiality

The scope of our audit was influenced by our application of materiality. Our audit opinion aims to provide reasonable assurance that the financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall materiality for the financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate, on the financial statements as a whole.

PricewaterhouseCoopers SA, avenue Giuseppe-Motta 50, case postale, 1211 Genève 2, Switzerland  
Téléphone: +41 58 792 91 00, [www.pwc.ch](http://www.pwc.ch)

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<b>Overall materiality</b>	EUR 480'000
<b>Benchmark applied</b>	Pre-tax loss
<b>Rationale for the materiality benchmark applied</b>	We chose pre-tax loss as the benchmark because, in our view, it is the benchmark against which the performance of the Group is most commonly measured.

We agreed with the Audit Committee that we would report to them misstatements above EUR 48'000 identified during our audit as well as any misstatements below that amount which, in our view, warranted reporting for qualitative reasons.

#### Audit scope

We designed our audit by determining materiality and assessing the risks of material misstatement in the financial statements. In particular, we considered where subjective judgements were made; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits, we also addressed the risk of management override of internal controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud.

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the financial statements as a whole, taking into account the structure of the Company, the accounting processes and controls, and the industry in which the Company operates.

#### Key audit matters

Except for the matter described in the 'Material uncertainty related to going concern' section, we have determined that there are no key audit matters to communicate in our report.

#### Other information

The Board of Directors is responsible for the other information. The other information comprises the information included in the annual report, but does not include the financial statements and our auditor's report thereon.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

#### Board of Directors' responsibilities for the financial statements

The Board of Directors is responsible for the preparation of financial statements in accordance with the provisions of Swiss law and the Company's articles of incorporation, and for such internal control as the Board of Directors 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, the Board of Directors 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 the Board of Directors either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

### Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Swiss law and SA-CH 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 part of an audit in accordance with Swiss law and SA-CH, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our 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.
- Obtain 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 Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.
- Conclude on the appropriateness of the Board of Directors' 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. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.

We communicate with the Board of Directors or its relevant committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Board of Directors or its relevant committee with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them regarding all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

From the matters communicated with the Board of Directors or its relevant committee, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

### Report on other legal and regulatory requirements

In accordance with article 728a para. 1 item 3 CO and PS-CH 890, we confirm the existence of an internal control system that has been designed, pursuant to the instructions of the Board of Directors, for the preparation of the financial statements.

We further confirm that the proposed carry forward of the accumulated losses complies with Swiss law and the Company's articles of incorporation. We recommend that the financial statements submitted to you be approved.

Furthermore, we draw attention to the fact that the financial statements of the Company disclose an excess of liabilities over assets. Interim financial statements as at 31 December 2023, prepared according to article 725b para 1 CO show, that the Company's liabilities are no longer covered by its assets on the basis of going concern and liquidation values

and the Company is overindebted according to Art. 725b CO. The Board of Directors must notify the court unless creditors of the Company subordinate their claims to all other creditors to the extent of the over-indebtedness and defer payment or in case there is a reasonable prospect that the over-indebtedness can be remedied within a reasonable period, but no later than 90 days, after the audited interim financial statements become available, and that the claims of the creditors are not additionally jeopardized.

PricewaterhouseCoopers SA



Luc Schulthess  
Licensed audit expert  
Auditor in charge



Adelina Todorova

Genève, 30 April 2024

Enclosures:

- Financial statements (balance sheet, income statement and notes)
- Proposed carry forward of the accumulated losses



## **2023 Financial statements**

**GeNeuro SA,  
Plan-les-Ouates**

## GeNeuro SA, Plan-les-Ouates

### Balance sheet at December 31

Assets	Notes	2023	2023	2022	2022
		Audited EUR	For information (CHF)	Audited EUR	For information (CHF)
<b>Current assets</b>					
Cash and cash equivalents		871,305	806,828	4,935,421	4,859,909
Other current receivables from third parties	7	78,516	72,706	114,196	112,449
Prepaid expenses		269,407	249,471	1,993,134	1,962,639
<b>Total current assets</b>		<b>1,219,228</b>	<b>1,129,005</b>	<b>7,042,751</b>	<b>6,934,997</b>
<b>Non-Current assets</b>					
Participations	3	2,668,364	2,470,905	2,668,364	2,627,538
Other non-current financial assets	4	250,964	232,393	240,145	236,471
Property, plant and equipment	5	627,851	581,390	831,820	819,093
Intangible assets		1,152,326	1,067,054	1,139,768	1,122,330
<b>Total non-current assets</b>		<b>4,699,505</b>	<b>4,351,742</b>	<b>4,880,097</b>	<b>4,805,432</b>
<b>Total Assets</b>		<b>5,918,733</b>	<b>5,480,747</b>	<b>11,922,848</b>	<b>11,740,429</b>
<b>Liabilities and Equity</b>					
Liabilities and Equity	Notes	2023	2023	2022	2022
		Audited EUR	For information (CHF)	Audited EUR	For information (CHF)
<b>Current liabilities</b>					
Trade payables		5,585,972	5,172,610	3,600,336	3,545,251
<i>third parties</i>		1,922,636	1,780,361	508,955	501,168
<i>group companies</i>	6	3,663,336	3,392,249	3,091,381	3,044,083
Current financial liabilities	7	253,065	234,338	228,743	225,243
<i>third parties</i>		253,065	234,338	228,743	225,243
Other current liabilities	8	51,626	47,806	88,573	87,218
<i>third parties</i>	8	51,626	47,806	88,573	87,218
Accrued liabilities	9	2,681,205	2,482,796	1,202,673	1,184,272
<b>Total current liabilities</b>		<b>8,571,868</b>	<b>7,937,550</b>	<b>5,120,325</b>	<b>5,041,984</b>
<b>Non-current liabilities</b>					
Non-current financial liabilities	7	470,905	436,058	661,292	651,174
Forgivable loan	7	5,809,388	5,379,493	5,463,078	5,379,493
<b>Total non-current liabilities</b>		<b>6,280,293</b>	<b>5,815,551</b>	<b>6,124,370</b>	<b>6,030,667</b>
<b>Total liabilities</b>		<b>14,852,161</b>	<b>13,753,101</b>	<b>11,244,695</b>	<b>11,072,651</b>
<b>Equity</b>					
Capital		1,161,830	1,249,951	1,161,830	1,249,951
Legal reserves from capital	10	120,047	32,664,356	30,120,047	32,664,356
Other reserves from capital	10	42,750,000	46,400,850	42,750,000	46,400,850
Treasury shares	10	-828,390	-784,688	-827,008	-824,478
Carried forward loss		-42,526,716	-46,150,596	-62,850,620	-68,963,190
Loss for the year		-9,610,199	-9,339,191	-9,676,096	-9,721,574
Translation adjustment			221,132		-138,137
<b>Total equity</b>		<b>-8,933,428</b>	<b>-8,272,354</b>	<b>678,153</b>	<b>667,778</b>
<b>Total Liabilities and Equity</b>		<b>5,918,733</b>	<b>5,480,747</b>	<b>11,922,848</b>	<b>11,740,429</b>

The accompanying notes form an integral part of these financial statements



## GeNeuro SA, Plan-les-Ouates

### Income statement for the 12 months ended December 31

	Notes	2023	2023	2022	2022
		Audited EUR	For information (CHF)	Audited EUR	For information (CHF)
Income	11	13,986	13,592	12,781	12,841
Research and development expenses		-6,677,086	-6,488,792	-6,801,340	-6,833,306
General and administrative expenses		-2,548,903	-2,477,024	-2,807,569	-2,820,765
<b>Operating loss before interest and taxes</b>		<b>-9,212,003</b>	<b>-8,952,224</b>	<b>-9,596,128</b>	<b>-9,641,230</b>
Financial income	12	140,392	136,433	286,841	288,189
Financial expenses	12	-534,425	-519,354	-364,722	-366,436
Impairment to financial assets	4, 12	-	-	-	-
<b>Operating loss before taxes</b>		<b>-9,606,036</b>	<b>-9,335,145</b>	<b>-9,674,009</b>	<b>-9,719,477</b>
<b>Pre-tax loss</b>		<b>-9,606,036</b>	<b>-9,335,145</b>	<b>-9,674,009</b>	<b>-9,719,477</b>
Direct taxes		-4,163	-4,046	-2,087	-2,097
<b>Net loss for the period</b>		<b>-9,610,199</b>	<b>-9,339,191</b>	<b>-9,676,096</b>	<b>-9,721,574</b>

The accompanying notes form an integral part of these financial statements

**Notes to annual financial statements**

**Additional information**

Additional information in the notes to the financial statements, such as the cash flow statement and the management report as required by art. 961d CO is not included in the notes as the entity prepares consolidated accounts in accordance with IFRS.

**1. Principles used in preparing the annual financial statements**

These annual financial statements have been prepared in conformity with the provisions on commercial accounting of the Swiss Code of Obligations (art. 957 to 963b, applicable since January 1, 2013). The main balance sheet items are accounted for as follows.

Certain amounts from the prior year were reclassified for comparison purposes.

Since January 1, 2016, the Company maintains its accounts in euros, this currency being considered as the functional currency.

The financial statements provided in Swiss francs (CHF) are for information purposes. Amounts have been converted from euros into CHF at the following rates:

	<u>2023</u>	<u>2022</u>
Income statement items	0.9718	1.0047
Balance sheet items	0.9260	0.9847

*except for equity items which are converted at the applicable historical rate*

**Revenue recognition**

The "Income" line item includes income derived from collaborative agreements entered into by GeNeuro SA.

The Company recognizes income from license fees, the provision of R&D services and management fees on the arrangement of R&D services. Income is recognized when control of the goods or services passes to the customer. For the provision of a license, this is dependent on whether the license conveys a right of use or right of access to the underlying intellectual property. The R&D services are recognized over time as the Company performs the clinical trials and the customer benefits from those services. The Company identifies the performance obligations in each contract with a customer. A performance obligation is a promise to deliver goods and services that is distinct from other promises in the contract.

Where a contract contains more than one performance obligation, the Company allocates the transaction price based on the stand-alone selling price of each separate performance obligation. The Company receives upfront payments and variable consideration in the form of milestones. The Company uses the most likely method to estimate variable consideration and includes such consideration in the transaction price and income if it is not highly probable of reversal.

Income from licenses that convey a right to use intellectual property is recognized when the customer is able to use that intellectual property. R&D services are recognized over the clinical study period based on an input method. This method is calculated by the clinical trial costs incurred over the estimated costs to complete the study.

The Company provides management services, where it arranges clinical trials with an external provider on behalf of a customer. In these arrangements, the Company is acting as agent and recognizes the management fee as income as the management services are delivered.

**Material uncertainty and ability to continue as a going concern**

The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern. These financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

GeNeuro SA is a biopharmaceutical company at the clinical stage developing innovative therapeutics. The Company is exposed to risks and uncertainties inherent in establishing and developing a business that are common to development-stage companies in the biotechnology industry, including, but not

limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The Company's success may also depend on its ability to:

- establish and maintain strong patent position and protection;
- enter into collaborations with partners in the pharmaceutical industry;
- acquire and retain key personnel;
- acquire additional funding to support its operations.

The Company has sustained operating losses since its formation, except for the 2014 financial year. Such losses, which amounted to €38 million for the previous past five financial years, reflect both the significance of the expenses incurred in research and development and the absence of revenues. In addition, for the year ended December 31, 2023, the Company incurred a net loss of €9.6 million (2022: €9.7 million). Since its incorporation, the Company has primarily funded its growth through issuances of shares, including the capital increases conducted at the time of its initial public offering in 2016 and the subsequent capital increases completed in January 2020, July 2021 and May 2022; additional funds have been provided by a subsidy agreement with the Swiss Federal Office for Public Health (FOPH)'s Federal Funding Programme for COVID-19 Medicines, pursuant to which the Company is entitled to receive a grant of 6.7 million Swiss francs (€7.2 million) to co-fund up to 50% of a Phase II clinical trial to treat patients with long-standing COVID who exhibit severe neurological and psychiatric ("neuropsychiatric") symptoms. In 2022, the Company received the first two instalments from the FOPH grant for its post-COVID program, of €3.0 million and €2.3 million. In addition, in February 2024, the Company completed a capital increase of €5 million.

We draw attention to the fact that the Company is over-indebted as per Article 725b CO, as of December 31st, 2023. The Company has no revenues and cannot predict when, if at all, one of its drugs under development will reach commercial stage; the Company is currently undertaking a Phase 2 clinical trial with temelimab, its leading drug candidate, in the post-COVID indication, with results are now expected by the end of June 2024. The costs for this clinical program are such that the Company's operations will continue to require significant amounts of capital. The Company determined that there are currently insufficient financial resources to fund its operations for at least twelve months from when the 2023 financial report is approved on 29 April 2024, based on the funds available as of December 31, 2023 in the amount of €0.9 m (cash and cash equivalents) together with the net proceeds of the February 2024 capital increase and the expected negative cashflow for the next twelve months based on the Company's current business plan. Furthermore, the Company considers that from the date when the 2023 financial report is approved on 29 April 2024, its net working capital is sufficient only over the next five months taking into account the last payment of €1.4 million expected from the FOPH, which is conditional upon submitting to Swissmedic a marketing authorization application and submitting to the FOPH the preliminary final material & financial report. Without the FOPH payment, the net working capital is sufficient until mid-August 2024. Based on the Company's available cash and cash equivalents on the date when the 2023 financial report is approved on 29 April 2024 (which takes into account the cash available at December 31, 2023 and the net proceeds from the February 2024 capital increase), the Company estimates that the amount of insufficient working capital that would allow it to fund its operations for at least twelve months from when the 2023 financial report is approved on 29 April 2024 amounts to approximately €3.5 million.

In order to remedy such insufficient net working capital, the Company continues to be engaged in discussions with investors, suppliers and lenders, with the objective to secure further additional or earlier financing, or cost cuts. In case these discussions would not be fruitful, the Company may not be able to continue as a going concern, which could lead the Company to initiate a debt restructuring moratorium or enter into bankruptcy proceedings in the short or mid-term. While the Company is actively seeking to raise additional funding, there can be no assurance that the necessary financing will be available. Shareholders should note that whilst Management and Board of Directors consistently continue to apply best efforts to evaluate and execute all available options, there is no guarantee that any transaction can

be realized or that such transaction would generate sufficient funds to finance operations for twelve months from when the 2023 financial report is approved. If the Company is unable to obtain adequate capital resources to fund the operations, it will need to substantially modify its operations by significantly reducing spending as well as seeking to monetize assets under development through outlicensing transactions. This may impact the ability to complete the current Phase 2 clinical trial. If such measures are not sufficient, and/or additional funding is not obtained in due course, the Company may be forced to discontinue its operations entirely.

Liquidity risk management is assessed in Note 16.

### **Non-current assets**

Property, plant and equipment are carried in the balance sheet at their purchase cost, less the appropriate economic depreciation. As from January 1, 2019, the Company has applied IFRS 16 "Leases", pursuant to which, at the commencement date of a lease, a lessee recognizes a liability to make lease payments (i.e., the lease liability) and an asset representing the right to use the underlying asset during the lease term (i.e., the right-of-use asset). Lessees are required to separately recognize the interest expense on the lease liability and the depreciation expense on the right-of-use asset. In applying the new standard, a lessee determines each lease's term including any lessee's extension or termination option that is deemed reasonably certain. The assessment of such options is performed as of the commencement of each lease and requires judgment by management. Measuring the lease liability at the present value of the remaining lease payments requires using an appropriate discount rate in accordance with IFRS 16. The discount rate is the interest rate implicit in the lease or, in the event it cannot be determined, the incremental borrowing rate at the date of the lease commencement. The incremental borrowing rate can have a significant impact on the net present value of the right-of-use asset and lease liability recognized and requires judgement.

As per IFRS 16, lessees must remeasure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee generally recognizes the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset.

Intangible assets primarily comprise license rights on patents.

Research and development expenses are accounted for as expenses when incurred, based on the fact that the criteria for recognizing them as intangible assets are not fulfilled.

### **Lease agreements**

Since January 1, 2019, the Company applies IFRS 16 "Leases" for lease agreements and has elected to use the exemption proposed by the standard on lease contracts for which the lease terms end within 12 months as of the date of initial application; and to exclude the low-value assets (with an individual value in USD of less than 5'000 when new).

At the inception of the lease a right-of-use asset and a lease liability are recognized in the balance sheet. The asset is initially measured at the amount of the lease liability plus any initial direct costs incurred.

The lease liability is initially measured at the present value of the lease payments payable over the lease term, including variable lease payments depending on an index at the commencement date and the exercise price of purchase options if it is reasonably certain that the option will be exercised. The lease liability is discounted at the rate implicit in the lease. If that rate cannot readily be determined the incremental borrowing rate is used. Lease liabilities are subsequently re-measured to reflect possible changes in the lease terms. Right-of-use assets are depreciated over of the duration of the lease contract including contractually agreed optional extension periods, whose exercise are deemed to be reasonably certain. The depreciation is recognized in operating income. The unwinding of the discounting effect is included in the financial expense. Lease payments are accounted for as a repayment of the lease liability. Expenses for lease contracts for objects with a value of less than USD 5 thousand and lease contracts with a duration of up to twelve months are recognized directly in the income statement.

## Information, detailed structure and comments on the annual financial statements

2. The annual average full-time employee number was 8.8 employees for 2023 and 7.3 employees for 2022.

### 3. Participations

Name and legal form	Headquarter	2023		2022	
		Capital	Voting rights	Capital	Voting rights
GeNeuro Innovation SAS	Lyon, France	100%	100%	100%	100%

### 4. Other financial assets

	2023		2022	
	Audited EUR	For information (CHF)	Audited EUR	For information (CHF)
Currency derivatives	-	-	-	-
Loans granted to employees	-	-	-	-
Current financial assets	-	-	-	-
Rent deposit	201,986	187,039	189,786	186,882
Cash reserve for liquidity contract	48,978	45,354	50,359	49,589
Other non-current financial assets	250,964	232,393	240,145	236,471

### 5. Property, plant and equipment

	2023		2022	
	Audited EUR	For information (CHF)	Audited EUR	For information (CHF)
<b>Gross value</b>				
Building (right of use)	1,778,813	1,647,181	1,752,540	1,725,726
Office and computer equipment, furniture	226,512	209,750	226,512	223,046
Fixtures and fittings	12,120	11,223	12,120	11,935
<b>Total Gross Value</b>	<b>2,017,445</b>	<b>1,868,154</b>	<b>1,991,172</b>	<b>1,960,707</b>
<b>Accumulated depreciation</b>				
Building (right of use)	-1,174,626	-1,087,704	-961,383	-946,674
Office and computer equipment, furniture	-202,848	-187,837	-185,849	-183,006
Fixtures and fittings	-12,120	-11,223	-12,120	-11,935
<b>Total Gross Value</b>	<b>-1,389,594</b>	<b>-1,286,764</b>	<b>-1,159,352</b>	<b>-1,141,615</b>
<b>Net Book Value</b>				
Building (right of use)	604,187	559,477	791,157	779,052
Office and computer equipment, furniture	23,664	21,913	40,663	40,040
Fixtures and fittings	-	-	-	-
<b>Total Net Book Value</b>	<b>627,851</b>	<b>581,390</b>	<b>831,820</b>	<b>819,092</b>

### 6. Trade payables

The increase in trade payables to group companies from 2022 to 2023 is attributable to the invoice of services provided by the Company's French subsidiary, less any repayments of advances made by subsidiary to the Company during the year. On April 20, 2023, the Company entered into a "Development Collaboration And Option For A License Agreement" with its French subsidiary, pursuant to which the French subsidiary committed to finance the manufacturing of temelimab

required for the Phase 2 clinical trial in the post-COVID indication and to bear development costs with respect to the Post-COVID Trial for an amount of EUR 5 million, in exchange for an option for an exclusive license on temelimab for the post-COVID indication for the European Union. The amount of trade payables due to the French subsidiary includes the EUR 5 million referred to above.

Trade payables to third parties have increased during the year in connection with the expanded clinical trial activities of the Company.

## 7. Current and non-current financial liabilities

At December 31, 2023, current financial liabilities are comprised of the current portion of the lease liability corresponding to the right of use.

The non-current financial liabilities at December 31, 2023, are comprised of:

- Non-current financial liabilities, corresponding to the non-current portion of the lease liability corresponding to the right of use; and
- A forgivable loan provided by the Swiss Federal Office for Public Health pursuant to the FOPH's Federal Funding Programme for COVID-19 Medicines, pursuant to which the Company was selected to receive a grant of 6.7 million Swiss francs (€7.2 million) to co-fund 50% of a Phase II clinical trial to treat patients with long-standing COVID who exhibit severe neurological and psychiatric symptoms. Based on the terms of the subsidy contract entered into with the FOPH, the Company considers that it has received a forgivable conditional loan from the FOPH. The amount recognized at December 31, 2023, of € 5,809K, corresponds to the two instalment payments which the Company received from the FOPH during 2022.

## 8. Other current liabilities

At December 31, 2023, other current liabilities are mostly comprised of accrued liabilities for directors' fees, which were paid in January 2024.

### Amounts due to pension institutions

At December 31, 2023, there was €756 (CHF 700) due to the Swiss occupation pension scheme (nil in 2022).

## 9. Accrued liabilities

At December 31, 2023, the accrued liabilities include nil (2022: € 221K) of accruals for executive management bonuses attributable to 2023 and related social charges, and €2,295K (2022: € 354K) of accruals for costs related to the post-COVID clinical trial.

## 10. Equity

On May 13, 2022, the Company completed a €7.7 million share capital increase through an international private placement reserved to qualified institutional investors, through the issuance of 2,678,251 new ordinary bearer shares.

Accordingly, at December 31, 2023 and 2022, the Company's share capital amounted to € 1,161.8K (CHF 1,250.0K, converted into euros at the applicable historical exchange rates) and was divided into 24,999,028 common bearer shares with a nominal value of CHF 0.05. All shares are fully paid up.

At the June 14, 2023, annual general shareholders' meeting, a new capital band was approved, representing 12,499,514 bearer shares each with a nominal value of CHF 0.05. The approval for this capital band lapses on June 14, 2028. Also at the 2023 AGM, shareholders approved the allocation of EUR 30'000'000 (CHF 29'541'000 at the December 31, 2022 exchange rate) from the "Legal reserves from capital" to the "Carried forward loss".

## Own shares of the Company held by the Company or its subsidiaries (book values)

	2023			2022	
	Number	Value (EUR)	Value in CHF for information	Number	Value (EUR)
January 1	157,672	827,008	824,478	126,023	758,761
Exercise of stock options	-	-	-	-	-
Purchases	184,656	312,555	303,741	193,990	492,232
Sales	-177,589	-311,174	-302,399	-162,341	-423,985
Currency translation	-	-	-88,167	-	-
December 31	164,739	828,389	737,653	157,672	827,008
<i>Nominal value of own shares</i>	<i>CHF 8,237</i>			<i>CHF7,884</i>	

## 11. Income

The Company's reported income for 2023 and 2022 relates primarily to withholding tax administrative payments.

## 12. Financial income and expenses

Financial income decreased in 2023 compared to 2022 due to lower unrealized currency gains (€99 K vs €279 K). Financial expenses increased due to higher unrealized currency losses (€523 K vs. €349 K), whereas interest expenses remained flat.

## 13. Commitments

As mentioned in Note 1, as of January 1, 2019, the Company has applied IFRS 16 "Leases", pursuant to which it recognizes a liability to make lease payments in connection with its current premises.

## 14. Participation rights and options granted to Management, Board of Directors and employees

	Nominal value (2023 grants)		Number of options	
	EUR	CHF	2023	2022
	Board of Directors/ Management	12,834.45	11,884.70	237,694
Employees	-	-	-	-

During 2023, the Company's Board of Directors approved new awards under the 2020 three-year Equity Incentive Stock Option Plan, pursuant to which it made additional grants of 237,694 (2022: 183,627) stock options during 2023 to management with an exercise price of €2.86 (2022: €3.48) per share and an exercise term of 10 years.

In addition to the above information, a total of 11,027 (2022: 202,274) stock options were cancelled due to non-exercise during their term or forfeited by departing employees.

The Group has no legal or constructive obligation to repurchase or settle any of the stock options in cash.

## 15. Information required in the case of income statement presentation by function

	2023	2023	2022	2022
	EUR	For information (CHF)	EUR	For information (CHF)
Personnel expense	2,439,621	2,370,824	2,381,779	2,392,973
Amortization, depreciation and impairment on non-current assets	230,300	223,806	225,201	226,259

## 16. Other information

Based on the fact that the Company presents consolidated financial statements established pursuant to IFRS accounting standards, the Company does not present in its statutory accounts a cash flow statement nor a statement of change in net equity.

### Contingent liabilities

GeNeuro SA is not involved in any litigation.

#### *bioMérieux license agreement*

In 2006, the Company entered into an exclusive license agreement with bioMérieux (France) (the "2006 Agreement") with the sole aim to develop, manufacture and sell products covered by bioMérieux patents, with bioMérieux retaining in this 2006 Agreement the rights related to diagnostics.

The 2006 Agreement mainly provides for:

- an initial payment of KCHF 150, paid in 2006 (EUR 138 K at the January 1, 2016 exchange rate used at the time the Company changed its functional currency from the CHF to the euro);
- an annual contribution of KCHF 50 (approx. EUR 51 K) for the maintenance costs of the patents;
- milestone payments based on development stages of up to CHF 72.6 million in total (approx. EUR 73.7 million);
- royalties based on net license income and net sales of GeNeuro

On commencement of the Phase IIa clinical trial in multiple sclerosis in 2012, the first milestone was reached, triggering a payment by the Company of KCHF 200 (approx. EUR 171 K at then applicable exchange rate). The opening of the first investigational site of the Phase IIb clinical trial in multiple sclerosis in the first half of 2016 triggered a payment by the Company of KCHF 1,000 (EUR 907 K at the then applicable exchange rate). In addition, the start of the Phase IIa clinical trial in type 1 diabetes triggered a contingent payment of KCHF 200 (approx. EUR 171 K), to be paid only if certain conditions (such as entering a phase III clinical trial in this indication, or sub-licensing the product for that indication) are met. Owing to the uncertainties surrounding the results of this type 1 diabetes clinical trial, the Company treats this milestone as a contingent liability.

In 2015, pursuant to an exclusive license agreement on companion diagnostics (the "Diagnostics Agreement"), bioMérieux also granted an exclusive license on companion diagnostics. This Diagnostics Agreement commits the Company to make milestone payments of up to EUR 100 K. On the commencement of the Phase IIb clinical trial in 2016, the first milestone was reached, triggering a payment of EUR 50 K to bioMérieux. The balance of EUR 50 K will be due in the event of the start of a Phase III. No royalties are due pursuant to the Diagnostics Agreement.

#### *NIH license agreement*

In 2018, pursuant to an exclusive license agreement entered into with the National Institutes of Health of the USA for the development of an antibody program to block the activity of pHERV-K Env (pathogenic envelope protein of the HERV-K family of Human Endogenous Retroviruses), a potential key factor in the development of ALS (Amyotrophic Lateral Sclerosis), the Company made an up-front payment of KUSD 50 (approximately EUR 44 K), and is committed to make annual minimum payments of KUSD 25 (approximately EUR 23 K) and milestone payments up to a total sum of USD 11.6 million (approximately EUR 10.9 million) subject to clinical development achievements; in addition, GeNeuro will have to pay the NIH royalties based on its net licensing revenues and net sales.

#### *EIB financing agreement with GeNeuro Innovation SAS*

In March 2023, the Company's fully-owned French subsidiary, GeNeuro Innovation, entered into a €25 million Venture Debt credit facility with the European Investment Bank, designed to finance the GeNeuro Group's Long-COVID development program, of which a first Tranche A of €7 million was drawn in March 2023.



This Venture Debt credit agreement is guaranteed by the Company. In addition, in connection with the drawdown of Tranche A, the Company issued to the EIB 642,031 share purchase warrants representing 2.4% of GeNeuro SA's diluted share capital. Each warrant entitles the EIB to acquire one common share of the Company in exchange for the exercise price of €2.58 per share; the warrants are exercisable at any time after March 2028 and until their expiration date in March 2030. The EIB holds a put option, as soon as the warrants become exercisable, to request GeNeuro SA to repurchase all or part of the exercisable but not yet exercised warrants at their intrinsic value (within the limit of a ceiling equal to the amount drawn under the credit facility). Because the warrants are not yet exercisable and because the exercise price of €2.58 is significantly above the €1.09 December 31, 2023, closing price for GeNeuro shares, the Company has not made any accrual for this put option contingent liability.

#### Liquidity risk

Since its incorporation, the Company has primarily funded its growth through capital increase and additional funds provided by research collaborations. The Company has never had recourse to bank loans. As a result, the Company is not exposed to liquidity risk through requests for early repayment of loans.

Significant R&D expenses have been incurred from the start of the Company's activities, generating negative cash flows from operating activities.

As at December 31, 2023, the Company's cash & cash equivalents amounted to € 871 K (December 31, 2022: € 4,935 K).

Refer to Note 1 "Material uncertainty and ability to continue as a going concern" of the Notes to the financial statements.

#### Post balance sheet events

On 2 February 2024, the Company announced that it had completed a €5 million capital increase through an international private placement reserved for specialized or strategic investors of 4,666,901 new ordinary bearer shares and through a public offering for retail investors in France via the PrimaryBid platform of 95,004 new ordinary bearer shares.

On March 18, 2024, the Company held an extraordinary shareholders' meeting that approved a new capital band with an upper limit of CHF 2,232,069.95 through the issuance of new, fully paid-up bearer shares (Capital Band).

## Appendix

Abbreviation / Term	Definition
ALS	Amyotrophic lateral sclerosis
Beta interferons	Self-injectable product that reduces the rate of relapse or flare-up in RRMS patients by approximately 30% compared to placebo
CDR	Regions for determining the complementarity of antibodies
CIDP	Chronic inflammatory demyelinating polyradiculoneuropathy: a rare autoimmune disorder of the peripheral nervous system and orphan disease that is also called "Peripheral MS"
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.
	Phase II: Assessment of the safety and efficacy of the molecule and determination of the therapeutic dose of the molecule.
	Phase III: Comparison of the efficacy of a new drug to the treatment of reference. This phase involves a large number of patients. The patients are selected on the basis of precise criteria that will make it possible to ascertain the efficacy and benefit of the drug tested as a new treatment for the targeted disease.
CMO	Contract Manufacturing Organization, a company that acts as an external contract manufacturer
Coronavirus	Coronaviruses are a large family of viruses that can cause illness in animals or humans. In humans there are several known coronaviruses that cause respiratory infections. These coronaviruses range from the common cold to more severe diseases such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and COVID-19.
CRO	Contract Research Organization, a company specializing in the organization and conduct of clinical trials
EDSS	Expanded disability status scale; a scale of disability for measuring the severity of MS
FDA	US Food and Drug Administration
GMP	Good manufacturing practices
GNbAC1 (now temelimab)	A humanized monoclonal antibody that neutralizes a HERV protein called W-ENV
HERV	Human endogenous retrovirus
HERV-K	Human endogenous retrovirus of the K family
HERV-W	Human endogenous retrovirus of the W family
IgG1 / IgG4	Immunoglobulins, also called antibodies
IND	Investigational New Drug application with the US Food and Drug Administration
KOL	Key opinion leaders
mAb	Monoclonal antibody
MS	Multiple sclerosis: degenerative, inflammatory and chronic disease that affects the central nervous system, consisting of the brain and spinal cord
MSRV-ENV	Previous name of W-ENV. Envelope protein of the endogenous retrovirus MSRV or HERV-W and the target of the monoclonal antibody temelimab
OPC	Oligodendrocyte precursor cell
PK	Pharmacokinetic
PPMS	Primary progressive multiple sclerosis: a clinical form of MS in which the symptoms of the disease get progressively worse in a linear way from the onset of the disease
Pre-clinical phases	Laboratory tests to evaluate the principal effects of a molecule and its toxicity
RRMS	The most common form of MS, called relapsing-remitting MS; characterized by repeated occurrences or attacks of neurological symptoms
SARS-CoV-2	Novel coronavirus first identified in humans in December 2019 that is the cause of COVID-19.

Abbreviation / Term	Definition
SPMS	A more aggressive form of MS; the secondary progressive form during which the loss of neuronal function gets worse
T1D	Type 1 diabetes: A chronic disease that results from the autoimmune destruction of insulin-producing beta cells in the pancreas. The pancreas, therefore, produces little or no insulin, the hormone necessary for the penetration of sugar (glucose) into cells for conversion into energy.
Temelimab (previously GNBAC1)	A humanized monoclonal antibody that neutralizes a HERV protein called W-ENV
W-ENV	Envelope protein of the endogenous retrovirus MSRV or HERV-W and the target of the monoclonal antibody temelimab

## **Annual Financial Report Cross-reference Table**

In accordance with Article 222-3 of the AMF's General Regulations, the Annual Financial Report referred to in Article L. 451-1-2 of the French Monetary and Financial Code contains the information described in the following sections of the Registration Document:

<b>Information required in the Annual Financial Report</b>	<b>Corresponding sections and chapters of the Registration Document</b>
1. Statutory financial statements 2023	CHAPTER 23
2. Consolidated financial statements 2023	18.3
3. Management report	
a) True and fair presentation of business evolution, results and financial situation of the Company and of the Group it consolidates	Chapters 3-5-7-8
b) Major events occurring after the year-end closing	10.1
c) Foreseeable development of the Company	5.1.2
d) Research and development activities	5.6
e) Information about shares buy-backs	19.1.3
4. Statement of the person responsible for the annual financial report	1.2
5. Statutory auditors' report on the statutory financial statements	CHAPTER 23
6. Statutory auditors' report on the consolidated financial statements	18.3.1